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**The Political Economy of Pharmaceutical Patents: US Sectional  
Interests and the African Group at the WTO**

A Case Study in International Trade Decision-Making  
and the Possibility for Change

**By**

**Sherry Suzette Marcellin**

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## List of Acronyms

9/11	September 11, 2001 Terror Attacks on US Territory
ACTPN	Advisory Committee on Trade Policy and Negotiations
AG	African Group at the WTO
AGOA	Africa Growth and Opportunity Act (US)
APAC	Agricultural Policy Advisory Committee
AZ	AstraZeneca Pharmaceuticals
BMS	Bristol-Myers Squibb
CARICOM	Caribbean Common Market
CEO	Chief Executive Officer
CIPR	UK Commission on Intellectual Property
CL	Compulsory License/Licensing
CPTech	Consumer Project on Technology
DC	Developing Country
EC	European Communities
EFPIA	European Federation of Pharmaceutical Industries and Associations
EU	European Union
FAC	Federal Advisory Committee
FACA	Federal Advisory Committee Act
FDA	US Food and Drug Administration
FDI	Foreign Direct Investment
GAO	General Accounting Office
GATT	General Agreement on Tariffs and Trade
GDP	Gross Domestic Product
GMS	Global Market Share
GNG	Group of Negotiations on Goods
GNP	Gross National Product
GPE	Global Political Economy
GSK	GlaxoSmithKline
GSM	Global Social Movements
GSP	Generalized System of Preferences
HAI	Health Action International
IAC	Industry Advisory Council to the Department of Defense
IC	Industrialised or Developed Country
IFI	International Financial Institution
IGPAC	Intergovernmental Policy Advisory Committee
IMF	International Monetary Fund
IO	International Organisation
IP	Intellectual Property
IPC	Intellectual Property Committee
IPE	International Political Economy
IPP	Intellectual Property Protection
IR	International Relations
ISI	Import-Substituting Industrialisation
ITAC	Industry Trade Advisory Committee

ITAC 15	Industry Trade Advisory Committee on Intellectual Property Rights
JNJ	Johnson & Johnson
LAC	Labour Advisory Committee
LDC	Less/least Developed Country
M&A	Mergers and Acquisitions
MFN	Most Favoured Nation
MNC	Multinational Corporation
MSF	Medecins Sans Frontieres
NET	Net Exporters of Technology
NGO	Non-Governmental Organisation
NIT	Net Importers of Technology
NIC	Newly Industrialising Country
NT	National Treatment
NTB	Non-Tariff Barrier
OUA	Organisation for African Unity
OECD	Organisation for Economic Cooperation and Development
PEG	Private Enterprise Growth
PhRMA	Pharmaceutical Research and Manufacturers Association of America
PTO	US Patent and Trademark Office
QCA	Qualitative Content Analysis
QR	Quantitative Restriction
R&D	Research and Development
ROI	Return on Investment
SAP	Structural Adjustment Programme/Policy
SSA	Sub-Saharan Africa
TAG	Trade as Growth Theory and Practice
TDI	Transnational Drug Industry
TEPAC	Trade and Environment Policy Advisory Committee
TNC	Transnational Corporation
TNC	Trade Negotiations Committee
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TWN	Third World Network
UDHR	Universal Declaration on Human Rights
UNAIDS	The Joint United Nations Programme on HIV/AIDS
UNDP	United Nations Development Program
UR	Uruguay Round of Trade Negotiations
US	United States
USCIB	United States Council for International Business
USTR	United States Trade Representative
WIPO	World Intellectual Property Organisation
WHA	World Health Assembly
WHO	World Health Organisation
WTO	World Trade Organisation

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## **DECLARATION**

This dissertation is my own work, and it has not been submitted for a degree at another university.

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## ABSTRACT

The public international backlash against the TRIPS Agreement and the global pharmaceutical industry that followed in the wake of the March 2001 lawsuit brought by 39 pharmaceutical companies against the government of South Africa prompted a critical investigation into how the current order came into being and how it might be in a process of changing. To do this the thesis follows Cox's insight in Critical IPE that each successive historical structure generates the contradictions and points of conflict that bring about its transformation (Cox, 1995: 35). The research therefore first looks at the making of the patent provisions in TRIPS as a case study in institutional capture by the transnational drug industry (TDI), dominated by American interests. This question is developed theoretically as well as empirically by first developing a theoretical framework that explains continuity in the global political economy (GPE) as a way of intimating how the TDI was able to secure all of its demands for pharmaceutical patents under TRIPS despite the prevalence of conflict and opposition from developing countries in the Uruguay Round (UR), and notwithstanding the single undertaking of the UR package. The thesis then examines the negotiations on patents in the UR to determine the nature of decision-making and to probe the questions of conflict and contradictions in the present that provide a framework of analysis on the shakiness of the prevailing order.

The thesis then looks at how, why and under what circumstances the initial 'capture' of TRIPS by the TDI was arguably successfully challenged by probably the weakest global economic actor, the African Group (AG) at the WTO. Specifically looking at the role of conflict in change this question probes further points of conflict and contradictions in the present to set the scene for the wide scale offensive against TRIPS as a result of its implications for access to healthcare in the poorest countries which already suffer overwhelmingly from a high disease burden. The post-TRIPS challenge mounted by transnational civil society and the AG (the two constituting a counter-society) take the thesis from its analysis of continuity in the GPE, towards theorising the circumstances under which the prevailing historical structure can at least partially be transcended to render legitimate the demands of the poor. The thesis advances its contribution, both theoretically and empirically, to Critical International Political Economy, particularly as it concerns the work of Robert Cox.

## INTRODUCTION

Firstly, the thesis analyses the *making* of the patent provisions of the TRIPS Agreement as a case study in institutional capture by private interests, specifically focusing on how the transnational drug industry or TDI<sup>1</sup> (particularly of US origin) was able to secure its demands for an international patent code under TRIPS. This first question is therefore decidedly a case study in international trade decision-making, explaining how and why particular decisions prevailed over others in the area of patents at the GATT. One hypothesis is generated from this first research question.

### **Hypothesis I (Empirical):**

That the Transnational Drug Industry was a key player in the making of the international patent code inscribed in the original TRIPS Agreement, ensuring that its interests were fully reflected in the code despite the high intensity of the conflict characterising the negotiations on patents.

Secondly, the thesis examines how, why and under what circumstances this capture of TRIPS by the TDI was, to some measure, successfully challenged by arguably the weakest global economic actor, the African Group (AG) at the WTO.<sup>2</sup> This second question looks specifically at the role of conflict in change. Three further hypotheses are drawn from this second research question.

### **Hypothesis II (Empirical):**

That the TRIPS Agreement has been renegotiated because of the conflict triggered by the distributional implications of some of its patent provisions, particularly as they impacted on poor countries' access to public health.

### **Hypothesis III (Empirical):**

That the rise of the African Group at the WTO was itself a manifestation of the conflict in the making of the original agreement, the distributional

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<sup>1</sup> For the purpose of this research the TDI is seen as a homogeneous category on the issue of a strengthened international patent code. It refers exclusively to the research-based sector of the transnational industry with an overwhelming reliance on patent protection for pharmaceuticals and does not consider the generics sector. Although many major industry actors rely on both segments, the research is concerned with the patent-dependent segment in both the run-up to TRIPS and the aftermath.

<sup>2</sup> The actors are justified on the bases that the global pharmaceutical industry (primarily of US origin and starting with Pfizer's CEO Edmund Pratt) was the impetus behind a trade-based approach to intellectual property protection in the GATT; while the African Group (operational since 1999, four years after the Uruguay Round came to a close) followed in the post-TRIPS period with formalising the relationship between patents and healthcare at the level of the WTO. The level of post-TRIPS engagement and activism over the impact of patents on access to medicines also makes the latter, and the roles it exhibited, fundamentally research-worthy.

implications for the African continent, and the emboldened calls for change emanating from transnational civil society.

**Hypothesis IV (Empirical):**

That the African Group at the WTO was a key player in the post-TRIPS agitation and negotiation of the Doha Declaration on the TRIPS Agreement and Public Health; the Paragraph 6 negotiations leading to the 30 August 2003 Decision; and the paragraph 11 negotiations leading to the 06 December 2005 Decision to Amend TRIPS.

These research hypotheses provide the empirical basis for an overarching theoretical hypothesis which encapsulates the entire thesis.

**Hypothesis V (Theoretical):**

That the Coxian approach to the dual dynamics of continuity, and change through conflict, provides the best analytical means of making sense of the making and re-making of patent provisions under TRIPS.

The general thread of the research therefore follows Cox's insight that each successive historical structure generates the contradictions and points of conflict that bring about its transformation (Cox, 1995: 35). In pursuit of its objectives, the research spans the Uruguay Round (UR) negotiations up to the December 2005 Decision to amend the TRIPS Agreement. To set the scene, the introduction analyses the significance of intellectual property (IP) to the major economies and surveys the competing perspectives on IP protection. It also looks at the enabling legislative climates particularly in the US, that facilitated the mega-corporation phenomenon, which subsequently facilitated the role the pharmaceutical industry would exhibit in the TRIPS landscape. This is significant because in order to understand the active role the pharmaceutical industry played in the TRIPS process, it is necessary to take stock of the factors that facilitated this role. Key among these are the legislative changes that enabled corporations to expand both physically and in terms of the political power they command. The introduction also includes a discussion on the theoretical and methodological frameworks deployed; the thesis' contributions to IPE; and a chapter outline.

## **1. The Research Problem**

Pharmaceutical patents<sup>3</sup>, and particularly the issue of compulsory licensing, are arguably the most controversial and contentious components of the WTO's TRIPS Agreement because the debate is almost always tipped towards a winners/losers scenario in the global political economy (GPE). There are ardent supporters of the patent framework consisting most visibly of the TDI and economies that are net exporters of technology (NETs); but also an increasingly louder, more organised pool of vociferous critics comprising the greater part of the developing world (primarily net importers of technology/NITs), and a wide range of civil society organisations. The composition of these camps suggests that pharmaceutical patents are a deeply divisive issue around which both sides appear absolutely convinced of the correctness and justification of their respective positions. Debates on the issue are therefore mired in conflict, making positions mutually inconsistent at best.

The emergence of manufacturing powerhouses in the developing world in the last three decades has meant that former leading industrialised economies like the US have witnessed a considerable decline in their manufacturing base. Since the 1980s, the US and other industrialised economies began to lose older, labour-intensive manufacturing to the newly industrialised economies (NIEs) in Asia and Latin America, thereby producing downward pressures on the former economies. Between 1980 and 1985, the US trade deficit increased by 309 percent, from \$36.3 to \$148.5 billion (Sell, 1999: 176), thereby compelling serious attempts to relocate trade competitiveness in technological innovation and research-intensive areas like pharmaceuticals (Capling, 1999: 83). In 1947 for instance, intellectual property accounted for less than 10% of all US exports. By 1986, the figure rose to 37%, and by 1994, well over 50% (Shiva, 2001: 19; see also Ryan, 1998: 2). The international protection and enforcement of IP therefore have particular relevance for the US, thereby explaining its role, and that of its global

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<sup>3</sup> This refers to patented products and products manufactured through a patented process in the pharmaceutical sector.

business, in promoting the multilateral protection of intellectual property rights.<sup>4</sup> The US is home to the largest firms in the pharmaceutical industry, accounting in 1995, for 13 of the top 20 leading producers in the world (Richards, 2004: 145, taken from Schweitzer, 1997: 21). These 20 firms in 1995 produced 70% of the top-selling products in the world, with the 10 largest firms accounting for 45% of sales (ibid). Also, between 1980 and 1994, the share of knowledge-intensive or high-technology products in total world trade doubled from 12% to 24% (Fink and Primo Braga, 1999: 2)<sup>5</sup>, making the issue of their protection a matter of urgency for the industries concerned.

As a result of the sheer significance of IP (and some other areas) to the major economies, there has been a fundamental shift in conventional thinking of trade as goods-orientated, and a corresponding explosion in a specifically *trade-related* theory, practice and enforcement of new issues in trade and political economy. When the old GATT emerged in 1947, trade policy was confined to the progressive elimination of quantitative restrictions (QRs) on a most-favoured nation (MFN) basis because the prevailing consensus at the time equated the removal of QRs with free trade (Tussie, 1993: 71). The concept of ‘intangibles’ trade was not considered before 1972 when services were so construed in an OECD expert report which cautiously suggested that transactions in services could be considered trade, that the norms and principles covering trade in goods might apply, and that the challenge in the emerging transition was to avoid protectionism (Ruggie, 1995: 514). With successive trade rounds it became increasingly clear that trade encompassed more than just the entry and exit of *goods* at the border, and the UR

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<sup>4</sup> This is not to say that the US and its pharmaceutical industry were solely responsible for the elevation and maintenance of intellectual property as a trade issue in the GATT. Indeed, as the research will show, it is difficult to separate the active role played by the European Communities, Japan, other industrialised countries and their respective industries when it looks at the role of the Intellectual Property Committee (IPC). See however Matthews (2002) and Pugatch (2004) for arguments which touts the role of the EC and European industries; as well as Devereaux, *et al*, (2006) for an overview of other very important industries. Devereaux also looks at inter-agency (USPTO and USTR) collaboration as vital.

<sup>5</sup> The material aspects of the transnational drug industry are further examined in Chapter I: 1.3.

ensured that intellectual property protection occupy the crux of this new trade-related paradigm, thereby making IP a definitive fixture in the growth and development discourse.

The key rationale for the multilateral protection of intellectual property rights (IPRs) finds expression in the neoclassical tradition which postulates that unless invention or creation is compensated at its full social value, there will be suboptimal incentives to undertake it (Trebilcock and Howse, 1995: 250; Vandoren, 2002: 7). Similarly, those who favour a rule-of-law approach to economic development tout the greater legal certainty of well-specified rules of engagement which make businesses more willing to undertake additional investment (Primo Braga, 1996; Maskus, 2000; Matthews, 2002). The compensation+predictability→incentive-to-innovate dynamic is further captured by the idea that IP, or knowledge, has the attributes of a public good, characterised by two critical properties: non-rivalrous consumption – consumption by one does not detract from that of another; and non-excludability – it is difficult, if not impossible, to exclude an individual from enjoying the good (Stiglitz, 1999: 308).

These attributes together facilitate the problem of free-riding, whereby IP can be used or copied at a fraction of its initial cost of creation (Grabowski, 2002: 849; Sherwood, 1993: 75-6). One argument put forward by the US in its efforts to strengthen the global protection of IPRs under the GATT stemmed from estimates that its pharmaceutical corporations lose \$2.5 billion annually from developing countries that fail to recognise patents for IP (Shiva and Holla-Bhar, 1996: 147); this, against industry's claim that it requires an average of \$500 million, and ten to twelve years, to introduce a new medicine to market.<sup>6</sup> If these purported estimates (representing

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<sup>6</sup> Maskus, 2000: 53, taken from PhRMA, 1999. This figure varies widely. In its 1996-1997 report, PhRMA put that figure at \$350 million (See Ryan, 1998: 30). In a 2001 pro-industry study, the Tufts Center for the Study of Drug Development put the figure as high as \$802 million, asserting that the clinical-trial phase of drug development was largely responsible for the rapid increase. See Goozner, 2004; the study's news release can be found at: <http://csdd.tufts.edu/NewsEvents/NewsArticle.asp?newsid=6>. Many note however, that the pharmaceutical industry spends more on direct marketing and advertising than it does on R&D. See Richards 2004: 146. Furthermore, the

lost revenue and investment averages) are juxtaposed, purportedly industry loses the equivalent of five new marketed medicines annually, thereby providing compelling reasons for an aggressive campaign aimed at the multilateral protection and enforcement of IP.

The free-riding problem, otherwise called piracy/theft/counterfeiting, is subsumed under what economists call market failure and can potentially lead to distortions in international trade. In much the same way that government-imposed tariffs restrict imports, lax or non-existent IP regimes in some countries may create a demand for pirated products, thereby undermining the returns for those who incurred the initial research and development (R&D) costs. Assuming that piracy-related revenues represent revenues that would have accrued to IP firms in the absence of market failure, then TRIPS is attending to IP in much the same way that the old GATT attended to the removal of QRs on the movement of goods. More poignant is the assertion that discrepancies among national IPR regimes generate effects analogous to nontariff barriers (Primo Braga, 1996: 360, taken from Stern, 1987). This realm of the debate is therefore decidedly 'rights-orientated'.

This realm of the debate regards as sacrosanct the legal judgement that “the inventor has a property in his invention; a property which is often of very great value, and of which the law intended to give him the absolute enjoyment and possession...involving some of the dearest and most valuable rights which society acknowledges, and the Constitution itself means to favor”.<sup>7</sup> It contends that while the costs associated with stronger IPRs are real – such as the sustenance of high monopoly prices for patented pharmaceuticals – stronger IPRs will provide competitive advantages for innovative firms, allowing them to appropriate larger returns for creative activity and generating incentives for additional invention (Mansfield, 1993; Maskus, 2000). Sherwood

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industry is criticised for its reliance on 'me-too' or copycat drugs, which have little or no therapeutic gain over drugs that already exist (Public Citizen, 2003b: 13-14).

<sup>7</sup> US Supreme Court Justice Joseph Story, the acknowledged intellectual property expert of the early courts, made this perspective in the *Lowell v. Lewis* case (15 F. Cas. 1018 [1817]). Extracted from Khan and Sokoloff, 2001: 236.

(1993: 79) also asserts that the introduction of new technology into an economy has been shown, not only to contribute handsomely to growth, but also to provide a high social rate of return, and that... intellectual property rights are an important ingredient in the introduction of new technology.

In an empirical investigation involving 100 firms, Lee and Mansfield (1996) would later conclude that a country's system of IPR protection influences the volume and composition of US foreign direct investment (FDI); and because it “is well known” that “foreign direct investment is generally regarded as an important means of transferring technology to developing countries” (Mansfield, 1993: 111), “there will be no transfer of technology to countries that de facto grant no patent protection for pharmaceuticals” (Stamm, 1993: 227). Without adequate patent protection, no investment will be made in pharmaceutical research (ibid) of relevance to these countries. This realm of the debate therefore takes an especially one-dimensional, neoclassical spin that what is good for business is also good for society<sup>8</sup>, and by extension, developing countries (DCs), a point that often obscures and undermines the very real distributional implications that opponents argue are a legitimate consideration.

To be sure, not all neoclassical economists believe in this clear-cut relationship where IPRs are concerned. Bhagwati (2002: 127) for instance contends that the TRIPS Agreement does not belong in the WTO; that it enforces payment by the poor countries (which consume IP) to the rich countries (which produce it); and by putting TRIPS in the WTO, “we legitimated the WTO to extract royalty payments”. In a letter to the *Financial Times*, Bhagwati argued that the WTO must be about mutual gains in trade, whereas IP protection is a tax on poor countries (quoted in Khor, 2002: 212), speaking specifically to the distinction that separates competitive from monopoly capital as a means to understand the firm-specific rents associated with knowledge-

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<sup>8</sup> Macdonald (2002) argues instead that the strong disguise their own interest in the patent system by emphasising society's interests in the system, and the benefits for the weak.

based outputs and processes (Richards, 2004: 15). In fact, this Bhagwati standpoint has been used for decades by prominent economists who believe in the virtues of free market competition, from Burns (1936), to Hayek (1944), to Vaughan (1956).<sup>9</sup>

Concurring with this kind of reasoning<sup>10</sup> are the net importers of technology and social activists which emphasise mutual benefits to holders and society, of IP protection. They subscribe to a less clear-cut relationship between compensation and incentives-to-innovate since other factors play a crucial role in investment decisions, such as “intellectual work potential, infrastructure, political stability and economic structure” (Stamm, 1993). This realm of the debate contends that countries which are now industrialised instituted IP regimes as and when they developed, thereby making their demands on the poorest countries both unreasonable and unjustifiable (Chang, 2001, 2002, 2003; Lee, 2006),<sup>11</sup> a point which provides fodder for DC negotiating positions as essentially “kicking away the ladder” (Chang, 2002). Nogues (1990) chronicles that the UK introduced patents for pharmaceutical drugs in 1949, France in 1960, Germany in 1968, Japan in 1976, and Switzerland in 1977<sup>12</sup>, even though the US did use strong patent rights in the sector (LaCroix and Konan, 2006: 1).

Moreover, this realm of the debate maintains that “TRIPS was *designed* to ensure higher priced medicines” and that trade ministers signed a “death warrant” for the poor (Stiglitz, 2006: 105); that excessive protection can lead to a transfer of rents to developed countries, restrain consumer access to new goods (LaCroix and Konan, 2006: 3; Sell 2006), and increase domestic prices of essential goods (Primo Braga, 1996, taken from Rodrik, 1994). Pre-empting these concerns and

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<sup>9</sup> For a very good overview of earlier controversies about the patent system, see Machlup (1958), especially the chapter on economic theory. He looks at contributions from Hayek, Burns and Vaughan, among others.

<sup>10</sup> We will see this Bhagwati-like position of developing countries when we come to examine the TRIPS UR negotiations in Chapter III.

<sup>11</sup> This 'kicking-away-the-ladder' argument is explored in greater depth in Chapter III.

<sup>12</sup> See also Pretorius, 2002.

suggesting the welfare-reducing implications for countries without the necessary industrial base, Penrose (1951: 116) made a frank assertion that “any country must lose if it grants monopoly privileges in the domestic market which neither improve nor cheapen the goods available, develop its own productive capacity nor obtain for its producers at least equivalent privileges in other markets. No amount of talk about the “economic unity of the world” can hide the fact that some countries with little export trade in industrial goods and few, if any, inventions for sale have nothing to gain from granting patents on inventions worked and patented abroad except the avoidance of unpleasant foreign retaliation in other directions”, a point which underscores the intensity displayed by many DCs in the UR against the patent protection framework.

More than four decades later, Deardorff (1992) developed a simple economic model of invention and patent protection to examine the welfare effects of extending patent protection from the home country to a host country. He found that while the welfare of the inventing country certainly rises with the extension of patent protection, that of the other country probably falls, and may well fall by more than the increase in welfare of the inventing country.<sup>13</sup> He found in particular, that as patent protection is extended to a larger and larger proportion of the world, the effect on the welfare of the world as a whole, of extending it to the rest of the world, becomes negative.<sup>14</sup> Moreover, as Nogues (1993) argues, the social costs of introducing patent protection depend very much on the pre-patent structure of the pharmaceutical drug market. This is so because patents sustain monopoly prices and if the pre-patent market situation is characterised by competition, the introduction of patents will entail higher social losses than if that situation is characterised by monopolistic behaviour. This is especially poignant because prior to TRIPS, many developing countries did not recognise patents for pharmaceuticals (Kuyek, 2001),

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<sup>13</sup> See also Borrus (1993: 367) who argues that it is not obvious whether a country derives greater long-term benefits from stricter IPR protection that rewards innovation, or from protecting less and choosing to favour the more rapid exploitation and use of technology.

<sup>14</sup> See also Deardorff, 1990.

indicating that such countries had more to lose since the pre-patent market situation was not characterised by monopolistic behaviour. More recently, Richards (2004: 3) argued that intellectual property protection, in the expression of the TRIPS Agreement, is not in the best social welfare interest of poor countries; that its effective imposition on them by the rich countries has far more to do with the exercise of real political and economic power than it does with the positive economic benefits the agreement's supporters claim it can deliver,<sup>15</sup> a characterisation this thesis supports both empirically and theoretically.

Accordingly, because patents confer monopoly privileges for a period of no less than 20 years, the cost of patented pharmaceuticals means that most people from poor countries are effectively denied access. The 'access' issue which animated this research was magnified in the wake of the global HIV/AIDS pandemic which mostly affected sub-Saharan Africa (SSA) where an estimated sixty-three percent of HIV-infected people in the world live (UNAIDS, 2006). It is estimated that 4.7 million people in South Africa alone have AIDS, and almost 20 percent of the adults there have HIV, with some communities suffering from infection rates as high as 70 percent; about 20,000 people die each month from AIDS-related illnesses, about one million children are infected with the disease, and a more staggering number has been orphaned because of AIDS (Halbert, 2005: 88, various citations). The standard triple-therapy for HIV infection was priced at approximately US\$10,000 annually, at a time when the annual per capita expenditure on drugs in the sub-Saharan region stood at \$8.4 (t'Hoen, 2000), thereby making treatment impossible for the majority of people in these countries, remaining cognizant that healthcare represents an out-of-pocket expenditure for most people in DCs. This is particularly poignant since more than a billion people in DCs lack access to essential drugs (Oh, 2000). Any policy

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<sup>15</sup> See also Watal (2000) for an overview of the welfare costs on India with the introduction of pharmaceutical patents. See also, Rozek and Berkowitz (1998) for further discussion on the relationship between patents and prices in developing countries.

that further inhibits access is therefore bound to attract profound resistance from civil society and those countries most implicated.

The protection of IP therefore has fundamental human rights implications, and since TRIPS' inception, the debate over the impact of patents on people's fundamental rights and freedoms have only intensified. In fact, the concerns of various human rights actors over IP issues have led to a series of initiatives within UN human rights institutions. To mark the fiftieth anniversary of the Universal Declaration of Human Rights (UDHR), WIPO and the Office of the UN Commissioner for Human Rights held a seminar on IP and human rights in 1998 and then published a volume on that topic (Chapman, 2002: 862).<sup>16</sup> The UN Sub-Commission for the Promotion and Protection of Human Rights adopted resolutions on intellectual property at its sessions in both 2000 and 2001 (ibid).<sup>17</sup> At the request of the Sub-Commission, the High Commissioner for Human Rights prepared a report on the human rights impacts of the TRIPS Agreement and other issues relating to intellectual property and human rights (ibid; see also Picciotto, 2002). This intensified institutional focus was the result of the global social activism mounted against the globalised property regime under TRIPS since the agreement's inception.<sup>18</sup>

The human rights considerations of IP protection appear to be three-fold, aptly captured by Sell's 2006 title, "Books, Drugs and Seeds: the Politics of Access", in which she makes the case that "all intellectual property is not alike", that "one could argue that movies and compact discs are not core components of economic development. One could not make that case for books, drugs and seeds. Access to educational materials (including scientific and other scholarly journals and

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<sup>16</sup> The volume is entitled *Intellectual Property and Human Rights* (Geneva: World Intellectual Property Organization and the Office of the UN Commissioner for Human Rights, 1999), WIPO Publication No. 762(E).

<sup>17</sup> Sub-Commission for the Promotion and Protection of Human Rights, resolutions 2000/7 and 2001/21 respectively.

<sup>18</sup> Chapter VI goes into more detail about the global social activism mounted against the TRIPS Agreement, including other initiatives at the international institutional level, and how this precipitated the rise of the African Group at the WTO.

educational software), life-saving medicines, and seeds for sustainable agriculture is the *sine qua non* of economic development” (Sell, 2006), a point which underlines the points of conflict during the TRIPS negotiations and the renewed activism in the post-TRIPS context.

Research also suggests that because of the huge returns on investments (ROI) that patents enable, it can discourage R&D on diseases of particular relevance to developing countries (CIPR, 2002: 35-6; Richards, 2004: 146-151), because private R&D in new drugs is causally related to affordability in prospective markets. The WHO reports that global investment in research on diseases that mainly affect the poor is a drop in the ocean in relation to the high disease burden involved; that an estimated 10% of global investment in health research targets diseases which account for 90% of global disease burden (WHO, 2003: 6). In 1998, less than 1% of the US\$70 billion spent on the R&D of new medicines, vaccines and diagnostic tools was used for HIV/AIDS, malaria and TB – which together account for 6 million deaths a year (ibid). In the preceding 22 years, between 1975 and 1997, out of 1223 new chemical entities invented, only 13 (1%) were for the treatment of tropical diseases (t’Hoen, 2000).<sup>19</sup> Equally important is the argument that patent protection may hinder the development of important inventions, a point usually bolstered with reference to James Watt's patent grant for his 1769 invention of the steam engine (Machlup, 1958: 42; Sell and May, 2001: 472-3; May and Sell, 2006: 26-7; Mytelka, 2000). In instances when the issue underscores such fundamental aspects of life as healthcare, the likelihood of pent-up passion evolving into widespread activism and calls for change increases exponentially as in the case of the post-TRIPS landscape of renewed conflict.

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<sup>19</sup> These figures show that global expenditure into tropical R&D has remained staggeringly constant for at least three decades. For a comprehensive analysis on drug development and neglected diseases, see Trouiller, *et al*, 2002. See also Stiglitz, 2006: 122-4.

Furthermore, there is a huge disparity in patent ownership between nationals of NITs and NETs. Of the 3.5 million patents in existence in the 1970s, prior to the TRIPS negotiations, nationals of developing countries held about 1 percent (Drahos with Braithwaite, 2002: 11; see also Correa, 2002; Kumar, 1997), not surprising since DCs account for only four percent of world R&D expenditures (UNDP, 1999: 67). This effectively means that the globalisation of a patent regime overwhelmingly serves the interests of the major economies, and especially so considering the opportunity costs associated with the financial and institutional requirements of such a regime,<sup>20</sup> as well as the dearth of R&D into tropical diseases. The conundrum is therefore captured in seeking the right balance between the diverse and contentious understandings of the rationale for a global pharmaceutical patent system; and especially the nature of the social bargain underlying this system against the backdrop of pecuniary gains.

## **2. The Argument in Context**

The thesis maintains that the potency of these diverse positions was ill-considered during the Uruguay Round of multilateral trade negotiations, thereby making the outcome akin to a winner-takes-all scenario in which the disaffected perceive a gross miscarriage of justice; that the demands of developing countries<sup>21</sup> to stick to the letter of the Paris Convention<sup>22</sup> were effectively negotiated out of the Round, creating further resentment of the outcome; and argues that the making of the TRIPS Agreement represents an instance of institutional capture by private interests (the TDI dominated by American industry). The nature of this institutional capture was the consequence of the privileged place of transnational capital in American politics

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<sup>20</sup> See Ringo (1994); Correa (2000), Finger and Schuler (1999, 2000), Finger (2001) for overviews on the implementational challenges facing developing countries in the TRIPS area.

<sup>21</sup> For the purpose of this research, the terms 'developing countries', net importers of technology (NITs), Global South/South are treated as a single category. Whenever empirically possible, differences are established between this category and least developed countries (LDCs). However, the terms do not refer here to Asian 'tiger' economies and the formerly communist states of Eastern Europe. Similarly, developed/industrialised countries/economies, net exporters of technology (NETs), Global North/North are used interchangeably in this research, although much of the emphasis is on the United States.

<sup>22</sup> See for instance, Deardorff, 1990: 498, that many developing countries especially argued that WIPO should remain their sole arbiter.

and the extension of this at the international level, and the pro-business grounding of the major economies that increase both the economic and political power of capital. From these standpoints the thesis contends that the post-TRIPS challenge, and the rise of the African Group that followed, were the direct result of the legitimacy shortfalls that were the basis of a 'consensus' agreement.

The pro-TDI results of TRIPS were not entirely unexpected since this can be attributed to exponential rise in the power of transnational capital (TNCs), which today, comprises more than 50% of world trade (O'Brien and Williams, 2004: 167). By virtue of their resource base and their significance to the international competitiveness and domestic stability of primarily the major industrialised economies, TNCs command a level of power that was previously unimaginable. Several business-oriented perspectives have sought to explain their rise in the post-war period, namely internalisation theory, product life-cycle theory, obsolescing bargaining theory, oligopoly theory, and tariff-jumping hypothesis (Spero and Hart, 1997: 109-112), all of which have explanatory strength depending on firm-specific circumstances.

From a political economy perspective, domestic politics in Britain, and particularly the US, served as catalysts in the extraterritorial expansion and dominance of TNCs in the GPE. The particular neoliberal political rule of the Reagan and Thatcher administrations in the US and UK paved the way for the evolving 'big business' of today. Some illustrations are crucial to set the scene for the rise of the TDI. It became increasingly clear during the 1980s that the growing knowledge-intensity of production meant that product life cycles across a wide range of industries began to shorten and firms were obliged to spend increasing amounts on R&D and other intangible investments (Mytelka and Delapierre, 1999: 130; Mytelka, 2000: 47). This meant that in order for business to continue to be operational in an increasingly technologically

volatile climate, firm size had to be adjusted upward to reflect the rising cost structure, noting specifically that R&D represents a fixed cost.

To cope with these challenges, government enacted a range of deregulation policies such as the relaxation of anti-trust legislation which prohibited R&D collaboration. In 1984 the US passed the National Cooperative Research Act to encourage joint R&D (ibid), which provided that registered joint ventures cannot be sued for punitive and treble damages under antitrust laws (Carlton and Perloff, 2000: 521). In that same year the European Community followed by exempting R&D collaboration from a number of restrictive business practices (Mytelka and Delapierre, 1999: 130). The corporate world was however presented with another dilemma since there was an optimal point at which a firm's internal expansion could serve the local market before becoming saturated. The answer lay in privatisation and transnationalisation. Policies were aimed at the elimination of public monopolies through privatisation in order to encourage further private investment and partially remedy domestic saturation problems; and the liberalisation of investment restrictions made the expansion of business possible.

Arguably more important was the US extraterritorial mission to liberalise external markets through aid and trade mechanisms, and bilateral investment treaties (BITs), to grant its corporations predictability and transparency in international investments. Herein lies the rationale for a global economic policy-convergence project, as the US was able to almost single-handedly re-build the post-war order on the basis of neoliberal economic expansion. Such policies did not only enable corporations to expand globally and substantially reduce production costs, but also instigated the growth of the corporate merger movement of the 1980s which saw a

spate of mergers and acquisitions (M&A) aimed at consolidating positions at home and accessing markets abroad (ibid: 131; Richards, 2004: 145).<sup>23</sup>

Also significant to the 1980s neoliberal facilitation of the growth and power of the TDI were a series of legislative amendments in the United States such as the 1981 Bayh-Dole Act, and the Omnibus Trade and Competitiveness Act of 1988. Domestically, the Bayh-Dole Act enabled universities and small businesses to own patents in inventions that they had developed with federal funds (Drahos with Braithwaite, 2002: 163).<sup>24</sup> Prior to Bayh-Dole, patents on federally funded inventions were the property of the relevant federal funding agency, or the inventions were immediately directed to the public domain by means of publication (ibid). In the five years following the adoption of the Act, universities, small businesses and hospitals increased their patent applications in the area of human and biological sciences by 300 percent, and the university sector, in particular, saw its income catapult from licensing IP (ibid). Many small businesses were eventually the takeover subjects of the colossal life sciences corporations. This Act essentially paved the way for a more transnationalised focus on the protection of intellectual property.

The 1988 Omnibus Trade and Competitiveness Act has had similar, though more immediate extraterritorial ramifications. It dealt with much more than trade issues as it contained provisions on international financial policy, foreign corrupt practices, technology competitiveness (Low, 1993: 62), and inscribed the protection of IPRs as one of the principal priorities of US trade policy (Gadbow, 1989: 223). Crucially also, the Act set out to strengthen the role of the private-

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<sup>23</sup> For an overview of economic concentration in the life sciences as a consequence of a relaxation of anti-trust, and a list of recent examples of mergers in the pharmaceutical industry, see Sell, 2006: 8-9; Harrison, 2004; Rosenberg, 2006.

<sup>24</sup> See also UNDP, 1999b: 67; CPtech 2000; Mytelka, 2000: 50; Chang, 2001: 297, 2003: 289-90; Public Citizen, 2003b; Richards 2004: 149 for some examples of federally funded, privately appropriated, research. See particularly Abbott (2005: 397, 421-2) for an illuminating account on the role of the US National Institutes of Health (NIH) in federally funded research, and the extent of private appropriations by pharmaceutical firms of such research.

sector advisory committees established under the Trade Act of 1974. Composed of private sector interests, these committees were charged with the responsibility of advising the United States Trade Representative (USTR) on how to tackle issues that affected US international competitiveness, export performance, and by extension, the national economic interest.<sup>25</sup> The Act mandates that within 30 days of releasing the *National Trade Estimates* at the end of April each year,

the USTR must identify those foreign countries that deny adequate and effective protection of intellectual property rights, or deny fair and equitable market access to United States persons that rely upon intellectual property protection, and those foreign countries ... that are determined by the Trade Representative to be priority foreign countries that have the most onerous or egregious acts, policies, or practices.<sup>26</sup>

Under Special 301 the agency lists the countries that are the most onerous or egregious offenders with which negotiations are being conducted under threat of retaliatory sanctions (Ryan, 1980: 80). It also announces a “priority watch” list of countries that may have sinned no less but are not the target of deadlined negotiations (ibid). In addition, it announces the countries in which IP protection problems persist but that are not the subject of negotiations (ibid). One year after the Act was passed, the priority offenders included Brazil, India, South Korea, Mexico, Saudi Arabia, Taiwan, Thailand and China (ibid). The 1988 Act was therefore a piece of legislation aimed at forcing international compliance with the US economic worldview in a bid to strengthen its global position and that of its multinationals. Moreover, as Picciotto (2002) maintains, the establishment of the USTR in US trade politics was intended to serve the interests of US transnational capital, mandated to open foreign markets for US firms under provision s.301 of the Trade Act.<sup>27</sup>

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<sup>25</sup> The last section of Chapter I will examine the role of such committees during the Uruguay Round as well as their significance in American politics as a powerful force which feeds onto the international trade decision-making landscape.

<sup>26</sup> Ryan, 1998: 79. Taken from Omnibus Trade and Competitiveness Act (1988, sec. 1303). See Committee on Ways and Means (1989, p. 761).

<sup>27</sup> Some (notably Matthews, 2002: 85; see also Ryan, 1998: 80) argue that the USTR has serious resource deficiencies, and so, must rely on US business advice and expertise to provide information that is used as the main basis of Special 301 decisions and complaints made to the WTO. However, if we lean towards Picciotto's stance that the USTR was established as a tool of US transnational capital, it suggests a broader US strategy aimed at securing a space for business within US politics. It is certainly not the case that the US could not afford the expertise

Therefore while it is possible to argue that the growth of the multinational was internally driven, there is also compelling evidence to discern the specificity of domestic politics, primarily within the United States as a decisive push-factor which lay the foundation for the wide-ranging remit that helped to redefine the current GPE. It is no coincidence therefore, that the evolution of trade strategies at the global level and the overall redefinition of the international regulatory trade framework have coincided with similar trends in domestic politics in the United States and the resulting evolution of big business at the international level. These trends have created an environment in which the concerns of transnational capital are perceived by many to override that of the poor, and arguably, nowhere is this perception more pronounced than in relation to the TDI and the protection of pharmaceutical patents. It is against this backdrop that the thesis gathers its momentum.

Significantly, while the arguments making the case for a trade-related IP code came with an overwhelming mainstream emphasis on the importance of protection for growth, competitiveness and innovation (neoclassical rationality), the post-TRIPS climate would usher in a diametrically opposed interpretation that would force a re-think of the agreement itself, appealing to developing countries' claims for justice and fairness (what dominant approaches deem as value-laden), and a greater emphasis on the social bargain underlying patent policy. While the success of industry in the first instance was a function of the prevailing theory as practice, the post-TRIPS legal clarification in favour of the poor (although not without flaws), represents, not a subversion of industry's stance *per se*, but an instance in which the circumstances of the marginalised in the GPE could not be disregarded. The tumultuous episodes

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to properly equip the USTR. Also, when we examine the politics of trade advisory committees in the US in Section 1.5 of Chapter I, and the role deployed by US industry in the trade advice structure, it will come as no coincidence why the USTR relies so extensively on industry. Significantly, Section 135 of the 1974 Trade Act mandates the USTR to seek advice from industry-dominated trade advisory committees before, during and after entering into trade deals, thereby highlighting that the USTR was never intended to be an autonomous agency, separate from transnational capital. See Stopford and Strange (1991) on the necessary collusive relationship between states and TNCs for national competitiveness.

of the TRIPS story, together with the 2005 Decision to amend the agreement carry the hallmarks of the critical agenda in which conflict and political struggle prefigure transformation in social relations, although less the classic Coxian moment of a change in world order.

### **3. Theoretical Framework**

The thesis adopts a two-fold theoretical approach inspired by the Marxian-influenced critical social theory tradition, and based on the transnational historical materialist variant of Robert Cox's work in IPE that “each successive historical structure generates the contradictions and points of conflict that bring about its transformation” (Cox, 1995: 35). The first part of this two-pronged approach develops an analytical framework that explains why certain decisions prevailed over others at the end of the UR negotiations on patents, recalling the sheer diversity and contentious nature of the debates on patents chronicled in 'The Research Problem'. This is essentially a static approach to theorising which seeks to understand and explain decision-making from the conceptual lens of a prevailing historical structure. It also takes into account elements of 'The Argument in Context' such as the preponderance of the US in the GPE and its rebuilding of the post-war order on the basis of neoliberal economic principles; as well as the legislative inducements that have made the expansion of business possible. The second aspect of the theoretical framework adopts a more dynamic approach to theorising and searches for contradictions in the prevailing order, specifically those tendencies within the structure that propel people towards mobilised forms of resistance. It explains conflict as a harbinger of transformation and looks at the UR negotiations as a site of political struggle which resulted in a disaffected Global South; as well as the post-TRIPS challenge and emboldened calls for change.

The point of this dual approach is to depict the material and ideological underpinnings of prevailing power, to condition these interpretations on a non-linear view of historical process, and to examine the role social, cultural and economic forces play in constituting and

reconstituting the established order, and in generating those specific oppositional tendencies that arise from the ranks of the oppressed (Falk, 1997: 43). Importantly however, the study does not aim to generate theory. Rather, it applies and verifies the conceptual framework devised by Cox, thereby testing the explanatory strength of his perspective, in seeking to understand and explain continuity and change in the GPE.

The first approach explains why one particular constitution of trade-related pharmaceutical patents (with its emphasis on minimum global standards that the TDI proposed) prevailed under TRIPS, as opposed to 'the other' (the terms of the pre-existing Paris Convention that developing countries favoured), arguing as a consequence, that the making of the patent provisions under TRIPS represents an instance of institutional capture by private interests, dominated by American industry. To account for this institutional capture, a Coxian triangular historical structures ideal-type framework<sup>28</sup> (material capabilities, ideas and institutions) is deployed to explain the prevailing structural dynamics that *enabled* the TDI to secure its demands for a multilateral patent code to protect its pharmaceuticals, despite the prevalence of widespread opposition. This first approach therefore explains the constitution and reconstitution of established order and the role of social, economic and cultural forces in this process of constitution/reconstitution. Also, in order to appreciate the extent and particularity of the role of the pharmaceutical industry in the TRIPS process, and to fully address the first empirical hypothesis, the first approach supplements Cox's triangular historical structures framework with an overview of the trade advice structure in the US and the legalised space created for transnational capital in this advice structure. This supplement does not only give explanatory strength to an analysis of the prevailing historical structure, it crucially locates agency in the constitution and reconstitution of established order.

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<sup>28</sup> This is elaborated below in a discussion of the Braudelian provenance of Cox's historical structures approach.

The second aspect of the theoretical approach traces the trajectory of conflict and opposition from the Uruguay Round negotiations to the post-TRIPS emergence of transnational activism, in order to account for the role of conflict in change. It explains why the 'capture' of the patent provisions of TRIPS (analogous to a reconstitution of established order), was arguably, successfully challenged in the post-TRIPS period by probably the weakest global economic actor, the African Group at the WTO. Success here is measured by the fact that the post-TRIPS climate of renewed contestation could not be ignored by the dominant structures of power; and that the calls for TRIPS to take account of its impact on public health could not be negotiated out of the Doha Round in the way that DC demands were negotiated out of the Uruguay Round; that in fact, African Group concerns were a legitimate agenda item under negotiation. Theoretically, the thesis situates the success of this challenge within a critical perspective of agency-driven transnational activism, and locates the prospects for the transformation of the prevailing power structure in the activism of social movements, arguing, like Cox, that the struggle for change will take place primarily in civil society (1997: 112). The thesis traces the trajectory of opposition in the TRIPS negotiations, with the expressed purpose of weaving through the role of conflict in social change. It examines the level of opposition and acrimony in the negotiations as a way of explaining the post-TRIPS scenario of renewed contestation, and the re-making of TRIPS to take account of public health imperatives. This historical account is not intended to be teleological, and does not aim to discover a logic in history. It uses historical analysis as a tool which recognises the inherent changeability of social institutions and structures, and in so doing, identifies potential crisis points or contradictions within the prevailing structure that tend to propel people towards mobilised forms of resistance, thereby making social reality sensitive to processes of historical change.

The choice of a Coxian criticality therefore is a conscious one, not only because of its fluidity and openness, but also because it more aptly entertains my own historically conditioned

worldview, that power relationships, mediated by structures, dominate all areas of social life; a preoccupation with capitalism's systemic processes of inclusion and exclusion; that the theory and practice of multilateralism has the result of “reinforcing the dominance of the few over the many” (Cox, 1997: 103, taken from Ramphall, 1988); but within which the seeds of an alternative, just order can be sown. Cox famously wrote in a seminal 1981 article that “Theory is always *for* someone and *for* some purpose... There is, accordingly, no such thing as a theory in and of itself, divorced from a standpoint in time and space...” (1981: 128). As such, one's experiences invariably guide one's theoretical persuasions, in turn, conditioning what one considers legitimate, thereby affirming the subjectivity of the knowledge-generating process.

Cox's work, though not without widespread criticism,<sup>29</sup> has been hailed as a major contribution to the rise of critical theory in international relations, and his version of historical materialism as perhaps the most important alternative to realist and liberal perspectives in the field today (Griffiths, 1999: 118; Mittelman, 1998: 63). Indeed, he is lauded as one of the “Magnificent Seven” in “an IPE Hall of Fame” (Cohen, 2008: 8) as he “clearly broke new ground” (ibid: 88). His work has served as an intellectual canon for many, including Gill and Law, 1989; Ronen, Palan and Gills, 1994; Sinclair, 1996; Mittelman, 1998; Schechter, 2002; Underhill, 2006;<sup>30</sup> and Murphy and Tooze, 1991. Cox's insights are manifold, with influences from a range of critical thinkers such as Vico, Braudel, Gramsci, and Polanyi; as well as Marx and Machiavelli (Falk, 1997: 43), among others. Probably the most resonating theme in his work concerns his essentially Marxian outlook that “philosophers have only interpreted the world in various ways; the point is to change it” (Marx, 1977: 158; Cox, 1995: 35; 1996: 28).<sup>31</sup>

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<sup>29</sup> Cox's critics are indeed many and come from the entire spectrum of IR theory. See for instance Brown (1992: 202) who saw Cox's version of critical international theory as disappointingly conventional, that while his historical materialism is based on an explicit rejection of positivist accounts of Marxism, it seems closer to these sources than he is. See more generally a range of criticisms of Cox in Cox (2002), chapter by Schechter. In conjunction, See Sinclair's chapter in Cox (1996) for an overview of the evolution in Cox's thinking.

<sup>30</sup> See Cohen, 2008: Chapter Three.

<sup>31</sup> See Cox, 2002: 3, especially critiques concerning Cox's Marxist credentials, whether too Marxist or not enough.

A pivotal Coxian influence of relevance to this thesis is French historian, Fernand Braudel, from whom Cox took over the notions of the synchronic and diachronic (Cox, 1999: 392; 1997b: 24-26, 2002: 28; 1995: 34). Looking at the synchronic dimension (space rather than time) can lead to seeing the world or society as a system of interrelated parts with a tendency to equilibrium or coherence. Looking at the diachronic dimension (time rather than space) leads naturally to dialectic enquiry; enquiry into the ruptures and conflicts that bring about system transformation. Understood in the diachronic dimension is Braudel's notion of a *longue duree*: the long passage of history associated with the embedding of fundamental social structures – including prevailing mentalities, social hierarchies, language, political community, exchange systems – that may take on an almost geological, quasi-permanent character (Gill, 1997: 11; Mittelman, 1997: 259; Cox, 2002: 32). In fact, the synchronic and diachronic make up a central feature of Cox's work, and consecutively, they form the thrust of the two-fold theoretical approach of this thesis outlined earlier. Essentially, the synchronic dimension explains why industry's demands prevailed at the end of the UR, while the diachronic dimension engages the ruptures, contradictions and points of conflict that lead to the re-making of the international patents code under TRIPS.

The first part of the theoretical approach presents the synchronic dimension (not unquestioningly) in which theorising assumes a trans-historicity, which purpose is to problem-solve. Thus, problem-solving theory takes the world as it finds it, with the prevailing social and power relationships and the institutions into which they are organised, as the given framework for action. The aim of problem-solving is to make these relationships and institutions work smoothly by dealing effectively with particularly sources of trouble. The strength of this approach lies in its ability to fix limits or parameters to a problem area and to reduce the statement of a particular problem to a limited number of variables which are amenable to relatively close and precise examination. Consequently, it is possible to arrive at statements of laws and regularities which appear to have general validity, but which imply the institutional and

relational parameters assumed in the problem-solving approach (Cox, 1981: 128-9). The synchronic dimension is associated with notions of immediacy, fixity and regularity in social and political time and space; knowledge is confined to the problem-solving mode and performs the ideological function of perpetuating the international *status quo* (Linklater, 1996: 283, 1990: 28) since it simply explains those relationships that produce/reproduce the prevailing order.

The second aspect of the two-pronged theoretical approach engages the diachronic dimension in which theorising assumes a profound transcendentalist purpose, and gives rise to critical conceptions of theory. Here, theory is critical in the sense that it stands apart from the prevailing order of the world and asks how that order came about. Unlike problem-solving theory, critical theory does not take institutions and social and power relations for granted, but calls them into question by concerning itself with their origins and how and whether they might be in the process of changing (Cox, 1981: 129) and it is for this reason that the thesis engages so extensively with conflict/struggle both during the UR and in the post-TRIPS context and what this means for alternative order prospects. Critical theory is directed towards an appraisal of the very framework for action, or problematic, which problem-solving theory accepts as its parameters. It is a theory of history in the sense of being concerned not just with the past but with a continuing process of historical change (Cox, 1981: 129). Consequently, the thesis does not simply stop at an explanation of the prevailing order and why industry was able to capture the TRIPS process. It continues on the critical path of examining how unacceptable social conditions can be in the process of changing through the medium of conflict.

Cox also admits that the synchronic and diachronic dimensions (or space and time considerations) are never separate and opposed categories; they are aspects of the same thing, and both techniques of analysis are necessary for understanding social life (Cox, 2002: 28), hence the reason the thesis engages both dimensions. Critical theory regards the analysis of

social regularities as useful for understanding the constraints on political change, but it transcends positivism (the belief that there is only one kind of knowledge, of which the laws of natural science provide the model) by analysing tendencies which may bring about the transformation of social systems (Linklater, 1996: 283; Devetak, 1996: 156). Linking the two therefore integrates both action and structure in explanations of historical change.

Correspondingly, Cox took over from Braudel the notion of historical structures (Cox, 1996: 29; 2002: 29; Sinclair, 1996: 8-12). An historical structure, or framework for action is a picture of a particular configuration of forces which is formed by collective human action over time, and in turn, influences thought and action. This configuration does not determine actions in any direct, mechanical way but imposes pressures and constraints (Cox, 1981: 135). Individuals and groups may move with the pressures or resist and oppose them, but they cannot ignore them. To the extent that they do successfully resist a prevailing historical structure, they buttress their actions with an alternative, emerging configuration of forces, a rival structure (ibid). Fundamentally, the historical structure does not represent the whole of reality but rather a particular sphere of human activity in its historically located totality (ibid: 137). Historical structures must be understood dialectally, with reference to three categories of forces (or ideal types) which interact in a structure: material capabilities, ideas and institutions (ibid: 136), all of which, along with an overview of the trade decision-making structure in US politics, inform an analysis of the prevailing order within which the TDI was able to capture TRIPS, but which contained major contradictions.

Material capabilities include natural resources and technologies that enable the production and accumulation of wealth and thus, the projection of power (ibid). The thesis looks at this 'category of force' in relation to the political economy of the TDI and shows its projection of power by way of the sheer wealth that it commands in terms of R&D determination and concentration,

pipeline, worldwide employment, legislative inducements that further enable this projection of power, and revenue; and conducts a preliminary comparison between the industry's revenue and profit margins, and sub-Saharan Africa's GDP figures in order to highlight the disparities between the economies that the thesis examines.

Ideas are of two kinds, disjuncture between which is a major source of structural change: historically conditioned intersubjective meanings, or those shared notions of the nature of social relations which tend to perpetuate habits and expectations of behaviour; as well as collective images of social order which constitute differing views as to both the nature and legitimacy of prevailing power relations (ibid).<sup>32</sup> The thesis engages with the significations attributed to the prevailing structure of meaning and how this was projected as a major 'category of force' which *enabled* the TDI to capture TRIPS. Here, the dominance of particular interpretations and preferences over others, and the apparent privileging of one group over another, can be seen as a function of the prevailing theory as practice which stems from a trade-as-growth (TAG) rationality, instantiated through the mechanism of private enterprise growth (PEG).

This discourse provides the essential tool for understanding the nature of relations of power in the GPE, asserting that because industry's demands fit perfectly with the prevailing theory as practice, its TRIPS victory was no coincidence. By extension, because the developing world could not legitimately locate its demands for distributive justice within this dominant structure of meaning, its pleas were negotiated out of the UR through a mixture of intervening strategies that interact to maintain the power structure. This story supports the critique of mainstream research that there is no such thing as an objective social reality since it locates actors in space and time

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<sup>32</sup> Cox later sharpened this perspective with his emphasis on civilizations as contested spheres of inter-subjectivity, meaning that civilizations exist in the mind rather than on the ground, consisting of shared assumptions about the natural order of things. Civilisations therefore constitute the mental frameworks through which people understand and interpret their world and contrive their responses to the challenges that confront them. See Cox 2000, 2002, 1997, 1997b, 1997c.

actively constructing their reality. Indeed, it shows how powerful actors consciously utilise the meanings attached to the dominant theory as practice as a strategy to steer the IP protection agenda. These actors make no attempt to subvert the dominant politico-economic framework, and in fact, by actively seeking to reinforce it, they increase their chances of success.

Institutions are particular amalgams of ideas and material power, which in turn influence the development of ideas and material capabilities. They reflect existing power relations, stabilise and perpetuate the prevailing order (ibid: 136-7). Paraphrasing Gramsci, Cox noted that ideas and material conditions are always bound together, mutually reinforcing one another, and not reducible one to the other. Ideas have to be understood in relation to material circumstances, which in turn include both the social relations and the physical means of production (Cox, 1993: 56). Whether institutions take on an organisational fixture or are inter-subjectively contextualised, their reality is made meaningful by the mutual reinforcements of ideas and material capabilities. In this research, their multifarious forms are expressed in terms of international organisations, global market institutionalism and the belief systems that accompany this, the institution of private property and the expanding base of intellectual property protection.

Cox noted the close connection between institutionalisation and Gramsci's concept of hegemony (discussed below). Institutions, which are expressions of hegemony, provide ways of dealing with internal conflicts so as to minimise the use of force. There is an enforcement potential in the material power relations underlying any structure, in that the strong can clobber the weak if they think it necessary, but force will not have to be used in order to ensure the dominance of the strong to the extent that the weak accept the prevailing power relations as legitimate. This the weak may do if the strong see their mission as hegemonic and not merely dominant or dictatorial, that is, if they are willing to make concessions that will secure the weak's acquiescence in their leadership and if they can express this leadership in terms of universal or

general interests, rather than just as serving their own particular interests (Cox, 1981: 137). The degree of congruence between material power, ideas and institutions lends itself to a cyclical theory of history; the three dimensions coming together in certain times and places, and coming apart in others (ibid: 141). Cox therefore suggests that social forces engendered by the production process,<sup>33</sup> forms of state and world orders (levels of social organisation in the GPE to which the method of historical structures can be applied) can represent particular configurations of material power, ideas and institutions (ibid: 138).

Concerned with dialectic and the potentialities for change expressed in the diachronic dimension, Cox develops this further by adopting Vico's concern with social transformation through class struggle (Cox, 2002: 28). Cox does not envisage class in the conventional two-faction Marxist mode of antagonism. Instead, "the essence of class is social domination and subordination" (ibid: 30),<sup>34</sup> and he develops a 3-level model (forces; precarious elements; and the excluded) to represent the contemporary restructuring of global society (Cox, 1999: 394). Here, the thesis engages particularly with the 'forces' and 'the excluded' by virtue of its focus on the TDI in the first instance, and the African Group in the second. The forces are a globally-integrated set of people – multinational corporations (such as those in the TDI), large institutions (such as the WTO), and governments (such as the US and EC) – which deal with or administer the economy. This level includes the secure elements of the workforce, with highly valued skills and long-term expectations (Cox, 1999: 394). The excluded reside at the bottom end, are excluded from the workforce, and live in poor and marginalised areas such as Africa. They include those on behalf of whom the 'access to medicines' campaign was waged. They have

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<sup>33</sup> While Cox's production thesis has been variously criticised, for instance, as reductionist, see Spegele, 1997: 221; and economistic, see Deibert, 1999: 289, he has more recently (2002: 31) clarified that production included the existing organisation for the production of goods and services, as well as the production of institutions, law, morality and ideas.

<sup>34</sup> This characterisation essentially prefaces some of Cox's critics who lament his initial privileging of social class over other kinds of oppression anchored in, for instance, patriarchy, nationalism, racism etc.

become a preoccupation for the top level, who must prevent them from destabilising the system that keeps prosperity confined to the integrated elites (ibid).

In this vein, Vico's 'modification of mind' thesis has been particularly telling for Cox in the sense that mind is transformed by reaction to the changing material conditions of existence, or “the human necessities or utilities of social life” (Cox, 2002: 45, taken from *NS*, 347; see also Berry, 2007: 16), an insight which is antithetical to orthodox perspectives on a static, unchanging social reality.<sup>35</sup> Vico's 'mind' thesis is a central pillar to understanding Coxian historicism, that structures and institutions are made by human action, and to understand structural and institutional change, we need to understand changes in mind, that is, people's understandings of and attitudes towards their environments/reality (Cox, 1981: 132; Berry 2007: 16), stressing agency-driven structural change. To account for this, the thesis traces the trajectory of African Group participation in the GATT/WTO IP negotiations and chronicles the transition from non-participation to active engagement as a 'modification of mind' moment; a moment in which, united by a common marginalisation, the African Group took ownership of the 'TRIPS and Public Health' issue at the WTO.

This Vichian perspective is similar to Cox's invocation of Gramsci, who built upon Vico, Marx and Sorel. Taking Gramsci's cue, Cox took on a more sophisticated analysis of class and class conflict and of the mental imagery that gives social groups self-awareness and an understanding of where they stand in society and how they must act for their emancipation (Cox, 2002: 29). Cox also applied a Gramscian analysis of power to problems of world order. Gramsci took over from Machiavelli the image of power as centaur: half man, half beast, a necessary combination of consent and coercion. To the extent that the consensual aspect of power is in the forefront, hegemony prevails (Cox, 1993: 52, taken from Machiavelli, 1977: 49-50 and Gramsci, 1971:

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<sup>35</sup> See Linklater 1990, 1996, 1996b for an overview of notions of immutability.

169-90). Coercion is always latent but is only applied in marginal, deviant cases. Hegemony is enough to ensure conformity of behaviour in most people most of the time (ibid), bearing in mind that consent wears thin as one approaches the periphery, where the element of force is always apparent (Cox, 1981: 144; 1987: 266). This is important insofar as it provides a frame for the thesis to analyse the UR negotiations and the strategies utilised to conclude them, particularly since it is concerned with the dual dynamics of continuity, and change through conflict. Cox's extrapolation of Gramsci's concept of hegemony therefore enables a probing of the nature of conflict, depending on where, on Gramsci's yardstick of coercion and consent, the negotiations lie.

Subsuming the making and re-making of the patent provisions under TRIPS is the work of another major influence on Cox, that of Hungarian born Karl Polanyi, and his notion of the “double movement” (Cox, 1995: 39-41; 1996: 31-35; 1997: 107; 2002: 29). In his analysis of nineteenth-century industrialization in England, Polanyi considered that the first phase of a double movement was to disembed the economy from society to allow the unfettered rule of the self-regulating market over society, thereby resulting in social immiseration. These conditions then provoked the second phase of the movement, society's self-protective response, through politics, that aimed to subordinate the economy to social goals, a movement that led to the creation of the welfare state (ibid; see also, Burchill, 1996; Watson, 2005; Birchfield, 2005). Cox then suggests that transposed from the time and place of Polanyi's critique to current global circumstances, the thesis suggests that we may now be approaching the limits of the first phase of a “double movement” and could be on the threshold of a second phase that would seek to bring the global economy under social control (Cox, 1997: 107).

To highlight the possibility of this second phase of social control and affirming his historicist and emancipatory commitments, Cox developed his thesis on the prospects for counter-

hegemony. Echoing Gramsci, Cox contends that world orders are grounded in social relations, and accordingly, a significant structural change in world order is likely to be traceable to some fundamental change in social relations (Cox, 1993: 64). Polanyi's second phase therefore “turns our attention towards society, towards identifying the crisis points in societies that are likely to mobilise people into resistance and to generate social movements seeking an alternative future” (Cox, 1997: 107). According to Cox, to do this would require an analysis of social movements both within particular societies and at the transnational level (*ibid*), because historically, the challenge to established order has come about through the building of a counter-society formed around principles that contradict those of the established order (Cox, 2002: xv). This counter-society is peopled by the marginalised and the excluded, by those who are intellectually alienated from established order in thought, behaviour and institutions, and by those deprived of the possibility of satisfying their material needs according to the prevailing norms of social order (*ibid*: xvi).

The first part of this thesis presents a replication of the first phase of Polanyi's double movement, in which society was subordinated to the rent-seeking opportunities of the TDI through the multilateral protection of pharmaceutical patents, a scenario with similar levels of social depravity concerning poor people's access to essential drugs. The second part of the thesis presents a replication of the second phase of the double movement in terms of calls by transnational civil society for changes to the multilateral discipline governing patents, and the African Group's rise and self-protective engagement at the WTO that would lead to an amendment of TRIPS. In his extrapolation of Polanyi and others, Cox's historicism is poised as a dialectic between continuity and change, understood as an explanation for the interactions between mental processes through which people conceive action and the material structures that constrain action in different historical periods (Mittelman, 1998: 66). Moreover, he urges IPE scholars to place social forces at the heart of the subject field, and to study their mode of

incorporation into the global political economy without resorting to an ontology of social action that accords explanatory primacy to the role of the state (Watson, 2005: 16; Falk, 1997: 43).

Below is a tabular presentation of Cox's intellectual influences of relevance to the thesis.

**Table 0.1: Coxian influences & the common thread of conflict and historical process**

<b>Figure</b>	<b>Analytical Influences</b>	<b>Relevance for Thesis</b>
<b>Fernand Braudel</b>	The synchronic dimension: regularities in social and political time and place.	Ideal-type explanation of the prevailing order & why industry was able to secure all of its demands from TRIPS.
	Historical Structures: framework for action.	An elaboration of the synchronic using Cox's ideal-type 'configuration of forces' (material capabilities, ideas, and institutions) that explain the particular circumstances of the TDI & the prevailing structural dynamics that enabled it to capture the TRIPS process. The particularity of decision-making authority within American politics supplements the explanation.
	The diachronic dimension: dialectic analysis	Conflict & contradictions generated from the prevailing order that enabled industry's win, from which the seeds of a more just order are sown, which takes account of public health considerations.
<b>Giambattista Vico</b>	Transformation through class struggle	Struggle between globally integrated elites (those representing the TDI, their governments, and the WTO) and the excluded elements (those on behalf of whom the 'access to medicines' challenge was waged; African countries during the UR; and civil society unconnected to the mainstream).
	Modification of Mind	The precise moment of the AG's self-understanding and attitudes towards a common reality of marginalisation that propelled the group towards the formalisation of the issue of TRIPS & public health at the WTO; and steering it towards transformation.
<b>Antonio Gramsci</b>	Analysis of class and class conflict: mental imagery that gives groups self-awareness and understanding of where they stand and how they must act for their emancipation.	This is essentially an aspect of Vico's impact on Gramsci's thinking as it is identical to Vico's two elements above. The thesis engages it as it does the Vichian perspective above.
	Hegemony: fit between consent and coercion, in which consensual aspect of power is at the forefront. Consent wears thin as one approaches periphery.	Provides a frame within which to analyse the UR negotiations and the theme of conflict that runs throughout the research. It leads to an analysis of TRIPS as non-hegemonic, having been concluded on the basis of 'consent without consent', a method of decision-making that made it prone to challenges.
<b>Karl Polanyi</b>	Double Movement	Dialectic inquiry subsuming the two phases of the research.
	First Phase: subordination of society to the economy, resulting in social immiseration.	Subordination of the Global South to the rent-seeking opportunities of the TDI, and the resulting welfare-reducing implications for poor people's access to essential drugs.

	Second Phase: society's self-protective response through politics, aimed at subordinating the economy to social goals.	Emboldened justice claims by transnational civil society; the African Group's formal engagement with the issue of patents and access to public health that would eventually lead to the 2005 Decision to amend TRIPS.
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The examination of the making and re-making of pharmaceutical patents in the GPE, with a particular focus on transnational capital and the AG, underscores the critical agenda which perpetually searches for new and interconnected ways to understand power and oppression and how these shape everyday life and human experience (Kincheloe and McLaren, 2005: 306). It starts by unveiling and understanding how the neoclassical appreciation for pharmaceutical patents prevailed at the end of the UR by looking at the developments before and during the Round to gain a better understanding of the extent of the foothold of private interests on the current order. Despite years of seemingly unyielding opposition to the UR TRIPS package, developing countries finally acquiesced at the twenty-fifth hour and supported the precise IP framework they resisted. The purpose of this research is not merely to narrate the story of the making of the patent provisions in TRIPS, remaining cognizant that it is a fundamental aspect. It is also aimed at gaining a ‘fuller understanding of the forces shaping who gets what, when and how’, to use Lasswell’s phrase (Devetak, 1996, 155), thereby assessing the stakes in a politico-normative inquiry of transcendence. ‘Forces’ here refers, not only to actors, but also to their interactions with the various *institutions* (organisational structures and intersubjective meanings) in the formation and maintenance of systems of privilege.

In this context of an unsurprising neoclassical victory over the demand for distributive justice by the Global South, the research looks at why one group of actors ‘won’ and the other ‘lost’, by examining conflict and the strategies utilised in the UR negotiating process. Providing an explanation for this win-lose configuration is aimed at establishing whether the global pharmaceutical patent regime under TRIPS represented a hegemonic framework in the

Gramscian sense. With the primacy of 'consent without consent'<sup>36</sup> and the absence of legitimacy, the globalisation of pharmaceutical patent protection in its TRIPS personality does not carry the hallmarks of hegemony, hence the conscious decision against looking at the rise of the AG as a chronicle of counter-hegemony. The rationale being, to counter hegemony, it would have to exist in the first place. Using Gramsci's Machiavellian yardstick of coercion and consent, Cox maintained that hegemony was more secure at the centre of the world system, less secure in its peripheries (Cox, 1987: 266), a lens through which to frame an analysis of the UR negotiations. The yardstick further enables an analysis of more subtle episodes of coercion and consent (particularly in such areas as consensual lawmaking) and informs a discussion of Chomsky's 1997 extrapolation of Giddings' 1900 notion of 'consent without consent' in Chapter V.

The other pivotal theoretical implication of this research and its link with the critical tradition is its portrayal of the modern capitalist state (the United States in particular), not only as deeply embedded in the politics of who gets what, but also, as inseparable from the economy and the legal form. The TRIPS case study will show the inaccuracy in the distinction between the American state apparatus and its global pharmaceutical corporations in the context of industry's demands from TRIPS and the negotiating position of the US; the federalised system of advisory committees which strategically seats many industry-specific CEOs; US trade law aimed at forcing the international compliance of developing states, to name a few. The examination of pharmaceutical patents in this research begs a view of the state and the economy, and the various institutions that sustain them, as mediating components of a social whole, thereby debunking the artificial separation between the various spheres.

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<sup>36</sup> This term is attributed to Giddings (1900) and not Cox. See also McGilvary, 1900.

#### 4. Methodological Issues

Decision-making research speaks to a process whereby the context, background and dynamics of political decisions are analysed. Practically, it seeks to understand how and why a particular legislative proposal or government policy came to fruition. Key research strategies include elite interviews and analysis of official documents (McLean, 2006: 60), both of which are employed in this research. The research adopts a broad qualitative outlook which uses the *making* of the patent provisions of TRIPS as a case study in institutional capture by private interests, and the subsequent challenge to this capture by civil society groups (broadly defined) and developing countries, particularly the African Group at the WTO. These two aspects of the research fit within Robert Cox's method of historical structures which first looks at an ideal-type definition of a particular structure of existing power relations in a given historically located limited totality;<sup>37</sup> and then introduces dialectic by looking for the possible emergence of rival structures expressing alternative possibilities of development (Cox, 1981: 137). Because the research seeks to explain *how* and *why* particular decisions were made, its choice in favour of qualitative methods is no coincidence, since quantitative methods, with an emphasis on scientific measurement, would fail to capture the richness and the nature of the conflict that characterised the IP negotiations in both the Uruguay Round and the post-TRIPS negotiations, remaining cognizant that a crucial part of this research is to look at the role of conflict in change.

The aim in utilising the qualitative method (incorporating analysis of official documents, semi-structured elite interviews, qualitative content analysis, and the comparative method through the use of a case study) is to construct as neat a narrative as possible of the making of the global pharmaceutical patent regime from its ideational inception at the close of the Kennedy Round, to the end of the Uruguay Round in order to capture the various dynamics that collaborated in the formation of the patents provisions of TRIPS. This level of 'storytelling' therefore requires an

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<sup>37</sup> Limited totality is used to denote that the historical structure does not represent the whole world, but rather a particular sphere of human activity in its historically located totality.

emphasis on pre-UR initiatives by industry representatives for a GATT IP code; as well as the detail of what went on during the Round, and in the post-TRIPS period. To do this, the research relies on secondary sources in a bid to contextualise the direction the thesis takes, and for analyses and chronicles on pre-UR initiatives employed by various industry representatives to steer the global trading agenda conducive to their particular interests. The core of the methodology however, is an extensive use of documentary data coming from both primary and secondary sources,<sup>38</sup> but particularly minutes of meetings and semi-structured elite interviews in the primary category.

Official documents are an important source for analysing institutions and the policy process because they constitute a record of “the development and implementation of decisions and activities that are central to their functions” (Hakim, 2000: 46). Indeed, one can learn a lot by looking at documents (Travers, 2001: 5). Therefore, in order to tell the story of the UR of trade negotiations – the centrality of conflict between the two main camps, as well as the extent of participation by the various delegations – the research relies heavily on the minutes of the meetings of the Round, as well as submissions by the participants on their negotiating positions. This component of the thesis employs qualitative content analysis (QCA) in a Lasswellian formulation, that is, to answer ‘who says what, to whom, why, to what extent, and with what effect’.<sup>39</sup> This method was useful because it provided a frame within which to qualitatively assess and categorise who said what, in favour of or against whom, as well as the language used to communicate.

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<sup>38</sup> In social science research, primary sources refer to materials that provide first-hand accounts of a situation or subject of study, and include court records, minutes, contracts, letters, memoranda, notes, memoirs, diaries and reports. Secondary sources refer to published material based on primary sources and include treaties, agreements, press releases, government white papers, official publications, and parliamentary debates. See Burgess, 1984/90.

<sup>39</sup> While Lasswell was concerned with the standard procedures of scientific investigation by imposing general categories, developing quantitative indicators and objectifying the process of inference (see Lasswell, 1968; Janowitz, 1968-1969), this simple formulation can be applied to qualitative methods in social science without attempting to generalise. See also Wikipedia’s entry on Content Analysis at: [http://en.wikipedia.org/wiki/Content\\_analysis](http://en.wikipedia.org/wiki/Content_analysis).

Like quantitative content analysis, QCA is the study of recorded human communications (Babbie, 2007), although this thesis is not concerned with the use of word frequencies and space measurements that define the former. QCA enables the researcher to include large amounts of textual information and systematically identify its properties<sup>40</sup> in a non-rigid manner. First, since the thesis concerns the negotiations on patents, it was relatively straightforward to single-out just those segments of all negotiating texts that related to patents, as well as the general texts on enforcement procedures, since these also pertained to patents. The material was then categorised thematically, and then analysed for evidence of positioning/posturing, opposition and conflict. The same was done with participants' submissions since these were usually longer versions of what delegates said at meetings, although it was found that in most instances, speakers appeared more vociferous during the negotiations, than their submissions/communications would suggest. This is crucial because one of the many benefits of QCA is that it allows the researcher's interpretation of meaning within the text.

Gaining access to these documents was not unproblematic.<sup>41</sup> When the research was actually started at the end of 2003, most of the GATT-based documents were still restricted. After two years of trying to source many of the communications by participants during the UR, and only after finally sourcing them in February 2006 from a WTO Director whom I met at a Trade Capacity Building Workshop in Budapest, these documents were de-restricted in May 2006.

While these primary sources were fundamental for the quality of specific information they provided for this research, they did present problems at times because they sometimes left gaps in the story. This was especially so when upon reading through the text of the meetings, there would appear to have been developments arrived at through the phenomenon of 'informal

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<sup>40</sup> Content Analysis at: [http://en.wikipedia.org/wiki/Content\\_analysis](http://en.wikipedia.org/wiki/Content_analysis).

<sup>41</sup> See Scott (1990), Altheide (1996) for methodological problems associated with using documentary data, including access, cost and utility.

consultations'. Because of their informality, the proceedings in such consultations are not transparent, and therefore, no minutes are available for inquiry. As such, secondary sources proved very useful to fill in the gaps left by primary sources. In such instances, there was a reliance on scholarly works on the negotiating history of the Uruguay Round, specifically those with an interest in the negotiations covering patents. In many respects both types of sources complemented each other since the latter did not attempt a detailed narrative of what transpired in the negotiations on patents.

The narrative of the post-TRIPS period also relied on the minutes of the meetings of the TRIPS Council, submissions from participants, as well as valuable information from semi-structured elite interviews. The minutes and submissions functioned in much the same way they did for that on the UR. In order to attest to the rise of the AG at the WTO, an attempt was also made at comparative analysis between the Uruguay Round and post-TRIPS negotiating climates, particularly in terms of articulation and participation of AG participants. The semi-structured interviews were also particularly useful as the African Group at the WTO gained momentum on the international stage. As May (2001: 120) points out, interviews yield rich insights into people's experiences, opinions, values, attitudes, aspirations and feelings. Interviews are sometimes necessary when a researcher wishes to produce work with textual depth and empirical strength (Lilleker, 2003: 208). Through interviews, we can learn more about the inner working of the political process, the machinations between influential actors, and how a sequence of events was viewed and responded to within the political machine, thereby compensating for insufficient accounts in official published documents or other contemporary media (ibid).

A total of ten interviews with nine individuals were conducted, each lasting 40-50 minutes. One interviewee from the WTO's Intellectual Property Division; another from the WHO, formerly a researcher with the Third World Network (an important research-based NGO in the post-TRIPS

context); the 2005 Chair of the TRIPS Council; a member of the Agency for International Trade, Information and Cooperation (AITIC) and a former AG negotiator of Senegalese origin; and five AG participants, including the first Chair of the Council when patents and access to medicines was formally put on the WTO agenda; one interviewee requested partial anonymity for some responses.

At first glance ten interviews may appear limited in number, however, three separate, written and unsuccessful attempts were made to interview members of the Geneva-based International Federation of Pharmaceutical Manufacturers and Associations (IFPMA) which functions as the negotiating arm of the TDI; members of the USTR in Geneva; as well as some other NGOs which played a vital role in the post-TRIPS context. The individuals addressed never acknowledged receipt of letters requesting their participation. An attempt was also made to speak with the former Chair of the Council (who presided at the time the Doha Declaration on the TRIPS Agreement and Public Health was tabled) at an Evian Group plenary in the Netherlands, October 2005. However, while a breakfast session was scheduled before the day's events, the former Chair arrived late and politely remarked that it had been a long time since his chairmanship and I should speak to those currently involved. These obstacles meant especially that while the post-TRIPS analysis of this research benefited from input from African Group personnel, interview material from other stakeholders was absent. While the minutes did provide valuable NET arguments and positions, this research will never benefit from what other stakeholders 'might have said' in interviews, for instance, what some would have divulged in their personal capacities.

Interviews were not recorded because it was felt that in so doing, respondents would be less inhibited. This was particularly useful since members of the AG appeared to be unconstrained when they spoke, both in terms of what they said and their intonations. They often appeared

maddened by what they perceived to be an injustice, a very powerful experience for an analysis of the contradictions and points of conflict within the current historical juncture, that give rise to change. The decision not to record interviews was also useful because one respondent in particular requested partial anonymity for some responses, some of which were utilised in the research. However, most of the information from interviews could be attributed to the relevant respondent.

Importantly also, information on the pharmaceutical industry was not easily accessible especially that related to investor relations. Because of the high returns associated with the industry many consultancies have sprung up in order to provide financial information for potential investors. As a result of the target market of such outputs, they are financially inaccessible for most research students. While some information could be gleaned from providers such as IMS Health (see Chapter I), it was piecemeal. For this reason it was necessary to consult company balance sheets to arrive at relevant data.

Lastly, attempts were made to get the names of especially US delegates who attended the UR Ministerial meetings in order to ascertain whether some TDI-specific names (such as Pfizer's Pratt) would come up, but information on lists of representatives remains restricted. However, in an effort to determine how easy it was for some sectional interests to attend WTO meetings, I went through the channel of requesting that the government of Saint Lucia enlist me as Saint Lucia's representative to the TRIPS Council at the 14-15 June 2005 formal session. The process was easier than I had anticipated and there was no requirement to go through accreditation processes. Needless to say, I attended.

## **5. The Contributions of the Study to IPE**

The study is broadly located within a critical, multidisciplinary framework of analysis. It navigates between the analytically differentiated spheres of politics, economics, society, law, (as well as their domestic and international expressions), with a conscious emphasis on their interrelatedness and inseparability. It is only after an appreciation of these areas as amalgamated components of social inquiry that one captures the magnitude of the making of trade-related pharmaceutical patents, not simply as an economic issue (as in its initial framing); or a political issue (if we simply look at the surface level of WTO negotiations); as a social issue (if we mainly heed the welfare ramifications in most studies on the ‘access’ debate); or a legal issue (if we subscribe to a matter-of-fact/substantive view of the law); as a domestic or international issue (because of its multi-layered contiguity). The making and re-making of pharmaceutical-related patent policy in the GPE are all of these areas at once. Disaggregating them would underestimate the multiplicity and pervasiveness of power, thereby dealing injustice to the inquiry.

At the heart of this contribution to multi-disciplinarity is a challenge to the enterprise of IPE, to move beyond its core focus on the interactions between domestic/international and politics/economics, and to consciously embrace the study of law, particularly its international economic counterpart, into its remit. IPE has made important advances in the last three decades, by unsettling previously settled dualities in social science research. In an era when the legalisation of global power relations has gained unprecedented momentum, it is a wonder that IPE and International Law (including its public/private dimensions) remain separate disciplines. This is significant because an analysis of the making and re-making of pharmaceutical patents debunks some of the most important settlements of the legal tradition.

Because the “access to medicines” issue generated a public international outcry against both the TRIPS Agreement and the global pharmaceutical industry, a substantial body of work has

emerged primarily covering the welfare implications of pharmaceutical patents on the poor. In this context, an analysis of the making and remaking of pharmaceutical patents generally can be prized for its tremendous global social significance. This work however, is not a welfare assessment of pharmaceutical patents on the poor. It is a case study in international trade decision-making which utilises the making and remaking of patent provisions in TRIPS to understand and explain the sustenance and reconstitution of power in the GPE, and to consider the prospect for structural transformation, based on the work of Robert Cox in IPE. At the time of writing, a thorough empirico-theoretical analysis on the making and re-making of the patent provisions of TRIPS was absent from the IPE literature, and especially so, an analysis of the making and re-making of patent policy from a Coxian standpoint that “each successive historical structure generates the contradictions and points of conflict that bring about its transformation” (Cox, 1995: 35).

In 2006, while this study was well under way, May and Sell co-wrote their critical history of intellectual property rights,<sup>42</sup> and derived their “initial inspiration... from the interactions that Robert Cox identified among material capabilities, institutions, and ideas” (2006: 31). They contend (2006: 27) that:

“Our account of the rise of intellectual property is informed by an analytical triangulation, linking the development of IPRs to material, institutional, and ideational changes in the international political economy. The significant material capabilities we focus on are those controlled through informational resources (including information-related technologies and innovations defined as intellectual property). The institution at the centre of our treatment is the legal construction of intellectual property, and the ideas that influence and shape these developments are those that identify what is considered to be intellectual property and-most important-who has the right to claim ownership of intellectual goods (and why this might be legitimate).”

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<sup>42</sup> Their focus is on the history of IP in general and not on the decision-making aspects that resulted in the patent provisions in TRIPS.

The current study differs from the above, not only because it focuses on one aspect in the making of TRIPS as opposed to the entire history of IP, but also because it employs a more dynamic and holistic appreciation of Cox's triangular framework, or historical structure. It explains the initial success of industry's TRIPS victory in the context of the prevailing historical structure which is not limited to a technology-specific framework. In other words, the material capabilities are more than just that controlled through information resources, notwithstanding their relevance; the institution at the centre of the current treatment is inclusive of, but not limited to the legal construction of IP; and the ideas therein are not exclusive to an IP-specific discourse. These categories of forces that interact in a structure, that essentially *enabled* the TDI to secure its specific demands for patents under the GATT despite the high intensity of the conflict characterising the negotiations (Hypothesis I), were also specific to the broader structure of global capitalism, and the various institutions and ideas that give it its quasi-permanent character. Aligned to this explanation is what can be considered a dependent variable in the form of the strategic involvement of industry in the American domestic political landscape, a variable which adds explanatory weight (and an additional dimension) to the forces interacting in Cox's prevailing historical structure. Consequently, applying and verifying Cox's conceptual framework to an empirical case study of the making of the patent provisions of TRIPS, and adding another dimension to his 3-pronged historical structure to explain the TDI's initial success, are important contributions to the field of IPE.

Importantly also, the study locates the post-TRIPS challenge, and the rise and success of the African Group, in an emerging configuration of forces, a quasi-rival structure, and not in a fully-blown Coxian rival structure which would signal a change in world order. This is a quasi-rival structure because, while it has shaken the prevailing order, it has not toppled it, and certainly has not resulted in a change in world order as Cox envisions. Notwithstanding, the quasi-rival structure is not akin to the stalemate in Gramsci's passive revolution (Cox, 1993; 2007) in which

neither an old order, nor a new one can triumph. Rather than impasse, the concept of a quasi-rival structure simultaneously explains dynamics of continuity and change in the GPE. It explains how some forms of emancipation can emerge without necessarily unravelling the current world order structure. It gives the impression that if sufficient forms of emancipation can emerge, each covering different aspects of social life, then there could be a sequence of quasi-rival structures, as opposed to a singular Coxian rival structure. The question then emerges as to whether the sum of these quasi-rival structures can be sufficiently numerous to eclipse the prevailing order.

Also, the application of Cox's Gramscian concept of hegemony to interpret the UR negotiations<sup>43</sup> provides the study with a conceptual frame to analyse the contradictions that would ultimately call into question the consensual underpinnings of the agreement. The seeds of the quasi-rival structure are therefore sown in the contradictions that typified the negotiations; the absence of a hegemonic position on the part of the TDI, its state counterparts and GATT intermediaries; and the prevalence of decision-making based on 'consent without consent'.<sup>44</sup> The application of this concept to the making of the patent provisions of TRIPS, although not attributable to Cox, is a novel way of explaining coercive decision-making in the GPE, and provides a further conceptual lens through which a critical analysis of hegemony can be enlarged. Legitimacy shortfalls, the absence of hegemonic consolidation in the making of pharmaceutical patents, and ultimately, 'consent without consent', nourish Cox's counter-society, one that is peopled by the marginalised and the excluded, by those who are intellectually alienated from established order in thought, behaviour and institutions and by those deprived of

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<sup>43</sup> Richards (2004: 131-133) discusses Gramscian hegemony and the *actual* TRIPS Agreement, and not *how* it was made. Accordingly, he sees the task of TRIPS as presenting IP standards and law, not as the ideological manifestation of a particular class interest, but rather as serving global economic welfare...representing a mantle of moral authority and historical necessity. While Chapter I re-presents this view, upon examination of the texts of the negotiations, it becomes evident that developing countries never saw this position as legitimate, hence the absence of hegemony. Richards therefore misses the opportunity to critique the *making* of TRIPS as non-hegemonic.

<sup>44</sup> Note that this concept has nothing to do with the pros and cons of a particular policy. It speaks to a top-down manner of decision-making without any support and ownership by intended subjects, and implies a coercive presumption of superior judgement on the part of the architects of policy. See Chapter V.

the possibility of satisfying their material needs according to the prevailing norms of social order (Cox, 2002: xvi). The emergence of this counter-society becomes key to examining the prospects for change in the GPE. The thesis therefore advances a claim towards transformation through the counter-society, and makes an empirical contribution to this theme in critical IPE through its coverage on how the African Group, marginal by prevailing norms and formed four years *after* the Uruguay Round came to a close, could become a change agent, along with civil society, in a seemingly enduring structure.

A further empirical contribution is the extent of the coverage on the negotiating history on patents especially in the Uruguay Round, but also in the post-TRIPS period. Because the thesis concerns the *making* and *re-making* of the agreement's patent provisions relevant to pharmaceuticals, an analysis of the actual negotiating texts was paramount. This is crucial because as much emphasis is on process as on outcome.<sup>45</sup> While for instance, Ross and Wasserman (1993), Stewart (1995), Gervais (1998), Watal (2001), Matthews (2002), and UNCTAD-ICTSD (2005) went into some detail of the TRIPS Uruguay Round negotiating history as a whole, perhaps as a result of their wide focus, such studies were unable to delve into the full detail relevant to pharmaceutical patents in particular, a quality which this study generates in sufficient quantity. This narrowed focus<sup>46</sup> enabled a greater concentration on every negotiating detail relevant to patents, paying specific attention to who said what to whom, with what effect, the language used, and an interpretation of the atmosphere in the negotiations. This is especially pertinent given that Hypotheses I and III signal conflict in the making of TRIPS. Also, while some have concluded that African countries<sup>47</sup> played no meaningful role in the

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<sup>45</sup> See Wang and Winters (1997: 7) who contend that while it is true that Africa fared poorly in the round, it is not because the process was biased. Yet they offer no analysis of process.

<sup>46</sup> Gad (2006) authored a text on representational fairness in WTO rule-making and focuses on pharmaceutical-related provisions. However, his treatment of the UR negotiations is done summarily, and he ends his analysis with the 2001 Doha Declaration, while the current thesis ends with the decision to amend TRIPS in December 2005.

<sup>47</sup> Recall that there was no African Group during the Uruguay Round, and therefore, the detail during this period can only refer to African countries.

negotiations (Blackhurst, et al, 2000; Drahos, 2002, 2007),<sup>48</sup> there is no study that systematically verifies the sub-continent's non-participation. Because of the method used in this research, this non-participation in the UR was empirically substantiated.

Importantly also, many welfarist approaches<sup>49</sup> have emerged to look at impact assessments of TRIPS on poor countries, including patents and access to medicines. While this study may have been sparked by the welfare expositions in this area (reflected in Hypothesis II and III), it moved beyond this, with an emphasis on theory, empiricism and process-examination in international trade decision-making, providing a theoretical explanation of the empirical material concerning the making and re-making of pharmaceutical-related patent provisions in the GATT/WTO. Perhaps the most ambitious aim of the thesis was to demonstrate that while structures matter, even economically weak jurisdictions can sometimes determine the course of their development amidst a seemingly enduring power structure, hence the focus on the African Group in the post-TRIPS period.

## **6. Outline of the Thesis**

The thesis develops through six chapters, each developing the thread which takes the argument from its pre-UR setting, until the Decision to amend TRIPS in December 2005. Chapter I outlines the theoretical framework which applies to industry's institutional capture of the patent provisions of TRIPS, while the following three develop the nature of this institutional capture empirically. Chapter V makes the theoretical transition from examining institutional capture empirically, to an explanation of the contradictions in the system that would ultimately propel transnationalised resistance and mobilisation against the patent framework. Chapter VI looks at

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<sup>48</sup> For case studies on negotiating difficulties faced by countries in the region, see , Rudaheranwa, *et al*, 2005; Bilal, *et al*, 2005; Odhiambo, *et al*, 2005; Kandiero, 2005; Bonaglia, *et al*, 2002.

<sup>49</sup> See 'The Research Problem' above for discussion on welfare.

this mobilised resistance both empirically and theoretically, while the conclusion provides a synthesis and prospects for future research.

Chapter I starts by outlining various IPE perspectives in order to justify the use of a Coxian criticality to the case study under examination. In building on the fifth hypothesis, it applies and verifies Cox' historical structures approach – material capabilities, ideas and institutions – by testing this framework on the TDI in the GPE, and makes some initial comparisons between the TDI and sub-Saharan Africa (SSA). The chapter finds that while Cox' framework is indeed compelling in explaining the prevailing historical structure, the missing link lay in the nature of decision-making in American politics, and particularly the politics of federal advisory committees (FAC) as co-constitutive of the American polity. These FACs do not merely *influence* decision-making, but are themselves part and parcel of a domestic decision-making process that feeds unto the global arena, findings that set the scene for industry's dominant role in the TRIPS process (first part of Hypothesis I), that would effectively enable it to capture the process and secure its demands from TRIPS.

To measure industry's success based on the explanatory framework outlined in Chapter I, the second chapter builds on the second part of the first hypothesis and juxtaposes the patent provisions of the transnational industries' 1988 proposal for a GATT treaty on IP, with the patent provisions of the 1995 TRIPS Agreement, in order to ascertain the similarities. The contention in this chapter is that if industry is so well-placed both domestically and internationally according to the theoretical framework outlined in Chapter I, then it should be able to claim victory in the precise regulatory framework it wanted, thereby establishing a reasonable correlation between an analysis of the prevailing historical structure and industry's success in international trade decision-making.

The third chapter then goes on to examine the circumstances of industry's TRIPS victory, that is, the level of opposition and conflict that industry's state counterparts faced during the negotiations (part three of Hypothesis I). Headed by the Indian and Brazilian contingents, the Global South opposed the entire Northern agenda, in every area under investigation. The chapter also confirms that there was no participation from SSA in these negotiations which were obviously paramount to their particular circumstances.<sup>50</sup> So fierce was the opposition from developing countries, that there was a need to understand exactly what made these countries surrender to the precise agenda they rejected, notwithstanding that TRIPS was part of a single undertaking. To build further on part three of the first hypothesis, Chapter IV explores this question and finds a series of non-transparent strategies on the part of the NETs to arrive at a consensus. It also associates high-level staff at the GATT in facilitating the surrender of the South. These chapters therefore frame the negotiations on patents within Cox's extrapolation of Gramsci's concept of hegemony to examine where, on Gramsci's yardstick of coercion and consent, the negotiations lie.

Following from this, Chapter V questions the status of TRIPS as a public international legal instrument, and the quality of consensus that legitimated it. In this context, the chapter challenges the legal form in general as implicated in the politics of 'who gets what'. In explaining the contradictions, it argues that TRIPS takes the form of an *agreement* only because it was arrived at on the basis of 'consent without consent', a quality which made it bereft of legitimacy, and therefore, prone to challenges. Its legitimacy shortfalls and distributional implications (Hypothesis II) would propel the post-TRIPS challenge through the counter-society, and would usher in the rise of the African Group (Hypothesis III) in a way that could not be ignored by the

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<sup>50</sup> While the African Group at the WTO is one of the two main actors examined in this research, the third chapter could not examine the negotiating performance of the group for the obvious reason that it was formed, and subsequently came to prominence, several years after TRIPS was finalised. Its relevance in the research therefore relates specifically to the post-TRIPS period in which TRIPS faced its most sustained, public backlash from African countries.

prevailing power structure (Hypotheses III, IV, & part two of V), the subject of Chapter VI. The post-TRIPS challenge may not have upended the prevailing power structure, or engendered a change in world order, but its force can certainly be viewed through the lens of a quasi-rival structure.<sup>51</sup> The concluding section provides a synthesis of the study and discusses its relevance for future research.

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<sup>51</sup> In Cox's historicism, a rival structure emerges when the counter-society successfully resists a prevailing historical structure. However, because the strength of this post-TRIPS challenge was not inconsequential, and did provide some results, albeit imperfect, this research looks at the possibility of a quasi-rival structure on the basis of incremental gains.

# Chapter I

## Explaining 'Who Gets What' In International Trade Decision-Making

### 1.1 Introduction

Decision-making analysis is one way of studying power relations, and while decisions do not reveal power directly, they may show influence and the way in which power is translated into action. It begins with an analysis of the structure of existing power relations; and it seeks to understand how the decision process may tend to sustain or change that structure (Cox with Jacobson, 1996: 349-350).

The first part of the thesis argues that the making of the patent provisions in TRIPS represents a case study in institutional capture by the transnational drug industry, dominated by American interests. In order to account for this institutional capture, and to understand why one group was able to prevail over another at the end of the Uruguay Round (UR) negotiations on patents, this chapter develops a theoretical approach that explains outcome in international trade decision-making as a function of the dominant politico-economic framework (structure of existing power relations). This addresses the first part of the theoretical hypothesis, which utilises Cox's Braudelian historical structures framework to explain conditions of continuity in world order, that is, the synchronic dimension in which the *status quo* remains stable, and is in fact reinforced. The chapter also addresses one aspect of the first empirical hypothesis, namely, that the transnational drug industry (TDI) was a key player in the making of patent policy in TRIPS.

By initially juxtaposing the material dimensions of the TDI with sub-Saharan Africa's GDP figures, the first part of the historical structures approach draws attention to the magnitude of the variations between two of the most significant actors in the post-TRIPS 'access to medicines' debate; as well as those empirically observable aspects of the TDI's presence in the GPE that explain its significance and potential. By analysing the ideational and institutional components of the prevailing power structure, the chapter also draws attention to structural and strategic

dimensions which work in tandem to consolidate the power of the TDI, thereby enabling it to 'capture' the TRIPS process. The final section of the chapter then looks at the specific nature of trade decision-making in American politics, and the institutionalisation over time, of private-sector advisory committees. These committees, whose members include high-level TDI representatives have come to dominate the trade advice structure of the United States, a process which proves poignant in the articulation of an 'American' stance on IP protection. Because of the centrality of this component (decision-making authority), the chapter regards it as fundamental to treat it, not autonomously, but as an additional component of the prevailing historical structure that ultimately enables the TDI to capture the TRIPS process.

Prior to elaborating this Coxian framework however, the following section outlines various IPE traditions in order to demonstrate their utility in explaining decisional outcomes in international trade negotiations, and by so doing, justifies the use of the Coxian perspective adopted here. It provides a brief survey of the explanatory potentials of the three dominant approaches in IPE in accounting for the win-lose scenario recorded at the end of the Uruguay Round negotiations on patents, namely mercantilism, liberalism, and Marxian-inspired perspectives.

## **1.2 The Terrain of International Political Economy Perspectives**

Susan Strange made a provocative observation in 1970 when she called the void between international economics and International Relations (IR) “the dialogue of the deaf”, a moment many regard as announcing IPE's birth (Cohen, 2007: 208; Brown, 1999: 531-2; see also Murphy and Nelson, 2001)<sup>1</sup>. She wrote of the absence of “a substantial literature on the theory of international political economy” and the need to fill the 'gap' between international relations and international economics (Strange, 1970: 309). Two years later, she called for a “radical

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<sup>1</sup> Underhill (2000: 5n) notes that Strange enthroned Kindleberger as the founder of contemporary IPE. He however credits Cooper (1968) as paving the way.

desegregation” and dismantling of artificial disciplinary barriers separating international economics, politics and law: “These barriers needed to be overthrown, broken-up, and done away with” (Cutler, 2000b: 160, taken from Strange, 1972: 63). These Strange exhortations (somewhat belated given that structuralist perspectives on North/South relationships had been around since the 1950s; and classical political economy long before)<sup>2</sup> came against the backdrop that since the 1960s the world economy was undergoing rapid change: international trade was increasing exponentially; corporations (especially of US origin) had become transnational in character (Underhill, 2000: 810); the Bretton Woods system of stable exchange rates was disintegrating; recognition of the geo-politics of oil after the devastating global impact of the 1970s oil price hikes crippled many developing countries and plunged the world economy into stagflation (Woods, 2001: 278-281); the pressures by developing countries for a New International Economic Order (NIEO) that would transform the rules governing relations between the wealthy 'North' and a poverty-stricken 'South' (Cohen: 2007: 201); the resonance of the Washington Consensus in the convergence of global economic policy, and the resulting experience of the Global South with austerity measures under structural adjustment (Bangura, 1986; Devlin and Yap, 1994).

Whatever the events presaging the diversity of interests in the field, since the 1970s many have heeded Strange's calls with designations of IPE as either a “distinct sub-field” of IR (Gilpin, 1987; O'Brien and Williams, 2004); or as rooted in the broad tradition of political economy which emerged in the European Enlightenment (Underhill, 2000; Watson, 2005). Notwithstanding, the discipline has been increasingly marked by three fundamental premises: that the political and economic domains cannot be separated in any real sense, and even doing so

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<sup>2</sup> See Maclean, 1988 who sees the neglect of Marxism in IR as the root of the problem Strange identifies. See also Jessop and Sum (2001) on the evolution from pre-disciplinarity, to disciplinarity, to post-disciplinarity in political economy.

analytically has its perils; that political interaction is one of the principal means through which the economic structures of the market are established, and in turn, transformed; that there is an intimate connection between the domestic and international levels of analysis, and that the two cannot meaningfully be separated (Underhill, 2000: 806; 1994). For much of its relatively short history therefore, IPE has engaged the dualities of orthodox research that were imprinted as 'normalities' on scholarship, particularly as it concerned states and markets.

The tensions between the domains persist between those who continue to see a state/market dichotomy, thereby maintaining separateness (Gilpin, 1987; Katzenstein, *et al*, 1998; Krasner, 1996); those who theorise a state-*and*-market approach, which, while stressing interaction, still present the domains as separate (Strange, 1988; 1994; 1996; Stopford and Strange, 1991; Keohane and Nye, 1972; 1989; Grieco and Ikenberry, 2003); and those who theorise the political and economic as co-constituted within a single social reality (Watson, 2005; Wood, 1981; Gill and Law, 1988; Cutler, 2000b; Cox, 1995; Rupert, 1995). The diversity in approach of this central issue in IPE is testimony to the heterogeneity in the field, subsumed under a range of theoretical perspectives, each prioritising different issues, actors and processes in the constitution of world order. Three such perspectives are now briefly surveyed to account for explanatory capacity in the making of pharmaceutical patents under TRIPS, prior to elaborating Cox's historical structures framework.

### ***1.2.1 Mercantilist Explanation and the Making of Pharmaceutical Patents***

Mercantilism derives its explanation from the realist tradition in IR, and realism, in all its forms, emphasises the continuities of the human condition, particularly at the international level (Buzan, 1996: 50). It starts from the assumption that international life is inherently conflictual, with

anarchy<sup>3</sup> the rule; order, stability and justice, the exceptions (Gill and Law, 1988: 25). This assumption governs the central idea that economic activities are and should be subordinate to the goal of state-building and the interests of the state (Gilpin, 1987: 31).<sup>4</sup> While the perspective sees an intimate connection between power and wealth, mercantilists ascribe to the primacy of the state, of national security, and of military power in the organisation and functioning of the international system (ibid). Wealth creation is therefore a means to the ultimate objective of state survival in a hostile international environment. Powerful states are accorded rational-actor status as they pursue the national interest, defined in terms of military security and political independence.<sup>5</sup> Power and power relations play the major role in international affairs, and in a 'self-help' international system, states must constantly guard against actual or potential threats to their political and economic independence (Gilpin, 2002: 238).

In the area of foreign economic policy state relations are therefore guided by competitive survivalism because the assumption holds that the interests of states are in perpetual conflict. Notwithstanding, the mercantilist position holds that states join international institutions and enter into cooperative arrangements only in those areas where their interests coincide (ibid). Nonetheless, scholars working within this perspective argue that the nature of the global economy reflects the interests of the most powerful states (O'Brien and Williams, 2004: 16), a view which intimated ideas such as 'regime theory' and 'hegemonic stability theory' to demonstrate the continuing relevance of the state in a newly globalised economy (Burchill, 1996b: 83) in which the 'primacy' of the state came under attack.<sup>6</sup> Therefore, while there may be

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<sup>3</sup> Realists use the term to mean the absence of a legitimate authority to which sovereign states are subordinate and give allegiance (Gilpin, 2002: 237).

<sup>4</sup> See Haggard, 1988, for an analysis of the Reciprocal Trade Agreements Act of 1934 as a case of state building.

<sup>5</sup> See Gilpin (2000) for a more recent piece on the continued relevance of the state in a globalised economy.

<sup>6</sup> For the theory of hegemonic stability, see the works of Keohane, 1980, and Kindleberger, 1973. For regime analysis, see Krasner, 1983. Chapter V also looks at regime theory when it analyses the relative absence of law as a shortcoming of IPE. For analyses on the decline of the state in a globalised economy, see Schmidt, 1995; Held and

cooperation, the rules of the game will be drawn by the most powerful states, thereby ensuring that their interests predominate at all times. Consequently, in an anarchic international system in which survival and power are key, the aim in cooperative arrangements is to maximise gains because states are more concerned with how they fare in relation to others (relative gains) than with how they fare individually (absolute gains).

A focus on conflict, power, relative gains, hegemonic dominance and national interest would appear to lend support for a mercantilist explanation of the making of the patent provisions of TRIPS, particularly since, as the hypotheses indicate, the thread of conflict runs throughout the thesis; and, as subsequent chapters will demonstrate, despite intense opposition and acrimony in the negotiations, the pharmaceutical industry secured all of its demands from TRIPS, an outcome which supports Richards' (2004: 3) claim that TRIPS was concluded on the basis of real political and economic power. The accounts of conflict, versus the account of industry's overwhelming gains from TRIPS, also appear to confirm the mercantilist focus on relative gains, since the mutually inconsistent positions chronicled in 'The Research Problem' indicate that outcome would be premised on a winner-takes-all scenario. The dominance of the US in the GPE, as evidenced through its re-building of the post-war order, suggest that the mainly-US origins of the transnational industries seeking a strengthened multilateral patent code is also a key factor explaining the TDI's capture of TRIPS, again lending credence to mercantilist notions. Also, recalling 'The Research Problem', the timing of industry's demands in the US coincided with exponential increases in the trade deficit, a point which prompted industry representatives to invoke national interest considerations as they made their case to state officials.

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McGrew, 1993; Cable, 1995; Sassen, 1995; Strange, 1995, 1996. For counter-proposals, see Weiss, 1997; Gilpin, 2000.

All of these explanations appear sound, but at its core, mercantilism remains a state-centric account of IPE, and as Sell notes, state-centric accounts are at best, incomplete, and at worst, misleading (1999; 171), since they obscure the role social forces play in constituting and reconstituting the prevailing order.<sup>7</sup> This thesis does not diminish the state as a non-entity, and in fact, sees its role as co-constitutive. However, a state-centric ontology, by its very nature, accords explanatory primacy to the state in a way that would seriously handicap an inquiry of the TRIPS story because of the pivotal role played by transnational capital. To begin with, conflict in mercantilism presupposes horizontal rivalry between powerful states, however, this research incorporates a vertical dimension of conflict which does not accord explanatory primacy to states. By extension, by insisting on the primacy of politics over all areas of social life, an ontology of state-centrism cannot intelligibly capture the nature of the dynamics that collaborated in the making of TRIPS, not to mention the naiveté in a perceived singularity of the national interest, bearing in mind that the demands for multilateral IPR discipline under the GATT were categorically sectoral. Furthermore, mercantilism's insistence on the continuity of the human condition (Buzan, 1996: 50; Wight, 1966: 26) essentially repudiates the historical, transcendentalist approach adopted here.

### ***1.2.2 Liberal Explanation and the Making of Pharmaceutical Patents***

Arguably the dominant perspective of the contemporary period (Burchill, 1996), the liberal theory of political economy emerged in eighteenth and nineteenth-century Britain in the aftermath of the industrial revolution. It developed as a response to, and critique of, mercantilism, in the classical thought of Adam Smith and David Ricardo who preached the virtues of government non-interference in the economy and free trade (O'Brien and Williams,

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<sup>7</sup> See Ashley (1984) in which he critiques neorealism's "orrery of errors", including statism.

2004: 18).<sup>8</sup> At its core, liberalism also embraces a commitment to individualism and private property, including private enterprise. It is a doctrine or set of principles for organising and managing a market economy in order to achieve maximum efficiency, economic growth and individual welfare (Gilpin, 1987: 27), and its basic question in IPE is how best can the regulatory authority of the state be harnessed to ensure that individuals are sufficiently uninhibited by political demands to establish systems of exchange that operate on the basis of free will (Watson, 2005: 22).

The assumptions hold that the market arises spontaneously in order to satisfy human needs, and that once in operation, it functions in accordance with its own internal logic; that human beings are by nature economic animals, and therefore, markets evolve naturally without central direction; that politics and economics should and can be separated into distinct spheres; that government should not intervene in the market except where a market failure exists, or in order to provide public/collective goods (Gilpin, 1987: 27-29).<sup>9</sup> Liberals also focus on a plurality of actors in the global GPE, including transnational corporations, states, international institutions and interest groups. However, the key economic actor is the individual (corporations are also considered private individuals); and individuals in pursuit of self-interest/profit supposedly maximise the benefits of economic exchange for society (O'Brien and Williams, 2004: 19). This is so because individuals behave rationally and attempt to maximise or satisfy certain values at the lowest possible cost to themselves, an assumption which places liberalism on par with the rationality accorded the state in mercantilist discourse. This rationality is also underpinned by the

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<sup>8</sup> See Watson, 2007 on the superficial understanding in IPE of the origins of liberal thought, particularly on the generally singular appreciations of Smith and Ricardo.

<sup>9</sup> See Nozick (1974: 149) on the minimal state or night watchman, as the most extensive state that can be justified, any extension of which would constitute a violation of people's rights. See also Friedman, 1993. For a cautious approach, see Rapley, 2002.

fundamental, inescapable condition of scarcity<sup>10</sup> (limited supply) because every decision involves a trade-off among alternative uses of available resources. In conditions of scarcity, the pursuit of self-interest/profit in the market economy leads to the maximization of efficiency, and the resulting economic growth 'trickles down' to the rest of society (Moon, 1999: 42; Gilpin, 1987: 29-30). This trickle-down concept implies that everyone will benefit, hence a focus on absolute gains, as opposed to that of relative gains in mercantilism.

Fundamentally also, a market economy is governed by the law of demand which holds that people will buy more of a good if the relative price falls, and less if it rises; people will tend to buy more of a good if their relative income rises, and less if it falls. Any development that changes the relative price of a good, or the relative income of an actor will create an incentive or disincentive to participate in a market system of economic exchange (ibid). For the market economy to function optimally, and for the endpoint of individual freedom to be fully realised however, property rights need to be properly enforced, a necessity summed-up in Locke's famous rights doctrine as "life, liberty and property" (Locke, 1980), and a crusade later taken up by Hayek (1944) and Friedman (1962), among others. Here, the role of the state to provide the legal framework and the enforcement mechanism becomes paramount, and shows the state's indispensability in liberal thought despite the disdain for politics. Fundamentally, because the corporation is accorded 'private individual' status within the liberal framework, it is entitled to the Lockean framework of rights that have become part and parcel of liberal democratic society.

Drawing on the liberal internationalist variant, and based on the Enlightenment prescriptions of classical figures such as Paine, Kant, Bentham and Mill (Dunne, 2001), liberals strongly advocate the application of liberal principles to the management of the international system, or

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<sup>10</sup> On the legal construction of the condition of scarcity in order to justify IP as property, see May, 2000, 2006.

the domestication of international affairs (McGrew, 2002: 268) including fostering international cooperation through the development of a functioning world economy, international law and global governance institutions. Liberal internationalists offer an account of the possibility of transcendence from power politics – or the anarchy problematic – in international relations. They consider that international institutions tame the powerful by creating international norms, incentives and new patterns of multilateral politics which limit the scope for power politics (ibid).<sup>11</sup> The WTO, and the legal framework it espouses to foster multilateral discipline governing trading relations, is therefore a liberal internationalist brainchild, thereby making liberalism, in principle, more proficient than mercantilism in explaining the making of pharmaceutical patents under the GATT/WTO.

From this short survey, several key points demonstrate the consistency of liberal explanations in relation to the making of patent policy in the UR. While liberals stress government non-intervention in the economy, they accept that some state involvement is necessary to correct market failure. We recall from 'The Research Problem' that the problem of free-riding (piracy/counterfeiting) is subsumed under what economists call market failure, thereby justifying the role played by the major IP jurisdictions in pressing for the multilateral protection and enforcement of patents. Liberals also stress social harmony amongst a plurality of interests, therefore, it is not impossible to examine the entire gamut of actors (transnational capital, states, institutions, civil society) that collaborated in the making of patent policy. More poignant, liberalism regards the individual, private enterprise and private property as sacrosanct. Therefore while some prominent liberals such as Bhagwati and Hayek (who are themselves avid believers in the institution of private property) have criticised the patent system on the basis of the distinction that separates competitive from monopoly capital, it is not difficult to locate liberal

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<sup>11</sup> For works in this area see for instance, Mitrany (1943; 1948); Haas (1964); Keohane and Nye (1972); Zacher (1999); Little (1996).

support for patent protection from within liberal thought, the bedrock of private property.<sup>12</sup> To begin with, the rationality assumption implies that individual (remaining cognizant that corporations are private individuals) pursuit of self-interest/profit leads to an efficient outcome for the economy as a whole, recalling the compensation+predictability→incentive-to-innovate dynamic encountered in the Introduction. This point therefore provides a powerful explanatory basis to examine the making of patent provisions of TRIPS within the liberal tradition, and it is for this reason that the research incorporates a prevailing-theory-as-practice analysis within the explanatory framework adopted, further highlighting the flexibility in utilising the Coxian approach.

Notwithstanding, Bhagwati, Hayek and others make a telling observation in defence of the market economy. If liberals centre analysis on the effective operation of the market economy, it becomes impossible to reconcile the laws of supply and demand with the operation of a global patent system premised on monopoly capital. Indeed, these classic demand/supply arguments were made by developing countries in their bid to maintain the pre-existing Paris Convention framework, and as will be seen in Chapter III, these were precisely the arguments, amongst others, negotiated out of the UR. This inconsistency therefore presents a dilemma in utilising the liberal approach, not to mention its unsophisticated assumption that society as a whole benefits from the pursuit of self-interest.

A greater liberal explanatory disability however is the liberal internationalist pretence that international institutions tame the powerful by creating international norms, incentives and new patterns of multilateral politics which limit the scope for power politics (McGrew, 2002: 268). The assumption that international norm-setting represents a problem-solving flight from power

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<sup>12</sup> See Boyle (1996), chapter 5, on intellectual property and the liberal state.

politics suggests that as the dominant perspective, liberalism does more to conceal power relations in the GPE, hence its “system-maintainer” designation (Lamy, 2001: 184). Moreover, because liberalism presupposes an inherent social harmony amongst a plurality of interests, it ignores the centrality of conflict in situations determining who gets what, and assumes that global governance institutions benignly resolve conflicts and facilitate cooperation (See Young, 1994; Prakash and Hart, 1999). Liberalism would therefore deal an injustice to the thread of conflict that runs throughout the research. Also, because the making of patent provisions is seen first and foremost as a case study in institutional capture by the TDI, the neglect of power in liberalism (see Hurrell, 2005; Barnett and Duvall, 2005; Barnett and Finnemore, 2005; Tooze, 2000) further limits its explanatory capacity. As Howard reminds us, liberalism is a deeply flawed discourse since it is marred by naiveté, by intellectual arrogance, by ignorance, by confused thinking and sometimes, alas, by sheer hypocrisy (Howard, 1981: 134).

### ***1.2.3 Marxian-Inspired Explanation and the Making of Pharmaceutical Patents***

Although the 'Theoretical Framework' outlined earlier highlighted the Marxian roots of the Coxian approach adopted here, it is necessary to briefly sketch the broader Marxist perspective as a way of intimating broadly where the thesis' audience is located. There is no such thing as a singular 'Marxism'.<sup>13</sup> There is a Marxism which reasons historically and dialectically, and seeks to explain, as well as to promote, changes in social relations (historical materialism); there is also a Marxism which turns its back on historical knowledge in favour of a more abstract and static conceptualisation of the mode of production (structural Marxism) – (Cox, 1981: 133). Coalescing around the tradition of the former, several general themes appear relevant in an examination of the making of the patent provisions under TRIPS. While the liberal tradition provides a useful guide to present the prevailing theory-as-practice as a framework which

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<sup>13</sup> See Linklater, (1996: 3n) for a range of interpretations of Marxism that have circulated within IR.

explains how the pharmaceutical industry was able to capture the TRIPS process to secure all of its demands, Marx's forensic examination of both the extraordinary dynamism and inherent contradictions of capitalism (Hobden and Jones, 2001: 202; Rupert, 2003: 182) provides a powerful lens which takes the thesis from one research question to the next: industry's victory scenario which characterised a condition of consolidation and continuity; and the ensuing contradictions which formed the impetus for change in the post-TRIPS context. At the same time, a Marxian-inspired perspective helps explain why one group 'lost'.

Marxism's great strength has been its incisive analysis of capitalism as an economic and political system, how that system came into existence, the social relations and institutions which define it, and how these are reproduced and sustained both temporally and spatially (Gamble, 1999: 133; Rupert, 2003: 182). The fundamental premise in Marx's methodology is that historical, material forces (as constituted by the forces and relations of production) are the foundation upon which class struggle and the movement of history rest, and upon which a critical analysis must concentrate (Gills, 1987: 265). While there is now little disposition to think about some stage of human development beyond capitalism guaranteed by the evolution of history (Gamble, 1999: 132),<sup>14</sup> the essence remains the same, that Marxists of every hue concur that an understanding of world politics should be based on a broader understanding of the processes operating within global capitalism (Wallerstein, 1974, 1996; Gill and Law, 1988; Halliday, 1994, 2002; Gamble, 1999; Hobden and Jones, 2001; Linklater, 1990, 1996, 1996b; Wood, 1981, 2002; Cox, 1987), a valuable starting point for an analysis on the making and remaking of global patent policy at the GATT/WTO.

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<sup>14</sup> In his critique of 'radical' theorists, Michael Cox (1998: 457; 2002: 71) saw Marxists as well-informed rebels without a political cause.

The assumptions hold that the *modus operandi* of global capitalism necessarily ensures that the powerful and wealthy continue to prosper at the expense of the poor (Hobden and Jones, 2001: 202; Linklater, 1996: 122), so as to safeguard the 'ceaseless accumulation of capital'. Noteworthy, this assumption is not entirely refuted within the dominant tradition, which presents the 'social costs' associated with global capitalism as those 'inevitable' short-term losses that will yield benefits in the long run (Amoore, 2002: 4), benefits that continue to delude many, particularly, though not exclusively, in the developing world (Thomas, 2000; Hoogvelt, 1997; Castells, 2000). Although a firm supporter of the global capitalist economy, and anything but Marxist in orientation, Bhagwati reasoned similarly, expressing that the TRIPS Agreement did not belong in the GATT, that it enforces payments by the poor countries (which consume IP) to the rich countries (which produce it); and by putting TRIPS in the WTO, 'we legitimated the WTO to extract royalty payments' (Bhagwati, 2002: 127). Similarly, Joseph Stiglitz, Nobel Laureate, World Bank-defector, and fervent critic of the market economy because of his analysis on asymmetric information, opposes TRIPS. He reasons that what separates developed and developing countries is not just the disparity, the gap, in resources, but also the disparity in knowledge, and closing that gap in knowledge is an essential part of successful development (Stiglitz, 2008: 102). TRIPS generally serves as an obstacle to closing that gap, and its signing was a "death warrant" for the poor (Stiglitz, 2006: 105) for the benefit of a utility-maximising TDI.

Marxists do not simply stop at a chronicle of human misery at the hands of global capital. Of central concern are the ruptures (class conflict) that characterise the relations between the powerful/wealthy, and the large mass of humanity which is confined to a materially constrained existence. This class antagonism is said to be the dominant form of conflict in history, and the engine of social transformation (Linklater, 1996; Gills, 1987; Burnham, 2002; Colas, 2002).

Recalling Cox's designation that “the essence of class is social domination and subordination” (Cox, 2002: 30), and his 3-level model (forces; precarious elements; the excluded) to represent the contemporary restructuring of global society (Cox, 1999: 394), the research contextualises this antagonism as the fissure between the globally powerful and the locally disenfranchised based on legalised global intellectual property relations; and in the post-TRIPS context, it considers the challenges and emboldened calls (from the counter-society and the African Group at the WTO) for TRIPS to take account of the impacts of patents on access to healthcare, as a pivotal moment of conflict aimed at transformation in the GPE.

Any Marxian-inspired undertaking therefore invariably demonstrates a commitment to the project of human emancipation, a condition described as “freedom from unacknowledged constraints, relations of domination, and conditions of distorted communication and understanding that deny humans the capacity to make their own future through full will and consciousness” (Ashley, 1981: 227). With its origins in the Enlightenment and encapsulated in the negative conception of freedom (freedom from), the concept of emancipation has been generally concerned with breaking with past forms of injustice to consider the conditions necessary for universal freedom (Devetak, 1995: 29-35). Some of those constraints on human freedom are captured by Booth as poverty, oppression and poor education (1991: 105); and taking Stiglitz's account above, the knowledge gap generally, and pharmaceutical patents under TRIPS in particular, act accordingly to circumscribe human freedom primarily in poor countries. Reconsidering Stiglitz's account, pharmaceutical patents can be extended to constitute a double-jeopardy since they further constrain the (non)freedom of the poor. An analysis of the making and remaking of patent provisions under TRIPS therefore contributes both empirically and theoretically to the way in which Marxian-inspired scholars try to make sense of the current world (dis)order, and how they articulate a vision for a future world order characterised by

human freedom. The next section considers the first part of Cox's historical structures framework (material capabilities) as observable aspects of the TDI's presence in the GPE that explain its significance and potential.

### **1.3 The Power of the Transnational Drug Industry: Material Capabilities**

In Cox's Braudelian historical structures framework, material capabilities include natural resources and technologies that enable the production and accumulation of wealth and thus, the projection of power (Cox, 1981: 136). Where the TDI is concerned, its capacity to project power comes first from the observation that health is a basic human need (Sen, 1999: 3), and because pharmaceutical products directly affect the health of a nation, they have greater social relevance than the products of almost any other industry (Gareffi, 1983: 167). Consequently, accessibility concerns are absolutely fundamental for all pharmaceutical-importing countries, which exceed ninety percent of the developing world, with notable exceptions being some larger developing countries such as Brazil, China, India, Mexico, and South Africa. This does not mean that this latter group does not also depend on a constant supply of imported pharmaceuticals; neither does this suggest that such issues are intrinsic only to the politics of developing areas. The debate also hinges on exorbitantly priced medicines in North American markets compared with much cheaper like-products across the border in Canada. There is also the issue of elusive access to basic health insurance to an ever-increasing number of people primarily in the US, indicating the extent to which such issues are not based simply on North/South geographical divisions, but also on similar north/south compositions within territories. Nonetheless, pharmaceutical dependency is like that of oil/energy: few countries are well endowed, but the sustenance of all is contingent upon it, a dynamic which arguably places the TDI in an unrivalled position in the GPE.

Incidentally, impressive advances in medicine and technology have boosted health and increased life expectancy, however, this picture is not universal when one factors-in tropical epidemics such as malaria, as well as the prevalence of tuberculosis and HIV/AIDS in developing areas. The disease burden is causally related to the weak state phenomenon as it impedes social transformation and the possibility of a sustainable and functioning civil society. Moreover, disease obstructs economic development, and without the pharmaceutical and healthcare sector, there would be no developed country. According to a report by the WHO Commission on Macroeconomics and Health (2001: 22), societies with a heavy disease burden tend to experience a multiplicity of severe impediments to economic progress.<sup>15</sup> Conversely, several of the great ‘takeoffs’ in economic history – such as the rapid growth of Britain during the Industrial Revolution; the takeoff of Japan and the US South in the early twentieth century; and the dynamic development of southern and East Asia from the 1950s and 1960s – were supported by important breakthroughs in public health, disease control and improved nutritional intake (ibid).

In a major 1998 Econometrics study, Bloom and Sachs, found that more than half of Africa’s growth shortfall relative to high-growth countries of East Asia could be explained statistically by disease burden, demography and geography, rather than by more traditional variables of macroeconomic policy and political governance (Bloom and Sachs, 1998: 270-1). Indeed, as Sachs himself points out, sub-Saharan Africa’s GDP would be up to 32% (approximately 1% annually) greater if malaria had been eradicated 35 years ago (WHO/28, Press Release, 2000). If this figure is accurate, the 2004 GDP for the sub-continent would have exceeded US\$500 billion,<sup>16</sup> or more than US\$100 billion higher than it currently is, far exceeding overseas development assistance to developing countries. Greater than the malaria burden are the losses

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<sup>15</sup> On this issue, see also Sachs, 2001; WHO, 2005; and Suhrcke, *et al*, 2006

<sup>16</sup> See figure 1.1 for a derived-at calculation.

from the HIV/AIDS pandemic in the region, which UNAIDS (2004) estimates to represent between 1% and 2% of annual economic growth.<sup>17</sup> These staggering growth penalties are a reminder of the value of a well-functioning healthcare system for development and poverty reduction in the developing world, further highlighting the TDI's significance in the GPE. Indeed, three of the Millennium Development Goals focus directly on health – reducing child mortality, improving maternal health, and combating HIV/AIDS, malaria, and other diseases. Another goal – reducing extreme poverty and hunger – is increasingly affected by the health of the population in developing countries, especially in rural Africa with the devastating impact of HIV/AIDS (Tansey, 2006).

Notwithstanding, the TDI's material power has not gone unnoticed, and has in fact been further magnified since its efforts in the landmark making of global trade-related intellectual property rules (Richards, 2004: 141). The global pharmaceutical industry is dominated by a few enormous entities – consisting of names such as Pfizer, GlaxoSmithKline (GSK), Sanofi-Aventis, Merck & Co. Inc (Merck), AstraZeneca (AZ), Bristol-Myers Squibb (BMS), Johnson & Johnson (JNJ), Abbott Laboratories, Novartis Pharmaceuticals Corporation (Novartis), and Roche Pharmaceuticals – which together account for more than half of the global market in pharmaceuticals.<sup>18</sup> As at December 31, 2004, Pfizer alone accounted for 9.6 percent of the global market share (GMS),<sup>19</sup> achieved more than US\$52 billion in revenues, and US\$16 billion in profits before certain one-time charges (Berenson, 2005). JNJ was the second largest drug company, accounting for more than US\$47 billion in sales, or 8.6 percent GMS, and more than

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<sup>17</sup> See also World Development Report 2007; Haacker, 2004; and Poku (2002) for an overview of the political economy of the HIV/AIDS crisis.

<sup>18</sup> See table 1.1.

<sup>19</sup> Based on Pfizer's total sales expressed as a percentage of total global sales of US\$550 billion as cited by IMS Health (see table 1.1 and figure 1.1 below). It is also important to note that pharmaceutical rankings change as new products enter the market, as patents expire, and when a company's reputation suffers.

US\$8 billion in net profits.<sup>20</sup> Next in line were GSK, Sanofi-Aventis and Novartis respectively, with tenth place held by BMS (seventh considering net profits) with total sales exceeding US\$19 billion.<sup>21</sup>

**Table 1.1: 2004 Global Market Share (GMS) of the top 10 pharmaceutical companies<sup>22</sup>**

Company	2004 Sales in US bn	Global Market Share	Net Profits in US bn
Pfizer <sup>23</sup>	52,516	9.6%	11,361
JNJ <sup>24</sup>	47,348	8.6%	8,509
GSK <sup>25</sup>	38,400	7.0%	8,100
Sanofi-Aventis <sup>26</sup>	33,000	6.0%	6,700
Novartis <sup>27</sup>	28,247	5.1%	5,767
Roche <sup>28</sup>	26,100	4.7%	5,547
Merck <sup>29</sup>	22,939	4.2%	5,813
AZ <sup>30</sup>	21,425	3.9%	3,814
Abbott <sup>31</sup>	19,680	3.6%	3,236
BMS <sup>32</sup>	19,380	3.5%	4,418
<b>Top ten total</b>	<b>309,036</b>	<b>56.2%</b>	<b>63,265</b>
<b>IMS Global Total<sup>33</sup></b>	<b>550,000</b>	<b>100%</b>	<b>****</b>

In the twelve months ending June 2004, the worldwide pharmaceutical market was worth US\$550 billion, surpassing US\$500 billion for the first time in the industry's history.<sup>34</sup> This figure exceeds the combined GDP of all least-developed countries (defined by the UN) which is significantly less than US\$300 billion;<sup>35</sup> as well as that of all of sub-Saharan Africa, which stood

<sup>20</sup> Based on JNJ's total sales as per 2004 financial report expressed as a percentage of total global sales of US\$550 billion as cited by IMS Health.

<sup>21</sup> All balance sheets were consulted to arrive at the rankings. See table 1.1 below.

<sup>22</sup> All sales and net profit figures were obtained from the companies annual financial reports as at December 31, 2004. Wherever other currencies were used in reports, figures were converted using the US\$ as a common base.

<sup>23</sup> Pfizer's 2004 financial report: <http://www.pfizer.com/annualreport/2004/financial/financial2004.pdf>

<sup>24</sup> JNJ's 2004 financial report: <http://www.investor.jnj.com/downloads/2004annual.pdf>.

<sup>25</sup> Although GSK's 2004 financial report cited figures in pound sterling, a conversion was made using the Universal Currency Converter at <http://www.xe.com/ucc/convert.cgi> on the 10/04/05. Financial report available at: <http://www.gsk.com/financial/rep04/annual-report-2004.pdf>.

<sup>26</sup> Sanofi-Aventis' figures are cited in Euros, and was converted in US\$ from the universal currency converter website on the 10/04/05. Financial report available at: [http://www.sanofi-aventis.com/images/101\\_25457.pdf](http://www.sanofi-aventis.com/images/101_25457.pdf).

<sup>27</sup> Novartis' 2004 report is available at: [http://www.novartis.com/downloads\\_new/investors/Novartis%202004-F%20OKTP%20with%20cover1003T11\\_CN.B.PDF](http://www.novartis.com/downloads_new/investors/Novartis%202004-F%20OKTP%20with%20cover1003T11_CN.B.PDF).

<sup>28</sup> Roche's 2004 report: <http://www.roche.com/pages/downloads/investor/pdf/reports/gb04/e01.pdf>.

<sup>29</sup> Merck's 2004 report: [http://www.merck.com/finance/annualreport/ar2004/pdf/Merck\\_2004\\_AR\\_FinSec.pdf](http://www.merck.com/finance/annualreport/ar2004/pdf/Merck_2004_AR_FinSec.pdf).

<sup>30</sup> AstraZeneca's 2004 report: <http://www.astrazeneca.com/sites/7/imagebank/typeArticleparam511562/astrazeneca-2004-annual-report.pdf>.

<sup>31</sup> Abbott's 2004 report: [http://www.abbott.com/investor/2004annualreport/includes/abbott\\_ar04\\_full.pdf](http://www.abbott.com/investor/2004annualreport/includes/abbott_ar04_full.pdf).

<sup>32</sup> BMS's 2004 report: <http://shareholder.com/Shared/DynamicDoc/bmy/815/BMS2004AR.pdf>.

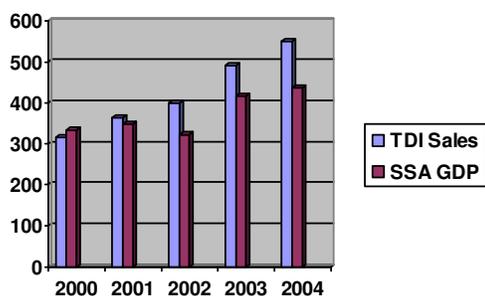
<sup>33</sup> See figure 1.1 below.

<sup>34</sup> See Figure 1.1 for the industry's global sales performance from 2000 to 2004.

<sup>35</sup> World Bank statistics based on groups of countries, available [www.worldbank.org](http://www.worldbank.org).

at US\$436 billion in 2004.<sup>36</sup> In fact the revenues from ten of the most profitable blockbusters<sup>37</sup> surpassed the GDP of many of the world's national jurisdictions, and in the sub-Saharan African (SSA) context, are only dwarfed by South Africa's GDP, and falls approximately US\$4.3 billion short of that of resource-rich Nigeria.<sup>38</sup> In the period ending June 2004, the global revenues from the 10 most profitable blockbusters stood at US\$51 billion, headed by Pfizer's Lipitor (cholesterol-lowering), with total sales of US\$11 billion, the first drug to have ever surpassed US\$10 billion (Class, 2004). Apart from South Africa and Nigeria in SSA, only Angola, Cote d'Ivoire, Cameroon, Kenya, and Sudan had a higher GDP than the revenues generated from the global sales of Lipitor.<sup>39</sup>

**Figure 1.1<sup>40</sup>: 5-year presentation on the global annual sales (US\$ billion) of the TDI compared with the current annual GDP of sub-Saharan Africa (US\$ billion).**



<sup>36</sup> This 2004 figure was derived from using the World Bank's 2003 base figure, and calculating the average growth rate of 4.5% for the region indicated by the African Development Bank Group's average growth for 2004. See: "President Kabbaj's analysis of Africa's economic performance in 2004: an exceptional year for Africa" on the following website: [http://www.afdb.org/en/what\\_s\\_new/focus/president\\_kabbaj\\_s\\_analysis\\_of\\_africa\\_s\\_economic\\_performance\\_in\\_2004\\_an\\_exceptional\\_year\\_for\\_africa](http://www.afdb.org/en/what_s_new/focus/president_kabbaj_s_analysis_of_africa_s_economic_performance_in_2004_an_exceptional_year_for_africa).

<sup>37</sup> A blockbuster is a drug with annual sales of at least US\$1 billion.

<sup>38</sup> Using drug revenue data, a comparison was made with data sets on sub-Saharan Africa from the Australian Government's Department of Foreign Affairs and Trade. Individual country information/economy fact sheets can be found at <http://www.dfat.gov.au/geo/>.

<sup>39</sup> Using drug revenue data, a comparison was made between data sets on sub-Saharan Africa from economy fact sheets by the Australian Government's Department of Foreign Affairs and Trade, <http://www.dfat.gov.au/geo/>, and the global sales for Lipitor.

<sup>40</sup> This chart was constructed using data obtained from IMS Health. This is a provider of market research, business analysis, forecasting and sales management services for the global pharmaceutical and healthcare industry. Annual statistics on the global industry can be found on the company's website at [www.ims-global.com](http://www.ims-global.com). Sub-Saharan Africa's GDP figures were taken from a variety of sources. Figures for 2002-3 were taken from <http://devdata.worldbank.org/external/CPPProfile.asp?SelectedCountry=SSA&CCODE=SSA&CNAME=Sub-Saharan+Africa&PTYPE=CP>. Figures for 2000-1 were calculated using the World Bank's 1999 base and the approximate growth rates (expressed as %) derived for 2000-1 from the UN's Economic Commission for Africa, *Africa Renewal*, Vol.16, Nos. 2-3, September, 2002, also online at <http://www.un.org/ecosocdev/genifo/afrec/vol16no2/162eca.htm>. See footnote 36 for the derived 2004 figure.

The second most profitable drug for the period was Merck's Zocor (also cholesterol-lowering) with total sales of US\$6 billion (ibid). Of the 53 countries that comprise the sub-continent, only 15 had a higher GDP than the total sales of Zocor.<sup>41</sup> Third in line was Eli Lilly's Zyprexa (schizophrenia compound) with total sales of US\$4.9 billion (ibid), surpassing the individual GDPs of 33 countries in the region.<sup>42</sup> At US\$0.2 billion short of Zyprexa's total revenue, is Pfizer's Norvasc for hypertension and angina (ibid). Moreover, each of the top ten corporations amassed net profits that outstripped the individual GDPs of at least 27 countries on the sub-continent.<sup>43</sup> Furthermore, five of the top ten global corporations are American-owned or at least head-quartered in the US (including the top two) indicating that the US accounts for the greatest component of total worldwide industry profits.<sup>44</sup> Other huge American entities with US\$ billions in sales and net profits include Wyeth, Eli Lilly and Schering-Plough, significantly widening the importance of the industry to US economic interests.

The industry is particularly profitable in the United States, followed by the European Union and Japan,<sup>45</sup> together accounting for more than 80 percent of the world pharmaceutical market. The North American market however, represented nearly half of total global sales in 2004, accounting for US\$248 billion or more than 45 percent of the global market,<sup>46</sup> most of which represents the US share. The US drug industry has also reportedly shown remarkable resilience to international shocks that impacted adversely on most industries and economies. Citing the 9/11 terrorist attacks on the US as testimony, Public Citizen<sup>47</sup> reports that while the overall 2001 profits of the Fortune 500 companies declined by 53 percent, the top ten US drug-makers' profits

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<sup>41</sup> See formula at footnote 39.

<sup>42</sup> See formula at footnote 39.

<sup>43</sup> Individual SSA GDPs were compared with the net profits of the top ten global corporations, using the figures shown on the companies' balance sheets and GDP information found on the Australian government website: <http://www.dfat.gov.au/geo/>.

<sup>44</sup> See also Richards, 2004, chapter 6.

<sup>45</sup> Japan ranks second as a single country market.

<sup>46</sup> See table 1.2 below.

<sup>47</sup> A national, non-profit, consumer-advocacy organisation in the US.

increased by 33 percent (Public Citizen, 2002). In 2002, the ten major companies in the US reported combined profits of US\$35.9 billion, compared with the combined total of US\$33.7 billion registered by the remaining 490 companies on the Fortune 500 (Public Citizen, 2003), further demonstration that it is the most profitable industry in the United States.<sup>48</sup>

**Table 1.2: World's major pharmaceutical markets as fraction of total sales in US\$ billion.<sup>49</sup>**

<b>Major Markets</b>	<b>1988</b>	<b>1999</b>	<b>2000</b>	<b>2001</b>	<b>2002</b>	<b>2003</b>	<b>2004</b>
<b>North America</b>	<b>118.1</b>	<b>135.6</b>	<b>152.8</b>	<b>181.8</b>	<b>203.6</b>	<b>229.5</b>	<b>248.0</b>
<b>Europe</b>	<b>89.3</b>	<b>***</b>	<b>75.3</b>	<b>88.0</b>	<b>101.9</b>	<b>129.7</b>	<b>144.0</b>
<b>Japan</b>	<b>***</b>	<b>53.5</b>	<b>51.5</b>	<b>47.6</b>	<b>46.9</b>	<b>52.4</b>	<b>58.0</b>
<b>Total</b>	<b>***</b>	<b>***</b>	<b>279.6</b>	<b>317.4</b>	<b>352.4</b>	<b>411.6</b>	<b>450.0</b>
<b>Global Total</b>	<b>307.0</b>	<b>337.2</b>	<b>317.2</b>	<b>364.2</b>	<b>400.6</b>	<b>491.8</b>	<b>550.0</b>
<b>GMS of major markets expressed as a %</b>	<b>67.6%</b>	<b>56.1%</b>	<b>88.1%</b>	<b>87.1%</b>	<b>88.0%</b>	<b>81.8%</b>	<b>81.8%</b>
<b>North American share</b>	<b>38.5%</b>	<b>40.2%</b>	<b>48.2%</b>	<b>49.9%</b>	<b>50.8%</b>	<b>46.7%</b>	<b>45.1%</b>

Not only do these markets account for a considerable sales dynamic, but the multiplier effects of the industry are also profound. According to disaggregated statistics by Datamonitor,<sup>50</sup> the top ten corporations employ more than 800,000 people globally. The US Department of Labor (2006) also cites that the pharmaceutical and medicine manufacturing industry provided 292,000 wage and salary jobs in 2006. Similarly, the European Federation of Pharmaceutical Industries and Associations (EFPIA) reported that the industry provided approximately 588,000 direct employment opportunities in 2004 (EFPIA Press Release, 2004). In the Japanese context, the industry employed more than 244,000 people in 1995 (U.S. ITC, 1999). While these figures are

<sup>48</sup> See also Richards, 2004: 152.

<sup>49</sup> Based on annual data sets comprised by IMS Health Inc., [www.ims-global.com](http://www.ims-global.com). North America includes the United States and Canada. Only 2003 & 2004 figures for Europe include information on the newer EU members. In cases where figures could not be obtained for all major markets (1998-1999), only available data was used to calculate market share.

<sup>50</sup> Datamonitor is an information-based consulting company which specialises in research on various industries and companies: [www.datamonitor.com](http://www.datamonitor.com).

important in their own right, they fail to represent the equally significant indirect component of the industry's employment generation. Pertinent and partially dependent sectors include media and advertising; iron and metal works; office machinery and computers; and higher education especially in biological and chemical sciences, as well as legal studies.

Arguably more important in the TDI's capacity to project power are its R&D capabilities and output, and the concentration of such activities in the three major pharmaceutical markets. In an increasingly knowledge-intensive global economy, scientific understanding and technological progress have become key determinants of competitive advantage. To maintain dominance, a continuous outpouring of investment in innovative dynamics in the pharmaceutical industry becomes fundamental. R&D represents the absolute driving force of the success of the industry, and one of the decisive signposts that investors scrutinise is the research pipeline of companies. For sustainable economic growth, innovation is also vital in order to tackle new diseases and to develop new compounds that fight older drug-resistant strains. The increasing demand for healthcare – shown by the annual growth in pharmaceutical sales – also emanates from huge ageing baby-boomer cohorts in the industrialised world which creates a vast target market for predominantly elderly-related diseases such as heart disease, cholesterol, stroke, arthritis, cancer, impotence, Parkinson's and Alzheimer's Diseases. The long-term concentration is even more pronounced when we look at global trends in the over-60 population, which is expected to rise to approximately two billion by 2050 (Borrus *et al*, 2002), the bulk of which will be in the industrialised world. Importantly also, a booming Chinese economy which resulted in a 28 percent growth in pharmaceutical sales in 2004 (Yahoo! Finance Press Release, 2005), is expected to fuel much of the future demand.

For these and other reasons, R&D expenditure<sup>51</sup> in the industry has grown exponentially in recent years, specifically targeting the ten major therapeutic classes: cholesterol and triglyceride reducers, antiulcerants, antidepressants, antipsychotics, anti-rheumatic non-steroidals, calcium antagonists, erythropoietins, anti-epileptics, oral anti-diabetics, and cephalosporins (Class, 2004). Revenues from these classes represented 33 percent of global sales, with cholesterol and triglyceride reducers growing more than 12 percent in 2004 to US\$30 billion, followed by antiulcerants at US\$25 billion.<sup>52</sup> The level of R&D in these therapy areas is understandably high as they represent 'diseases of prevalence' amongst high income earners and pensioners in the developed world, and therefore characterise the backbone of the industry's sales dynamic. These figures revisit an argument encountered in 'The Research Problem' about the dearth of R&D into tropical diseases, and further demonstrate the implications of R&D-concentration on development. Notwithstanding, the US is also the global leader in pharmaceutical R&D, accounting for 36 percent of global research; as well as global drug development, accounting for 45 percent of major global drugs developed between 1975 and 1994 (Borrus, 2002: 3). Pharmaceutical Research and Manufacturers Association of America (PhRMA) companies accounted for more than US\$33 billion in R&D expenditure in 2003 (PhRMA, 2004: 7), growing further in 2004. Pfizer alone recorded US\$7.7 billion in R&D investment in 2004 (Pfizer, 2004). The EFPIA (2004: 22) reported more than €20 billion in 2002 for its participating companies.

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<sup>51</sup> 'R&D expenditure' can be misleading as some argue (notably Public Citizen, 2003b) that many determinants are absent from this category. Public Citizen argues that missing from R&D figures presented by US pharmaceutical corporations, is a measure of the tax credit provisions to the industry. These include the research and experimentation tax credit as well as deductions for research expenditures which are worth 34 cents on the dollar (p. 15). They argue that R&D figures fail to credit the role of federally funded research (see Introduction, 24n) in drug development. Moreover, the industry waged and won a 9-year legal battle against the General Accounting Office (GAO), the investigative arm of Congress, to keep GAO from obtaining information about R&D expenditure (Public Citizen 2003b: 10). Furthermore, it is argued that the industry spends more on direct marketing and advertising than on R&D, hence inflated consumer prices (Richards, 2004: 146; Public Citizen, 2003b: 20-21).

<sup>52</sup> [http://biz.yahoo.com/bw/050309/95392\\_1.html](http://biz.yahoo.com/bw/050309/95392_1.html).

Such high earnings and economic dynamism of the industry<sup>53</sup> represent only part of the story as the challenges it faces are also immense. Many problems, despite huge current earnings, began in the 1960s and 1970s when increasing R&D costs featured alongside decreasing revenues. This was primarily a consequence of stricter regulation affecting drug safety, thereby resulting in cost increases and lengthier clinical trials. These additional demands led to longer time-to-market, and by extension, patent cover during commercialisation (Borrus, 2002: 14). A second factor was reduced ROI relative to R&D, as all obvious routes to the development of new drugs on the basis of the chemical synthetic paradigm had been exploited (ibid), a shortcoming that created opportunities for the now-thriving biotechnology industry, particularly in the American context. However, a series of legislative amendments and deregulation policies within the United States<sup>54</sup> were consequently enacted to cushion the effects of the new challenges.

Pivotal amongst these was the 1984 Drug Price Competition and Patent Term Restoration Act (Public Law 98-417), or Hatch-Waxman Act, which had the effect, *inter alia*, of lengthening the patent life for patented pharmaceuticals by giving investors a portion of the patent term lost to the federal regulatory review process. Because drugs receive patents from the Patent and Trademark Office (PTO) before they actually receive approval from the FDA (Food and Drug Administration), part of their time under patent is spent in clinical trials necessary for FDA

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<sup>53</sup> One crucial omission in the material capabilities of the industry are its lobbying activities, particularly in the US Congress. This omission was justified on an inability to assess the particularities of Congressional lobbying as a function of international trade decision-making, or more as a function of domestic public health expenditure. Public Citizen for instance commissioned a damning 2001 study on the nature of the industry's influence in the US. The industry spent \$262 million on political influence in the election cycle 1999-2000: \$177 million on lobbying; \$65 million on issue ads, and \$20 million on campaign contributions. 625 lobbyists were employed with the industry in 2000, more than half of whom were either former members of Congress or in other federal government positions. Former Congressional portfolios included Chiefs of Staff to members of Congress, members of the House Ways and Means Committee, the Senate Finance Committee and the Senate Judiciary Committee. For more information, see Public Citizen, "The Other Drug War: Big Pharma's 625 Washington Lobbyists". [www.citizen.org/documents/otherdrugwar.PDF](http://www.citizen.org/documents/otherdrugwar.PDF). See also Center for Public Integrity, 2005; Richards, 2004: 145-6. Notwithstanding this omission, the last section of this chapter rectifies this shortcoming with an analysis on Federal Advisory Committees in the United States and direct participation by the industry.

<sup>54</sup> See Introduction for further illustrations. See also Harrison, 2004 for an overview. Harrison (p. 76) makes the case that the US pharmaceutical industry was able to deflect from the domestically unpopular issue of the price of prescription drugs and reframe the debate in the context of the international unauthorised copying of patented drugs.

approval, thereby providing the pro-business justification of a patent-term extension beyond the 20-year exclusivity period – that equals the sum of all the time spent in the New Drug Application (NDA) review process, plus half the time spent in the clinical testing phase – which cannot legally exceed five years (Congressional Budget Office Report, 1998). In addition, the Act grants a 30-month stay to drug companies that file patent-infringement suits against generic manufacturers who challenge their patents, a provision that has been the subject of major controversy because it potentially acts as a legal loophole to extend exclusivity. Nonetheless, in the words of one of the co-authors of the Act, Senator Orrin Hatch (R-Utah), the purpose of this legislation is to help:

“restore to our domestic drug companies some of the incentive for innovation which has weakened as Federal pre-market approval requirements have become more expensive and time-consuming. That incentive will produce both the investment and the commitment to research and development that will again place the United States in unquestioned leadership in the field. And it will generate an increase in the number of important new drugs, among the most vital causes for this century's dramatic increase in the length and quality of life” (Findlaw, 1999).

Despite such bolstering legislation, the industry continues to face opposition from developing countries, NGOs, and patient groups generally, which have become increasingly incensed about what they perceive to be an asymmetric distribution of benefits. The level of opposition from these groups has been particularly intense over the issue of the impact of pharmaceutical patents on access to essential medicines, particularly Antiretroviral (ARV) treatment for HIV/AIDS patients clustered in SSA.<sup>55</sup> The industry has therefore had to commit a huge amount of financial, legal and political resources to litigate generic competitors on patent infringement matters. Other important challenges include upcoming patent expirations without a sufficiently attractive research pipeline with potential blockbusters; increased FDA scrutiny over drug safety; and the backlashes associated with an increasing incidence of drug-withdrawals from the market, especially those with blockbuster status. Amongst recent withdrawals were Merck's Vioxx

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<sup>55</sup> The post-TRIPS challenge from the counter society and the African Group is the subject of the last chapter.

(September 2004); Pfizer's Bextra (April 2004), both belonging to the class of anti-inflammatory drugs (Tomaselli, 2005).

But probably most important in the politics of international trade is the industry's push towards challenging developing countries with lax intellectual property laws. Noteworthy is the March 2001 patent-infringement case by 39 pharmaceutical companies against South Africa over a 1997 legislative amendment in its Medicines Act which appeared to grant the government unspecified power to issue compulsory licences and parallel importing contracts to its generic producers for HIV/AIDS pharmaceuticals (Shah, 2002; Halbert, 2005; Gad, 2006). The international public outcry that followed this court action forced the industry to drop the case the following month. The industry has therefore sought to restore a positive public image which suffered tremendously as a result of the heightened media coverage over the prevailing public perception that pharmaceutical companies comprised a disease-profiteering industry (Shiva, 2001) since profits were seen to be prioritised over medical emergencies which disproportionately affected the poor in developing countries.

Despite such anecdotal misfortunes, the TDI remains globally profitable and competitive. It is uniquely placed in the GPE because of the immeasurable significance of pharmaceutical products/services for the health and development of all nations. Its R&D decision-making also has huge implications for the poor since R&D tends to be causally related to affordability in prospective markets. It commands huge amounts of wealth that rival many national economies, and its technological/knowledge-intensive capabilities further fuel its production and accumulation of wealth. This in turn, enhances the industry's projection of power in the GPE and facilitates its utility-maximising behaviour. This projection of power however, remains ill-

defined without also considering the 'ideas and institutions' component of Cox's historical structures framework to explain why the TDI's capture of TRIPS.

#### **1.4 The Power of the TDI: Ideas and Institutions**

While the material components are a fundamental constituent in the power projections of the TDI, it is not sufficient on its own to determine the various forces that combine to produce the enormity of the industry in the GPE. The 'ideas and institutions' components of Cox's historical structures provide further insights because they enable greater understanding of the driving forces behind a consolidated and continuing structure. In effect, it is by employing and elaborating on the 'ideas and institutions' aspect of a Coxian criticality that one begins to appreciate material capabilities as the cornerstone of a broader perspective in the deliberations on 'who gets what'. Therefore, while the basis of power in the GPE is the material condition, the cementation of such power is only guaranteed through the hybridization of ideological harmonisation and institutional formation.<sup>56</sup>

Ideas are of two kinds in Cox's prevailing historical structure: historically conditioned intersubjective meanings, or those shared notions of the nature of social relations which tend to perpetuate habits and expectations of behaviour; and collective images of social order which constitute differing views as to both the nature and legitimacy of prevailing power relations. Accordingly, the ideational basis of the TDI's power is appropriately captured as first emanating from a harmonising or unifying discourse, with subsequent developments becoming avenues for persistent conflict regarding interpretation, moral application and enforcement. It is the 'unifying discourse' version of ideas that enable the TDI to secure its demands from TRIPS, while the latter presents contradictory developments that subsequently come to the fore. In its simplest

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<sup>56</sup> Hall (1997: 594) makes a similar argument in relation to material and ideational aspects of power, which he argues, are complementary.

form, the unifying discourse is grounded in the near-universal belief that a well-functioning, global integrative economic strategy is more enabling than destabilising; that in fact, there are truly destabilising consequences from a strict inward-looking and self-sufficient model of development, a discourse which is backed by well-grounded empirical evidence, and which further legitimises a global economic policy-convergence project; and that the private enterprise represents the epicentre of this stability paradigm. Therefore, the particular rational form which synonymises private capital accumulation with the generalised stability paradigm – the neoliberal assumption that well-functioning markets are the most important source of social and political order – represents the ideational foundation upon which the power of the TDI emanates. In this context, the TDI was well-placed to capture TRIPS because it was operating *within* the prevailing ideological framework which saw the virtues of a generalised harmonisation agenda; as well as an existing institutional structure which sought to secure this generalised agenda.

This particular mix of a hegemonic ideology with a supporting institutional structure, as well as an international environment geared towards the preservation of private enterprise growth (PEG), facilitated the subsequent role played by the TDI and other high technology industries<sup>57</sup> in spearheading the agenda that elevated IPRs as trade-related,<sup>58</sup> with verifiable trade-distorting and trade-enhancing ramifications. In fact, IP law and enforcement have become one of the definitive pillars of the global trading architecture, and according to an IP Counsellor at the WTO Secretariat, while some argue about the merits of linking IP to trade, we have to remind ourselves that the WTO is a rules-based organisation premised on promoting transparency and eliminating discriminatory practices in trade, and therefore, it is a non-issue whether it is the

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<sup>57</sup> This is examined in the last section of this chapter.

<sup>58</sup> Strategically, the problem of IP theft overseas was also framed as a morally objectionable issue, making its protection more appealing. See Devereaux *et al*, 2006: 51.

correct forum for trade-related intellectual property issues. It is *accepted* that intellectual property impacts on trade (Kampf, 2005 interview).

Consequently, this ‘acceptance’ of a causal link between IPRs and trade-enhancement or lack thereof; a well-defined structure of global capitalism, along with its institutional components; and the material capabilities of decidedly US owned corporations, were all crucial mechanisms in the making of the final TRIPS Agreement. The United States origin of the instigators of the globalisation of the linkage between IPRs and trade was fundamental to the subsequent victory scenario by virtue of the leadership position of the US and its role as rule-maker in the GPE. Had those industries originated in SSA, the outcome might have been dramatically different and the issue would probably not have emerged on the agenda in the first place. In this instance, territorial origin matters in deciding who gets what in the GPE.

Moreover, and as encountered earlier, was the extension of a particularly settled assumption in neoclassical economic theory in general, and in the growth paradigm specifically – that the institution of private property is part and parcel of the framework of economic activity; and that private property (intellectual property) encompasses a system of rules that generates one of the cornerstones of the theoretical enterprise, that is, utility-maximising behaviour (Caporaso and Levine, 1992: 87). Understood in the context of pharmaceutical patents, a well-functioning protection and enforcement framework provides the incentives for rational producers to increase investment in pharmaceutical R&D<sup>59</sup> in order to gain a competitive advantage and therefore maximise profits. The tension emerging is whether the level of protection demanded by

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<sup>59</sup> See footnote 51 above for a breakdown of pharmaceutical R&D.

pharmaceutical producers exceeds the level justified by the incentives argument, thereby raising concerns about the rent-seeking<sup>60</sup> motivations of the TDI.

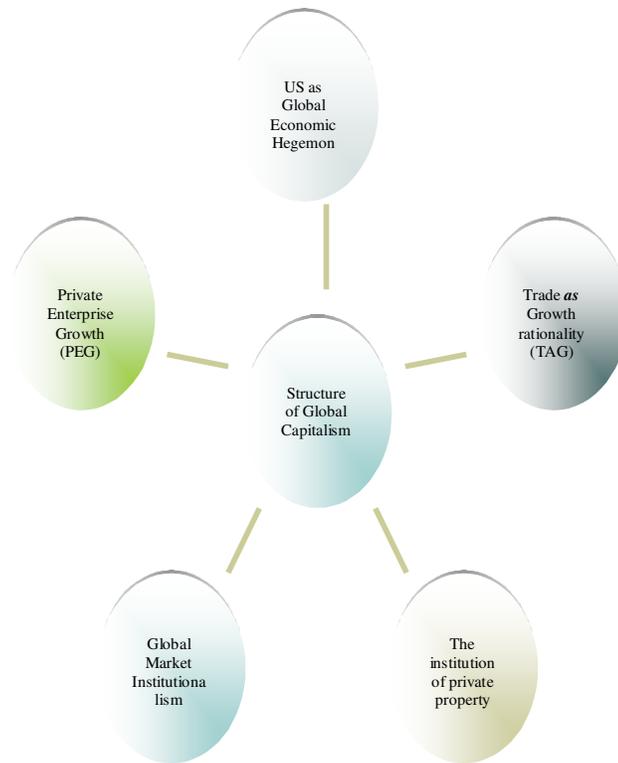
**Figure 1.2** illustrates the favourable structure within which the TDI was operating, a structure that effectively restricted the range of choices that could be made regarding the international patent regime; but importantly also, a structure which ‘enabled’ and ‘empowered’ high-technology actors to generate solutions to their problems by providing cues and scripts that ‘constitute’ legitimate forms of action (Campbell, 1998: 382).<sup>61</sup> Deductively, since trade is arguably the most important driver of growth in the prevailing discourse as practice, and since lax or non-existent IP protection impacts negatively on trade, then a growth-orientated policy would pursue strengthened IP protection and enforcement through the pre-existing structure which does not only explicitly identify with PEG, but also with the institution of private property. Since high-technology industries were already operating within a well-defined capitalist framework, the only challenge lay in articulating and effectively selling the linkage of how IP protection and enforcement strengthened the trade as growth (TAG) rationality.

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<sup>60</sup> Rent-seeking behaviour occurs when economic decision-making is guided by factor rents which are above and beyond the amount necessary to induce the supplier to offer the input to the market. See Drahos, 1996 for a view on IP law reform as a case of rent-seeking.

<sup>61</sup> Although Campbell's and some of the other references used here reinforce the point of ideas as causal as opposed to ideas as constitutive, this research does not see the two conceptions as mutually exclusive. For the distinction between causal and constitutive conceptions, see for instance Laffey and Weldes (1997); and Bieler and Morton (2008).

**Figure 1.2: Enabling Structure of the TDI<sup>62</sup>**



This well-defined global capitalist structure provided industry ‘participants with a conceptual repertoire for actively framing’ policy intentions since TAG rationality ‘facilitates action not only by serving as a road map, but also by providing symbols and other discursive schema that actors can use to make this map appealing, convincing and legitimate’ (ibid: 381). This road map equips corporate elites with the tools of a crucial technique to dominate decision-making that feeds onto the global arena. In this instance, if a strengthened IP framework improves trade prospects, it automatically favours the growth paradigm, thereby providing the ideational frame

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<sup>62</sup> This is a diagrammatically derived representation of the preceding analysis.

within which the TDI would co-package a subject area once confined to law, and present it to global institutional bureaucrats.

While the ability to effectively and convincingly frame or package demands does not reveal power directly, it is important insofar as there was recognition on the part of high-technology industries that structures impact significantly on outcome. For ideas to be sold to elites and the mass public, they must be 'packaged', usually in terms of existing social, institutional and normative patterns (Goldstein, 1993: 255-6). Consequently, by deploying their 'framework for action' in a way that fundamentally equalised their demands with the inter-subjective meanings (the range of norms, values, language, symbols and institutions) that constitute the prevailing order, the TDI and other high-technology industries had a clear end in sight. It is important not to underestimate this equalising strategy because it essentially meant that the demands of the IP class were synonymous with social and political order, not only because the equalising strategy was put forward as a TAG model (which is the dominant ideological position), but also because it was presented as causally related to market functionality which, according to neoliberal rationality, is the single most important source of social and political order.<sup>63</sup>

Recalling the foundations of neoclassical rationality (which informs the dominant neoliberal tradition), markets tend towards long-term equilibrium; are naturally efficient and productive; are responsive to what consumers both want and can afford; and most importantly, markets deliver fairness and economic justice because of the equality of opportunity they allow people, and because they are neutral arbiters between competing interests (Heywood, 2003: 56). According to this logic, the globalisation of strengthened IPRs could only further the natural order of things by neutrally delivering fairness and economic justice: by upholding a system of

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<sup>63</sup> See Bhagwati (2004) and Wolf (2004) for a view on the benign social function of economic globalization. See also Friedman (2002) for his causal link between market freedom and political and social freedom.

rules that mediates between the interests of producers and users of intellectual property, the market creates the investment incentives that will ultimately benefit the global public.

Fundamentally therefore, one has to see the ideational structure, not simply as delimiting or facilitating the behaviour of actors (remaining cognizant that this is fundamental), but as a technique or a conscious transnational corporate strategy aimed at influencing global public policy. By conceptualising 'ideas' not only as a structure but also as the main ingredient in a broader corporate technique, one can establish greater causality between ideas and outcome. That is, how elites and other actors deliberately package and frame policy ideas to convince each other as well as the general public that certain policy proposals constitute plausible and acceptable solutions to pressing problems (Campbell, 1998: 380). Consequently, the globalisation of strengthened IPRs is seen as a convincing policy proposal in an effort to remedy, among other things, an expanding US trade deficit which had very visibly increased by 309 percent between 1980 and 1985, from 36.3 to 148.5 billion (Sell, 1999: 176) – shortly before the UR of trade negotiations commenced)<sup>64</sup>.

Therefore, while there is great utility in the thesis that agents and structures are mutually constitutive (Wendt, 1987), the making of pharmaceutical patents does lend credence to the assumption that the structure of ideas, identifiable with the prevailing theory as practice, represents the playing field that enables political and economic elites to further accentuate and maintain a particular ethos, thereby juxtaposing a 'system maintainer' theory (Lamy, 2001: 182-199) with a system maintainer practice. Far from organisational institutionalism which stresses that people in organisational settings are motivated more by institutionalised routines, habits,

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<sup>64</sup> In February 2007, this figure had decreased to 58.4 billion . See US International Trade in Goods and Services, February 2007. Available online at [http://www.census.gov/foreign-trade/Press-Release/current\\_press\\_release/ft900.pdf](http://www.census.gov/foreign-trade/Press-Release/current_press_release/ft900.pdf)

rituals, scripts, and cues, rather than interests (Campbell, 1998: 381) - as if human behaviour was the result of forces that actors neither controlled nor comprehended (Giddens, 1984; Woods, 1995) - the current perspective sees behaviour as a product of interest which is astutely tailor-made to coincide with the prevailing structure of meaning in a way that mimics regularisation so as to induce an objective appreciation from onlookers. Such structures of meaning are *not* unknown to actors.

This can be further exemplified in light of the practice at TRIPS Council meetings<sup>65</sup>, whereby participants usually invoke a ‘consistent-with’ approach in order to demonstrate that their proposals are *consistent with* the TRIPS Agreement itself, and are in harmony with the legally defined structure of the trade institution. This is so, for the scripts and cues that participants/actors utilise in their daily deliberations, far from being conceived as ritualised behaviour by unthinking beings, can be more appropriately construed as a strategic, means-utilisation of the structure of ideas. Therefore, the transnational corporate class does not only occupy a privileged space within the dominant structure, and engage in the reconstitution of this structure. It also uses this structure as a strategic ‘consistent-with’ technique that enables business proposals to speak the language of the dominant TAG politico-economic model.

Actors are aware that “ideas are politically salient only when embedded within some set of existing cognitive and political structures. If entrepreneurs do not make these connections, even the most functional of ideas invariably will be ignored” (Goldstein, 1993: 255-6). What Goldstein failed to mention however, is that similarly, when entrepreneurs make these connections, even the most dysfunctional of ideas could be the basis of public policy outcomes.<sup>66</sup> Therefore, the structure of ideas is important, not only because it constrains *or* facilitates action,

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<sup>65</sup> Author served as St. Lucia’s Representative to the TRIPS Council meeting, June 14-15, 2005.

<sup>66</sup> See for instance, Woods (1995) on the question of the kind of economic questions most likely to be influential.

but also insofar as it is malleable to the business design techniques of transnational corporate actors. This is not to say that interests are given and logically prior to any beliefs held by actors (Jacobsen, 1995: 289). More specifically, it shows how actors strategically employ the language and meanings of a particular structure by equating it with the corporate agenda. Actors are thus more calculating than conventional structuralism would have us believe, and particularly so when one factors-in the liberal utility-maximiser. Indeed, what may appear to be regularised, mechanical behaviour, may in fact be the strategic use of a prevailing structure of meaning.

The institutional component has a similar, though not parallel, dimension, though the extent to which one can intelligibly maintain a separate space between ideas and institutions is highly debatable. Whether institutions take on an organisational fixture, or are inter-subjectively contextualised, their reality is made meaningful by the framework of ideas that define and legitimise them, thereby creating a continuing cycle in which ideas create institutions, and institutions come to represent and redefine ideas, while maintaining their core meanings. These variables are therefore in constant entanglement in the constitution and reconstitution of world order, to the extent that scholars have developed theories of ideational institutionalism which examine the various ways in which institutions mediate ideas and policies (Yee, 1996).

For instance, Haas (1992) devised the epistemic communities approach to demonstrate how particular ideas experts influence policy by occupying advisory-capacity<sup>67</sup> positions within national governments and international organisations, and then advise by transplanting their particular expertise. While ideational transplantation by experts in advisory roles is undeniable, this perspective falls short of considering the entry requirements for epistemic community experts in advisory bodies. Essentially, such ideas experts would have access to policy-making

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<sup>67</sup> Advisory committees as a function of how institutions mediate ideas and vice versa will be examined empirically in the next section.

circles only if they passed the ideological test. Goldstein for instance alludes to a mid-1970s American practice specifying that members of the House Ways and Means Committee<sup>68</sup> had to pass a ‘free trade’ test to be recruited onto the committee (Goldstein, 1988: 7n). This allusion can be applied to the selection process of ‘expert’ communities as political advisers since such experts would first have to demonstrate that the particular ideas of the group they serve are consistent with the prevailing TAG model of social and political order.

What appears to be more appropriate in the context of the global patent system is to link the epistemic communities approach with Critical IPE’s organic intellectuals (Cox, 1993: 49-66) who themselves operate as the builders and gatekeepers of the prevailing order. This linkage does not only draw our attention to the possibilities for ideational transplantation by expert communities once in advisory capacities, but it also demonstrates how ideas are invariably infiltrated through various institutional fixtures, primarily through scholarship or teaching. Cox, invoking Gramsci, comments that intellectuals are not a distinct and relatively classless social stratum, as they perform the function of developing and sustaining the mental images, technologies and organisations which bind together the members of a class, and of an historic bloc, into a common identity (ibid: 57; Cox 1999: 391). Gramsci contended that the role of organic intellectuals was to represent the ideas that constitute the terrain where hegemony is exercised (Augelli and Murphy, 1993: 131), where hegemony is represented as a “fit between material power, ideology and institutions” (Devetak, 1996: 160), “which frames thought and circumscribes action” (Cox with Sinclair, 1996: 151).

He further contended that such intellectuals must supply intellectual and moral support for the hegemon’s dominant political role, to the point that, ‘what is “politics” to the productive class

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<sup>68</sup> This is one of the crucial US Congressional committees with a mandate on trade liberalisation legislation; another is the Senate Finance Committee.

becomes “rationality” to the intellectual class’ (Augelli and Murphy, 1993: 131). Those intellectuals organically tied to the hegemonic class must demonstrate in every field of knowledge that the aspirations of the group they serve coincide with the interests of society as a whole (ibid). According to Gramsci, if philosophy, politics and economics are the necessary constituent elements of the same conception of the world, there must necessarily be a convertibility from one to the other (Gramsci, 1971: 403), a function performed by organic intellectuals, or the thinking and organising elements of a particular fundamental social class (ibid: 3). As actors of the ideological struggle, the intellectuals of the dominant class must prevail over the intellectuals from other classes by developing more convincing and sophisticated theories, inculcating other intellectuals with the dominant worldview, and assimilating them to the hegemon’s cause (Augeli and Murphy, 1993: 131). So fundamental is this class in the process of hegemonic reinforcement that ‘potential hegemons fail when they are unable to consolidate the support of intellectuals’ (ibid).

Most leaders (political, economic and otherwise), and their systems of thought and action, are themselves the products of intellectuals, and arguably, intellectuals do more than any other group in the dissemination of preponderant ideas. The group which comes to believe in the objectivity of a globalised pharmaceutical patent regime; the group which arrives at the monologic conclusion that astronomical profits for the pharmaceutical industry ultimately benefit humanity (since such profits act as an incentive for further R&D in pharmaceuticals); which equates trade with growth and growth with development, and believes in the moral superiority of the market; which believes in PEG neutrality; and which builds careers that uphold and defend such value systems – owes much to a dominant system of thought and scholarship. The globalisation of pharmaceutical patents would not gain such momentum if organic intellectuals were not also featured in claiming the neutrality of property rights generally, and IPR neutrality in particular.

As Goldstein observes, “it was only with the gradual expansion and professionalisation of the discipline of economics, *and the insistence by most major universities that all students have a grounding in classical economics did individuals who believed in these ideas become able to translate them into a form usable for policy prescription*” (Goldstein, 1993: 15) (emphasis added). From this example we see the role that major/reputed educational establishments and their mainstream intellectuals played in the scholarly support for, and teaching of, dominant ideas. Importantly also, because educational institutions and the system of scholarship generally, have an explicit alignment with the dictates of growth and the needs of the market, the products (experts, consultants, specialists) of those establishments are consequently engineered to see the liberal market economy, and the policies that serve it, as rationally and neutrally defensible.

There is a dominant body of thought in economics, for instance, which rationalises that investment in IP represents a sunken cost (Garber and Romer, 1996), that is, such costs are non-recoverable and therefore cannot be remedied via the free market. There is another group consisting of patent lawyers who have advanced careers in upholding the patent system. In fact, trade law in general and patent law in particular have gained considerable momentum in the last decade.<sup>69</sup> Therefore, not only are experts able to influence policy once in advisory positions, but more importantly, the ideational institutionalism that comprises the work of intellectuals and the institution of formal scholarship, compellingly illustrates how ideas become so commonplace as to erect a quasi-permanent ideational structure with real policy implications.

At another level, ideational institutionalists argue that ideas influence policy when they are embodied in institutions, which in turn, facilitate the implementation of those ideas by giving

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<sup>69</sup> Boldrin and Levine (2008: 79) demonstrate that in correspondence with the 50% explosion in patent applications in the US in the four year period 1997-2001, the increase in membership of the intellectual property section of the America Bar Association jumped from 5,500 to almost 22,000.

them organisational support and means of expression (Yee, 1996: 88, taken from Sikkink, 1991); that institutions reflect a set of dominant ideas translated through legal mechanisms into formal government organisations (Goldstein, 1988: 181-2); and importantly, ideas encased or embedded in political institutions through legal procedures have a durable policy impact (Goldstein and Keohane, 1993: 3). This branch of ideational institutionalism is arguably parallel to Coxian international organisations (IO) which serve as mechanisms through which the universal norms of world hegemony are expressed (Cox, 1993: 62). “Indeed, international organisations function as the process through which the institutions of hegemony and its ideology are developed” (ibid).

Cox further argues that IOs embody the rules which facilitate the expansion of hegemonic world orders (ibid) such as the rules that grant international pharmaceutical patent protection, which in turn facilitate the expansion of a world order built on corporate dimensions of success; that they are themselves the product of the hegemonic world order (ibid) since international organisations such as the WTO are the products of the liberal institutionalist architects of the post-war order; they ideologically legitimate the norms of world order (ibid) particularly with respect to the trade-relatedness of contemporary discourse as practice; they co-opt elites from peripheral countries, and absorb counter-hegemonic ideas (ibid) through various inducement mechanisms.

Arguably therefore, the WTO acts as a powerful hegemonic mechanism by virtue of the fact that ideas encased within it, reconstitute the prevailing power structure. While ideas and institutions are an insightful analytical tool to examine the dynamics that enabled the TDI to capture the TRIPS process, it fails to give sufficient attention to the linkage between the state and policy outcomes at the international level. That is, the decision-making intricacies of American politics and the structural position of corporate America (including elements of the TDI) within the

domestic trade decision-making apparatus that feeds onto the global arena, the subject of the following section.

### **1.5 The Institutional Origins of the TDI's Projection of Power: Trade Advisory Committees & Decision-Making in American Politics**

One of the fundamental dimensions in the making of the patent provisions of TRIPS, and in the power that the TDI wields, is the location of the industry within the more generalised American system which has institutionally and structurally legitimated a political space for interest-group participation within the decision-making apparatus, specifically, an advisory space for private sector actors. Further intimating the first parts of Hypotheses I and V, this section looks at the effects of the Trade Act of 1974 which constitutionally mandated private sector consultation and participation in American trade decision-making. As Destler points out, the advisory committee system gave Congress what its members particularly favoured: a place away from Capitol Hill where they could refer petitioning interests and assure them that they would get a fair hearing (Destler, 1995: 112). A short history of the story of how the issue of trade-related IPRs first emerged as a WTO agenda item is instructive in the first instance.

The push for a trade-based GATT IP code was initiated in the mid-1980s by a thirteen-member CEO coalition of US-based high-technology corporations, called the Intellectual Property Committee (IPC) (Drahos, 2002: 118; Devereaux, 2006: 55). Amongst the make-up of this special interest group were the CEOs of Pfizer, Merck, JNJ, and BMS, making pharmaceutical manufacturers the largest represented interest at 31 percent.<sup>70</sup> Moreover, one of the co-initiators of the IPC was then CEO of Pfizer, Edmund Pratt, further ensuring that the mandate of the coalition lay as intimate to pharmaceutical interests as possible. In effect, the IPC was a

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<sup>70</sup> The other members of the group were FMC, Du Pont, Monsanto, IBM, Hewlett-Packard, Warner Communications, General Motors, General Electric, and Rockwell International. See: [http://www.pfizer.com/are/about\\_public/mn\\_about\\_intellectualpropfrm.htm](http://www.pfizer.com/are/about_public/mn_about_intellectualpropfrm.htm).

pharmaceutical co-initiative, which makes the political economy of the making of pharmaceutical patents all the more important as an issue area under academic investigation.

In a March 1995 USCIB (U.S. Council for International Business) Conference, Pratt remarked not only that IPRs had been enshrined as a central and necessary part of the global economic architecture, but also, that this triumph represented “one of the highlights of my career” (Pratt, 1995). So highly visible was Pratt's role in pushing and steering strengthened IPRs on the trade agenda, that his name was amongst three that surfaced as a possible successor to then USTR, Clayton Yeutter (Fansworth, 1988).<sup>71</sup> Along with John Opel (then CEO of IBM), Pratt had been active in the US-based International Anti-Counterfeiting Coalition at the end of the Tokyo Round of GATT negotiations and had long been lobbying the US government to get serious about IP violators abroad (Sell, 2003: 82) and therefore had immeasurable experience in spearheading the IPC's agenda. Until then however, efforts at compliance and enforcement of an IP code had been bilateral, with private sector associations involved in direct negotiation with primarily developing countries and NICs regarding domestic IP regulation.<sup>72</sup>

To be sure, efforts to protect intellectual property at the multilateral level was not an IPC initiative *per se*, as the process can be traced at least as far back as the late 1800s, with the 1883 Paris Convention on the Protection of Industrial Property (covering patents, trademarks and industrial designs); and the 1886 Berne Convention for the Protection of Literary and Artistic Works. The need for these conventions arose precisely as a result of the unauthorised

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<sup>71</sup> Pratt also served as advisor to Yeutter's predecessor, Bill Brock, in the mid-1980s. See his profile at Pfizer, [http://www.pfizer.com/about/history/edmund\\_pratt.jsp](http://www.pfizer.com/about/history/edmund_pratt.jsp).

<sup>72</sup> See also Devereaux, *et al* (2006) for an overview of the bilateral efforts of the Anti-Counterfeiting Coalition in the US in the 1970s and how the coalition successfully lobbied the US government to frame IP as a trade issue in relation to agrochemical products being pirated in Hungary. The coalition also tried unsuccessfully to achieve trademark protection in the Tokyo Round 1973-79, however these efforts would pave the way for the IPC as IPRs were placed on the GATT agenda. See also Sell, 1998.

reproduction of the IP of foreign inventors and artists, in the absence of international protection and enforcement mechanisms. Until the end of the nineteenth century IP protection was the subject matter of the strategic economic management of national governments, and imitation of foreign IP was permitted, even encouraged, to boost national economic development (only then, the practice was seen as 'imitation' and not necessarily criminalised in its contemporary context)<sup>73</sup>. For instance, the Brazilian pharmaceutical industry was able to benefit from decades of a regime of non-patent protection, thereby contributing to its dominance in the domestic generics market. The legal right of local firms to produce on-patent drugs was expressed in domestic Law No. 5772 on Industrial Policy which took effect December 1971 (Cohen and Lybecker, 2005: 214-5). In fact, in much of the Global South patents were not allowed in the pharmaceutical sector because of ethics, colonial legacies, and the threat that statutory monopolies in health posed to people's basic treatment needs (Kuyek, 2001).<sup>74</sup>

In the 1870s, the Austro-Hungarian Empire sought to host international exhibitions of inventions in Vienna, but foreigners were reluctant to participate because they feared their inventions would be stolen (Sell, 2003: 11). German and American inventors were particularly concerned as they were widely recognised to be among the most innovative (ibid, taken from Murphy 1994). Therefore, the empire adopted a temporary law providing protection for foreigners in order to encourage foreign inventors' participation – but this protection was to last through the duration of the exhibitions (ibid). Some European countries already had domestic patent systems and met in Vienna in 1873 to discuss prospects for an international agreement to protect patents. They convened several follow-up congresses in 1878 and 1880, the latter of which adopted a draft convention which later became the basis for the 1883 Paris Convention (ibid).

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<sup>73</sup> See Chang (2001) for an historical overview of IP protection and 'theft' in industrialised countries.

<sup>74</sup> See Nogues (1990) for an overview of the pre-existing situation in developing countries regarding protection for pharmaceutical patents.

Later, the Berne Convention emerged as concerns were voiced over limited markets and diminished profits to legitimate editions caused by the lawful copying of primarily British books in America. In fact the United States acceded to the Berne Convention as recently as November 1988 (WIPO), attesting to the hypothesis that its economic prowess may also have encompassed and depended upon the reproduction/imitation of the IP of others.<sup>75</sup> The need for international IP codes therefore arose long before the efforts of the IPC, and imitation has, at least implicitly, been linked to trade distortions. However, the novelty in the TRIPS case study lies not only in the high level of corporate visibility it entails, but also the fact that it has created new substantive laws that must be enshrined in the domestic legal apparatus of states; and integrates intellectual property with the institution of criminal law, with clear protection and enforcement obligations. In stark contrast, the nineteenth century Conventions neither created new substantive law, nor imposed laws on member states. Rather, they reflected a consensus among member states that was legitimated by domestic laws already in place (Sell, 2003: 11, quoted from Gana 1995). These Conventions can arguably be seen as belonging to the area of ‘soft’ law, consisting of guidelines for state conduct, and not substantive in character as in the case of TRIPS.

Therefore, the efforts of the US-based CEO coalition can be hailed as a novel phenomenon with arguably the most far-reaching implications than any other international legal instrument of its kind. But how the IPC was able to garner support for a previously depoliticised and technical domain lay fundamentally in the US domestic legal and political structure and the possibilities over time that have enabled greater private sector involvement in decision-making generally, and trade policy-making in particular, a linkage which has received scant attention by scholars of the TRIPS story.<sup>76</sup> The United States Congress established the trade advisory committee system in

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<sup>75</sup> See Khan and Sokoloff (2001) and Chang (2001) for a history of American institutions and practices in this area.

<sup>76</sup> See for instance, Drahos with Braithwaite, 2002; Drahos, 2003; Sell, 1998, 2002, 2003, 2006; Richards, 2004; Matthews, 2002; Ryan, 1998; Devereaux, *et al*, 2006, who accurately speak of the lobbying activities of the

its Trade Act of 1974 to ensure that US trade policy and trade negotiation objectives adequately reflect US commercial and economic interests.<sup>77</sup> The timing of this Act is specific to American interest articulation during the Tokyo Round, which represented a departure from conventional trade politics, since it also focused extensively on non-tariff barriers.

The American political system has a reasonably long history of federal advisory committees (FACs) and they can be traced at least as far back as 1863 when formal recognition was given to the desirability of enlisting the cooperation of leading scientists outside the government in the solution of governmental problems. This was done by granting a federal charter to the National Academy of Sciences with the stipulation that the Academy would render advice to the government whenever necessary (Gill, 1940: 411). Since then, a small identifiable elite has dominated and continues to dominate the science-advising structure of the United States, acquiring labels such as 'elite', 'estate', and 'priesthood' (Mullins, 1981: 4). Today, there are approximately 1000 advisory committees in operation (Balla and Wright, 2001: 802), with more than 37,000 advisory positions filled (Moore, *et al*, 2002: 736).

The desirability of this committee system is justified on the bases that governmental services have become very technical in character, thereby warranting a steady stream of experts; the growth of new activities requires close and frequent contacts with representatives of the various groups most affected by those services; the belief on the part of many government agencies that it is advantageous for the agency to secure the support of the outside group to interpret the needs of that agency to the Congress, the Bureau of the Budget, the Civil Service Commission, and the public (Gill, 1940: 412-13). A 1957 Department of Justice report which referred to the FAC

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President's ACPTN, however, they summarily, if at all, touch on its co-constitution within the domestic political structure.

<sup>77</sup> USTR: [http://www.ustr.gov/Who\\_We\\_Are/Mission\\_of\\_the\\_USTR.html](http://www.ustr.gov/Who_We_Are/Mission_of_the_USTR.html)

system as the “Fifth Branch of Government”, and a subsequent 1970 Congressional report, both articulated that “the advisory body creates a contribution by the governed to the Government; it provides the means by which the best brains and experience available in all fields of business, society, government and the professions can be made available to the Federal Government at little cost. Our Government and leaders are continually in need of advice on a variety of problems at all times in their attempts to find answers to the problems of our increasingly diversified and complex society” (Karty, 2002: 214).

Despite the apparently logical rationale for such advisory committees however, FACs are little-known, little-studied, but often represent an important link between the corporate community and the federal government (Domhoff, 2005), and a crucial lens through which one can interpret the institutionalisation of corporate policy-making in the US in general, and the globalisation of corporate trade decision-making in particular. In fact, it was not until the early 1970s that FACs came under scrutiny when Senator Lee Metcalf (D-Mont.) began to question the clandestine operating nature of such committees. In March of that year, he told the House Government Operations Special Studies Subcommittee that the public interest might best be served by the abolition of such committees (Reinemer, 1970: 39). His Staff Executive Secretary Vic Reinemer, aptly reported that the advisory committee system gives large industries and their trade associations exceptional advantages; that members in these committees have a vantage point deep within an extraordinarily powerful agency (referring to the Bureau of the Budget); that they can anticipate and affect government policy; and that they can better protect their own interests and adversely affect the interests of others (ibid: 36). Illustratively, Roose documents a troubling story by unveiling the minutes of the meetings of the Industry Advisory Council to the Department of Defense (IAC) during its decade-long reign from 1962-1972, and how this 25-strong business-executive group influenced Pentagon contract spending (Roose, 1975: 53-63).

These indicting official criticisms of the system prompted Congress to pass the Federal Advisory Committee Act or FACA (Public Law 92-463, 5 U.S.C., App) of 1972<sup>78</sup> in which one fundamental stipulation, among others, was made. Specifically, FACA mandates that the membership of advisory committees should be “fairly balanced in terms of points of view represented and the functions to be performed.”<sup>79</sup> At its most obvious, this stipulation was intent on reducing business domination of the advisory committee system and, concomitantly, to facilitate participation by representatives of the public interest. According to the Annual Reports of the President on the Federal Advisory Committees, this FACA proviso meant that ‘in attaining balance, agencies are expected to ensure that a cross-section of the individuals directly affected, interested, and qualified, as appropriate to the nature and functions of advisory groups, are considered’.<sup>80</sup> Yet, despite its inauguration after FACA took effect, the trade policy advisory system, which consists of 27 advisory committees and approximately 700 advisors,<sup>81</sup> falls considerably short of the balance requirement, particularly, when one examines the membership make-up of major economic sectors such as intellectual property. A representation of the system is essential.

The trade committees are arranged in three tiers: the President’s Advisory Committee for Trade Policy and Negotiations (ACTPN); four policy advisory committees, namely, Trade and Environment Policy Advisory Committee (TEPAC), Intergovernmental Policy Advisory Committee (IGPAC), Labor Advisory Committee (LAC), and Agricultural Policy Advisory Committee (APAC); and 22 technical and sectoral advisory committees, 16 of which are Industry Trade Advisory Committees (ITAC) (USTR). The ACTPN, which is Tier one, houses

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<sup>78</sup> The passing of this Act is fundamental as it dates two years prior to the adoption of the 1974 Trade Act which established private sector advisory committees as part of the trade decision-making process in the US.

<sup>79</sup> Section 5, FACA Act: <http://www.accessreports.com/statutes/FACA.htm>.

<sup>80</sup> 23<sup>rd</sup> Annual Presidential Report on FACs, 1994: 2-3.

<sup>81</sup> See USTR website: [http://www.ustr.gov/Who\\_We\\_Are/List\\_of\\_USTR\\_Advisory\\_Committees.html](http://www.ustr.gov/Who_We_Are/List_of_USTR_Advisory_Committees.html)

up to 45 Presidential appointees who broadly represent key economic sectors affected by trade and acts as the official channel for businesses to provide private sector consultation directly to the President – the so-called “Fifth Branch of Government”. Although referring to another advisory committee which dissolved before the ACTPN emerged, Roose aptly maintained that “no high-level executive such as these would waste their time on such a committee if it were not to their significant advantage. These are extremely busy men” (Roose, 1975: 2). In addition to the lack of balance, members of the trade advisory committees “pay for their own travel and other related expenses”,<sup>82</sup> a very inexpensive way for the “Executive Branch to benefit from the knowledge and expertise of the nation’s citizens”.<sup>83</sup> Advice is a very valuable resource, and this calibre of corporate advice would not normally be extended, cost-free, if it did not significantly enhance the agendas of those involved.

At a minimum, this data highlights the *potentiality* of capture by private interests of the trade advice structure of American decision-making. More realistically, the data underscores American foreign economic policy as a *function* of its trade advice structure since, “Presidential advisory committees play a vital and important role in the development and implementation of Federal policies and programs”.<sup>84</sup> This tremendous lack of FACA-mandated balance would prove crucial to the efforts of the TDI and other high-technology industries in securing global IP protection under TRIPS.

When the Tokyo Round ended in 1979, Pfizer’s Pratt became one of President Jimmy Carter’s appointees to the ACTPN, and in 1981, he was elected chairman of the advisory group, occupying the apex of America’s trade advice structure, and representing one of the classic

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<sup>82</sup> USTR: [http://www.ustr.gov/Who\\_We\\_Are/Mission\\_of\\_the\\_USTR.html](http://www.ustr.gov/Who_We_Are/Mission_of_the_USTR.html)

<sup>83</sup> 23<sup>rd</sup> Annual Report of the President, 1994: 1-2.

<sup>84</sup> Ibid: 4.

examples of an “interlocking directorship” (Scott, 1991: 181-203), or “duality of leadership” (Lindblom: 1977: 175). He was to preside over the ACTPN’s work programme for the next six years – having also maintained his appointment under President Reagan<sup>85</sup> – establishing an ACTPN Task Force on Intellectual Property Rights charged with making recommendations on how best to design a trade-based IP strategy to protect American sectors, with sizeable intellectual property portfolios, from the problem of international piracy (Drahos with Braithwaite, 2002: 72). With a pharmaceutical chief at the helm of this top-level trade advisory panel, it is not difficult to see why a taskforce on intellectual property rights was deemed fundamental. This taskforce was headed by John Opel of IBM, a co-initiator of the IPC.

Among the taskforce’s contributions was to encourage the US government to utilise multilateral, bilateral and unilateral channels to enforce IP protection abroad (Sell, 1999: 178-183), strategies that were subsequently adopted in American statute and foreign economic policy. For instance, changes were made to Section 301 of the US Trade and Tariff Act of 1984, and were subsequently “substantially modified” in the Omnibus Trade and Competitiveness Act of 1988 (Low, 1993: 60-4). The amended 1984 Act included the failure to adequately protect IP as actionable under Section 301, and IP protection as a new criterion for assessing developing countries’ eligibility for non-reciprocal trade concessions under the GSP programme. Section 301 permits industries, trade associations and individual companies to petition the USTR to investigate actions of foreign governments; and to initiate cases against such governments whose actions were deemed “unjustifiable”, “unreasonable”, and “discriminatory” against US economic interests, terms which had been given explicit statutory definition in the 1984 Act (ibid: 61; Sell, 1999: 180). Pursuant to these amendments, Mexico (1987), Thailand (1989), and India (1992) came under Section 301 surveillance and respectively lost US\$50, US\$165, US\$80, million

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<sup>85</sup> See Pratt’s Pfizer profile: [http://www.pfizer.com/about/history/1951\\_1999.jsp](http://www.pfizer.com/about/history/1951_1999.jsp).

because they failed to meet certain standards of intellectual property (Drahos with Braithwaite, 2002: 88).

More importantly however, as chairman of the IP taskforce as well as of IBM (another case of interlocking directorship), Opel commissioned Jacques Gorlin (an economist who had served as consultant to the ACTPN and subsequently the IPC) to draft a paper for the group outlining a trade-based approach to intellectual property (Sell, 2003: 101). Gorlin's September 1985 paper, "A Trade-Based Approach for the International Copyright Protection for Computer Software", reportedly became the basis of the multilateral corporate IP strategy (ibid). One month later, the ACTPN's IP taskforce presented its report to the ACTPN and its recommendations appeared to be lifted verbatim from Gorlin's document (ibid: 102; Devereaux, 2006: 53). Amongst the strategies Gorlin proposed were: US accession to the Berne Convention;<sup>86</sup> the negotiation of an IP code with like-minded industrialised countries within the OECD or plurilaterally within the GATT; a campaign to educate IP experts on the economic aspects of the issues; consultations with WIPO in order to overcome its resistance to an international IP code; a continuation of complementary bilateral and unilateral efforts to combat piracy and weak enforcement abroad (ibid: 101). He maintained that developing a trade-based code "would help deal with the problems of piracy that are caused by governmental actions such as substandard legal protection and enforcement, by providing a forum with higher visibility, a tradition of finger-pointing, and a willingness to get involved in dispute settlement" (ibid: 102, taken from Gorlin, 1985: 43). There appears to be a striking similarity between the recommendations of the ACTPN's IP taskforce and the final TRIPS Agreement,<sup>87</sup> again accentuating the magnitude of the decision-making capabilities of private sector advisory committees in American politics.

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<sup>86</sup> Recall that the US acceded to the Berne Convention in 1988 Its ratification entered into force in March 1989. See [www.wipo.org](http://www.wipo.org).

<sup>87</sup> The subject of Chapter II.

Pursuant to Section 135 of the Trade Act of 1974 which requires the USTR to consult and seek the advice of trade advisory committees before entering into trade agreements; on the operation of trade agreements once entered into; and on matters arising in connection with the development, implementation, and administration of US trade policy (USTR), – in February and March of 1986, then USTR Clayton Yeutter, sought the advice of Pratt and Opel on how to place intellectual property on the Uruguay Round agenda. Yeutter pointed out that the European, Japanese and Canadian governments were not getting any industry pressure for IP and that without all of the big four onboard, there was no chance of an IP deal in the Uruguay Round. To develop an IP code, Pratt and Opel needed a core of committed and actively engaged companies with international connections, and therefore contacted their peers and convinced their fellow CEOs to form the IPC in March of 1986 (Sell, 2003: 104).

The IPC was therefore the strategic solution of an institutionalised private sector trade advisory structure within the United States. It was a brainchild of the “Fifth Branch of Government” which would then make contact with its peers in European and Japanese industry in order to devise and consolidate a trilateral consensus. In June 1986, the IPC met with the Confederation of British Industry (CBI), the Federation of German Industries (BDI) in Germany, the French Patronat, and through them, the Union of Industrial and Employers’ Confederations of Europe (UNICE) (ibid: 104; Devereaux, 2006: 55). The IPC also sent delegations to meet with the Japan Federation of Economic Organizations (Keidanren) in July of 1986 (Ibid). Despite a few competitor squabbles (Drahos with Braithwaite, 2002: 118-9) however, the IP-dependent cross border industrial network was able to forge the necessary cohesion, rallying around the idea that “the issue of intellectual property was too important to leave to governments” (Sell, 2003: 105).

Similarly, in March 1987, PhRMA's then President, Gerald Mossinghoff, declared that the industry was working with the US Congress to get it to “strengthen the hands of the US Government in urging all our trading partners to respect our rights in inventions and trademarks” (Finger and Nogues, 2002: 335, taken from Mossinghoff, 1987). During their deliberations, the IPC noted the threat posed by WIPO’s identification with the special interests of developing countries, and that since IP was essentially a trade and investment issue, it rightfully belonged in the GATT (Sell, 2003: 105). Other arguments were strengthened at IPC cross-border presentations in which astronomical figures representing lost revenues were accentuated, thereby awakening any initial apathy in industry counterparts in the core jurisdictions.

With this network of corporate power truly intact, the group continued to work closely with the USTR and Congress, while also forging connections with the Patent and Trademark Office (PTO); and Mike Kirk, the chief US negotiator for TRIPS (ibid: 107). More importantly however, in his capacity as chairman of the ACTPN, Pratt served as adviser to the official US delegation at the Uruguay Round of trade negotiations (ibid), thereby cementing industry’s hold on American trade decision-making and ensuring that the products of public international law remain as intimate to industry interests as possible. In June 1988, the trilateral corporate network released its “Basic Framework of GATT Provisions on Intellectual Property: Statement of Views of the European, Japanese and United States Business Communities”<sup>88</sup>, representing, in the words of Pfizer’s Pratt, a ‘multilateral blueprint’ for trade negotiators (Drahos with Braithwaite: 2002: 123), the text of which would be the basis of the TRIPS Agreement.

Another significant FAC in the context of American trade decision-making is the Industry Sector Advisory Committee on Intellectual Property Rights (ITAC 15) which, according to the USTR,

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<sup>88</sup> This document will be compared with the TRIPS Agreement in the next chapter.

provides specific technical advice concerning the effect that trade policy decisions may have on sectors dependent on intellectual property protection and enforcement (USTR). Like the ACTPN, the 15 members of the ITAC 15 in 2007 were all corporate representatives, five of which were pharmaceutical manufacturers, either represented by a senior level executive or a law firm.<sup>89</sup> The high visibility of law firms on advisory panels, as well as elsewhere in the government, is also another powerful recruiting mechanism that industry utilises to enable the most effective articulation and representation of its interests. Also, Jacques Gorlin, who served as consultant for both the ACTPN and IPC and wrote the first major trade-based approach to international copyright protection, is still today serving as vice-chairman of this panel.<sup>90</sup>

The membership of such committees sends a resonating message to observers, that in trade policy-making, primarily the interests of business matter. In a salient TAG neoliberal reckoning, FAC membership reverberates with the sentiment that the interests of business are synonymous with that of society as a whole. The Center for Policy Analysis on Trade and Health (CPATH),<sup>91</sup> for instance, has been voicing concerns over the absence of public health and healthcare representation in international trade advisory committees. In comparative assessment, the decision-making parallels between Roose's IAC (Roose, 1975) and the President's ACTPN are striking. At the heart of trade decision-making in American politics is an advisory network composed entirely of sectional interests, a structure which enables the imprint of such interests on the international trade policy orientations of the most powerful economy. The American trade advice structure therefore highlights an institutionalised mobilisation of bias (Lukes, 1974: 16, taken from Schattschneider 1960: 71), whereby those who benefit occupy privileged decision-making positions to defend and promote their particular interests (ibid: 17).

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<sup>89</sup> USTR, [http://www.ustr.gov/assets/Who\\_We\\_Are/Advisory\\_Committee\\_Lists/asset\\_upload\\_file786\\_5754.pdf](http://www.ustr.gov/assets/Who_We_Are/Advisory_Committee_Lists/asset_upload_file786_5754.pdf).

<sup>90</sup> See USTR website at:

[http://www.ustr.gov/assets/Who\\_We\\_Are/Advisory\\_Committee\\_Lists/asset\\_upload\\_file786\\_5754.pdf](http://www.ustr.gov/assets/Who_We_Are/Advisory_Committee_Lists/asset_upload_file786_5754.pdf)

<sup>91</sup> San Francisco based nonprofit focusing on the impact of trade on health. See: [www.cpath.org](http://www.cpath.org)

On trade-related IP advice in particular, and trade advice to the President generally, the American decision-making advice structure represents a classic case of “non-decision-making” (Bachrach and Baratz, 1962: 947-52; 1963: 632-42; 1970), that is, “a means by which demands for change in the existing allocation of benefits and privileges can be suffocated before they are even voiced; or kept covert; or killed before they gain access to the relevant decision-making arena” (Bachrach and Baratz, 1970: 44). This trade advice structure symbolises the extent of institutional capture by the TDI, not least because during the UR, a pharmaceutical CEO occupied the helm of the trade advice structure, giving actionable advice to the President as well as the USTR, and also participating in the actual trade negotiations.<sup>92</sup> To this end, the trade decision-making authority of the transnational private sector in general, and powerful elements from the TDI in particular, was instrumental in the making of patent policy in TRIPS. It therefore forms part of the explanatory basis of the structure of existing power relations. Arguably, without this trade decision-making authority, the outcome of TRIPS, if it was included in the final package, might have been very different.

### **1.6 Conclusion: An Additional Dimension to Cox’s 3-Pronged Historical Structures Approach**

The chapter has applied the first part of Cox’s Braudelian method of historical structures which explains the synchronic study of existing power relations in a given historically located limited totality (Cox, 1981: 137). Accordingly, it presented a particular configuration of forces (material capabilities, ideas, institutions, and decision-making authority) – an historical structure – to explain how and why the transnational drug industry (a social force engendered by the production process) was able to capture the TRIPS process. The chapter engaged with the material capabilities of the TDI, a component which enables wealth creation and accumulation,

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<sup>92</sup> See for instance Farnsworth (1988) of NYT on the delegation accompanying then USTR Clayton Yeutter to the Montreal Ministerial in December 1988., which includes Pfizer’s Pratt.

and thus, the projection of power. In showing the resources at its disposal, the TDI's revenues were also contrasted with SSA's GDP to demonstrate the gulf between a single industry and an entire continent, in order to set the scene for the disparity between the two actors prioritized in this research. The gaps were immediately apparent especially when the global annual sales of individual blockbuster drugs far exceeded the combined GDP of many countries on the sub-continent, many of which are awash with natural resources.

The chapter then went on to debate the centrality of ideas, not simply as a mechanism which facilitates or delimits action, but importantly, one which corporate actors consciously utilise to inform business techniques in order to enable the passage of policy. It therefore saw the compatibility between ideas as constitutive, and ideas as causal. Importantly, it was argued, because actors are aware that structures impact significantly on outcome, they strategically exploit the dominant structure of meaning in a way that appeals, convinces, and legitimises their interests. In this instance, the inter-subjective meanings (the web of language, symbols, beliefs, and institutions that constitute signification) which constitute the dominant TAG rational model were used by corporate actors as a transnational corporate strategy intended to equate the demands of business with the interests of the wider society. Therefore, so long as business proposals spoke the dominant language of meaning, it became relatively easy for the TDI and other high-technology industries to prevail in global economic policy-making since proposals were seen to equal social and political order definable by the dominant framework. Structures therefore, are not the 'immutable', *a priori* instruments that realist theorists (Waltz, 1996) make them out to be. Instead, their meanings are malleable to the business design techniques of major corporations.

The chapter also stressed the significance of institutions (a particular amalgam of ideas and material power which take on organisational settings as well as inter-subjective meanings), as fundamental in the constitution and reconstitution of the prevailing order. In particular, it engaged Cox's take on international organisations such as the WTO as mechanisms of hegemony. However, because of the difficulties in creating binaries between ideas and institutions and remaining cognizant that ideas also encompass institutions, this section of the chapter also looked at the insights of ideational institutionalism as a framework which complements Cox's analysis of international organisations. Of additional relevance is the work of organic intellectuals, or the thinking, organising and legitimating elements of a particular fundamental social class.

In delineating the configuration of forces in Cox's historical structures framework, the last section sought to engage in the process of trade decision-making in American politics, since such decision-making has practical implications for the entire global trading system. Of crucial significance is the private sector trade advisory committee system established under the United States Trade Act of 1974, and strengthened and enhanced in subsequent trade legislations, including the Trade Act of 2002.<sup>93</sup> Its purpose is to enable corporate stakeholders to have a say in regional and multilateral trade policy-making. When researchers speak with trade personnel representing developing countries, or NGO trade consultants, one of the most rehearsed commentaries is "under pressure from domestic constituents" or "under pressure from American pharmaceutical corporations".<sup>94</sup> What is not immediately apparent from such claims is the formalised nature of the access channels that major corporate actors have in Washington.

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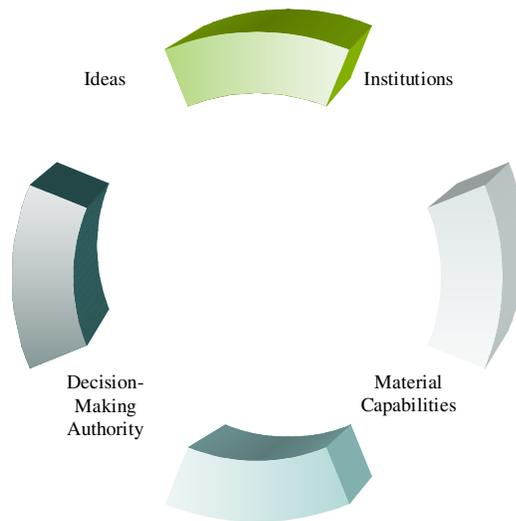
<sup>93</sup> See USTR website at: [www.ustr.gov](http://www.ustr.gov).

<sup>94</sup> All African Group personnel interviewed made such comments. See list of interviewees.

The make-up of such committees – particularly the President’s Advisory Committee on Trade Policy and Negotiations (ACTPN), and the Industry Sector Advisory Committee on Intellectual Property Rights (ITAC 15) – is categorically representative of sectional economic interests, despite the otherwise constitutional Federal Advisory Committee Act which legislated that such committees should be fairly balanced in terms of points of view represented and functions performed. This phenomenon speaks resonantly to the institutional capture of trade policy-making by sectional interests because of its categorically undiversified membership. As a result of the instrumental role played by key figures such as Pfizer's Pratt in the “The Fifth Branch of Government” in the making of IP policy in general, and patent policy under TRIPS in particular, the thesis treats the decision-making authority of the trade advisory committees as a complementary companion component of the prevailing historical structure which enabled the TDI to capture the TRIPS process.

The FAC system therefore adds a fascinating dimension to Cox’s work by incorporating a four-pronged, continuous cycle as opposed to his three-dimensional (Cox, 1981: 136) illustration of the prevailing historical structure. The use of the continuous cycle below is intended to portray the dimensions as complementary, although some may take precedence over others in policy-making at the international level. In the case of TRIPS in general and its patent provisions in particular, while all dimensions played a pivotal role, it was the institutionalised, private-sector decision-making attribute (with pharmaceutical manufacturers at the helm) which proved definitive, thereby also attesting to one component in Hypothesis I, that the TDI was a key player in the making of TRIPS. Cox's Braudelian historical structures also substantiated the first part of Hypothesis V, that his approach to continuity provides the best analytical means of making sense of the making of patent provisions under TRIPS. The following diagram illustrates this historical structure which maintained the stability of existing power relations in the GPE.

**Figure 1.3: Prevailing Historical Structure**



The next chapter goes on to address another component of the first empirical hypothesis, that is, the extent to which the TDI's interests were fully reflected in the original TRIPS Agreement, pursuant to its role in its making.

## Chapter II

### Measuring Industry's Gains from TRIPS

#### 2.1 Introduction

While decisions do not reveal power directly, they may show influence and the way in which power is translated into action (Cox with Jacobson, 1996: 349)

To support the argument that the making of the patent provisions in TRIPS represents a case in institutional capture by the TDI, the last chapter developed a theoretical framework to explain outcome in international trade decision-making as a function of the dominant politico-economic framework, or structure of existing power relations. To examine this prevailing structure the chapter employed Cox's three-dimensional historical structures approach (material capabilities, ideas and institutions), and consequently complemented this framework with a fourth dimension specific to the private sector decision-making component characteristic of American politics. The chapter concluded that in the case of TRIPS in general and its patent provisions in particular, while all dimensions played a pivotal role, it was the institutionalised, private-sector decision-making attribute which proved definitive. It was by examining this fourth dimension, specifically in the form of the President's Advisory Committee for Trade Policy and Negotiations or ACTPN (with pharmaceutical representation at the helm) that the chapter was able to provide a better insight that located key industry figures undertaking crucial trade decision-making portfolios within the American political system, thereby providing a crucial empirical link between the American state and policy outcomes at the international level. The centrality of this component in the making of patent policy in the Uruguay Round meant that it was treated as an additional dimension that gave explanatory weight to Cox's Braudelian prevailing historical structures.

Having developed this theoretical framework, the present chapter compares the actual demands from pharmaceutical actors existing within this structure, with the supply of decisions represented in the patent provisions of the TRIPS Agreement. In order to further develop the thread of the last chapter therefore, this chapter establishes a correlation between the enabling structure presented and decision-making outcomes. If the 'enabling structure' presented in the last chapter *enables* dominant actors to secure demands made within that structure, then the outcomes proffered should at least satisfy those demands. The chapter therefore engages the contents of the Intellectual Property Committee's June 1988 "Basic Framework of GATT Provisions on Intellectual Property: Statement of Views of the European, Japanese and United States Business Communities"<sup>1</sup> proposal for a GATT IP code, which became, in the words of Pfizer's Pratt, the "multilateral blueprint" for the IP negotiations.<sup>2</sup> It compares the patent-related demands and justifications contained in this proposal with the supply of actual patent provisions in the TRIPS Agreement. The aim is to address another component of the first empirical hypothesis, that is, that industry's interests were fully reflected in the original TRIPS Agreement. Since the first chapter also addressed the question that the pharmaceutical industry was a key player in the making of the international patent code inscribed in the original TRIPS Agreement, the current chapter moves a step further to determine the extent to which industry's interests were reflected in the TRIPS outcome as a result of its role.

## **2.2 Comparing Industry's "Basic Framework" with the 1995 TRIPS Accord**

More than five years before the TRIPS Agreement was concluded as part of the "Final Act Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations", the "Basic

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<sup>1</sup> Hereinafter 'Basic Framework', this is the June 1988 document proposing a trade-based approach to intellectual property produced by the Intellectual Property Committee (IPC) of the US; the Japan Federation of Economic Organisations (Keidanren); and the Union of Industrial and Employers' Confederations of Europe (UNICE). Reprinted in Friedrich-Karl Beier and Gerhard Schrickler, eds., *GATT or WIPO? New Ways in the International Protection of Intellectual Property* (Munich: Max Planck Institute for Foreign and International Patent, Copyright, and Competition Law, 1988).

<sup>2</sup> Provided as interview data (conducted with Pfizer's Pratt) in Drahos with Braithwaite, 2002: 123.

Framework” set forth in detail the kind of arrangement on intellectual property protection and enforcement that the three private sectors sought from the GATT multilateral negotiations. The anticipated deal was presented to the Japanese, European and American governments and represents the culmination of approximately two years of cooperation among the three groups to develop an international private sector consensus on GATT Provisions on Intellectual Property (GATT IPP) – (Basic Framework: 359). In an interview with Susan Sell, Jacques Gorlin (the consultant economist to the ACTPN and then the IPC, who John Opel from IBM contacted to draft the precursor to the Basic Framework)<sup>3</sup> asserted that except for the lengthy transition periods for developing countries, the Intellectual Property Committee got 95 percent of what it wanted (Sell, 2003: 115). A presentation of the basis of the IPC's proposal is therefore pertinent, bearing in mind that some of the arguments contained therein are similar to the pro-patent mindsets encountered in 'The Research Problem'.

The 50-page document provides a telling account of the industries' assessment of the magnitude of the problem of IP theft and cites inadequate and ineffective protection of intellectual property as a major cause of trade distortions (Basic Framework: 362). The legitimacy of this claim found expression in the purported results of a US ITC (International Trade Commission) questionnaire<sup>4</sup> in which 193 US firms estimated their aggregate world-wide losses due to inadequate intellectual property protection in 1986 at USD23.8 billion or 2.7 percent of sales affected by intellectual property. The ITC further estimated that world-wide losses in 1986 to all of US industry from inadequate foreign protection of intellectual property ranged from USD43 billion to USD61 billion (ibid). The IPC document went further to list the nature of lost sales, and the phenomenon of job loss as major functions of the sale in counterfeits, estimating for instance, that the United States had lost approximately 100,000 jobs due to copyright and patent

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<sup>3</sup> He is still today Vice-Chairman of the Industry Trade Advisory Committee on Intellectual Property Rights. See the current list on the USTR's website at: [http://www.ustr.gov/assets/Who\\_We\\_Are/Advisory\\_Committee\\_Lists/asset\\_upload\\_file158\\_5754.pdf](http://www.ustr.gov/assets/Who_We_Are/Advisory_Committee_Lists/asset_upload_file158_5754.pdf)

<sup>4</sup> Reference to this ITC questionnaire will resurface in the actual negotiations by US negotiators in the next chapter.

infringements (ibid). Recalling the discussion under the 'material capabilities' of the pharmaceutical industry in the last chapter, these are not insignificant figures, notwithstanding their source from precisely those industries with a vested interest in bringing IP under multilateral discipline.

The document continues that while it takes an average of ten years and USD125-160 million<sup>5</sup> to bring a pharmaceutical product based on a new chemical entity to market, a chemist could easily duplicate the product, and if not legally constrained, could produce the drug in sufficient quantities to effectively make it unprofitable for legitimate producers (ibid). Using very effective language that speaks to the heart of the dominant trade-as-growth (TAG) discourse, the industry coalition made a pressing conclusion, that the huge disparity between the inventor's costs and those of the imitator is a much more effective barrier to trade than any tariff (ibid: 372). Consequently, the loss of export and domestic markets by intellectual property-based industries makes the international protection of IP both a trade issue as well as an intellectual property issue (ibid: 362), hence the trade *relatedness* of IP.

The accuracy of the estimates and the scientific basis of the ITC's results notwithstanding, their assertion follows a clear logic and recommendation that appear to have been seconded by the GATT negotiating group at the time of the Uruguay Round of trade negotiations. In fact, the TRIPS Agreement begins with an undertaking to reduce distortions and impediments to international trade, taking into account the need to promote effective and adequate protection of intellectual property rights (WTO, 1999: 321), thereby lending legal legitimacy to the transnational private sector view of the causal relationship between ineffective IP protection and trade distortions. Whether this causal relationship is scientifically sound is not the purpose of this exercise, it is merely to ascertain the parallels between the two documents in order to

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<sup>5</sup> This figure has been variously represented. See 'The Research Problem', 6n.

establish a correlation between the structure of existing power relations drawn-up in the last chapter, and the outcome of international trade decision-making. By so doing, the chapter also presents a plausible case in which power is translated into action.

The “Basic Framework” also details the extent to which pre-existing international intellectual property regimes were never intended to address trade-related distortions since they (Berne and Paris Conventions) ostensibly required governments to implement their provision without the necessary bilateral or multilateral dispute settlement provisions that ensure compliance (Basic Framework: 363-4). Also, signatories to these conventions were merely bound to provide national treatment (NT), and in many countries, this extended to foreign right holders the inadequate protection that domestic law provided to domestic right holders (ibid: 363). The other assumption here is that NT would be meaningless in countries whose nationals did not own any of the total world stock of patents, since such countries had no reason to protect rights that their nationals did not yet have. Such shortcomings in international IP conventions sanctioned, not only the unilateral actions and bilateral negotiations aimed at obliging transborder respect for intellectual property (ibid: 364), but also legitimised the forum-shifting initiatives of industry leaders and their state counterparts, to bring IP discipline under the remit of the GATT (thereby institutionalising its trade-relatedness), and effectively circumventing the authority of WIPO.

Industry justified in its “Basic Framework”, that existing international trade rules developed under the GATT are based on a framework which includes not only standards of behaviour, but also mandatory consultation, dispute resolution and enforcement mechanisms (ibid: 365). Therefore, previous international instruments were simply well-meaning constructs without the necessary punitive capabilities required by IP-dependent industries. The document further asserts that the integration of international intellectual property into the GATT framework will supplement existing international IP provisions and conventions by facilitating the adoption of

increased protection for intellectual property and thereby substantially reducing trade distortions (ibid). Correspondingly, while Article II of the TRIPS Agreement alludes to Members' duty to comply with Articles 1 through 12, and 19 of the 1967 Paris Convention, its language, obligations, dispute settlement mechanism, as well as criminal and enforcement measures, all appear to significantly supplant the pre-existing conventions, as opposed to its designation as merely supplementary by industry. The transnational private sector coalition therefore got more than it actually anticipated from TRIPS.

One of the most fundamental aspects of the TRIPS Agreement is its enforcement framework and the specificity of substantive law which defines it. It also represents the critical distinguishing feature from the pre-existing legal framework, since it is arguably that which impinges most on a country's sovereignty. According to the "Basic Framework" 'patent protection, no matter how valuable in theory, is worthless unless reasonable standards of enforcement are provided' (ibid: 375). Consequently, the proposal for a multilateral response delineated the precise conditions which would, in industry's view, constitute the right mix of enforcement mechanisms necessary for effective international compliance. Table 2.1 aims to establish the congruities between industry's private output and the TRIPS public output concerning enforcement.

**Table 2.1: Two Patent Enforcement Frameworks: Main Elements Juxtaposed**

Industry's "Basic Framework"	The WTO's TRIPS Agreement
Since most legal systems are not identical, each country would be free to determine how best to comply with its obligations under the GATT IPP <sup>6</sup> and to implement its intellectual property laws to ensure effective and expeditious enforcement procedures. In establishing these enforcement procedures, the signatories would however be required to observe certain general and special rules on enforcement of intellectual property rights that would be set forth in the GATT IPP. <sup>7</sup>	Members shall ensure that enforcement procedures as specified in this Part <sup>8</sup> are available under their law so as to permit effective action against any act of infringement of intellectual property covered by this Agreement, including expeditious remedies to prevent infringements and remedies which constitute a deterrent to further infringements.

<sup>6</sup> The industry coalition refers to its proposal as the GATT IPP.

<sup>7</sup> "Basic Framework" op. cit., p. 366.

<sup>8</sup> Part III of the TRIPS Agreement on "Enforcement of Intellectual Property Rights".

<p>The availability of preliminary and final injunctive relief as well as damage awards adequate to compensate patentees fully and to serve as an effective infringement deterrent. Preliminary or interlocutory injunctions should be made available to prevent irreparable harm to the patentee, where an immediate need for such is justified and undue harm to the defendant avoided.<sup>9</sup></p>	<p>The judicial authorities shall have the authority to order the infringer to pay the right holder damages adequate to compensate for the injury the right holder has suffered because of an infringement of that person's intellectual property right by an infringer who knowingly, or with reasonable grounds to know, engaged in infringing activity; to order the infringer to pay the right holder expenses, which may include appropriate attorney's fees. In appropriate cases, Members may authorise the judicial authorities to order recovery of profits and/or payment of pre-established damages even where the infringer did not knowingly, or with reasonable grounds to know, engage in infringing activity.<sup>10</sup></p>
<p>Due process shall include the right of all parties to be heard in all proceedings, both preliminary and final, and to make a defence.<sup>11</sup></p>	<p>Decisions on the merit of a case shall preferably be in writing and reasoned. They shall be made available at least to the parties to the proceedings without undue delay. Decisions on the merits of a case shall be based only on evidence in respect of which parties were offered the opportunity to be heard.<sup>12</sup></p>
<p>Judicial procedures for litigating patents are preferable to administrative procedures. If administrative procedures are used, care is necessary to avoid discriminatory protectionism against imports and foreign defendants.<sup>13</sup></p>	<p>Members shall make available to right holders civil judicial procedures concerning the enforcement of any intellectual property right covered by this agreement.<sup>14</sup></p>
<p>If the court orders access to any information from the defendant, this must be on the basis of confidentiality so as to preserve his trade secrets and in particular, in considering reversal of the burden of proof, the court should not require the disclosure of any manufacturing or commercial secrets where this would be unreasonable.<sup>15</sup></p>	<p>The judicial authorities shall have the authority, where a party has presented reasonably available evidence sufficient to support its claim and has specified evidence relevant to substantiation of its claims which lies in the control of the opposing party, to order that this evidence be produced by the opposing party, subject in appropriate cases to conditions which ensure the protection of confidential information.<sup>16</sup></p>
<p>Wilful infringement calculated to deceive the consuming public into believing that the goods in question are genuine often invoke substandard goods, and may pose serious safety and health problems. These are wilful, fraudulent activities and therefore, criminal sanctions are necessary and appropriate, and special measures are needed at the border.<sup>17</sup></p>	<p>Members shall provide for criminal procedures and penalties to be applied. Remedies available shall include imprisonment and/or monetary fines sufficient to provide a deterrent, consistently with the level of penalties applied for crimes of a corresponding level of gravity. In appropriate cases, remedies available shall also include the seizure, forfeiture and destruction of the infringing good and of any materials and implements the predominant</p>

<sup>9</sup> "Basic Framework" op. cit., p. 375.

<sup>10</sup> Article 45 "Damages", paragraphs 1&2 of the Agreement on Trade-Related Aspects of Intellectual Property Rights, in World Trade Organisation, *The Legal Texts*, op. cit., p.341.

<sup>11</sup> "Basic Framework", op. cit., p. 375.

<sup>12</sup> Article 41 "Section 1: General Obligations" TRIPS Agreement in, World Trade Organization, op. cit., p. 339.

<sup>13</sup> "Basic Framework", op. cit., p. 375.

<sup>14</sup> Article 42 "Fair and Equitable Procedures" of the TRIPS Agreement, in World Trade Organization, op. cit., p. 340.

<sup>15</sup> "Basic Framework", op. cit., p. 376.

<sup>16</sup> Article 43 of TRIPS, "Evidence".

<sup>17</sup> "Basic Framework", op. cit., p. 363.

	use of which has been in the commission of the offence. <sup>18</sup>
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The above table represents a fairly comprehensive presentation of the enforcement framework proposed by the transnational private sector coalition compared with that of the actual TRIPS Accord of the WTO. In all six subsections juxtaposed, there were no inconsistencies that disfavoured the 1988 industry proposal for a GATT IPP. In fact, in most instances, the TRIPS Agreement went further than the anticipated patent enforcement provisions that industry had articulated. For instance, in the first comparison, industry recognised the heterogeneity of countries' legal systems and as such, appeared to allow for some level of policy space on how best to comply with obligations, given differentiated legal systems. In fact, while the IPC's proposal recognized the importance of adequate national laws (Basic Framework: 368) for the success of the GATT IPP, it nonetheless saw harmonisation of national intellectual property systems as unnecessary, citing that countries whose national systems already satisfy the fundamental principles would not have to significantly adjust their IP laws (ibid). One could argue that industry was well aware of the political backlash of an agenda based on harmonisation, and the transitional implications for resource-poor countries. In the TRIPS Agreement however, there is an expressed harmonisation intent in Article 41, since enforcement procedures *as specified* should be available under Member's law (emphasis added). While Article 1(1) does state that members shall be free to determine the appropriate method of implementing the provisions of the TRIPS Agreement, the "as specified" emphasis in Article 41 does appear to be contradictory, also remaining cognizant that a law enforcement framework is the precise mechanism which validates and gives weight to the substantive components of any legal system.

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<sup>18</sup> Article 61 "Criminal Procedures" of the TRIPS Agreement, in World Trade Organization, op. cit., p. 347.

The remaining five enforcement items contrasted were almost verbatim, suggesting a strong correlation between industry's demands and the TRIPS outcome. As such, on the basis of the six enforcement items examined above, it would not be unreasonable to conclude that industry secured everything it wanted out of the crucial territory of the administration of justice in national legal systems.

Another crucial area concerns the specificities of the burden of proof, an area which industry thought should be part of an overall enforcement framework. According to its proposal, where the burden of proof of infringement falls on the patentee 'as it usually does', it is imperative that fair, reasonable and effective procedures be provided to obtain evidence of infringing activities (ibid: 375). Procedures could include powers of the court to order access to documents, on-site inspection, seizure of samples and evidence, and to make available suitable measures for the preservation of evidence (ibid). The procedural components of Article 57 of TRIPS, "Right of Inspection and Information" have a striking correspondence to industry's demands in cases where the burden of proof falls on the patentee, that is, cases involving goods detained by customs authorities. It mandates that without prejudice to the protection of confidential information, Members shall provide the competent authorities the authority to give the right holder sufficient opportunity to have any goods detained by the customs authorities inspected *in order to substantiate the right holder's claim* (emphasis added). It also mandates that Members may provide the competent authorities the authority to inform the right holder of the names and addresses of the consignor, the importer, and the consignee; and of the quantity of goods in question, all of which facilitate the right holder's efforts to prove an infringement.

Moreover, industry demanded a reversal of the burden of proof in cases involving a new patented process for obtaining a new product. Correspondingly, Article 34 on "Process Patents: Burden of Proof" of the TRIPS Agreement mandates that the burden of proof for process patents

should fall squarely on the defendant or alleged infringer, and not on the patentee as would have ordinarily been the case under customary international law. It legislates that for the purpose of civil proceedings in respect of the infringement of the rights of the owner, if the subject matter of a patent is a process for obtaining a product, the judicial authorities shall have the authority to order the defendant to prove that the process to obtain an identical product is different from the patented process. Ruling enormously in favour of the TDI, this provision essentially reverses the procedural principle under which the person asserting a fact must prove it (UNCTAD-ICTSD, 2005: 496). While the provision was included in the patent laws of Germany, Italy, Belgium and Spain, it had no counterpart in the Paris Convention (ibid: 497), although it was an agenda item under the proposed WIPO treaty for the harmonisation of patent law. Because of difficulties involved in proving infringement, process patents are considered a weak form of protection (ibid: 503), a possible motivation by many countries to bar pharmaceutical products from patent protection. Article 34 is therefore a sizeable victory for the pharmaceutical industry as alleged infringers are now obliged to prove their innocence in process infringement litigations.

Another crucial position of the 1988 proposal was an emphasis on the incorporation of a dispute settlement mechanism aimed at ensuring compliance with a multilateral IP code. According to the proposal, where intellectual property owners are unable to obtain redress because of failure of signatory countries to carry out their obligations under the GATT IPP, the government of the IP owners will be able to invoke the dispute resolution mechanism of the GATT IPP (Basic Framework: 366). In fact, the alleged absence of a dispute settlement body was seen as a crucial determinant in undermining the functionality of earlier IP conventions. While industry leaders cannot be credited with bringing the concept of dispute settlement to the GATT, one of the greatest milestones of the current multilateral trading framework is the Dispute Settlement Body (DSB) which ensures that after exhausting other possibilities, countries of origin can bring cases against signatory countries deemed by industry to gravely prejudice the rights of intellectual

property owners within their borders (see Picciotto, 2003, 2005), a welcome victory for business in general, and the TDI in particular.

Also significant in an appraisal on how much industry gained from the TRIPS Agreement is an assessment of the mandatory legal enlargement of the concept of patentable subject matter. According to the “Basic Framework”, inventions which meet the triple criteria of novelty, non-obviousness, and industrial applicability, “should be entitled to patent protection without discrimination as to subject matter” (“Basic Framework: 373). Similarly, the TRIPS Agreement provides that patents shall be made available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.<sup>19</sup> This is important, not only because it subjects patent grants to non-discrimination and multilateral discipline (which is good for business), but also insofar as it removes the flexibility of policy space in many developing countries that prevailed prior to TRIPS. Patent protection for products as well as processes has become binding whereas, under the pre-existing law, the exact scope of protection was widely discretionary, depending on the development and technological needs of member countries, especially that of LDCs.

For instance, many countries denied patent protection for pharmaceutical products in order to contain the cost of necessary medicines, a practice which appeared to be acceptable under the terms of the Paris Convention (Sell, 2003: 12). The GATT industry proposal itself acknowledges that in the case of pharmaceuticals, some countries permit only a patent for a specific process which is used to make a product, while others provide protection for the product only when made by that process (product-by-process protection) (Basic Framework: 373). Industry explains however, that chemical substances can almost always be made in a variety of ways, and when the invention resides in a new valuable chemical substance (product), a process patent is simply

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<sup>19</sup> See Article 27 of the TRIPS Agreement on “Patentable Subject Matter”.

an invitation to imitators to manufacture the substance via another route, “usually a straightforward exercise for a competent chemist” (ibid). Therefore, the requirement that product and process patents shall be made available for any invention without discrimination<sup>20</sup> represents a seminal victory for industry participants in overcoming one of the greatest statutory hurdles to full enclosure of their intellectual property.

Yet another fundamental area, and which has sparked most of the recent controversy, is that of compulsory licensing. To this end, the industry proposal reiterated that grant of an exclusive right is an essential element of an effective patent system, noting therefore that if for valid reasons (for instance abuse by the patentee’s exercise of exclusive rights), a compulsory licence is granted, the patentee shall be fully compensated; the compulsory licence should be limited to a bare non-exclusive licence under the patent in question, that is, freedom from suit; that working requirements should reflect commercial reality, and compulsory licences issued as a result of non-working should be granted only to permit local manufacture (ibid: 374). Similarly, Article 31 of the TRIPS Agreement maintains that where the law of a Member allows for other use without the authorisation of the right holder (the compulsory licensing provision), 12 provisions shall be respected, including that such use shall be permitted only if, prior to such use, the proposed user has made efforts to obtain authorization from the right holder on reasonable commercial terms and conditions and that such efforts have not been successful within a reasonable period of time;<sup>21</sup> the scope and duration of such use shall be limited to the purpose for which it was authorised; that such use shall be non-exclusive; that such use shall be authorised predominantly for the use of the domestic market; that the right holder shall be paid adequate remuneration in the circumstances of each case, taking into account the economic value

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<sup>20</sup> This requirement is not absolute as Article 27 also speaks of exclusions from patentability such as measures to protect *ordre public*; (a) diagnostic, therapeutic and surgical methods for the treatment of humans and animals; (b) plants and animals other than micro-organisms, biological processes for the production of plants and animals other than non-biological and microbiological processes.

<sup>21</sup> According to Art. 31 (b), this requirement may be waived in cases of emergency, circumstances of extreme urgency, or cases of public non-commercial use.

of the authorisation. The similarities between the compulsory licensing provisions of these two texts is particularly striking, notwithstanding the impartial exterior and superior language of the TRIPS accord. The terms of this article are also fundamental in this context especially since pharmaceuticals have arguably been far more subject to compulsory licences than other fields of technology primarily because of the sheer significance of the health sector to disease-burdened developing countries.

A crucial counterpart of compulsory licensing is the local-working requirement stipulated in the Paris Convention. This saw local exploitation of a patent as a fundamental obligation on patent holders, a requirement which was seen as specific to the prospects of technology transfer for technologically deficient countries, essentially addressing the technology gap that Stiglitz identified in the previous chapter. Industry reasoned in its proposal that many countries subject patents to compulsory licensing, or even revocation for failure to put the invention into commercial use within as little as one to three years from grant; and that importation of a product authorised by the patentee to meet local market needs does not satisfy such countries' 'working requirements' despite the obvious fact that local manufacture in all markets can be hopelessly uneconomic and impractical, particularly in countries with small market size and those which lack an industrial infrastructure (ibid: 374). Moreover, "where commercial development or regulatory review consume 10 years or more, such working deadlines are literally impossible to meet", making it incomprehensible to see why "the Paris Convention allows non-exclusive compulsory licensing in member countries for failure to work locally within three years of patent grant or four years from filing an application" (ibid).

Industry consequently made it clear in its proposal that patents should not be revoked on the basis of non-working; that non-working requirements should reflect commercial reality; and that justified reasons for non-working should include instances where commercialisation is delayed

by circumstances beyond the patentee's control, such as regulatory review, unfavourable economies of scale, and lack of necessary personnel (ibid). The TRIPS Agreement subsequently accorded in Article 32 that an opportunity for judicial review of any decision to revoke or forfeit a patent shall be available. While this provision does not appear to be biased, and does not speak specifically to working requirements, it alludes to another juncture at which industry anticipated a microscopic ruling out of a possibility of many. The IPC saw revocation/forfeiture in the context of non-working of a patent, however, the TRIPS Agreement avails the opportunity of judicial review for *any* such decision, thereby ruling enormously in industry's favour. An unequivocal pro-industry ruling, the decision also effectively removes any notion of a mandatory local-working requirement in international patent law, thereby purging the system of the belief that associated local working with technology transfer.

Yet, probably the most recognisable parallel between the 1988 GATT Industry proposal and the 1994 TRIPS Agreement is the 20 year exclusivity period awarded to patent holders. According to the "Basic Framework", since there is a strong incentive to file the patent application at the earliest possible date in order to ensure that the patent is not awarded to an earlier, rival applicant, the early portion of the patent term is consumed before the patent reaches commercial use (ibid: 373). Consequently, a short term can be seen as an effective barrier to trade for sectors which have to undergo extensive development phases and regulatory reviews before commercialisation. In light of this, the proposal noted the desirability of the framework provided under the European Patent Convention for a 20-year period from the filing date; that of the United States which provided 17 years from the grant of a patent; and the Japanese system which provided 15 years from publication or 20 years from filing, whichever is shorter (ibid: 374). Industry's preference for these specific patent systems should not go unnoticed since these were the precise home jurisdictions of the IPC, and precisely the jurisdictions which mounted the case for a trade-based approach to the multilateral protection and enforcement of intellectual

property under the GATT. To discredit these existing statutes might have been a political miscalculation on the part of industry; and especially recognising that the anticipated laws would mean very little infrastructural cost adjustments for the major capitalist countries. This can be seen as yet another victory for industry since Article 33 of the TRIPS Agreement accords that “the term of the protection available shall not end before the expiration of a period of twenty years counted from the filing date”, a stipulation which implicitly avails the possibility of extensions to right holders, such as that accorded under the US Patent Term Restoration Act (Hatch-Waxman Act) encountered in the 'Material Capabilities' section of Chapter I.

The gains thus far appear to be entirely in favour of industry, however, if we recall Susan Sell's interview with IPC consultant Jacques Gorlin,<sup>22</sup> the misfortune came in the lengthy transition periods for developing countries. According to the “Basic Framework”, developing country Parties should be permitted to delay implementation of the Fundamental Principles of Intellectual Property Protection for a reasonable but limited period of time. This period would permit them to (a) bring their national laws into conformity with the GATT IPP and (b) to deal with any dislocation directly due to adherence (ibid: 370). In an attempt to ‘help’ developing countries through transition, the trilateral coalition proposed that the GATT IPP could include pledges by the developed country Parties to increase their funding for technical assistance to developing country Parties for the development and implementation of the Fundamental Principles (ibid). Industry also proposed that developed Parties could also increase their allocation under bilateral assistance programmes to help developing Parties to increase their protection (ibid: 371).

The TRIPS Agreement consequently allowed in Article 65 that developing countries not be obliged to apply its provisions before a period of five years from the entry into force of the

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<sup>22</sup> See introductory paragraph to this section.

Agreement; and that developing country members which did not extend product patent protection to areas of technology not so protectable in their territory on the general date of application of the agreement, may delay the provision of product patents to such areas of technology for an additional period of five years. In the case of least developed Members (Article 66), and taking into account their economic, financial and administrative constraints, the 1995 Agreement allowed a ten year delay from the application date of the agreement, with possibilities of extensions.

It remains unclear what industry meant by a “reasonable but limited period” of transition to enable countries to get their IP systems in harmony with the multilateral framework, especially considering the fact that it was forthcoming in articulating the exact patent terms it thought reasonable. Therefore, it can be argued that the transitional terms awarded were indeed reasonable, particularly as they related to least developed countries and the justifications provided for lengthier adjustment periods. As such, whereas Jacques Gorlin estimated that industry gained 95% of what it wanted as a result of the lengthy transition periods awarded to developing countries, the transitional time frame provided by the TRIPS Agreement does appear to conform to industry’s proposal of a “reasonable but limited period”, and especially so considering that industry gained in other areas, more than it had anticipated. Accordingly, on the basis of the 1995 agreement, it appears justifiable to suggest that industry did also triumph in this category.

Also consistent with industry's proposal, Article 67 of the TRIPS Agreement provides that in order to facilitate the implementation of the Agreement, developed country Members shall provide, technical and financial cooperation in favour of developing and least developed country Members. This provision also affirms the view (tacitly held by industry by virtue of the inclusion of technical cooperation in the 1988 proposal) that as a result of their economic and

social circumstances, developing and least developed countries should at least be allowed a period of adjustment in the process of domestic institutional reform; again confirming that the transitional periods contained in the agreement were not impracticable, and that industry did appear to get what it thought 'reasonable' out of Articles 65 and 66 of TRIPS.

### **2.3 Conclusion: Industry's Overwhelming Gains from TRIPS**

The narrative consists of a fairly comprehensive account of the proposal put forward by industry in its 1988 "Basic Framework" offer for a GATT IPP, representing the views of the transnational private sector coalition of IP-dependent industries. The fundamentals on patents and enforcement in industry's proposal were compared with that contained in the Agreement on Trade-Related Aspects of Intellectual Property Rights. The comparison demonstrates that industry's interests were indeed fully inscribed in the original TRIPS Agreement, and that in many instances, "the industries concerned received more protection than anyone had believed possible at the outset of the talks" (Devereaux, et al, 2006: 42).

Therefore, in addition to the four-dimensional enabling structure within which the pharmaceutical industry was operating – a structure which did not only restrict the policy options available, but which also provided the 'conceptual repertoire' intended to enable industry's proposal to speak the language of the dominant structure of meaning – this chapter highlights the IPC's influence and the way in which power is translated into action. While the IPC was composed of several industries, this chapter has looked at the enforcement and patent provisions – and as far as possible, the pharmaceutical-relevant language in both documents, remaining ever-cognizant that the IPC was a pharmaceutical co-initiative. It would therefore be insufficient to simply theorise the prevailing historical structure – consisting of material capabilities, ideas, institutions and decision-making authority – within which the pharmaceutical industry was operating. What is also fundamental is an assessment of what emanates from such a

structure, that is, the actual advantages that result directly from it. One can therefore establish a reasonable correlation between the prevailing historical structures approach deployed in Chapter I, and the overwhelming rewards that industry secured from TRIPS, thereby compellingly confirming the institutional capture argument.

While this chapter confirms that industry secured all of its demands from TRIPS and correlates this back to the structure of existing power relations, it does nothing to reflect on the nature of this victory, specifically, how developing countries reacted to industry's demands during the actual negotiations on patents in the Uruguay Round. Because of the level of mutual inconsistency between the two sides of the debate on patent encountered in 'The Research Problem', industry's win signifies major losses for developing countries which generally oppose patents by virtue of the knowledge gap, and their net-importer status. Chapter III introduces the wide-scale offensive by developing countries against the industries' IP agenda presented by their state-based delegations in the Uruguay Round. It crucially addresses the final component of the first empirical hypothesis, namely, that industry secured its demands *despite* the high intensity of the conflict characterising the negotiations.

## Chapter III

### North/South Controversies in the TRIPS Negotiations: Between Hegemony and Domination?

#### 3.1 Introduction

Corresponding to the historical structures approach developed in Chapter I, the last chapter presented an instance in which power was translated into action by juxtaposing industry's demands for an international patent code with the supply of decisions in the TRIPS Agreement. Reverting to the complexity of the debates on patents encountered in 'The Research Problem' the current chapter seeks to ascertain the circumstances behind a trade policy victory for industry at the end of the Uruguay Round, notwithstanding that the Uruguay Round package was guided by the single undertaking principle.<sup>1</sup> The chapter presents a narrative analysis of the level of opposition and resistance that typified the actual trade talks between the North/South<sup>2</sup> compositions in the TRIPS Negotiating Group. It builds on the final component of Hypothesis I, namely, that industry secured its demands despite the high intensity of the conflict characterising the negotiations. The chapter frames this discussion within Cox's extrapolation of Gramsci's concept of hegemony as a way of continuing the general thread of the research, that is, each historical structure generates the contradictions and points of conflict that bring about its transformation (Cox, 1995: 35). The point of the chapter, as well as the next, is to examine some of those contradictions that lay bare the unsettled nature of the prevailing historical structure, thereby highlighting the potential for change.

To do this, the current chapter sectionalises the various components under negotiation and documents the exchanges between the major North/South compositions. The chapter is also concerned with the level of participation from the countries that comprised the major

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<sup>1</sup> The Ministerial Declaration launching the UR stated in its General Principles Governing Negotiations B (ii) that the launching, the conduct, and the implementation of the outcome of the negotiations shall be treated as parts of a single undertaking. See Stegemann, 2000: 1243-4 for more on the single undertaking requirement.

<sup>2</sup> See 'Introduction', footnote 21 for a description of how North and South are utilised in this research.

jurisdictions of the transnational private sector coalition (IPC) examined in Chapter I, namely, the United States, Japan, and the European Communities, but particularly the US; as well as the inputs by developing countries (DCs). Because the thesis will also examine the post-TRIPS challenge by the African Group at the WTO, the current chapter will also sift through the negotiating details of the Round for inputs by sub-Saharan African<sup>3</sup> countries as a way of tracing their negotiating trajectory.

### **3.2 Framing the Negotiations: Cox's Extrapolation of Gramsci's Concept of Hegemony**

Cox is celebrated as the one who initiated the application of Gramsci's concepts to the study of IR (Germain and Kenny, 1998: 3; Gill, 1993: 4), and one such concept, as indicated in the 'Theoretical Framework', is the adaptation of Gramsci's analysis of power to problems of world order. Gramsci's concept of hegemony differs from the orthodox realist account which refers to the Weberian version of 'power over' or dominance of one state over others (Gill and Law, 1989: 476). By contrast, Gramsci took over from Machiavelli the image of power as centaur: half man, half beast, a necessary combination of consent and coercion (Cox, 1993: 52; Augelli and Murphy, 1993: 127; Arrighi, 1993: 149; Gill and Law, 1989: 476). Gramsci maintains that the supremacy of a social group manifests itself in two ways: as "domination" and as "intellectual and moral leadership". A social group dominates antagonistic groups, which it tends to "liquidate" or subjugate perhaps by armed force; it leads kindred and allied forces (Gramsci, 1971: 57). The respective weight of these two pairs of concepts is not equivalent, and in fact, to the extent that the consensual aspect of power is in the forefront, hegemony prevails (Cox's 1993: 52).

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<sup>3</sup> It needs to be further clarified that while the African Group is one of the two main actors in this research, this chapter cannot examine the group for the obvious reason that it was formed several years after the Uruguay Round came to a close. The chapter finds testimony of the offensive mounted by developing countries in general against the Northern IP agenda. Importantly, locating African countries in the trade talks was not a requisite for examining the prevalence of conflict and opposition. The point is to look at industry's victory despite conflict in general. Notwithstanding, while it is generally agreed that SSA countries were overwhelmed by the complexity of the negotiations and the technical nature of many issues being negotiated (Blackhurst, *et al*, 2000: 494), this chapter goes further to *verify* the exact nature of non-participation by SSA countries as a by-product of the method of data collection.

As such, a class or fraction of a class exercises leadership over other classes and strata by gaining the *active consent* of those classes and strata through ideological cooptation and political incorporation, or at least institutional neutralisation rather than repressive exclusion (Robinson, 1996: 627-8). The hegemony of a particular class, or fraction of a class, requires that it has succeeded in persuading other classes in society to accept its leadership as well as most of its moral, political and cultural values (Gill, 1986: 210). Hegemony as a social relation therefore binds together a “bloc” of diverse classes and groups under circumstances of consensual domination (Robinson, 1996: 628) and implies a minimisation of the use of force (Gill, 1986: 210).

However, “when hegemony is not ethical, that is, the exercise of power without the critical, reflective consent of the governed, and when it is based upon fraud or deception, Gramsci considers it a form of domination” (Augelli and Murphy, 1993: 127-8). He asserts that between consent and force stands corruption/fraud (which is characteristic of certain situations when it is hard to exercise the hegemonic function, and when the use of force is too risky). This consists in procuring the demoralisation and paralysis of the antagonist (or antagonists) by buying its leaders – either covertly, or, in cases of imminent danger, openly – in order to sow disarray and confusion in his ranks (Gramsci, 1971: 80n). Corruption and fraud are thus tactical weapons in a rearguard struggle to preserve power. They are the expression, not of power, but of a failure of power (Arrighi, 1993: 149).

The preference of the class that rules therefore, is for coercion to remain ever-latent, and only applied in marginal, deviant cases (Cox, 1993: 52), however, one must remain cognizant that in the world hegemonic model, hegemony is more intense and consistent at the core; and more laden with contradictions at the periphery, where the element of force is always apparent (Cox, 1993: 61; 1981: 144); the developing world is the site of some revolts against the global

hegemony (Cox, 1987: 266).<sup>4</sup> Cox's extrapolation of Gramsci's concept of hegemony therefore enables a probing of the nature of conflict, depending on where, on Gramsci's yardstick of coercion and consent, or a combination thereof, the negotiations lie. The Punta del Este Declaration is now reviewed briefly since its mandate also proves conflictual in the negotiations.

### **3.3 The 1986 Punta del Este Ministerial Declaration**

Perhaps the first indication of the conflictual nature of international trade negotiations is the manner in which the launching phase incorporates virtually all initiatives by any member, carrying with it, the implication that the trade round could result in a Pareto-improving or equitable outcome for all parties (Steinberg, 2002: 350). Typically, a consensus on the draft negotiating mandate has been blocked until virtually all topics of interest to members have been included, and until the language has been sufficiently vague so as not to prejudice the outcome of negotiations in a manner that any country might oppose (*ibid*).<sup>5</sup> The same appears evident for the mandate launching the Uruguay Round. The Punta del Este Ministerial Declaration of September 1986<sup>6</sup> sits as a quintessential example of an embedded liberalism compromise (Ruggie, 1982: 379-415; 1998: 62-84) in the way it sought to balance the General Agreement's mandate to eliminate impediments and distortions in international trade, with the development objectives of developing and least developed countries (LDCs). The contradictory terms of the declaration are important insofar as they provide a yardstick by which to ascertain the difficulties that trade ministers encountered when faced with the prospects of finding a negotiating position that was sufficiently suitable to meet the diversity of interests characterising the trading system.

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<sup>4</sup> See also Chapter I, p. 89 on international organisations as mechanisms of hegemony which function to co-opt elites from peripheral countries and absorb counter-hegemonic ideas by inducing antagonists.

<sup>5</sup> See also Croome (1995) for an analysis of the conflictual circumstances in the pre-launching phase of the UR.

<sup>6</sup> Hereinafter, Declaration. See document online at:

<http://www.jus.uio.no/lm/wto.gatt.ministerial.declaration.uruguay.round.1986/portrait.pdf>.

Under ‘Negotiations on Trade in Goods’, *Objectives (iii)*, the Declaration calls for an increase in the responsiveness of the GATT system to the evolving international economic environment... taking account of changes in trade patterns and prospects, including the growing importance of trade in high technology products. More specifically affirming the trade distortions-IP linkage championed by the transnational private sector coalition, the penultimate subject matter (*Trade-related Aspects of Intellectual Property Rights, including trade in Counterfeit Goods*) reads that in order to reduce distortions and impediments to international trade, and taking into account the need to promote effective and adequate protection of intellectual property rights, and to ensure that measures and procedures to enforce intellectual property rights do not themselves become barriers to legitimate trade, the negotiations shall aim to clarify GATT provisions and elaborate as appropriate new rules and disciplines; and the negotiations shall be without prejudice to other complementary initiatives that may be taken in WIPO.<sup>7</sup>

At another level however, in the *General Principles Governing Negotiations (iv)* the Declaration states that the contracting parties agree that the principle of differential and more favourable treatment embodied in Part IV and other relevant provisions in the General Agreement and in the Decision of the contracting parties of 28 November 1979 on Differential and More Favourable Treatment, Reciprocity and Fuller Participation of Developing Countries applies to the negotiations; that (v) developed countries do not expect that developing countries, in the course of the negotiations, to make contributions which are inconsistent with their individual development, financial and trade needs; and that (vii) special attention shall be given to the particular situation and problems of least-developed countries. Importantly also, in its *Standstill (iii)* component the Declaration notes that each participant agrees not to take any trade measures in such a manner as to improve its negotiating positions. A review of the negotiating positions is crucial.

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<sup>7</sup> See Abbott, 1989: 712-13 on the contentious negotiations between the US (with support from other OECD countries) and the GATT in 1985 and 1986 to get IP included in the UR.

### **3.4 The Negotiating Postures**

In the context of the elements of the Ministerial Declaration reviewed above, this section examines the various issues debated in the Negotiating Group on Trade-Related Aspects of Intellectual Property Rights in order to assess the level of opposition and resistance that typified the negotiations. The narrative that follows highlights the opposing views on patent protection, from a national interest perspective. As we recall from 'The Research Problem', on the one hand, some see IP as a private right that should be protected as any other form of tangible property while others see IP as a public good that should be used to promote economic development (Ross and Wasserman, 1993: 11).

#### **3.4.1 The Negotiating Objective**

One of the highly contentious issues in the IP trade talks concerned the precise nature of what was mandated of the Negotiating Group from the Declaration. The initial phase of these negotiations began in March 1987 with participants delineating their respective positions on IPRs. An initial group of participants indicated that trade problems were arising as a result of deficiencies in the protection accorded to IP, both because of the inadequacies in the scope and availability of IPRs under many national laws, and because of the lack of effective procedures and remedies for the enforcement of such rights where they existed (MTN.GNG/NG11/1: 3)<sup>8</sup>. As regards the scope and availability of rights, these participants made reference to the absence, in certain countries, of patents and other laws; exclusions of categories of products from protection; insufficient duration of protection; misuse of compulsory licensing; and procedural obstacles or *de facto* discrimination that makes it difficult for foreign firms to obtain protection for their intellectual property (ibid). With regard to difficulties facing IPR owners in the enforcement of their rights, and representing fully the views articulated in the industries' "Basic Framework" examined in Chapter II, mention was made of the lack of police enforcement or access to border

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<sup>8</sup> All such documents are minutes of meetings or submissions by participants at the meetings. See references for full details of all such documents used in this research.

enforcement measures in appropriate circumstances; difficulties with gaining access to competent judicial or administrative bodies; procedural problems with the burden of proof and assembly of evidence; unavailability of preliminary relief; insufficient penalties; and the duration and cost of legal proceedings (ibid).

All industrialised countries represented in the sessions, at some point, (some more than others and some emphasizing some areas while neglecting others), echoed some or all such views in their country suggestions, including the United States (MTN.GNG/NG11/W/2: 1-4), the European Communities (MTN.GNG/NG11/W/16: 4), and Japan (MTN.GNG/NG11/W/17: 3). In a suggestion tabled before the Group in October 1987, the US reiterated some of the positions upheld above, and echoing the “Basic Framework”, insisted that “inadequate and ineffective protection of intellectual property rights result in trade distortions and impairment of concessions previously negotiated. Among the principal causes of trade distortions and nullification of concessions are inadequate international norms and lack of effective means for enforcing international obligations. Losses as a result of counterfeiting and piracy<sup>9</sup> to the trading system as a whole have been extensive and are growing” (MTN.GNG/NG11/W/14: 181). During the second phase of the negotiations, the US representative informed the Group of the results of the ITC's study on “Foreign Protection of Intellectual Property Rights and the Effects on United States Industry and Trade” (MTM.GNG/NG11/6: 10). According to the representative's account, respondents to a questionnaire sent to 736<sup>10</sup> US firms, including the largest 500, had estimated their aggregate worldwide losses in 1986 as a result of inadequate foreign protection of their IP

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<sup>9</sup> See Deveareaux's (2006: 46) 1998 interview with Scherer in which he talks about the emotive appeal associated with the word 'piracy' and the resulting public relations impact.

<sup>10</sup> In the last chapter industry indicated that the results from the survey were based on responses from 193 US firms and not 736 as indicated by the US representative, an irregularity of 381%. If however, the ITC did in fact send questionnaires to 736 (this is substantiated by Abbott, 1989: 700), out of which 193 responded, it appears that almost 74% of firms did not perceive the linkage between insufficient IP protection and lost sales strong enough to warrant a response to the ITC's questionnaire. Correspondingly, IP protection abroad may not have featured prominently in these firms investment calculations.

at USD\$23.8 billion, of which their lost exports from the United States were estimated at USD\$6.2 billion (ibid).

Attempting to impute some level of scientific rigour to the results of the survey, the US representative elaborated by affirming the ITC's conclusion that if the losses indicated by respondents were extrapolated to all United States industry at the same rate of loss per unit of sales, a total figure of USD\$102 billion would be arrived at; if the extrapolation was at half the rate of loss, the total would be USD\$61 billion; and if it were at one quarter, the total would be USD\$43 billion (ibid). Responding to a question about the methodology used in the study, the US representative upheld that the information by respondents to the ITC's questionnaire "was provided under oath and cross-checked by the staff of the ITC" (ibid: 11).

Later, another similarly inclined participant informed the Group of the main conclusions which had emerged from a survey of industry in his country aimed at identifying some of the trade-distorting effects arising in connection with IPRs (MTN.GNG/NG11/8: 23), naming pharmaceuticals as one of the severely affected industries within the industrial property category. Overall, the survey had indicated significant trade losses to his country's economy from the displacement of genuine exports by pirated and counterfeit goods; and more general economic losses had also been identified in the form of reduced incentives to innovation and creative activity, and consequent lower levels of R&D and economic growth (ibid).

The Canadian delegation later stated that it had been informed by Canadian-based companies and industries that they had not pursued potential market opportunities in selected countries because of unfair competition from counterfeit or otherwise infringing products; and to an even greater extent, Canadian companies had been hurt by unfair competition from infringing products which had found their way into the domestic market (MTN.GNG/NG11/15: 26). In a

similar vein, negotiators from developed countries had tabled earlier compilations before the Group on trade problems encountered in connection with IPRs, including a joint, though jurisdictionally sectionalised, document produced by the United States, Japan and the European Communities<sup>11</sup> (MTN.GNG/NG11/W/7: 2-30); a submission from the Nordic countries (MTN.GNG/NG11/W/7/Add.1); and one from Switzerland (MTN.GNG/NG11/W/7/Add.2). All such participants stressed what they perceived as clear evidence that trade problems related to IPRs have grown significantly in scope and magnitude, arguing that problems were encountered primarily because of a lack of a legal framework in the field of IP; insufficient or inadequate levels of protection; discriminatory application of IP law; lack of, or inadequate national procedures; counterfeit goods; and problems with international IP law itself. In effect, all such submissions sought to demonstrate, although the extent of scientific validity in arguments brought forward was not clear-cut, that insufficient or nonexistent IP protection and enforcement measures was tantamount to *de facto* discrimination in international trade, and hence, required international legal resolutions that were substantive in character. The EC maintained in a 1988 submission that the alternative to effective multilateral action will undoubtedly be increased recourse to bilateral or unilateral measures of a character which cannot but undermine the multilateral system to the detriment of most trading partners (MTN.GNG/NG11/W/26: 1).

As a result of such concerns, the obvious hurdle lay in convincing mostly ex-colonies, which, by virtue of their historical experiences harboured a resolute cultural ambivalence towards foreign ownership generally, that the protection and enforcement of IP was in everyone's self-interest. Consequently, DCs became incensed by what they perceived to be an attempt by the industrialised North to halt and essentially reverse their economic development. As such, participants representing the South generally, focused for much of the initial and second phases, and episodically in subsequent phases, on the precise signification of the mandate of the

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<sup>11</sup> The core IPC jurisdictions.

Declaration. These representatives asserted that the Negotiating Group should abide strictly by the mandate given to it by the Declaration, and that this related to trade in goods only (MTN.GNG/NG11/1: 8).<sup>12</sup> They were of the view that the mandate did not provide for an exercise to set standards for IP protection, or an attempt to raise the levels of such protection through the strengthening of enforcement procedures (ibid). These tasks, in their view, should be undertaken in other negotiating fora, such as WIPO; that the task of the Group was not to deal with IPRs themselves, but with the effects on trade in goods of action to protect such rights, particularly so as to ensure that such action does not create barriers to legitimate trade (ibid). Therefore, opponents to the establishment of substantive IP standards within the GATT chose instead to focus on a specific conception of trade-related aspects of IPRs, that is, the negative effects on trade that may result from their protection (MTN.GNG/NG11/8: 5).

Moreover, some participants maintained that IP protection was granted as a function of the domestic situation and that it was not sufficient to establish that a matter was trade-related for it to fall within the scope of the Group; that the Group had not been assigned the task of questioning the appropriateness of national standards for the protection of IPRs, especially where countries were in conformity with international conventions; that such a task would seriously prejudice the initiatives of WIPO and elsewhere, and would thus be inconsistent with the Group's Negotiating Objective (ibid: 29).

In a subsequent meeting DCs further contended that the proposals being tabled appeared to address exclusively the interests of the NETs and did not take adequate account of the need to facilitate technology transfer (MTN.GNG/NG11/9: 15). These participants further asserted that there was a need to make a clear distinction between the protection of IPRs *per se*, which fell in the domain of IP law, and the trade-related aspects that created distortions and impediments to

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<sup>12</sup> See also, Braga, 1989: 249-251.

international trade (ibid: 16). Such countries therefore demonstrated the necessity to limit deliberations to trade issues and not to include the entire spectrum of IP law. Attempting to clarify the issue before the Group, Brazil submitted a communication asserting that “intellectual property is a concept applied to the protection of inventions and intellectual work”, while “trade involves the sale and purchase of goods and services” (MTN.GNG/NG11/W/57: 3-4). The communication continued that “the two concepts begin to interrelate when intellectual property starts influencing the factors which determine a commercial transaction, that is, price, quality and availability, and that the lesser or greater degree of protection may affect, to a lesser or greater extent, the price of products, their quality and their availability” (ibid: 5), indicating that the fundamental issue at hand was the *trade-relatedness* of intellectual property. The Brazilian submission is worth quoting at length:

“On a conceptual basis, the protection of intellectual property allows holders of these rights a temporary and monopolistic control over their invention or work, which, in principle, contradicts the notion of free competition and, likewise, the improvement of international trade rules embodied in the General Agreement. When analysed exclusively from the point of view of international trade, such protection would be tantamount to a highly unacceptable technological protectionism. However, through a legal perspective, the protection of intellectual property rights is justifiable as an element for the promotion of inventive activities and technological development. Nevertheless, when examined solely in these terms, it would favour technological concentration, as well as market concentration, which would produce equally unacceptable trade distortions” (ibid: 8-9).

Consequently pointing towards the dilemma of negotiating an issue between diametrically opposed factions, DCs maintained that “the text of the Group’s Negotiating Objective reflected the fact that at Punta del Este, it had not been possible to reach a decision on the inclusion of substantive standards within the negotiations; that the Ministerial Declaration also reflected, in both this and other areas, concern not to attempt to make the Uruguay Round a forum for resolving problems that had their source outside the trade field” (MTN.GNG/NG11/9: 16).

In another attempt to clarify their objection, these participants noted that if the substantive aspects of protection of IPRs could be regarded as trade-related, then it could be inferred that the substantive aspects of any economic activity could also be regarded as trade-related, including for example, money and finance; but that no action was being taken in the Uruguay Round on the substantive aspects of those issues; nor was action being taken on matters that clearly fell within the scope of the General Agreement such as the stabilization of markets for primary products (ibid). Furthermore, highlighting the slanted nature of the negotiations, it was said that while the standards for the protection of IP being proposed in the Group impinged on issues relating to technology transfer and the activities of transnational corporations, multilateral efforts elsewhere to reduce trade barriers arising in these fields such as the Code of Conduct on the Transfer of Technology, and the Code of Conduct on Transnational Corporations, were being blocked by the same countries that were seeking mandatory standards in IP (ibid).

In response an IP advocate maintained that the reason for disagreements was because of differences in views on substance, and not because the Negotiating Objective was not clear (MTN.GNG/NG11/10: 2). He declared that the Negotiating Objective should not be used as a pretext for not understanding the work that the Group has been asked to do, that the first paragraph neither compelled a negotiation of new rules and disciplines nor prohibited it, that it did reflect an expectation that new rules would be elaborated if found appropriate to reduce impediments and distortions to international trade (ibid). Nonetheless, DC continued to maintain that the scope of the Group's Negotiating Objective, as well as of the General Agreement itself, which had been established to deal with trade in goods, did not provide a legal context for a negotiation on the evolution of the IP system, that would take account, in a balanced way, of the interests of both groups of countries (ibid: 9). Developing countries maintained this stance throughout the negotiations, remaining convinced that the proposed GATT-IP framework would serve the interests of the NETs to the detriment of their development needs.

### 3.4.2 GATT or WIPO? Debating the Appropriate Forum

The divisiveness over the Negotiating Objective also fuelled an intense GATT/WIPO controversy. NETs believed that the most appropriate way to proceed with the negotiations was to engage in a discussion on substantive standards to remedy trade problems caused by IP theft, while the NITs thought that substantive negotiations were not only contrary to the Declaration's mandate, but also categorically asymmetrical in their unbalanced treatment of rights and obligations. Since WIPO was established as the official UN body with oversight on the functioning of the international IPR system, the debate over its utility in the trade-relatedness of IP is crucial. Switzerland submitted that "the very fact that the notion of property is inadequately recognised and protected with regards to an important aspect of goods – their intangible components – is thus in itself fundamentally harmful to trade. It is therefore right that GATT, whose task it is to create favourable conditions for the expansion of trade, should deal with this problem from the commercial standpoint ... it is therefore by no means paradoxical for GATT, in its efforts aimed at liberalisation, to seek to improve the protection of intellectual property" (MTN.GNG/NG11/W/7/Add.2: 1-2).<sup>13</sup>

More provocatively, the US issued a denunciation of the existing legal framework, and justified what it perceived to be the forum-worthiness of the GATT as *the* institutional facilitator for IP talks. It contended that while "the international intellectual property regimes have assisted in producing the level of intellectual property protection available today, they are not sufficient to stop the excessive worldwide trade losses to economies caused by counterfeiting and piracy. These IP conventions were never intended to be used as enforcement mechanisms for intellectual property rights. They do not have effective dispute settlement provisions. The integration of IP into the GATT framework as a supplement to existing international intellectual property

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<sup>13</sup> See also Gad, 2006: 93-96 for the background to the choice of GATT as a forum.

agreements and conventions would facilitate the increased protection of intellectual property and thereby substantially reduce trade distortions” (MTN.GNG/NG11/W/14).<sup>14</sup>

This assertion was met with heated opposition by participants from DCs who contended that the furtherance of protection of IP was the responsibility of other international organizations, chiefly WIPO, and not the GATT; that most of the proposals tabled by the NETs would involve duplication of and possible conflict with the work of WIPO (MTN.GNG/NG11/5: 13). Some delegations affirmed that much of what was said in the United States paper and in some of the other suggestions did not fall in the mandate of the Group, which did not call for the establishment of norms and standards for the protection of IP (MTN.GNG/NG11/4: 11). They said that it was not the job of the Group to establish a new system for the protection of IPRs in the GATT; that these matters were for WIPO and were under extensive consideration in the various parts of WIPO’s current activities (*ibid*). The opponents continued that if some countries felt that existing WIPO treaties were inadequate, they should seek improvements in that forum (*ibid*).

The industrialised countries then sought to identify the gaps in the existing framework (seconded by the GATT Secretariat in submission MTN.GNG/NG/NG11/W/18), emphasising that it appeared that the existing IP conventions contained rather limited mechanisms for resolving disputes between member countries (MTN.GNG/NG11/6: 25). A WIPO representative who was present at the meeting subsequently maintained that “if the dispute settlement provisions of the Berne and Paris Conventions were not more far-reaching, it was because the member states at the time of the introduction of these provisions had not judged it desirable to make them so” (*ibid*: 26). He confirmed that the establishment of international norms for the protection of IP was a fundamental task of WIPO, and the extent to which it had been possible to draw up norms

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<sup>14</sup> For an early assessment on the competence of WIPO-administered conventions, see Kunz-Hallstein, 1989.

of a binding character had depended on the willingness of member states to accept such obligations (ibid: 27), highlighting the negotiators' bias in branding WIPO as inefficient and ineffective, for what was essentially a member-driven international legal apparatus.

WIPO's Secretariat then furnished a document (MTN.GNG/NG11/W/24) which drew mixed reactions from the distinct camps in the negotiations. While the group of core states generally alluded to the gaps in the existing law that contributed to trade distortions (MTN.GNG/NG11/7: 5), DCs championed that if there were indeed lacunae in the field of IP law, they did not arise from shortcomings in the international conventions so much as from problems in the application and enforcement of existing international norms in national legislation (ibid: 6). Therefore while industrialised countries sought to supplant or at least supplement the pre-existing law, developing countries maintained that WIPO's activities provided for broad coverage and effectiveness and therefore should remain the rightful forum for the elaboration of IP disciplines.<sup>15</sup> In further support of this perspective, such countries noted that virtually all matters that had been raised in the Negotiating Group were already under consideration in the context of current WIPO activities, such as the work on the treaties for the harmonization of patent and trademark law, the conference on the revision of the Paris Convention, and the work on measures against counterfeiting and piracy (ibid).<sup>16</sup> These countries maintained that this demonstrated that WIPO recognised the need for constant adaptation of international law in this area, in line with changing circumstances (ibid). It was then reiterated that "if countries felt that their commercial interests were not adequately protected by the present international system for the protection of intellectual property, they should seek solutions in the appropriate fora, notably

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<sup>15</sup> Prominent neoliberal economists such as Bhagwati (2002: 127; footnote 6) also contend that IP protection has no place in WTO because it simply sanctions royalty payments by the poor to the rich; and that such issues should be dealt with in appropriate international organisations, and not the GATT. See however, Maskus, 2000: 238-9 for a more nuanced view.

<sup>16</sup> For analyses on previous attempts to revise the WIPO conventions, see Ryan, 1996: 125-139; Stegemann, 2000: 1238-9; Matthews, 2002: 10-12; Drahos with Braithwaite, 2002: 110-114; Devereaux, 2006: 46-47; Watal, 2001: 15-19; Adede, 2003: 24-5. See also Beier and Schricker, eds., 1989.

WIPO; the present work programme of that organization gave them ample opportunity to do so” (ibid).

These participants reaffirmed their view that the Negotiating Objective did not mandate a negotiation on norms for the protection of IP, and noted that the document had clearly demonstrated that these were matters that fell within the competence of WIPO rather than the GATT, by virtue of the fact that they were legal questions related to the property rights of *persons*, rather than trade matters related to the *goods* of countries (ibid) (emphasis added). WIPO’s representative at the meeting defended the institution, saying that “WIPO did not disregard such questions”; that work on combating counterfeiting and piracy, which had been underway for some years in WIPO, had been initiated because of concerns about important trade problems in this connection (ibid: 8). He continued that it was not, at least for the moment, in WIPO’s area of competence and traditional expertise to undertake detailed economic studies on trade matters; any such suggestion would have to come from the WIPO Governing Bodies in determining WIPO’s work programme (ibid). Responding to the NETs’ criticism concerning the absence of a dispute settlement mechanism in WIPO however, the representative also clarified that as far as he was aware, “no case had been brought so far before the International Court of Justice under the dispute settlement provisions of WIPO treaties” (ibid).

The conclusion drawn from this revelation centres on the fact that WIPO represents a UN agency, traditionally perceived to be more responsive to the interests of developing countries than the GATT, which tended to privilege the trade interests of industrialised countries (Capling, 1999: 259). From an American perspective, WIPO was neither adequate nor appropriate to secure the IPRs of US interests (ibid).<sup>17</sup> Referring to dispute settlements, a participant said that while the WIPO document illustrated that the Paris Convention provided for recourse to the

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<sup>17</sup> The image of WIPO has changed as a tool for promoting the interests of the most protectionist IP interests. See Sell, 2003: 20.

International Court of Justice (ICJ), this was, “in any event, a weak and limited way of settling disputes” (MTN.GNG/NG11/7: 15). This was seconded by another participant who said that the ICJ generally did not constitute a practical way of dealing with disputes between countries regarding international obligations on IP matters, and that his delegation was proposing the establishment of a dispute settlement mechanism (DSM) following GATT practice (ibid). A DC participant retorted that the provisions of dispute settlement in the Paris Convention reflected the fact that disputes over IPRs were typically private conflicts over private rights and that it would be inappropriate to attempt to regulate such disputes among states (ibid).

Nonetheless, the assault on WIPO-administered conventions was manifold, attacking not just dispute settlement, but also every issue area that was previously the competent domain of WIPO, including rights conferred, subject matter, patent term, compulsory licensing, minimum standards, and non-working. In effect, what the NETs wanted, was to re-enact the substantive IP standards/norms within a 'more appropriate' GATT; to devise how to enforce such a re-enactment both internally and at the border; and to establish a DSM that would ensure the necessary compliance. On the other hand, since IP was a definitive feature of the UR, developing countries did not question its legitimacy as an agenda item once the Round was started. However, they thought it unnecessary and inappropriate to discuss norm-setting under the GATT since this had the propensity to supplant the existing law, or at the very least, “to establish a parallel system for the protection of patents that would regulate matters that under the Paris Convention had been recognized for over 100 years as being matters properly left to national law” (MT.GNG.NG11/8: 37).

This might be sound judgement if we recall that at Punta del Este, it was decided at ministerial level that the negotiations should be without prejudice to complementary initiatives in WIPO (itself a contradiction since the Declaration *also* called for an elaboration of new rules and

disciplines as appropriate). Importantly however, a Swiss representative noted that standards established under GATT would, in accordance with Article 30 of the Vienna Convention on the Law of Treaties, replace existing IPR standards in other instruments to some extent, or overlap or amend them within GATT (MTN.GNG/NG11/9: 5). Moreover, a participant later declared that Article 19 of the Paris Convention explicitly allowed members to conclude agreements on subjects contained therein, that provided for higher levels of protection (ibid: 24) and therefore, norm-setting did not contravene the Paris Convention<sup>18</sup> and neither was it technically inconsistent with the Ministerial Declaration. The problem was therefore, a political one. In a manner which appeared to circumvent IP work previously done nonetheless, a US representative made reference to its latest submission (MTN.GNG/NG11/W/70), that the new proposal incorporated the entirety of what his delegation considered to be the relevant provisions of the Paris and Berne Conventions, and that the proposal was not only “Paris plus” and “Berne plus”, but also “GATT plus” (MTN.GNG/NG11/21: 12), adjectives that aptly describe the TRIPS accord, and capture the objections by developing countries of the new IP framework being proposed. The narrative now turns to some of the other contentious areas of the negotiations, which also reflect the deep-seated cleavages in the GATT/WIPO debate.

### **3.4.3 Patentable Subject Matter**

Another contentious theme concerned patentable subject matter, as countries were at odds with each other concerning exclusions from patentability. As a result of its significance to the health of a nation generally, and the development objectives of developing countries in particular, pharmaceutical products were particularly susceptible to the national interest invocations of many developing countries. In fact, of the 19 categories delineated in Annex II ‘Exclusions from Patent Protection’ of a WIPO document (MTN.GNG/NG11/W/24: Annex II), pharmaceutical products recorded 49 jurisdictions, the highest number of countries excluding protection in a

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<sup>18</sup> See Kunz-Hallstein, 1989: 266 for this principle in the Paris Convention.

given area. Contrary to the atmosphere in the negotiations that DCs were the least respectful of IP laws, WIPO revealed that virtually all countries, including the more advanced ones, excluded a variety of different types of subject matter from patent protection and that no clear pattern was discernible among countries regarding such practices (MTN.GNG/NG11/7: 9). According to WIPO's representative, "the matter was very complex and there was a variety of reasons why exclusions were sometimes found necessary" (ibid). Amongst the 49 countries in the 1988 report, 10 were OECD member states, including Greece, Finland, Norway, Portugal and Spain<sup>19</sup> from Europe, and Canada in North America; as well as many high-income developing countries. The number of abstaining countries was significantly less for pharmaceutical processes, totalling 10, two of which were OECD members.

This record prompted an upsurge in 'WIPO-bashing' from the major NETs. A participant noted that the Paris Convention was largely silent on minimum standards, and that patents should confer the right to exclude others from the manufacture, use, sale or importation of a patented product; and in case of a patented process, from the use, sale or importation of a product directly produced by that process (ibid: 10); and that all countries should be required to grant patents for all products and processes in all fields of technology, with the exception of inventions aimed at illicit activity (MTN.GNG/NG11/14: 75). This, he said, would encourage broad-based innovation and inventions, the dissemination of ideas and technology, and allow a free flow of trade in goods resulting from these inventions (ibid). As expected however, the debate over product/process patents was not so clear-cut, as countries had previously employed differential modalities to manage their domestic systems.

Some participants believed that there were sound reasons to exclude pharmaceutical products from patent protection, while only providing such protection for processes. They contended that

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<sup>19</sup> Spain was derided by the global pharmaceutical industry as one of the worst offenders in the developed world. See Rice, et al, 1991.

R&D activity in the invention of new and more efficient processes of production could be hamstrung by product protection (MTN.GNG/NG11/20: 31), since researchers and potential investors would be obliged by the terms of the product patent for a fixed period which unnecessarily stifled innovation.<sup>20</sup> In a submission from India which specifically tackled the issue, it stated that until the mid-1960s and 1970s, the patent laws of a number of industrialised countries allowed only process patents in the pharmaceutical sector; that the present technological strength of some of those countries in this sector is attributed at least in part to their following only the process patent system for several decades; and that the development of the pharmaceutical industry in some of the highly industrialised countries of today owes its origin to their deliberately adopting a legal framework that excluded or limited patent protection for drugs (MTN.GNG/NG11/W/37: 21). The submission continued that given the size of the population of several developing countries and their extremely low level of per capita income, it is imperative that essential articles, such as medicine, are available to them at reasonable prices, and that the monopoly rights granted through the patent system do not either lead to artificial prices in these sectors, or competition being thwarted altogether (ibid: 23), assertions which had been made earlier by Brazil (MTN.GNG/NG11/20: 33), and later seconded by Peru (MTN.GNG/NG11/W/45: 1).

In the interest of uninhibited R&D initiatives therefore, it seemed a fundamental development initiative to continue to exclude products from protection. However sound this argument may seem from the point of view of the peculiar circumstances of DCs, the IPC presented an equally sound rationale in its proposal, that when the invention lies in a valuable chemical substance, a process patent is simply an invitation to imitators to manufacture the substance by another route, usually a straightforward exercise for a competent chemist (“Basic Framework”: 373). The juxtaposition of these contradictory arguments is fundamental insofar as the TRIPS Agreement is

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<sup>20</sup> See Machlup, 1958: 42; Sell and May, 2001: 472-3; May and Sell, 2006: 26-7; Mytelka, 2000; Stiglitz, 2008: 114.

concerned since it highlights which demands/interests prevailed irrespective of the intensity of the conflict that typified these negotiations.

DCs further insisted that exclusions from patentability should be allowed on grounds of public interest, healthcare, nutrition, or promotion of sectors of vital interest for economic and technological development; and that the flexibility available to developing countries should be preserved (MTN.GNG/NG11/20: 22). The Brazilian delegation noted that it wished to see countries retain the flexibility to determine exceptions in light of their situation; that “there should be no attempt in the Group to harmonize standards in this area” (MTN.GNG/NG11/17: 43). As in India’s submission, Peru's representative challenged that the freedom to determine the scope and level of protection of IPRs had often been used in the past by today’s industrialised countries to promote emerging industries or to develop local competitive practices; and that many of those countries had excluded, and some of them still excluded, certain products and processes from patent protection<sup>21</sup> (MTN.GNG/NG11/22: 7). In an earlier submission, Brazil noted that for more than 500 years, the main objective of the protection of IPRs has been the promotion of industrial creativity to the benefit of a country’s social and economic development (MTN.GNG/NG11/W/30: 13).<sup>22</sup>

In response, an industrialised country (IC) participant stated that it would be wrong to equate the issue of pharmaceutical prices with that of patent protection; and that most pharmaceuticals, including the overwhelming majority of those on the WHO list of essential drugs, were in the public domain and not under patent protection (ibid). Representing pharmaceutical interests, he continued that “patent protection contributed greatly to the public interest” by stimulating the

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<sup>21</sup> Recall that this was substantiated in the aforementioned document produced by WIPO’s Secretariat (MTN.GNG/NG11/W/24).

<sup>22</sup> For a history on the emergence of intellectual property rights in general; a trajectory of how such rights evolved from a status as monopoly privileges to intellectual property rights; and the history of the strategic employment of intellectual effort for the benefit of the state, see May and Sell, 2006.

development of new drugs and other valuable products; and that one of the unfortunate consequences of the low levels of protection for pharmaceuticals in many developing countries was the small amount of private R&D into tropical diseases (ibid).<sup>23</sup> Therefore, the delegate sees the scarcity in research on tropical diseases, not as a consequence of the rent-seeking<sup>24</sup> opportunities that the patent system enables, but instead, as a consequence of inadequate protection. Notwithstanding industry's gains from TRIPS, there remained an intractable and deep-seated rift between the two camps as to what should and should not be protected based on economic development considerations.

#### **3.4.4 Compulsory Licensing, Working & Competition Policy**

Linked to the politics of patentable subject matter are the equally controversial areas of compulsory licensing, competition and working. Arguably arousing the most vitriol from both camps in the negotiations, these issues have had particular relevance for pharmaceutical interests as well as developing countries. During the second phase of the negotiations, a participant commented that the Paris Convention provided for a low level of protection for the patentee; and that many practices for the application of compulsory licenses were permitted under this Convention without limitations. Examples are, compulsory licenses for the interdependence of patents irrespective of the value of the second patent; in the public interest; in the interest of public health, "which penalised in particular pharmaceutical inventions" (MTN.GNG/NG11/7: 13). He continued that the WIPO Model Law contained a reference to exclusive compulsory licenses, which would deprive the patentee from exploiting his own invention, including through exportation; this, combined with the requirement on the compulsory licensee to produce locally and possibly a certain quantity for export, had clear trade effects (ibid).

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<sup>23</sup> See Gadbow and Richards, 1988: 20-21; Sherwood, 1993: 78-9; Matthews, 2002: 108-111, for accounts on the benefits to developing countries of IP protection. See also Stamm, 1993 in relation to pharmaceuticals in particular.

<sup>24</sup> Rent-seeking behaviour occurs when economic decision-making is guided by factor rents which are above and beyond the amount necessary to induce the supplier to offer the input to the market.

Reinforcing this view was a US representative who maintained that compulsory licensing was “not satisfactorily dealt with in the Paris Convention because the relevant provisions were so open and permissive as to allow mischievous use by countries”; and that his delegation favoured a practical approach that would impose realistic restrictions so that compulsory licensing was only used for “legitimate purposes spelt out in his delegation’s submission” (MTN.GNG/NG11/14: 83.2). In its revised suggestion for achieving the Negotiating Objective (MTN.GNG/NG11/W/14/Rev.1)<sup>25</sup>, the US, like the IPC, maintained that “a compulsory license may only be given to address, only during its existence, a *declared* national emergency or to remedy an *adjudicated* violation of antitrust laws ... a compulsory license must be non-exclusive and all decisions to grant compulsory licenses as well as the compensation to be paid, shall be subject to judicial review” (emphasis added) (ibid: 197). The suggestion did not however spell out whose legal system would prevail when adjudicating violations of antitrust; what was the maximum allowable time-span for an adjudication to become final, since such measures tended to crawl through the court system because of extensive and protracted litigation; or more specifically, whether appeals were sanctioned in cases of antitrust misconduct, which could serve as a legal loophole to delay the introduction of a compulsory license.

In another quintessential “Basic Framework”<sup>26</sup> disposition, the point was made that although the prohibition of the use of compulsory licenses would be the most trade-promoting solution, there were many safeguards to limit the possible abuse of compulsory licenses that could be considered, for example, the requirement that such licenses be non-exclusive; that they be granted only to meet the needs of the local market by local production, without the right of importation; that provision be made for judicial review; that compulsory licenses on the grounds of non-working should only be granted where the working was economically feasible in that

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<sup>25</sup> This document was produced on 17 October 1988, approximately 4 months after industry wrote its ‘Basic Framework’

<sup>26</sup> Noteworthy, this discussion took place seven days after industry’s “Basic Framework” was produced, 14 June and 21 June 1988, respectively.

country; and that patents should not be revoked for non-working (MTN.GNG/NG11/7: 13). This would essentially supplant the Stockholm Text of the Paris Convention which permitted countries to grant compulsory licenses for non-working (MTN.GNG/NG11/14: 75). In this context, NITs maintained that rights and privileges granted by society to IP owners should be balanced by obligations on those owners vis-à-vis society at large. Several participants contended that given that the nationals and companies from developing countries owned hardly any of the total world stock of patents, the commercialisation of patents in the host country on reasonable terms was a matter of crucial importance to such countries (MTN.GNG/NG11/20: 34). Without working, patent protection would be a legalised monopoly to import patented articles into a host country, and a device for the reservation of the host market by the patent owner (MTN.GNG/NG11/W/37: 8). Without working, there could scarcely be any transfer or diffusion of technology and the promotion of industrial activity in the host country (ibid). Moreover, working generally led to the saving of scarce foreign exchange and the lowering of the price of products, particularly in crucial areas like pharmaceuticals (ibid).

However, a US negotiator asserted that compulsory licensing on the grounds of non-working was an outmoded idea, not reflecting modern business trends; that it would be difficult to contemplate the working of a patent in every country because modern technology rendered that economically undesirable (MTN.GNG/NG11/14: 83.2). DCs retorted that “far from being outmoded, compulsory licensing was relevant to the situation of developing countries that suffered from an overwhelming rate of non-working of patents” (ibid: 83.3); and that it was also a very useful instrument to control the misuse of exclusive rights conferred by patents (MTN.GNG/NG11/16: 24). India's representative stated that compulsory licensing had to be viewed in the context of balancing the monopoly rights conferred on patent holders by obligations and responsibilities (MTN.GNG/NG11/14: 83.3). He contended that “this had been accepted as part of the patent system for over 100 years”; that it was not clear how trade,

investment in production, and technology transfer could be facilitated by non-working of the patent; and that the granting of licenses of right was necessary to remedy the extreme forms of abuse that might arise, especially in certain critical sectors like pharmaceuticals (ibid).

A US negotiator reiterated the text from his revised suggestion that the abuse of an IPR should be judicially determined and “based on sound competition policy rather than on ephemeral notions of what constituted public interest” (MTN.GNG/NG11/16: 33). The Indian delegate went further by declaring that “the greatest distortion of trade was that resulting from non-working (ibid: 34) since there were instances in which the lack or insufficiency of exploitation could constitute an anti-competitive practice such as, for example, where a patent owner chose not to meet the demand for his product in order to maintain a high price” (MTN.GNG/NG11/17: 37). Other examples of anti-competitive practices which Brazil and India deemed justified the application of compulsory licenses include, tied purchases of inputs; the prohibition or restriction of exports from the host country; restrictions on the use of technology after the expiry of the agreement; restrictions on research, use of personnel, adaptations, marketing, publicity; price-fixing; and cross-licensing agreements (MTN.GNG/NG11/W/57: 29; MTN.GNG/NG11/W/37: 30). In this context, the Group “could make a positive contribution by discussing means to avoid, control and eliminate unfair competition and restrictive business practices in the field of patents, since such practices had a significant and direct impact on international trade” (MTN.GNG/NG11/16: 24).

Japan’s delegate intervened by noting that limits on compulsory licences were necessary to create business certainty and to promote innovation, which would not only favour the patentee, but the interests of the public at large, including, in the case of developing countries, through the promotion of technology transfer (MTN.GNG/NG11/17: 39). He contended that exploitation of a patent did not only cover local working, but also importation, which meant that mere importation

should not constitute justifiable grounds for compulsory licensing so long as such importation met local needs (ibid).

This NET standpoint contradicts its earlier argument that compulsory licenses (which should be non-exclusive) should only be granted to meet the needs of the local market, without the use of importation (MTN.GNG/NG11/7: 13). It is unclear how exploitation covers importation in one instance and should be disallowed in another. Moreover, there was major incongruity between demands that compulsory licensing be granted to meet only the needs of the local market, without importation, while local working requirements on patentees amounted to “an outmoded idea, not reflecting modern business trends”. Nonetheless, in a “Basic Framework” parallelism, the Japanese delegate commented that compulsory licensing should not be permitted where insufficient or lack of working resulted from reasons beyond the control of the patentee, for example, where regulatory procedures placed limitations on the exploitation of the invention; and that “the notion of anti-competitive practices was too vague and ambiguous to be used in a TRIPS context” (MTN.GNG/NG11/17: 39) despite the fact that anti-trust was a recognised and developed category in international commercial law, as well as in national legal systems.<sup>27</sup>

A DC delegate therefore referenced a 1974 Recommendation adopted by the OECD Council (MTN.GNG/NG11/9: 19) which recognised that it was desirable to scrutinise and remedy the harmful effects of practices relating to the use of patents and licenses, since economic development was dependent on the dissemination of scientific and technological innovation through patents, and that by granting licenses subject to unjustifiable restrictions, the rights attached to patents could be used to exercise excessive economic power. The Recommendation urged OECD members to be particularly alert to the harmful effects to national and international

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<sup>27</sup> For instance, the US Sherman Antitrust Act dates back to 1890, and the US has had some of the most punitive antitrust laws in the world, although there has been a shift to a more permissive attitude with regard to antitrust matters in recent years. See Mueller, 1996.

trade which might result from abusive practices in this field (ibid). This Recommendation, conceived as early as 1974, supports the thesis that anti-competitive business practices were not at all vague and ambiguous as suggested by Japan, since it was also OECD-specific. India would later comment that “India is of the view that only the restrictive and anti-competitive practices of the owners of intellectual property rights ... distort or impede international trade” (MTN.GNG/NG11/W/37: 2).

In a philosophical interjection by the Peruvian delegate on behalf of DC, the point was made that “the objective of any multilateral negotiation was to achieve a compromise which would reflect the interests of all countries, developed and developing” (MTN.GNG/NG11/16: 6). Invoking Aristotle's conception of proportional equality,<sup>28</sup> he continued that balanced negotiations, “which required that unequal parties should not be treated equally”, would enable wider participation in a final agreement and in particular make such an agreement attractive to developing countries... “so that a cooperative rather than a punitive system could be achieved” (ibid). He examined particular aspects of the Andean Pact legislation and commented that the legislation on the matter of compulsory licensing had been drawn in light of the experience that the protection of IPRs had mainly served the interests of transnational companies and had had undesirable effects on developing countries; and that the purpose of the Andean legislation was “to ensure that IPR protection promoted the social, economic and technological development of Andean countries” (ibid: 13). The positions appeared irreconcilable at best.

### **3.4.5 The Patent Term**

Another area which attracted maximum antagonism was the patent term, with some participants focusing on rights while others highlighting obligations on right holders. An IC participant noted that the Paris Convention provided for no minimum term of protection, speculating that an

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<sup>28</sup> See for instance Foster, 2004 for an analysis on Aristotle's proportional equality as a requisite for justice as fairness. See also Stanford Encyclopedia of Philosophy at: <http://plato.stanford.edu/entries/equality/>.

inadequate term had significant trade effects because it discouraged the creation of new projects in all countries and thus the creation of new trading opportunities (MTN.GNG/NG11/7: 11). A US delegate substantiated that the absence of an international standard on this matter was a gap in international law that was giving rise to serious trade problems and needed to be closed (MTN.GNG/N11/21: 22). While the WIPO Model Law provided for 15 years as a minimum term, it was specifically non-binding and created uncertainty about the possibility of renewal for an additional five years (MTN.GNG/NG11/7: 11). Another participant considered that the draft patent law harmonization treaty provided for 20 years from filing and his country had indicated its willingness to amend its legislation to comply with such a term because “it was not excessive to provide the necessary incentives to innovation, and might be too short where regulatory requirements delayed commercialisation of a product” (ibid). Rebutting, an Indian delegate maintained that “patent terms greater than 15 years were excessive” (MTN.GNG/NG11/16: 31), joined by a like-minded participant who said that the Paris Convention was deliberately silent on this subject because of the difficulty in arriving at an optimum duration for all countries (ibid).

Launching an assault on this perspective, another participant noted that the patent term should be 20 years from the date of filing, since that appeared to reflect “an emerging international consensus”, generally allowed an investor to obtain a reasonable return on his investment; and that the owner of a patent should have the right to exclude others from making, using or selling the patent or invention for a specified period (MTN.GNG/NG11/14: 75). Echoing these sentiments, a US representative said that his delegation approached the negotiations with a willingness to change its law to join “the emerging consensus of granting a period of 20 years from the date of filing as the appropriate term” (ibid: 81.1). Just how the 20 year period surfaced as “an emerging international consensus” was not clear from the texts of the negotiations, since developing countries objected so vociferously to such proposals which may well be described as

an explicit ‘core country consensus’; or in David Truman’s words, “a consensus of the elites” (Bachrach, 1962: 439).

DCs attacked the suggestion that a 20-year term should become binding,<sup>29</sup> arguing that while a shorter duration might limit private gains, it remained unclear how this constituted a restraint on legitimate trade, and whether the suggestions for a longer duration were consonant with the increasing rate of change in technology, with consequent shorter and shorter product life cycles (MTN.GNG/NG11/7: 11). India’s representative added that the determination of an optimal term was largely speculative, lacking a clear rational basis; that it was more advisable to allow the host country to determine the duration, taking into account national factors (MTN.GNG/NG11/14: 81.4). He continued that it was difficult to envisage, and argue for, an optimum duration applicable to all sectors and products alike and therefore, the possibility of variation should be allowed for; that because of the difficult circumstances facing developing countries, they should be free to set shorter terms of protection than that in developed countries; and that since commercial working of the patent was a fundamental obligation, the duration ought to be linked to that obligation, that is, unworked patents should be subject to revocation (ibid). Other DC participants concurred, asserting that “it would not be possible to determine, on the basis of economic analysis, the appropriate term of protection” (ibid); that it could not be scientifically or objectively demonstrated that there was an optimal term (MTN.GNG/NG11/27: 4); that a scientific study was necessary to establish approximate ideal terms for different sectors; and that a commitment to establish a single term would only make sense if this reflected an average of the terms required for various fields of technology (MTN.GNG/NG11/16: 24).

However, the core jurisdictions were intent on reconstructing international IP law in order to maintain their dominance in the GPE, a move developing countries outrightly opposed. Since the

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<sup>29</sup> This point is also seconded by Bhagwati (2002, footnote 6). He attacks the 20-year term as exorbitant.

20 year term appeared to the rule-makers of the system as ‘an emerging consensus’, there was an attempt to stretch the notion of a patent term beyond any previous US-conceived limits. Attempting a transborder application of US law, and firm in his resolve with pharmaceutical interests, a United States delegate suggested that the restoration of the patent term should be possible where the effective use of an invention had been delayed by regulatory approval processes for pharmaceuticals (MTN.GNG/NG11/14: 81.1). While the TRIPS Agreement does not make specific reference to a patent restoration term, it does state in Article 33 that the term of protection shall not end before a 20-year expiration counted from the filing date. Its stipulation of a minimum term, without simultaneously making reference to a ceiling (higher than which can be potentially trade-distorting as well as welfare-reducing), implicitly sanctions a restoration of the patent term in a TRIPS-plus, American-construed framework, thereby placing weaker economies at a disadvantage, especially when entering into bilateral deals with NETs.

It was precisely because of this institutional stance, whereby minimum standards were mandated and maximum standards omitted, that DCs argued for the need to ensure a proper balance to safeguard against inadequate as well as excessive standards of protection, both of which could be trade-distorting (MTN.GNG/NG11/4: 21). In fact, Brazil’s first submission was almost entirely devoted to the issue of excessive standards, in which it argued that problems arising from excessive protection of IPRs are indeed multiple, for instance, the artificial increase of production costs, and consequently, the prices of products; as well as limitations on the variety of products traded among nations (MTN.GNG/NG11/W/30: 20). One can therefore reasonably argue that this imbalance between negotiating minimum standards with a premise to eliminating trade distortions, while overlooking the potentially trade-obstructing effects of excessive standards, sits as one of the cardinal failures of the global trading system, as excessive standards can themselves be barriers to legitimate trade. The narrative continues with the negotiating exchanges on the special economic circumstances of DCs and LDCs.

### **3.4.6 The Transition Problem and Special & Differential Treatment for Developing Countries**

In seeking to address the persistent problem of development, especially against the backdrop that the majority of the jurisdictions represented in the Round were developing and least developed economies, and remaining cognizant that the consent of such countries for an eventual IP code was paramount for the Round's completion, an attempt was made to tackle some of the age-old subject areas of the GATT, namely, transition periods for DCs and especially LDCs, as well as Special & Differential Treatment (S&D) for such countries. In an attempt to justify this special circumstance, a participant reminded the Group that The GATT Enabling Clause provided a permanent legal basis for S&D in favour of developing countries (MTN.GNG/NG11/7: 12) and as such, these countries approached the matter as a right due to them by virtue of their economic underdevelopment. They argued that this principle was applicable in all fields of international economic relations involving countries at different stages of development and was based on the notion that obligations should be commensurate with the level of economic development of participants (MTN.GNG/NG11/15: 15).<sup>30</sup>

Part IV of the Punta del Este Declaration made explicit reference to the circumstances of LDCs warranting particular attention, stipulating that S&D for DCs was also applicable to the negotiations. Paragraph 5 of the TNC Decision of April 1989 also reiterated the significance of differential treatment when it specified that the rights of patent owners had to be balanced by responsibilities so that the system served the public interest, in particular the interests of the poorer sections of the population of developing countries (MTN.GNG/NG11/14: 69). However, as in every other agenda item, there was no uniform conceptualization on what constituted transition and S&D, at times conflating the two concepts altogether.

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<sup>30</sup> See Whalley, 1999; and Pangestu, 2000: 1286-1289 for analyses on the historical evolution of the S&D principle in the GATT.

Subsumed under notions of asymmetry, inequality, injustice and unfairness, developing countries criticised proposals submitted by the European Communities, the United States, Switzerland and Japan which called on all countries to provide IP protection equivalent to that found in developed countries (MTN.GNG/NG11/21: 5). They asserted that such proposals ran counter to the wisdom of the present international IP regime; undermined the territorial nature of IP protection; implied unqualified reciprocity; and implied serious asymmetry in the relative welfare costs and benefits to be derived by developed and developing countries from IP protection (ibid). These participants maintained that too much emphasis was placed on the protection of patents and not enough on S&D for developing countries (MTN.GNG/NG11/14: 70). They insisted that such treatment should include their right to exclude certain products and processes from patentability on public health and scientific grounds, and to accord shorter terms of protection for patents than was the case in developed countries (ibid). A participant wondered how developing countries would benefit if, on the one hand, the bargaining power of intellectual property owners was strengthened, but on the other, adequate consideration was not given to the principle of S&D for developing countries, enshrined in the GATT as well as the Punta del Este Declaration (ibid).

Another participant reasoned that “the patent system had to be designed in light of the situation of developing countries, rather than the question being one of special and differential treatment” (ibid). Accordingly, it was not a question of special treatment *per se*, but one of proportional equality, since harmonised treatment for economies at different stages of development had a built-in discriminatory tendency. DCs were primarily NITs and only held five percent of patents granted worldwide, suffered overwhelmingly from non-utilization and under-utilization of

patents, had low levels of technological development which prevented the local adaptation of foreign technology, and suffered from resource inadequacies for investment in R&D (ibid).<sup>31</sup>

In a submission on behalf of LDCs, the Bangladeshi delegate intervened by recalling the political commitments undertaken in the GATT, reflected in its Enabling Clause, the 1982 Ministerial Declaration, and the Punta del Este Declaration, to grant special treatment to LDCs in light of their disadvantaged situation; and that LDCs wished to see special treatment accorded in all aspects of TRIPS including substantive standards, enforcement, and dispute settlement, as well as the provision of technical assistance in the preparation of domestic legislation to accommodate TRIPS (MTN.GNG/NG11/17: 22). All such countries were incensed because proposals submitted did not adequately consider the practical difficulties they faced; arguing that they could not be expected to enter into obligations that would entail considerable additional administrative or financial burdens (MTN.GNG/NG11/15: 34).

An EC representative subsequently submitted that having taken into consideration the different levels of development that participants had attained, and the varying degrees of infrastructural or institutional difficulties these participants would have to overcome, his delegation proposed to include “reasonable but finite transitions” in a TRIPS agreement (MTN.GNG/NG11/17: 15), inferring that reasonable but finite transitions were synonymous with S&D and therefore sufficient to tackle the problems of development and capacity shortfalls in such countries.<sup>32</sup> The WTO would later offer a six-fold typology of what constituted S&D: provisions aimed at increasing the trade opportunities of DC Members; provisions under which WTO Members should safeguard the interests of LDC Members; flexibility of commitments, of actions and use of policy instruments; transitional time periods; technical assistance; and provisions related to LDC Members (Singh, 2005: 237). While the list may appear vague, it highlights transitional

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<sup>31</sup> Recall also Stiglitz’s discussion in Chapter I on the knowledge gap.

<sup>32</sup> Subramanian (2002: 117) describes S&D as the politically correct terminology intended to obscure the hierarchy inherent in the status of developing countries as supplicants in the trading system.

time periods as one component among many aimed at addressing the disadvantaged position of developing and least developed countries in the GPE.

Notwithstanding, another participant, almost completely relegating the GATT Enabling Clause, commenced with a more hard-line approach that “all signatories to a TRIPS Agreement should undertake the same level of obligations on standards and enforcement”; that “the relevant provisions in this regard should constitute an international “rule of law” in the same way as perhaps provisions on national treatment and MFN” (MTN.GNG/NG11/17: 18). Moreover “establishing differential levels of obligations based on, among other things, levels of economic development, would only serve to perpetuate existing trade distortions, instead of addressing them by providing strong protection that was consistent in scope and application among trading partners” (ibid). He continued that as a result of practical considerations such as enacting laws, promulgating regulations and staffing national patent offices, limited transition periods for certain DCs can be justified, bearing in mind that some might require longer durations than others, but most importantly, that all such transitions should be of a specified duration and should be agreed before the conclusion of the negotiations (ibid), essentially leaving no loopholes for interpretation challenges and possibilities for misuse by ‘free riders’.

Developing countries were consequently further vexed by this blatant tendency of the North to equate development with a time-bound conception of transition in deliberations that supposedly fell under the guise of S&D. This time-bound reading of development has its origins in the neoliberal intellectual mainstreaming of the 1980s whereby ‘preferential’ schemes were regarded as synonymous with inefficiency (Singh, 2005: 233). Prior to the UR, S&D was crafted to provide market access for developing countries in advanced countries’ markets on a preferential and non-reciprocal basis (ibid: 237; Whalley, 1999: 1066-9; Pangestu, 2000: 1286-9). However, the post-Uruguay Round S&D measures have been of a different character, where the objective

is to encourage the TRIPS mindset and assist developing countries in implementing WTO disciplines (ibid; May, 2004), hence the focus on 'extra time'. Therefore, extra time in order to implement WTO disciplines is distinctly development-oriented according to the architects of the trading system. Showing indignation, a participant made it clear to the Group that his delegation would have serious difficulties in accepting uniform obligations applicable to both industrialised and developing countries; that time-limited transitional arrangements would be insufficient to induce developing countries into accepting these obligations; and that different substantive standards and principles for developing countries reflecting their legitimate developmental, technological and public-interest needs would need to be provided (MTN.GNG/NG11/17: 19).

In a classic “kicking-away-the-ladder” thesis (Chang, 2002), a participant later remarked that one of the fundamental principles of relevant international IP conventions was the freedom of states to adapt their IP regimes in accordance with their public interests, and that full advantage of this freedom was taken in the past by now-developed countries (MTN.GNG/NG11/18: 27). Speaking on behalf of a number of DCs another participant reaffirmed the view that economic and technological development was not a time-bound phenomenon; that it was a qualitative process which could not correspond to any specified number of years; and that the slow manner in which the IP systems of the NETs had been gradually modified as and when they developed, illustrated this point (MTN.GNG/NG11/27: 4). He continued that rather than transitional provisions for a limited period, it was more important to have adequate provisions allowing for the special economic and technological needs of developing countries, thus affording them the opportunity to build their technological capabilities without the external constraints that would be imposed by uniform standards of IPR protection (ibid). Concurring, the Indian delegate emphasized that IPRs by nature were state conferred monopolies which states were entitled to regulate and balance with obligations (MTN.GNG/NG11/19: 12). He stressed that paragraph 5 of the April 1989 TNC Decision noted the importance of public policy objectives, and technological and

developmental dimensions; that it was clear that all related aspects, such as balance of rights and obligations, public interest, non-reciprocity, independence of protection, special and differential treatment, and freedom of scope and level of protection should be recognised as principles (ibid). Despite the intensity characterising these negotiations however – with DCs rebuking harmonisation as a gross injustice, and ICs submitting to a singular time-bound conception of S&D – the end results was a trade-off in favour of the latter. As Wade aptly put it, developing countries’ rights and developed countries’ obligations are unenforceable, while developing countries’ obligations and developed countries’ rights are enforceable (Wade, 2005: 83), thereby revealing major contradictions. The analysis moves to the politics of enforcement of IPRs.

### **3.4.7 Enforcement**

Because enforcement procedures impinge directly on a country’s sovereign ability to govern, particularly in the administration of justice, the expectation was that it too would have been a subject of intense controversy (UNCTAD-ICTSD, 2004: 578). However, the negotiations in this area, though far from evolving peacefully, lacked the intense conflict characterising other areas. As such, the pro-industry results of the TRIPS UR negotiations on enforcement should not be entirely surprising. In their “Basic Framework” exactness, the NETs, particularly the United States, argued that the pre-existing ‘intellectual property conventions were never intended to be used as enforcement mechanisms for intellectual property rights’ (MTN.GNG/NG11/W/14: 181). The EC echoed that effective enforcement consisted of one of the two fundamental pillars of the IP framework, the other being, substantive standards (MTN.GNG/NG11/12: 10). Moreover, it contended that effective enforcement consisted of two main elements, that is, enforcement internally and at the border (ibid), a standpoint seconded by the US, Japan and Switzerland. The EC reasoned that internal enforcement was more effective in dealing with trade distortions arising from IPR infringements as they tackled the problem at source, and because, “often, goods infringing intellectual property rights did not enter into international trade” (ibid).

This disclosure appears to upend the entire exercise of seeking multilateral solutions to problems that impact on international trade. If infringing goods did not regularly enter the channel of international trade, then there was justification in the NITs' argument that IP protection did not belong in the GATT, since the GATT was unreservedly about the promotion of international trade. It also appears unreasonable that LDCs in particular, should commit scarce financial and administrative resources to create a functioning enforcement infrastructure since infringing goods did not *often* enter into international trade. Nonetheless, the Community delegate sustained that in addition to internal procedures, border enforcement measures did remain indispensable since they were an effective means of controlling infringing goods as they crossed borders through customs authorities (ibid) despite his admonition that border procedures ran a greater risk of giving rise to obstacles to legitimate trade (MTN.GNG.NG11/13: 16), again triggering reservations about the utility of the TRIPS/enforcement process in the UR. Therefore, the problem appeared to be more an issue of protecting and enforcing IPRs than it was to promote international trade.

A fundamental aspect of 'internal mechanisms' stipulated that all parties to an agreement should have judicial procedures which conformed to the rules of due process for the protection and enforcement of IPRs, including access to courts, the right to be heard, the right to defend one's rights, and open and transparent decision-making (MTN.GNG/NG11/12: 10). Major emphasis was placed, *inter alia*, on effective prevention and deterrence (MTN.GNG/NG11/W/14/Rev.1: 12-13); as well as civil and administrative procedures and remedies; and criminal procedures and sanctions, including imprisonment and monetary fines (MTN.GNG/NG11/W/31: 6).

India subsequently stated that enforcement at the border to check for imports of counterfeit goods through intervention by customs authorities can be regarded as a trade-related issue since it directly impinges on international trade. However, "such measures can easily become arbitrary

and unjustifiable barriers to international trade” (MTN.GNG/NG11/W/40: 2). India continued that “on the other hand, internal enforcement of intellectual property rights is not related to international trade in merchandise. Therefore, any set of rules that might be evolved on the subject cannot be linked to the GATT system” (ibid). India further asserted that it is not always expedient or feasible to provide separate procedures for internal enforcement of any particular category of rights; that it is not realistic to expect that changes can be brought about in the administrative and judicial systems of participants for the sake of enforcement of one category of rights; and that it was for this reason that the TNC text of April 1989 stipulated that account shall be taken of differences in national legal systems (ibid: 3).

India further maintained that it is only through their normal administrative and judicial systems that governments, particularly of developing countries, are in a position to provide for enforcement of IPRs; and that it shall not be expected of such countries to allocate additional resources establishing a separate machinery for the enforcement of IPRs (ibid: 4[e]). Similarly, in a 12-member DC communication<sup>33</sup> (MTN.GNG/NG11/W/71), it was maintained that while enforcement shall include administrative and civil remedies and, in appropriate cases, penalties under criminal law, these “shall be provided in consistency with each Party’s legal and judicial systems and traditions and within the limits of its administrative resources and capabilities” (ibid: Chapter VII, 2). These assertions came as a result of proposals by the core countries which appeared to have disregarded the practical limitations on the existing legal infrastructures of many participants, an absence DCs saw as much inequitable as it was unrealistic and disrespectful of existing domestic legal structures and judicial practices (MTN.GNG/NG11/27: 4). Some countries, especially those with long borders, were particularly concerned about the burdens that rules on border enforcement might put on their customs services, for instance, in terms of providing the expertise necessary to identify infringing products, and the facilities

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<sup>33</sup> This group includes Nigeria and Tanzania from sub-Saharan Africa, the first recorded input from any country in the region.

necessary for stocking such products where custom clearance had been suspended (MTN.GNG/NG11/15: 34).

The NET's proposals were categorically unidirectional, consisting of an accusatory infringement formula aligned to the belligerent methods of realist politics seen in Chapter I. The assumption was based purely on a belief that the only rights to be protected were those of IP owners who were invariably the victims of a flagrant disregard for their intellectual efforts. With the exception of a few scant acknowledgements by the EC on the possible rights of defendants in an infringement case, discussions almost exclusively concentrated on the 'rights' of IP holders. The EC reasoned for instance that a defendant wrongly restricted due to an abuse of enforcement proceedings would have the right to claim compensation (MTN.GNG/NG11/13: 16). However, in its submission on enforcement, it maintained that 'signatories may provide for the possibility that these parties may in appropriate cases *claim compensation from the authorities*' MTN.GNG/N11/W/31: 6) (emphasis added). All accountability was removed from IPR holders, despite the NETs' stipulation that a right holder shall be entitled to obtain adequate compensation of the injury he has suffered from the infringer, and to recover the costs reasonably incurred in the proceedings (ibid: 4). According to the NETs therefore, while the right holder is entitled to compensation from the alleged infringer, someone wrongfully enjoined *may* be compensated by the authorities depending on the circumstances. These countries were silent on issues regarding the accountability of right holders who instigate frivolous claims against legitimate traders.

Incensed, a participant exclaimed that the responsibility to prove infringement should fall on the right holder; that not only should the right holder bear responsibility in respect of direct damages to legitimate interests, but also, in respect of such matters as damage to reputation (MTN.GNG/NG11/13: 19). The positive aspect in light of such criticism was the result of Article

48 of TRIPS on “Indemnification of the Defendant”.<sup>34</sup> However, the rejoinder to this article can be that such an offence should also carry a criminal penalty as well as an administrative fine in much the same way that defendants are treated when found guilty of IP infringements.<sup>35</sup> The focus on enforcement lay almost exclusively on upholding the benevolence of right holders and corroborating the culpability of others, a prejudiced assumption with obvious practical policy implications.

### **3.5 Conclusion: Hegemony or Domination?**

The US-based National Law Center for Inter-American Free Trade asserts that ‘the historical record in the industrialised countries, which began as developing countries, demonstrates that intellectual property protection has been one of the most powerful instruments for economic development, export growth, and the diffusion of new technologies, art and culture’ (Chang, 2002: 2). This assertion comes despite the fact that the US acceded to the Berne Convention in November 1988, more than a century after the treaty was adopted. As if addressing the Center's claim, Scherer confirmed that “In the US, we are lovely hypocrites. When we were a developing nation, we systematically appropriated other people's technology. So that was the way we developed, but we don't want other people to appropriate our technology in order to develop. But of course we have no historical memory, so we don't even know we're being hypocritical”.<sup>36</sup> Scherer's view, a “kicking-away-the-ladder” account, resonates with DC views.

Notwithstanding the Center's ahistorical appreciation of the reasons behind America's burgeoning economic performance, the general thrust of the TRIPS negotiations contained a

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<sup>34</sup> Article 48 specifies that the judicial authorities shall have the authority to order a party at whose request measures were taken, and who has abused enforcement procedures, to provide to a party wrongfully enjoined or restrained adequate compensation for the injury suffered because of such abuse; and to order the applicant to pay the defendant's expenses, which may include appropriate attorney's fees.

<sup>35</sup> Notwithstanding, Article 53 on “Security or Equivalent Assurance”, requires the applicant to provide a security or equivalent assurance sufficient to protect the defendant and the competent authorities and to prevent abuse; but that such security or equivalent assurance shall not unreasonably deter recourse to these procedures.

<sup>36</sup> Charan Devereaux interview with Harvard Professor , F.M. Scherer in 1998. See, Devereaux, 2006: 45.

notable strand of the imitative logic in modernization theory, the harbinger of the neoliberal tradition. According to one such argument, the delay in extending full patent protection in certain sectors of industrialised countries was because it took time to learn from experience, the benefits of patent protection sufficiently to overcome sectoral interests that might be opposed; and that “developing countries were now in a position to profit from the experience which was gained at some expense in industrialised countries” (MTN.GNG/NG11/20: 32).

The arguments were therefore presented as consistent with the development objectives of developing countries in general, and their public interest concerns in particular (see also, Abbott, 1989: 698-99; Richards, 2004: 3). Exposing the inconsistency of these arguments, a participant recalled his country’s experience where high levels of patent protection had been in force for more than a century, but which had done nothing to promote economic development.<sup>37</sup> On the contrary, development had considerably accelerated subsequently in sectors where protection had been reduced (ibid), highlighting the view that there was no matter-of-fact causation between increased patent protection and enhanced development (Abbott, 1989: 699).

Nonetheless, what the narrative analysis in this chapter confirms is that developing countries mounted considerable, reasoned opposition against the more powerful North. Submissions seeking balance and a consideration for their concerns were tabled by India, Brazil, and Peru among others; as well as notable statements made during the course of the negotiations by participants representing developing countries in general, as in the case of India, and those representing LDCs, as did Bangladesh. From this general picture, one can also affirm an acceptable level of participation from developing countries with approximately twenty formal submissions, while developed countries made approximately 41 submissions. While participation based on formal submissions may have been on an approximate 2:1 ratio

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<sup>37</sup> For an alternative view, see Lee and Mansfield, 1996.

representing developing and developed countries respectively, it is not entirely unrepresentative since developing countries usually lack the technical capacity necessary for success in such negotiations.<sup>38</sup>

Despite the fierce opposition by developing countries in every issue area under discussion, with the exception of the less-than-characteristic resistance in the area of enforcement (which may have been due to capacity issues, negotiation fatigue, and pipeline concessions in other areas), as demonstrated in Chapter II, the resulting TRIPS Agreement at the end of the Round tilted manifestly towards the interests of the NETs and their corporate actors.<sup>39</sup> This result lends further support to the claim that by virtue of their peripheral standing in the GPE, developing countries have been assigned a mere rule-taking dependability that propels their persistent development challenge. From the narrative, two conclusions remain striking, that the system of IP convened through the UR was categorically re-written by the industrialised North, making such countries the effective rule-makers of the system; and that the high degree of consistency between the statements and submissions by the US, Japan and the EC (in some cases, the texts were very close or identical) (UNCTAD-ICTSD, 2005: 578), and the “Basic Framework” tabled by the transnational business coalition of the same jurisdictions, suggests the centrality of corporate dimensions of power in the GPE. One also recalls that Pfizer’s Pratt, by occupying the helm of the US President’s ACTPN, served as adviser to the official US delegation involved in the negotiations (Sell, 2003: 105).<sup>40</sup>

Pivotal from the texts and proceedings of the negotiations however, was the sheer absence of a submission/proposal or explicit standpoint that was specifically from sub-Saharan Africa (with the exception of Nigeria and Tanzania in the 12-strong group submission in May 1990)

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<sup>38</sup> Negotiating capacity is taken up further in Chapter VI.

<sup>39</sup> See Finger and Nogues 2002 for an overview of the unbalanced outcome of the UR and what the WTO can do to address this imbalance.

<sup>40</sup> See also Pfizer Inc online at [http://www.pfizer.com/about/history/edmund\\_pratt.jsp](http://www.pfizer.com/about/history/edmund_pratt.jsp)

(MTN.GNG/NG11/W/71),<sup>41</sup> ironically the most HIV/AIDS indebted continent and arguably the most to lose in an ill-conceived IP package affecting pharmaceutical patents. The dire capacity shortfalls of such countries in the TRIPS negotiations notwithstanding, and their probable absence due to resource constraints, one can reasonably argue that some of the more prominent developing countries, such as India and Brazil, sufficiently articulated the views of the entire developing world at the time. Importantly also, SSA countries have generally tended to subsume their interests under those of the broader group of developing countries (Blackhurst, *et al*, 2000: 494). However, strictly on the basis of the tests examined thus far, just how developing countries acquiesced to the very framework they rejected remains mysterious. They remained indignant throughout these negotiations and expressed their views that the framework being proposed was categorically asymmetrical and unjust. This is crucial particularly with reference to the framing of the negotiations within a Coxian extrapolation of Gramsci's concept of hegemony.

Gramsci maintained that the supremacy of a social group manifests itself in two ways: as “domination” and as “moral and intellectual leadership”. The highly fractious and tumultuous nature of the negotiations presented in this chapter therefore substantiates a major contradiction, that TRIPS was not concluded on the basis of moral and intellectual leadership. The high intensity of the opposition by developing countries against the Northern IP agenda suggests that they never internalised that the framework being proposed was welfare-enhancing. In fact, they argued the contrary throughout the negotiations. However, by substantiating that there was no moral and intellectual leadership, the chapter merely *implies* that TRIPS was concluded coercively, but it does not demonstrate this. Therefore, while the chapter was able to confirm the final component of Hypothesis I, that industry secured its demands from TRIPS *despite* the high intensity of the conflict characterising the negotiations on patents; and that the 'agreement' was not the result of moral and intellectual leadership, it merely infers the 'domination' aspect of

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<sup>41</sup> At the very last meeting in December 1991, an African representative spoke on behalf of the region, however, the minutes do not indicate what was said. See MTN.GNG/TRIPS/6: 2.

Gramsci's hegemony. The next chapter will therefore focus on the methods and strategies used to secure the acquiescence of the developing world, paying specific attention to what happened at pivotal moments in the Round, and who played what role/s.

## Chapter IV

### Consensus Formation in the TRIPS Negotiations: Agendas, Agents and Turning Points

#### 4.1 Introduction

Chapter III unpacked the making of patent policy in the UR with a narrative analysis of the high incidence of opposition and conflict characterising the TRIPS negotiations. So contentious were these negotiations, that the competing demands from the major North/South compositions were, at best, mutually inconsistent. Utilising Cox's extrapolation of Gramsci's concept of hegemony as a framing device to examine the contradictions within the prevailing historical structure developed in Chapter I, the last chapter was able to substantiate that industry's TRIPS victory (Chapter II) was not the result of Gramsci's notion of moral and intellectual leadership. On the contrary, developing countries expressed indignation throughout the negotiations, asserting that the patent framework proposed by the industrialised countries on behalf of the TDI and other high-technology industries, was morally indefensible by virtue of their underdevelopment. However, moral and intellectual leadership is one component of Gramsci's hegemonic model, the other being domination. To the extent that the latter prevailed, hegemony would be flimsy or non-existent. The current chapter assesses the role social, cultural and economic forces play in constituting and reconstituting the established order (Falk, 1997: 43) by examining further contradictions in the making of the framework that prevailed at the end of the UR.

The first part of the chapter looks at the first milestone of the Uruguay Round, the December 1988 Mid-Term Review and its corresponding text. The second part looks at the subsequent landmark, the Trade Negotiations Committee (TNC) Meeting of April 1989, and its resulting 'April Declaration'; while the third section focuses on the highly contentious road to the 1990 Brussels Ministerial. This Ministerial should have coincided with the end of the Uruguay Round,

slated for conclusion within four years of commencement.<sup>1</sup> However, as a result of the level of opposition characterising the negotiations, the last Draft Final Act by the Chairman of the TNC, GATT Director General (DG) Arthur Dunkel, was not tabled until December 1991, which was itself the subject of major controversy. Negotiations did not end until December 1992, further accentuating the negotiating atmosphere. Before concluding, the chapter critically analyses Dunkel's two Draft Final Acts, by focusing on their content and the reactions to them. The chapter builds on the last by mapping a trajectory of pivotal moments in the Round marked by clashes and high uncertainty, necessitating an unprecedented build-up of consensus formation strategies by the industrialised North, particularly the US; the GATT Secretariat and its then DG; as well as the Chairman of the Group, Ambassador Lars Anell of Sweden.

#### **4.2 The Montreal Ministerial Meeting of December 1988<sup>2</sup>**

In July 1988, prior to the Montreal Mid-Term Review, DCs had sensed that the approach being proposed by industrialised countries was desirable on the grounds that the alternative would be a proliferation of unilateral or bilateral actions (MTN.GNG/NG11/8: 31). These NITs maintained that acceptance of such an approach would be tantamount to creating a licence to force, in the name of trade, modifications in standards for the protection of IP in a way that had not been found acceptable or possible so far in WIPO (ibid). Brazil subsequently informed the Group that on 20 October 1988, unilateral restrictions had been applied by the US to Brazilian exports as a retaliatory Measure in connection with an IP issue; that this type of action seriously inhibited Brazil's participation in the work of the Group, since "no country could be expected to participate in negotiations while experiencing pressures on the substance of its position" (MTN.GNG/NG11/10: 27). The Brazilian delegate maintained that such action by the US constituted a blatant infringement of GATT rules and was contrary to the Standstill commitment

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<sup>1</sup> This time-frame was stated in the opening remarks of the Punta del Este Declaration.

<sup>2</sup> Hereinafter, Montreal or Montreal Mid-Term Review.

of the Punta del Este Declaration. “The United States action was an attempt to coerce<sup>3</sup> Brazil to change its intellectual property legislation, and furthermore represented an attempt by the United States to improve its negotiating position in the Uruguay Round” (ibid). A US delegate countered that the measures had been taken with regret and as a last resort after all alternative ways of defending legitimate US interests had been exhausted; and that the US further believed that the adoption of effective patent protection was in Brazil’s own interest (ibid: 28).

The US had therefore applied its strategy of coercive unilateralism against one of the two most important players championing the cause of the South in the TRIPS negotiations, the other being India. Apprehensive about the resistance of this dominant Southern duo, the United States sought to utilise its market size as a bargaining tool to secure changes to national IP regimes. It therefore decided to impact the more powerful of the two at the time, thereby indirectly admonishing India and the entire coalition against strengthened IP rules, as well as their domestic export constituencies who would be affected by US decisions to restrict imports. Moreover, because Brazil and India appeared to be collaborating extensively in maintaining a united front, a resulting strain on Brazil's economy would likely affect their cooperation. However, since market opening and closure have been treated as the currency of trade negotiations in the post-war period (Steinberg, 2002: 347), the move to place restrictions on Brazilian exports by the largest consumer market in the GPE should not have been entirely unanticipated. Brazil was also the regional leader in South America and disciplining it would send an unequivocal warning to other South American countries (Drahos with Braithwaite, 2002: 136), including Argentina, Chile and Peru who were also active participants in the negotiations. This would mark the start

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<sup>3</sup> The behavioural literature on deterrence and compellence strategies of coercive bargaining (particularly in the area of security studies) is vast. Such strategies use threats to persuade an actor to carry out, or refrain from carrying out, a specified behaviour. Successful threats must hold out the prospect of enough loss to make compliance more attractive than non-compliance. This first US strategy clearly falls within this category. See Lebow, 1998 for an appraisal.

of a series of coercive strategies aimed at compliance with the US private-sector envisioned GATT IPP.

Developing countries did however appear resolute in their central demands that TRIPS reflect their development needs, thereby balancing rights with obligations; and that it disallow negotiations on substantive law, since this was the rightful domain of WIPO-administered treaties. Consequently, implying a no-consensus scenario, the Chairman of the Group, Lars Anell, conceded three weeks before Montreal that he did not believe that there existed as yet, any text that would immediately command general acceptance; that he had taken into account the need to reconcile diverging views in the Group; but that the extent of the divergences was such that the points made were often mutually inconsistent (MTN.GNG/NG1111: 2). At this mid-November 1988 meeting, Anell introduced the text of his report to the GNG (Group of Negotiations on Goods), stressing the need for guidance from Ministers on the future conduct of negotiations to be clear and well understood by all participants, intimating that an understanding of the conduct of negotiations had eluded some participants. The situation immediately pre-Montreal from the Chairman's point of view can therefore be characterised as acutely discordant, with some participants remaining uninformed about the proper conduct of negotiations.

The Chairman indicated that his report had been drawn on the basis of informal consultations, suggesting "the common ground in which a compromise could be found" (ibid). For the first time in the negotiations, there is evidence of a consensus formation strategy based on the medium of informal consultations. By their very informality such consultations are not a product of open deliberation, but are specifically designed to manufacture consensus, either by coercive or asymmetrical contracting methods (Steinberg, 2002: 348-9). This is done by partitioning the group of opponents, and then utilising strategies to effect their acquiescence. By their very nature, tactics utilised in these 'informal' sessions, as well as the content of proceedings, are not

awarded the transparency of transcription, making it impossible to assess what goes on informally. Nonetheless, the text of the report circulated in the Group by the Chairman (based on informal consultations) was greeted with the level of division that had theretofore characterised the negotiations, whereby textual alterations were suggested under most areas under deliberation, including the negotiating objective; the trade-relatedness, or lack thereof, of substantive standards of IP; GATT/WIPO suitability; the legitimate interests of importers and exporters of technology; S&D for DCs; the appropriateness of fundamental GATT principles; and dispute settlement (MTN.GNG/NG11/11).

At the TRIPS working group in Montreal (chaired by Turkey's Minister of State, Yusuf Ozal) an informal draft paper prepared by Hong Kong and Australia (strongly supportive of US positions) was presented by Minister Ozal as a non-paper (Raghavan, 1990: 260). The draft was subsequently countered by an Indian proposal which argued that the issue of establishing substantive norms, including dispute settlement, should be remitted to WIPO, UNCTAD and UNESCO where one or another aspect of these issues was already under consideration (ibid). In additional informal consultations, or 'green room' discussions (ibid), the Indian paper was presented neither by Ozal, nor by the Secretariat, but nonetheless tabled at the insistence of India's Minister (ibid). The paper had however been informally circulated by India (ibid) which meant that despite the fact that it was not granted formal presentation in the green room, other participants were well aware of its existence. The Ozal compromise was consequently rejected by virtually all DC representatives, who fully supported the Indian alternative (ibid). The issue was therefore referred back to the Ozal group, but no compromise could be found between the two diametrically opposing viewpoints (ibid). Despite the high intensity of these divergences however, Ministers agreed in the Montreal report on TRIPS (MTN/TNC/7(MIN): 21-24), that further work was needed in the following areas:

- (a) The application of basic GATT principles and mechanisms: national treatment, non-discrimination, transparency and MFN;
- (b) GATT commitments to provide effective and appropriate means for the protection and enforcement, internally and at the border, of intellectual property rights;
- (c) The normative specification (availability, scope and use of IPRs) of these commitments in the form of references to existing or new norms or standards and of the elaboration within GATT of norms and standards, principles and indicative lists;
- (d) Effective multilateral procedures for dispute settlement, including commitments to bring the use of national trade policy instruments in this connection under multilateral discipline.

The Ministers' accord in December 1988 to work on a negotiated solution to points 'A'-'D' above demonstrates the extent to which substantive standards and enforcement provisions of IPRs, to the likes of the NETs, were an imminent *fait accompli*. The Chairman had therefore attained his wish to make the conduct of future negotiations unambiguous to all participants. Points 'B' and 'C' effectively cemented the transnational private sector's agenda onto the multilateral front, providing it with added legitimacy since the call came from ministerial level. Point 'C' categorically removed all doubt in the minds of DC delegates that substantive IP standards could be elaborated in the GATT. There was however, a noted absence: not one of the points above dealt with the concerns of the developing world, that in fact, while point 'A' appeared in complete conformity with fundamental GATT principles, it was the precise declaration denying S&D to developing countries in the way they had envisaged, that is, a system of differential standards justified on the basis of levels of development. Point 'D' essentially removed IP-related dispute settlement from the ICJ and placed it firmly under the remit of GATT. So resolute was this Ministerial declaration, that it did not appear necessary for another formal Group meeting before the April TNC the following year, although points 'A'-'D' were reviewed as areas needing further work. The speculation here is that the Group met strictly on an informal basis in preparation for the April meeting.

### 4.3 The April 1989 TNC Meeting

In April 1989 the TNC met again in the hopes of reaching agreement in the remaining four areas of negotiation: agriculture, intellectual property, textiles and safeguards (Stewart, 1995: 2268).<sup>4</sup> Success in the latter two appeared contingent upon reaching agreement in agriculture and IP, viewed by many as the two most contentious and difficult areas on the agenda (ibid, taken from USTR). Despite the urgency, the process after Montreal<sup>5</sup> can be characterised partly as one of disengagement of Southern capitals to follow up on Montreal and on the work of their diplomats in Geneva. The capitals continued to treat the Uruguay Round as just another trade issue, needing low political priority, either nationally or collectively. In Geneva the South continued to resist the Northern IP agenda, however ill-supported by political elites at home.

DG Arthur Dunkel decided to hold 'green room type' consultations between January and March 1989 in order to promote agreement in each of the remaining four areas, and if necessary, present a paper of his own. However, Dunkel too saw virtue in the industrialised countries' (IC) conception of how the IP regime should operate. While holding initial rounds of consultations in each of the four areas and appearing responsive to the concerns of DCs, Dunkel also paid several visits to Washington and Brussels and impressed upon the US and the EC, the need to arrive at a *modus vivendi* in Agriculture amongst themselves. His approach reflected the view that once the US and EC agreed, it could be forced on others; that once the Agriculture issue was settled, the broad front of DCs, including the Latin American Cairns Group members (on Agriculture) which had collaborated with others at Montreal (over Textiles and TRIPS), would dissolve and agreements could be reached in all other areas.

However, DCs met simultaneously in Talloires, France, where it was felt that the TRIPS issue was one in which they had a common interest and where there was a broad unity among ICs

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<sup>4</sup> See Devereaux's (p. 58) quote from then USTR, Yeutter on the importance of all these areas.

<sup>5</sup> The next three paragraphs are based on Raghavan, 1990: 265-81.

aimed against DC concerns. Further meetings in Talloires and Geneva resulted in a common position which received broad endorsement from the informal Third World Group in the GATT. This common position was presented to Dunkel as a contribution from DCs aimed at promoting consensus. It provided that the Negotiating Group shall identify: circumstances in which measures 'necessary' to secure compliance with laws and regulations relating to patents ... shall be considered to constitute a means of arbitrary or unjustifiable discrimination and/or disguised restriction on international trade; practices in arrangements to assign IPRs which may result in distortions or impediments to international trade.

To meet the viewpoints of ICs on the question of issues relating to substantive norms, their enforcement and dispute settlement, the Third World paper provided that the actions on TRIPS in the Uruguay Round would be complemented by time-bound "parallel actions in the competent international organisations such as WIPO, UNESCO and UNCTAD". These complementary initiatives were to address: (i) further specification of appropriate norms and standards covering the availability, scope and use of IPRs; (ii) appropriate disciplines to prevent abuse of IPRs; (iii) elaboration of procedures in WIPO for dispute settlement; (iv) working out disciplines in UNCTAD on related corporate practices. Work on these was to proceed "with due regard to developmental, technological and public interest needs of countries, in particular developing countries".

While there was a concerted stance from developing countries on the essence of an eventual TRIPS accord, there appeared to be a considerable level of 'easing-off' on the initial demands. Important here was the apparent compromise on substantive norms in point (i). Also, while developmental and public interest issues were mentioned as a category, there was no attempt to state matter-of-factly what this meant in ways that had been enunciated during the formal negotiations, as the industrialised countries had managed to articulate and justify their concerns.

Arguably also, the manner in which the paper stated the core concerns of the group seemingly took on the characteristic of an appendage, as opposed to that of a core demand.

During his ongoing consultations, Dunkel was presented with the Third World paper, expounded and presented by Egypt, and supported by about 10-12 developing countries (Raghavan, 1990: 268). Dunkel, the US and other ICs were reportedly incensed by the level of Southern mobilisation, while Dunkel virtually ignored the contents of the paper (ibid), and produced his own text which was later amended by Brazil, with the support of the informal Third World Group (ibid: 270). Arguably more important in the run-up to the April TNC was the level of pressure mounted in the capitals of key developing countries in a technique observers have coined the “disinformation campaign” aimed at destabilising the unified front on TRIPS that appeared to typify the Southern position in Geneva until then (ibid).

The message went out from the Secretariat to India that India was now isolated on the TRIPS issue (Drahos with Braithwaite, 2002: 135, taken from Raghavan 1989: 15). The reverse was in fact true (ibid). What armed the Secretariat’s divisive tactic was, in the words of a former Indian official to the GATT, “the impression went round that the show of firmness that the negotiators were making in the period from September 1986 to December 1988 was only a façade not backed by a firm political support at the capital. No negotiators can hope to muster support from other countries on difficult issues involving disagreement and even confrontation with major powers, if those countries suspect the inherent strength of the stand or even the sincerity of its propounders” (ibid). “In international negotiations, trust among allies is the key to success. Without it, cooperation dissolves rapidly” (ibid). The GATT Secretariat was therefore projecting the logic echoed in much of the negotiations by ICs that the effective protection and enforcement of IP was in fact in the self-interest of all involved. It therefore intervened and pioneered the ‘disinformation campaign’ to sow disarray and confusion in the ranks of the antagonists, as

observed by Gramsci. We recall from the 'Argument in Context' that GATT was convened as a framework to eliminate distortions and impediments to international trade, and since non-existent and ineffective IP laws have been shown by the prevailing logic as *de facto* trade discrimination, the Secretariat, one could argue, was simply acting in accordance with its mission.

The campaign funnelled by the Secretariat dealt a serious blow to what appeared to be a unified front as DC delegates became increasingly wary of India's commitment (Ibid). A series of occurrences would increase the level of mistrust: at a crucial time when India should have been communicating with the capitals of other developing countries, she did not; cooperation between India and Brazil began to drift as Brazil became worried about the strength of Indian support; in early April, India failed to attend a crucial Third World Group meeting (ibid). The role of the Secretariat as India's 'informant' that she was indeed isolated on TRIPS; Brazil, the *other* major player for the South (and incidentally the one against whose exports the US had retaliated the previous October) becoming distrustful of India's commitment; the lack of follow-up from capitals after Montreal and their treatment of Uruguay as just another trade issue undeserving of high political priority; and India's non-attendance at a crucial meeting, were all symptomatic of an irreparable breakdown and therefore, an ominous endpoint.

Partially explaining the disarray is the fact that India's GATT negotiator, S.P. Shukla (1984-1988), who had played an important role in the formulation of the Indian stance on new themes and in mobilising support among like-minded DCs, had been reassigned to India to take up a post as Secretary to the Government in the Ministry of Health and put in charge of family planning. His post in Geneva had not been filled at the time of the April meeting, and the Permanent Secretary of the Commerce Ministry, who came from New Delhi to negotiate, did not manage to establish that personal rapport and confidence among other DCs that negotiators had managed to establish over a long period (Raghavan, 1990: 281). What this does not explain

however, is whether ICs, or the Secretariat, or both, could have facilitated Shukla's departure. All of these events explain why on the one hand developing countries mounted such an offensive against the Northern IP agenda, and on the other hand, succumbed so spectacularly to the precise agenda they opposed. However, the two events which may have been most decisive were the decisions to tackle the two heavyweights of the South: the Secretariat's tackling of India; and the US move to retaliate against Brazil's exports. The blows to these two Southern leaders ensured that the developing world would be without leadership, and therefore, without guidance.

On 5 April, when the high official level TNC meeting formally opened, a number of participants complained about the lack of transparency in the processes for consultations and negotiations (ibid: 269). Among these were Tanzania's Amir Jamal and Colombia's Felipe Jaramillo (ibid). These complaints resulted in the announcement that the TNC would meet every morning informally at the level of heads of delegations to be briefed on progress reports (ibid). In the height of the TRIPS negotiations, Dunkel produced a second text (without any acknowledgement of Brazil's amendment to his first text encountered earlier) which was more starkly similar to the US-EC views than the first (ibid). It was clear at this point that DCs, already in serious disarray, were up against the ICs and their private sector coalition, as well as the GATT Secretariat and its DG. As such, a large number of developing countries were more opposed to the new Dunkel text, thereby prompting an exclusionary response, as the invited participants to the 'green room' consultations were restricted, with some small countries like Tanzania, which were normally invited, kept out altogether (ibid). This would enable an exclusionary decision-making process with an increasingly limited number of countries 'invited' to conclaves by the DG (ibid: 269). The negotiations became largely a US-EC vs. Brazil-India affair, however, the delicate relationship between the latter two had persisted, as each was unsure of the other's position (ibid: 271), and especially since the Commerce Secretary uprooted from India was in no position to establish a genuine working relationship with Brazil. Coupled with that, the delegates of many

other DCs who voiced opposition against the US-EEC demands and the Dunkel texts at their informal Third World Group meetings, were not allowed to actively participate in Dunkel's consultations, thereby sending the signal to India and Brazil that they were alone against the coercive power of the two major trading blocs (ibid: 270). There appeared to be no way out.

With the odds stacked up so significantly against developing countries at this crucial point of the Round, the April TNC agreed that future negotiations should cover standards concerning the scope and use of IPRs and the means of enforcing them (Stewart, 1995: 2269). In 'The Declaration of April 1989',<sup>6</sup> Ministers specifically agreed in paragraph "4" that the scope of future IP negotiations should encompass:

- (a) The applicability of the basic principles of the GATT and of relevant international intellectual property agreements and conventions;
- (b) The provision of adequate standards and principles concerning the availability, scope and use of trade-related intellectual property rights;
- (c) The provision of effective and appropriate means for the enforcement of trade-related intellectual property rights, taking into account differences in national legal systems;
- (d) The provision of effective and expeditious procedures for the multilateral prevention and settlement of disputes between governments, including the applicability of GATT procedures;
- (e) Transitional arrangements aiming at the fullest participation in the results of the negotiations.

Ministers also agreed in paragraph '5' of the April Declaration that in the negotiations, "consideration will be given to concerns raised by participants related to the underlying public policy objectives of their national systems for the protection of intellectual property, including developmental and technological objectives". Noteworthy here is the unambiguous manner in which the focus of the negotiations had tilted further in favour of the NETs, only acceding to a

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<sup>6</sup> Hereinafter the April Declaration, this document is reprinted in Beier *et al*, 1988, p. 405.

*consideration* of the public policy demands of the developing world at ministerial level. Also noteworthy, is the rhetoric espoused in bullet point ‘E’ that transitional arrangements were a means to an end of participation in the results of the round. Notwithstanding, as seen in Chapter III, DCs continued to mount an offensive against the establishment of a deepening and widening space for IP protection and enforcement, however uncoordinated. Nevertheless, some significant observations in the texts of the negotiations reveal further clues that arguably explain how and why developing countries eventually acquiesced to a legal framework which can be hailed as highly substantive in character (notwithstanding the single undertaking); with a compatible enforcement component; and a dispute settlement provision which has the propensity to legitimise a recourse to trade retaliation by industrialised countries which deem a country’s IP framework unfair and discriminatory to IP interests.

#### **4.4 The Road to Brussels**

Between May 1989 (the immediate post-April TNC period) and November 1990 (immediately leading up to the Brussels meeting in December), the TRIPS Negotiating Group held a total of 17 formal negotiating sessions, five more than the previous two years of the negotiations, suggesting the intensity of the post-TNC period. The negotiations on TRIPS are often said to have properly begun in the second half of 1989 when a number of countries made proposals, or in the first part of 1990 when five draft texts of an agreement were submitted to the Negotiating Group (Drahos with Braithwaite, 2002: 136). During those sessions, the major North/South compositions recalled whichever component of the April TNC Declaration that most suited their demands. ICs could now demonstrably maintain that the Punta del Este Declaration provided the basis for a discussion on substantive questions in the Group since this was firmly supported in paragraph 4(b) of the TNC decision as an area which needed further work (MTN.GNG/NG11/12: 2). DCs latched onto their calls for a balanced outcome in which there would be “no winners or losers” and which would reflect a strengthened confidence in the

multilateral system (ibid). Most importantly for the latter, every opportunity was seized to salvage paragraph '5' of the TNC decision to elevate its status as the defining feature of the Round, despite the fact that the Declaration only called for a *consideration* of the public policy concerns of developing countries.

Still uneasy about the continuing level of 'resistance' in spite of the April decision, the United States became more aggressive by turning the contents of its 1988 Trade Act into market action in order to effect the kinds of extraterritorial changes it deemed justifiable. At the Group's first July meeting, a number of participants stated their deep concern about 'certain' decisions taken by the US under Section 301 of its Tariff Act, in particular, the listing under "special" Section 301 relating to IPRs of countries on a "priority watch list" (MTN.GNG/NG11/13: 4). These participants insisted that such US actions were jeopardising the work of the Group and threatening to wreck the Uruguay Round as a whole; that such actions were also inconsistent with the compromise reached in April to enter into substantive negotiations in the Group (ibid). Referring to the Section 301 threat in the Group's subsequent July meeting, India's representative recalled the serious reservations of his delegation about the relevance and utility of the negotiations as long as measures of bilateral coercion and threat continued (MTN.GNG/NG11/14: 5). It was apparent from this statement that India had become concerned about suffering a similar fate as did Brazil nine months earlier.

Despite this well-founded fear, it was precisely in the immediate post-TNC context that India tabled its most comprehensive, critical and pro-development submission (MTN.GNG/NG11/W/37). Among some of the central themes in the document were an emphasis on the technological and developmental components contained in paragraph "5" of the TNC decision; that negotiations should be restricted specifically to trade-related aspects of IPRs as opposed to the automatic assumption in most proposals that all aspects of IPRs were trade-

related; that specifically, only restrictive and anticompetitive practices of the owners of IPRs can be considered trade-related as they alone distort trade. Therefore, while the relationship between India and Brazil may have soured by this time, and the chief Indian delegate may have been removed from Geneva, there still appeared to be a degree of determination from India to continue to defend its alternative vision of IP protection. This was of course in the Indian national interest since India, as did Brazil and a handful of other large developing economies, had developed reputable generics industries, and therefore had an interest in preserving the pre-existing framework. One can argue therefore that in the face of such hostility and threat characterising the trading system in the post-TNC context, India could only have persevered with its stance if it were acting, as realists would argue, in the national interest, and not as a symbolically benign power championing the cause of the developing world.

Re-reading the TNC decision in the context of the US threat, a participant referred to the structure within which commitments on standards and principles would lie, in particular, the provision of procedures for dispute settlement and dispute prevention as called for by paragraph 4(d) of the April TNC decision (MTN.GNG/G11/14: 7). He continued that dispute settlement provisions should not only encourage signatories to respect obligations but also provide effective protection against unjustifiable unilateral action; and that signatories should also undertake obligations to refrain from unilateral pressures on matters covered by the TRIPS Agreement (ibid). He expressed hope that the negotiations would not be adversely affected by recent US decisions to place countries on watch lists; and that the negotiations and their results would apply only if all participants participated willingly and freely accepted and applied the results (ibid).

As a result of the market access threats by the US under Section 301, and the extent to which such threats fell into the obvious category of “actions taken to improve one’s negotiating

position”,<sup>7</sup> DCs showed further resistance and reiterated their development orientated demands. ICs emphasised their belief that patent protection in their countries, including in sectors such as pharmaceuticals, had contributed to their development (MTN.GNG/NG11/14: 79.2). An EC representative said that this belief underlay the decisions that had been taken over the years by some Member States to increase the level of patent protection, and proceeded to cite the positive experience of ‘a’ Member State after having extended patents to pharmaceutical products (ibid). Another similarly affiliated participant questioned the belief that the general prices of pharmaceuticals would rise if product protection were to be granted by some countries since only 5% of medicines and drugs on the market were subject to patent protection (ibid: 79.3).

Another dominant debate in the post-TNC context was the relevance of basic GATT principles to an IP framework especially since some argued that IP had no direct relationship to international trade while others argued otherwise. Introducing yet another document, nearly two months from the first, India dealt with this subject (paragraph 4(a) of the TNC decision) on the applicability of basic GATT principles and of relevant international IP agreements and conventions (MTN.GNG/NG11/W/39). The document outlined the basic GATT principles and their applicability in the context of IPRs: MFN; NT; protection through tariffs; a stable basis for trade; transparency; and differential and more favourable treatment for DCs. It concluded that the stipulation inherent in the MFN obligation was specific to governmental measures at the border affecting international trade in like products, whereas IPRs were concerned with the protection of the rights of persons, thereby making GATT MFN rules inapplicable to IPRs (ibid: 4). With respect to National Treatment, the document again concluded that GATT NT rules were inapplicable because such rules applied to the treatment accorded imported products and like products of national origin, while IPRs pertained to the protection of the intangible rights of persons (ibid: 4).

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<sup>7</sup> Deemed illegal under the Punta del Este Declaration.

Where protection through tariffs was concerned, the paper argued that according to GATT Article XI on the general elimination of quantitative restrictions, where protection is to be given to domestic industry, it should be extended essentially through customs tariffs and not through other commercial measures, thereby making such a principle completely irrelevant to IPRs (ibid: 5). Similarly irrelevant was the provision for commitments by contracting parties to maintain tariffs at specified levels meant to stipulate predictability and stability requirements of rules governing trade (ibid: 6). On the subject of transparency<sup>8</sup> the paper continued that prompt publication of relevant laws and regulations has validity for the IP system so long as it is understood that the principle is confined to publication and is not extended to other obligations (ibid: 7). On these four basic GATT principles therefore, India concluded that just one had relevance to an international IP regime only insofar as it was confined to publication.

The only principle which India thought was fully applicable to a GATT IP framework was S&D for DCs. The submission argued at length (a familiar point seen in the last chapter) that the GATT Enabling Clause has provided that notwithstanding the provisions of Article I of the General Agreement, contracting parties may accord differential and more favourable treatment to developing countries, without according such treatment to other contracting parties (ibid: 8.2). India maintained that such a provision rested firmly on the recognition that there is a wide gap between the standards of living in developed and developing countries; that there is a greater urgency to promote the economic development of developing countries; that there is a need for individual and joint action to bring about rapid advancement of living standards in such countries; and most importantly, that developing countries could not be required to undertake obligations and make contributions which are inconsistent with their economic situation (ibid: 8.3). India maintained that it was not surprising that most GATT principles were not directly

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<sup>8</sup> A cardinal GATT principle requiring that laws, regulations, judicial decisions and administrative rulings of general application be published promptly to enable governments and traders to become acquainted with them.

applicable to IPRs because the GATT stood for free trade and fair competition whereas the essence of the IPR system was its monopolistic character (MTN.GNG/NG11/15: 3).

As anticipated, the document was in full accord with the main international IP agreements which recognize the freedom of Member States to attune their IP systems to their own needs and conditions (ibid: 10). The superiority of the existing IP conventions lay in the fact that they embodied certain basic principles, distinguishable from those of the GATT, which took account of the concerns of DCs. These principles included national treatment - which specifically envisages the equal treatment of nationals and foreigners - covering natural and legal persons as opposed to products, and extends only to the protection of IP and not its use; freedom of scope and level of protection of IP; balance of rights and obligations, also recognising the propensity for abuse when exclusive licenses are granted; the primacy of the public interest which legitimises measures by the state to protect the public, and also recognising that such measures may abridge the rights of IP holders; and lastly, the principle of non-reciprocity and independence of protection (ibid: 10-15), essentially the co-respective of the GATT Enabling Clause. India had essentially remade a case against a GATT IP regime, and restated, according to basic principles, the suitability and legitimacy of WIPO to administer international IP matters.

Despite this plea however, the fate of the South appeared to have been sealed. Negotiators subsequently debated the utility of fundamental GATT principles, in which context, a negotiator opined in that, assuming that there was no intention to derogate from existing obligations, it had to be realised that, irrespective of the content and forum of implementation of a final TRIPS agreement, the GATT national treatment and MFN, and the national treatment of international IP conventions already existed and would continue to apply. With respect to other principles enshrined in international IP conventions, ICs were largely silent, uttering when necessary, that the public interest of all countries was best served by providing for more effective protection as

this eliminates trade distortions (ibid: 19); and that while it was up to each country to determine what were its public interest needs, it had to be borne in mind that the assumption of international obligations with respect to nationals and products of other countries might also serve public interest needs (ibid), suggesting that the application of international obligations within domestic jurisdictions had a neutral impact across countries. Deliberations continued over elements of the TNC decision and the content of various draft proposals<sup>9</sup> of a TRIPS Agreement.

Significantly however, while India was mounting its offensive against the GATT, Brazil was seeking to overturn the Section 301 duties placed on its exports more than eighteen months earlier. It had succumbed to the pressure, and in June 1990 the President of Brazil announced that he would seek the legislation the US wanted (Drahos with Braithwaite, 2002: 136). On July 02, the increased duties were terminated by the USTR and in a subsequent meeting, the Brazilian negotiator told an Indian delegate, “I am only here to observe” (ibid). The US tactics worked, and Brazil effectively withdrew from the Round.

The Group met continuously, and in mid-July 1990, the Chairman held a meeting to discuss the content of informal consultations he had held since 9 July on the basis of a composite draft text he had circulated informally to the Group a month earlier (MTN.GNG/NG11/23: 1). As in the immediate pre-Montreal period, Anell expressed that while his informal consultations had been positive and were held in a very constructive atmosphere, they had not served to narrow significantly the gap on points where there were differences of substance (ibid: 2). He declared that “the number of such points, their complexity and the extent of the gap between participants in respect of many of them were such that the task of reaching an agreement in the Autumn remained a formidable one” (ibid). The Group then met again a week later to discuss an informal Chairman’s profile entitled, “Status of Work in the Negotiating Group: Report of the Chairman

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<sup>9</sup> These draft proposals were submitted individually by the EC, US, Japan, Switzerland and a contingent of 14 developing countries.

to the GNG” (MTN.GNG/NG11W/76),<sup>10</sup> a document which the Chairman claimed would simplify his earlier draft composite text.

One further point that captures the extent of difference was the Chairman’s statement that the profile was being submitted exclusively on his responsibility and did not commit any delegation (ibid: cover page). The profile was sectionalised into ‘A’ and ‘B’ approaches representing the preferred method of ICs and DCs respectively. Approach ‘A’ envisaged a single comprehensive TRIPS agreement covering all areas under negotiation, while ‘B’ provided for a separate part on counterfeit goods and sought to de-link trade secrets from the category of IPRs (ibid). The Chairman conceded that no point in the text was presented as having been agreed by all those participants associated with ‘A’ or ‘B’ approaches referred to (MTN.GNG/NG11/24: 2). Noteworthy, the cover-page of the document also explained why the Chairman felt it inappropriate to identify those issues which were the subject of objection, namely, that this would carry the misleading impression that other points were the subject of agreement (ibid).

Speaking on behalf of the 14 developing countries which co-sponsored the mid-May 1990 proposal (MTN.GNG/NG11/W/71), a negotiator remarked that in order to ensure that the Chairman’s text had a balanced structure, the principles proposed in the second part of the 14-nation suggestion should be incorporated in Part II of the Chairman’s text and not in the annex as at present (MTN.GNG/NG11/24: 3). This, the affiliate suggested, would put all proposals made on basic principles on an equal footing (ibid). This remark was the first in the context of formal negotiations which saw DC delegates question Anell’s objectivity. The principles enshrined in the DC proposal included the balance of rights and obligations; when formulating or amending national laws and regulations on IPRs, countries should be given the freedom to protect public morality, national security, public health and nutrition, and to promote the public interest in

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<sup>10</sup> Hereinafter the Anell Draft.

sectors of vital importance to socio-economic and technological development; protection and enforcement should be on the basis of mutual advantage of producers and users of technological knowledge; and the freedom of each party to take appropriate measures to prevent the abuse of IPRs (MTN.GNG/NG11/W/71, PART 11, Article 2[1-4]). Therefore, the very principles DCs stressed from the start of the negotiations, were precisely those annexed in Anell's text. Notwithstanding, the Chairman indicated in that meeting his decision to uproot the principles from its annexation into Part II of his text (MTN.GNG/NG11/24: 8).

Many participants at this July 20 meeting considered that the text of the Chairman's draft should reflect more fully the range of views expressed in the informal consultations (ibid: 4), further suggesting that the text masked the realities of fragmentation that hitherto characterised the negotiations. These participants voiced concerns that many of the paragraphs lacked precision and might be misinterpreted as implying that no divergences existed (ibid). Some delegations also indicated that there were specific points on which they were not happy with the Chairman's text, either because it omitted points to which they attached considerable importance, or because they felt that it had not reflected their position to their satisfaction (ibid: 7). The section of the Chairman's document covering patents consisted of sixty-two counts of bracketed language (MTN.GNG/NG11/W/76: 29-38) representing divergences between participants on the Chairman's choice of language. The two most highly bracketed sections were patentable subject matter and compulsory licensing, totalling twenty-three and eighteen respectively, again highlighting the centrality of conflict in the Group.

This meeting ended with an understanding proposed by the Chairman that two meetings would be held on September 10 and 21, while the period in between would be devoted to informal consultations, with some time set aside for bilateral and plurilateral meetings. The Chairman's overt support for such undertakings is crucial, because these are essentially the deal-striking sites

in multilateral negotiations, and represent a decisive push-factor in consensus formation at the WTO. Such strategies also force one to question the legitimacy of the multilateral system particularly when parties to bilateral negotiations have vastly asymmetrical power resources. Speaking on behalf of several DCs in the first of the two September meetings, a delegate emphasised the lack of certainty about the legal framework in which an agreement along the lines of the Chairman's text would be placed. He asserted that if the agreement was to regulate every aspect of IP, as ICs seemed to believe, one might wonder why some aspects were dealt with in a very detailed regulatory manner, while other aspects were barely mentioned (MTN.GNG/NG11/25: 7). Another fundamental observation in this meeting was the extent to which most parts of the Chairman's text (such as standards and enforcement) had been 'discussed' in informal consultations, with further such consultations to discuss remaining issues. While there is no indication that actual 'agreement' had been reached, the language of the formal meeting did point out that "the discussions had clarified the issues and the major difficulties had been identified in a rather clear fashion" indicating that "there had been progress" (ibid: 5).

The Group met formally again on October 8 and 18 for an update on the status of the work of the Group on the basis of informal consultations. In the Chairman's view, a constructive series of consultations had been held, which had enabled some advance in the negotiations. "These consultations had enabled a better understanding of each other's positions and proposals, and therefore the removal of a number of difficulties arising from misunderstandings" (MTN.GNG/NG11/25: 4). Note the Chairman's subtle use of *misunderstandings* to describe the conflict. These consultations had also provided "possibilities for finding language that could be acceptable in accommodating differing positions in some areas" (ibid). Continuing more forcefully with his support for bilateral means of consensus formation, Anell reiterated that "the point was now being reached where it was necessary to face, head-on, the difficult issues, solution to which could not be found merely through drafting, but would require participants to

be ready and willing to negotiate with each other, to exchange concessions and to change positions where necessary” (MTN.GNG/NG11/26: 4). The Chairman was therefore openly advocating concessionary consensus formation strategies as the underlying basis for public international law. He indicated that he was encouraged to see signs of such negotiations taking place, while also exerting pressure on delegations by reminding them of the Brussels Ministerial.

Notwithstanding, the Chairman later circulated another informal document on the Group's<sup>11</sup> work status, again compiled on the basis of informal consultations, and again made available on his own responsibility (MTN.GNG.NG11/27: 1). As in his previous draft, the current document reiterated, “the fact that a paragraph might appear without any square brackets or options did not necessarily mean that it had general support and it was clear that a number of such paragraphs remained controversial” (ibid). What is not immediately apparent from this assertion is *whose* demands were omitted. Another fundamental implication from this rehearsed quote is the extent to which the document potentially neutralises particular demands by removing brackets from language that was hitherto controversial. After further informal consultations on the basis of the latest document, the Chairman asserted that “the stage had now been reached in the work when, in order to make progress, the more basic differences between participants on points of substance had to be dealt with” (ibid: 2). He continued that the consultations had focused intensely on the key patent issues of exclusions from patentability and compulsory licensing, and that while in the past he had described such consultations as fruitful and constructive, his current assessment would have to be more nuanced (ibid). The progress had apparently evaporated.

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<sup>11</sup> As per the November 1 meeting, this document bore the reference number 2613.

Speaking on behalf of a number of DCs, Peru's Julio Munoz,<sup>12</sup> mounted a scathing critique of the Chairman's latest draft. Munoz stressed that he wished to put on record the view that the paper did not adequately take into account the special needs and problems of developing countries.<sup>13</sup> He continued that flexibility in favour of developing countries was required in any TRIPS agreement, in view of their special developmental and technological needs, and instead of such flexibility, there was a thrust towards harmonisation of IP systems in all essential respects; that uniform provisions were inappropriate for countries which were at widely differing levels of economic and technological development. Munoz warned that should these attempts at harmonisation be maintained, it would be difficult for developing countries to assume such obligations. He was also concerned that all the emphasis in the Chairman's document was on the provision of rights for IPR owners and little account was taken of their obligations, or of the underlying public policy objectives of national IP systems.

Munoz dissected Anell's document Article by Article, restating the arguments made by DCs in Chapter III, that the establishment of minimum obligations in Article I would excessively constrain the flexibility required by developing countries; that the obligation in Article II to comply with the major IP conventions was contrary to accepted principles of international law, according to which conventions were binding only upon those countries which adhered to them, unless such conventions codified general rules of customary international law; and that the preamble should more clearly reflect the elements proposed in the aforementioned 14-country proposal. Continuing, he said that working the patented invention in the country of grant was one of the obligations on the patentee; that the determination of the term of protection should be left to the discretion of countries as it could not be scientifically or objectively demonstrated that

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<sup>12</sup> While the minutes of the meeting did not identify Peru's representative as the speaker, its Julio Munoz was later interviewed by Chakravarthi Raghavan, in which he identified himself as the speaker. See 'Third World Countries Detail Their Objections to TRIPS Text', November 5, 1990, available online at <http://www.sunsonline.org/trade/areas/inteltec/11050090.htm>.

<sup>13</sup> Munoz's critique is based on paragraphs 3 & 4 of the minutes contained in Doc. No. MTN.GNG/NG11/27.

there was any optimal duration of protection; that the reversal of the burden of proof as formulated in Article 35 of the document was intrinsically unfair and contrary to the principles of natural justice and equity. He further maintained that while the document dealt with the control of abusive and anti-competitive practices, the consultation machinery was too weak and should be strengthened in order to be credible.

Munoz also expressed grave concerns that no allowance was made for the limits of the administrative and financial capabilities of countries with respect to the enforcement provisions in the Chairman's document. He maintained that the lack of such a provision would not only be inequitable, particularly for developing countries with limited capabilities, but would also fail to be realistic. He expressed unease about the continued maintenance of too much detail regarding domestic enforcement, which, in his view, should include safeguard measures, especially for developing countries, and should not lead to the creation of separate legal and judicial structures applicable only to the enforcement of IPRs. This he argued, would not only be unworkable, but would also undermine existing domestic legal structures and judicial practices.

The final critique of the Chairman's document concerned its section on transitional arrangements as Munoz failed to see the philosophy behind its proposed provisions. He maintained that economic and technological development was not a time-bound phenomenon, that it was a qualitative process which could not correspond to any specified number of years. In a quintessential "kicking-away-the-ladder" thesis he maintained that the slow way in which the IP systems of countries which are now technologically advanced had been gradually modified as and when they developed, illustrated this point. Instead, he argued, it was more important to have adequate provisions allowing for the special economic and technological needs of developing countries, thus affording them the opportunity to build up their technological capabilities without the external constraints imposed by uniform IPR standards.

Concurring strongly with Munoz' appraisal of the Chairman's latest document, another participant urged Ambassador Anell to "ensure that differences in the Group were clearly set before the TNC" (MTN.GNG/NG11/27: 5) in Brussels. Anell confirmed however, that since the Group had been asked to report to the TNC on the status of its work on November 02, it was his intention to forward to the Chairman of the TNC the text contained in the document of October 25, to which he would add a covering note making clear the status of the text (ibid: 7). The text would be submitted on his responsibility and was not committing any participant (ibid). Further, he was to send a covering note to the Chairman of the TNC indicating his appreciation of the stage reached in the work of the Group, notably an indication of the major outstanding issues that would need to be the subject of further negotiations (ibid).

One significant observation can be drawn from Anell's insistence, namely, that the views of developing countries would merely be reflected in a covering note, while ensuring that the Anell text would be the basis for any further work (Raghavan, 1990b). Another striking observation in the texts of the minutes is the sheer absence of opposition by industrialised countries against Anell's document. One can construe from this absence that the NETs were at the very least, *satisfied* with the Chairman's output, that this output mirrored TDI demands, recalling from Chapter I that Pfizer's Pratt was an advisor to the official US delegation in the UR. It remains appropriate however, to argue that up to this point, DCs were still vociferously against the IC version of an IP agreement, although the delegations mounting the leading offensive had altered.

On November 22 the Group held its final formal session before Brussels, at which Anell circulated yet another informal document he wished to submit to the Chairman of the TNC on his responsibility, and which committed no delegation (MTN.GNG/NG11/28: 1). As in the penultimate meeting, a DC delegate voiced his concerns that the brackets used in the present text were of a selective nature, and that many divergences were not reflected (ibid: 2). Also absent

from the text was a provision on S&D ‘as envisaged in the Declaration of Punta del Este’ (ibid: 4), and an inadequate appreciation of the vulnerable position of LDCs which could not be subsumed under fixed transitional periods (ibid: 5).

Regarding the provisions in the section on patents, including that on exclusions from patentability, another DC negotiator maintained that the stipulations should reflect “a well-balanced system” (ibid: 3). Ironically however, he proceeded to categorise the texts as “reasonably satisfactory”, contending that a positive attitude of his delegation towards them would depend to a large extent on progress in other areas of the negotiation (ibid). This was the second time in the negotiations that a DC delegate made such an obvious attempt to concede in TRIPS while seeking bargains in other negotiating areas, suggesting that the real access-to-medicines implications of patents were not fully appreciated by all such participants (Abbott, 2002: 43-4); and that such participants may have understood that the negotiations would not have culminated in their favour. Immediately after the April TNC of 1989 a similarly affiliated participant had also affirmed that if some participants were to be required to make sacrifices in the area of IPRs, there should be a readiness to make such sacrifices for their benefit in agriculture, natural resources or other negotiating groups (MTN.GNG/NG11/13: 5).<sup>14</sup> This first declaration could be construed as a signal of a prejudged outcome that disfavoured DCs.

Towards the end of this session another DC participant, supported by several others, pointed out that some other delegations had very high ambitions in the area of TRIPS and that the time had come to review the subject matter in the context of the Uruguay Round negotiations as a whole, particularly in relation to what was being offered in the more traditional areas of the GATT (ibid: 12). At these final stages in the negotiations, DCs were actively seeking trade-offs in other areas

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<sup>14</sup> See Devereaux (p.63) for then US TRIPS negotiator, Emery Simon's take on the mechanics of cross-sectoral trade-offs. Devereaux also quotes Argentina's negotiator as saying they did not give a damn what was in the IP code so long as they got what they wanted in agriculture. Steinberg (2002) refers to such trade-offs as asymmetrical contracting.

in return for agreeing to IPRs in the manner in which the NETs had anticipated (Adede, 2003: 30; Matthews, 2002: 109). Anell's informal consultations and his proposed bilateral bargaining strategies worked in tandem to consolidate the weakening position of DCs propagated during the April TNC meeting in 1989. Anell ended this final session by sharing concerns expressed about the need for results in all areas of the UR, explicitly urging delegations to manufacture consensus through concessionary bargaining. The effects would later be seen in Dunkel's "Draft Final Acts Embodying the Results of the Uruguay Round of Multilateral Trade Negotiations".<sup>15</sup>

#### **4.5 Dunkel's Draft Final Acts: 1990 & 1991**

Director General Arthur Dunkel tabled the first of two Draft Final Acts at the Brussels Ministerial on 03 December 1990 (Stewart, 1995: 2275). The section on TRIPS contained a commentary cover-page specifying that the attached texts were the results of the negotiations on TRIPS as of 22 November 1990 (Stewart, 1995b: 257). The Dunkel Draft was in fact the latest version of the Anell Draft, based almost entirely on the TRIPS Chairman's first July text. Correspondingly, the Dunkel Draft was greeted with a similar level of antagonism as its predecessor, captured in Munoz's scathing critique examined in the last section. Analogous to the informal document submitted by Anell at the last formal Group session, as well as its antecedents, the cover-page of the Dunkel Draft reiterated that "no point in this draft is put forward as having been agreed by all participants"; that "square brackets have been used to identify specific points on which further negotiation is necessary, but their absence from a particular provision cannot be taken as indicating that there is general agreement on it"; and that "participants are therefore not committed to any provision" (MTN.TNC/W/35/Rev.1: 193). Despite the recurrence of these assurances, the square brackets in the section on patents had been reduced from 62 to 25 intimating a narrowing difference of almost 150% although the document emphasizes that the absence of brackets in some provisions did not equal agreement.

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<sup>15</sup> Hereinafter, Dunkel draft/s.

The cover-page nonetheless delineated that basic decisions in the area of patents needed to take account of the complex of issues covering patentable subject matter and exclusions therefrom, the term of protection, non-voluntary licensing and government use, rights conferred by process patents, and reversal of the burden of proof (ibid: 194). It continued that decisions were also to be taken on the length of transition periods and on the extent of obligations to be taken during those periods (ibid). It referenced that “a number of developing countries have also stated that the texts should contain greater recognition of the constraints on their administrative capacity and of their development needs, in light of the provisions of the Declaration of Punta del Este on differential and more favourable treatment of developing countries”; and that there was insufficient time to give consideration to a proposal for the establishment of a dispute prevention system with respect to the transfer of technology (ibid: 195). Point ‘8’ in the Draft's preamble also reiterated that the endpoint being sought was that of a single undertaking.

Nonetheless, while the Brussels talks are said to have collapsed on December 07 primarily because of the impasse in Agriculture (Stewart, 1995: 2276), many issues in the Round remained unresolved, not least in TRIPS. Six formal negotiations were convened between June and December 1991, with an array of informal consultations, bilateral and other ‘group’ sessions in between. At the first of the restarted formal meetings, the Chairman explained that in his view, the main purposes of the meeting were: to enable participants to learn each other’s views as to the state of the TRIPS negotiations in light of the Uruguay Round as a whole; to re-establish the group as a functioning negotiating unit; and to take some procedural decisions about further work (MTN.GNG/TRIPS/1: 1). DCs nonetheless continued to voice their grievances over an IP package they thought “fell far short of addressing their special needs and problems” (ibid: 3). They distressed over the Special 301 provisions of US trade law, arguing that the unilateral actions taken by the US confirmed their apprehensions about what would happen if a balanced outcome was not achieved in TRIPS (ibid: 4-6). Nonetheless, commenting on “very useful” and

“encouraging” informal consultations he had held with a large number of delegations, Anell later impressed that “it had become clear that progress in other areas of the negotiations (in particular, Agriculture, Services and Market Access) would continue to affect the speed with which this Group could do its work” (ibid: 9).

At the TNC-held meeting in July 1991, Dunkel celebrated that “we have all the elements necessary to finally carry the Round to a successful conclusion... the general sense appears that matters are ripe for the final political tradeoffs since most, if not all, the preparatory work has already been done” (Stewart, 1995: 2279). The TNC also agreed on a ‘hands-on’ approach by the Committee, as the TNC would fully assume its role of “keeping the negotiating process constantly under review and supervision” (ibid: 2277). It also agreed to be available for both formal and informal meetings, and Dunkel reserved the right “to bring any matter which threatens the progress as a whole” to the TNC’s attention at any time (ibid). Dunkel also established a tentative schedule of meetings, including an accelerated schedule in September, and an “enormous negotiating effort” in October and November, which would be the “deal-making” stage (ibid).

Immediately prior to this “deal-making stage” however, there were renewed calls from DCs for an eventual TRIPS Agreement to contain a mechanism that would facilitate technology transfer (MTN.GNG/TRIPS/2: 3, 3, 11). In October, presumably when Dunkel’s deal-making stage was already under way, Anell admitted that his informal consultations ‘had not served to resolve important outstanding differences’ and that it was ‘clear’ that participants were not yet ready to negotiate in earnest (MTN.GNG/TRIPS/3: 7). Arguing for flexibilities for developing countries, a DC participant further noted that “in other areas, such as Textiles and Agriculture, where some developed countries were meant to undertake structural reforms, the negotiations had been based on an attempt to set up transitional mechanisms, safeguards and standards which these countries

had justified as a means of minimising the economic and social consequences involved in such reforms”. “Unfortunately”, he added, “a similar flexibility from these countries had not been shown towards developing countries in the area of TRIPS” (ibid: 11).

In November 1991 Dunkel distributed a new paper entitled ‘Progress of Work in Negotiating Groups: Stock-Taking’. In his overview of TRIPS, he targeted three groups of issues including patents, about which he noted that parties had to decide on a term of protection; determine the availability of patents without discrimination with regard to the place of invention, the field of technology, and whether the product (the subject of a patent) is imported or locally produced (Stewart 1995: 2279). This document also attempted to address the issue of transitional periods for DCs and LDCs (ibid: 2280). Nonetheless, at the Group’s late November meetings, Anell admitted that it had been clear that delegations were still not ready to settle certain key issues and was in no position to prepare a revision of the TRIPS text as a whole (MTN.GNG/TRIPS/4: 2).

Stewart further documents that in the final stages of 1991, the formal negotiations which included active participation by approximately 40 countries, were supplemented by informal negotiations at a smaller group level: “10 plus 10” informal negotiations which included the most interested parties; “Quad” negotiations amongst four of the largest trading interests, the US, EC, Japan, and Canada; as well as bilateral negotiations (Stewart, 1995: 2280). He affirms that as was true of most areas of the Round, the formal meetings took on a lesser importance as the process advanced with the hard negotiations occurring most often in the “Quad” or in bilateral settings (ibid). This affirmation is crucial because it points directly to the nature of international trade decision-making, that negotiating endpoints are customarily the result of an exclusive, undemocratic process involving core economies. Confirming this, Anell admitted that in order to produce a revised version of TRIPS which settled all outstanding differences by year-end, he intended to explore contentious points in informal groups with variable membership; and that the

acceptability of the texts so developed would be tested in progressively wider circles (MTN.GNG/TRIPS/5: 1).

Finally on 20 December 1991 Dunkel's second Final Draft Act was unveiled, bearing a similar identity to the first, only this time, there was no commentary and all square brackets had been effaced, lending the impression that all differences in the Group had vanished.<sup>16</sup> According to Stewart, the new TRIPS text provided an arbitrated resolution to issues undecided by the negotiators (Stewart, 1995: 2282). This 'arbitrated resolution' is unequivocally lopsided because the square brackets to which the developing world attached maximum importance were categorically eliminated.

What distinguishes Dunkel's first draft from the second is the former's acknowledgement of some of the demands of DCs, albeit entirely within bracketed limitations. Article 30 of the first draft: patentable subject matter, approach 'B'<sup>17</sup> stipulates that exclusions from patentability should include "certain products, and processes for the manufacture of those products, on grounds of public interest, national security, public health or nutrition, including food, chemical and pharmaceutical products and processes for the manufacture of pharmaceutical products" (Stewart, 1995b: 273). In the second draft, this component had completely disappeared. Similarly, Article 32 which dealt with obligations on patent owners specified, not only the local working requirement, but also, that licensing contracts should refrain from engaging in abusive and anti-competitive practices (ibid: 274). Both components were eliminated in the second draft, with the latter receiving scant attention in Article 31(k) (ibid: 266). Under Article 36: term of protection, approach 'B' indicated that it shall be a matter of national legislation to determine the term of protection (ibid: 276), another provision removed under Dunkel's arbitrated resolution.

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<sup>16</sup> Probably as a result of this, Croome (1995: 318-19) notes that a consensus of key issues in TRIPS emerged in December 1991, but as the remainder of this section shows, this was not the case.

<sup>17</sup> Some texts in the draft are categorized under approaches A or B distinguishing between the drafting preferences of developed and developing countries respectively.

Conversely, those issues which had specific relevance to ICs were simply neutralised out of their bracketed significance. Referring to Article 34 on other use, paragraph (n) spelt out in a classic “Basic Framework” manner that “Authorisation by a PARTY of such use on the grounds of failure to work or insufficiency of working of the patented product or process shall not be applied for before the expiration of a period of four years from the date of filing of the patent application or three years from the date of grant of the patent, whichever period expires last. Such authorisation shall not be granted [where importation is adequate to supply the local market or] if the right holder can justify failure to work or insufficiency of working by legitimate reasons, including legal, technical or economic reasons” (ibid). This demand, obviously an IC theme recurring throughout the negotiations was subsequently dropped in Dunkel’s draft, not because this would make the ICs worse off, but because the TRIPS Agreement would make no provision for a working requirement on patent owners, to the dismay of DCs. So much concern was generated in India that its government did not take a position on the acceptability of the Draft Final Act, labelled ‘DDT’ in India, as it was thought to be as dangerous as the corresponding chemical for the health of the country (Drahos with Braithwaite, 2002: 146). For bureaucrats in the Indian Patent Office who had seen the Indian-designed patent system produce a flourishing, globally competitive pharmaceutical sector, DDT dealt a critical blow (ibid).

Reactions to the Draft therefore maintained the clear North/South cleavage which had hitherto dominated the talks. Noteworthy though, is the fact that the dismay of developing countries at that point was not synonymous with convergence amongst the core states, as crucially also, the North was split over the sovereignty implications of such a legal and potentially far-reaching agreement embodied in TRIPS (ibid: 143). When it came to the detail of drafting patent standards, diverging viewpoints divided the US and the EC. The US wanted the draft to reflect the philosophy of the US Supreme Court that “everything under the sun made by man” is patentable (ibid: 144). And while the major players in European industry wished to uphold this

philosophy, the EC member states, which were also members of the European Patent Convention, were bound by provisions expressly prohibiting the granting of patents on plant and animal varieties; and for those in contravention of morality, among others (ibid). A US negotiator later exclaimed that in those areas where Europe and the US were unable to agree, the provisions of TRIPS are at their weakest (ibid). Clearly however, the squabbles between the NETs impeded neither the Round nor the successful conclusion of the TRIPS negotiations, a point which partly explains ICs' success in international negotiations.

Notwithstanding, reactions to the draft were also quite negative from two politically important industries, including pharmaceuticals (Stewart, 1995: 2284). Because of the existence of section 301 and 'Special 301' provisions of US law, the United States had been able to obtain IP law reform from a number of countries on a bilateral basis (ibid; Ryan, 1980: 80; Devereaux, 2006: 62). As such, the transition period was particularly troubling for the pharmaceutical industry both because of the existing alternative remedy in US law, and because of the longer timeframe given to pharmaceuticals and the lack of coverage of products in development (ibid: 2284-5). Following the presentation of the draft TRIPS Agreement, pharmaceutical manufacturers and IP groups in the US criticised Articles 65 and 66, arguing that transition periods of five and ten years for developing and least developed countries, respectively, were too long (ibid: 2285).<sup>18</sup>

The TDI is also reported to have fundamentally disagreed with the absence of "pipeline" protection concerning patents (ibid). Although absent from the IPC's 'Basic Framework', Stewart notes that the pharmaceutical industry wanted TRIPS to provide protection for drugs in development (pipeline), which is approximately ten years (ibid). In January 1992, Harvey Bale, Executive Vice President of PhRMA and former Assistant USTR for Policy Development, stated

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<sup>18</sup> Recall citation in Chapter II in which Jacques Gorlin (former IPC consultant, and now vice-chairman of the Industry Advisory Committee on Intellectual Property ITAC-15) reveals to Susan Sell in an interview that except for the lengthy transition periods for developing countries, the IPC got 95% of what it wanted.

with regard to the effects of the absence of pipeline protection in a TRIPS agreement: “if the Uruguay Round pact takes effect in 1993 and developing countries do not have to abide by its provisions until 2003, then drugs under development as late as 2013 could be pirated...We’re talking about \$100 billion in lost sales” (ibid: footnote 282). Notwithstanding, this can be seen as a newly emergent demand from the industry since it did not feature in its “Basic Framework”, was completely absent in the negotiations between September 1987 and November 1990, and in the US suggestions for achieving the negotiating objective in 1987 and 1988, as well as its draft GATT IP agreement in 1990; and neither did its absence appear to be a problem after the first Dunkel draft was tabled.

It can be reasonably concluded therefore that upon the presentation of Dunkel’s second draft, DCs failed to secure all their central demands, only ‘gaining’ a time-limited transition which they fought vehemently against during the negotiations; and PhRMA ‘lost’ on a central demand of pipeline protection which surfaced towards the end of the negotiations, and transition periods it thought ‘too long’.<sup>19</sup> Noteworthy is the fact that PhRMA contested no other provision in Dunkel’s draft, leading one to conclude that the remainder of the package was entirely in its favour. The fact that PhRMA was pleased with the remainder of the draft meant that developing countries were dismayed by it, since the two sets of demands were mutually incompatible.

Nonetheless, in an August 1992 communication, Dunkel noted that draft agreements already on the table from the Uruguay Round are “relevant, precise, balanced and urgently-needed answers to some of the biggest economic challenges of the day. They are results from which every trading nation will gain” (GATT Doc. 1550: 1). Dunkel also noted in “GATT Activities 1991” that “the Punta del Este Declaration envisaged the possibility of new rules and disciplines

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<sup>19</sup> This so-called ‘loss’ is contestable because Article 70.9 of TRIPS has been interpreted by the WTO’s Appellate Body in a 1997 US-India ruling, as sanctioning pipeline protection for pharmaceuticals. See Reichman, 1998: 593-596.

covering trade-related aspects of intellectual property rights in general, and trade in counterfeit goods in particular. In the event, negotiators have produced what is probably the most comprehensive intellectual property agreement ever – covering new standards of intellectual property; national enforcement measures; and an international dispute-settlement system” (ibid: 5). Calling on the most interested parties, Dunkel also stated that “the keys to a final conclusion are held in a very few hands. It is now up to them to provide the momentum for us to finalize the multilateral negotiations” (ibid).

Negotiations in Geneva were restarted in late November 1992 following the announcement of an agreement between the US and the EC in Agriculture (Stewart, 1995: 2286). While the main focus of the restarted negotiations should have focused on market access (agricultural and industrial products) as well as initial commitments in services, by mid-December countries were also addressing issues in the Dunkel Draft that were perceived as needing revision in any final package (ibid: footnote 290). India and the US proposed changes to the Final Draft TRIPS Agreement. In recognition of the concerns of US pharmaceutical manufacturers, the United States proposed that the TRIPS Agreement provide pipeline protection for patented drugs which have not been marketed in foreign countries (ibid). India proposed that the exclusive right to market patented products be omitted from TRIPS (ibid). The deletion of this right would extend the transition period for developing countries to implement patent protection (ibid). India also demanded that countries be required to establish facilities to “work” a patent, and that in the absence of such facilities, a patent should be revoked by a country through compulsory licensing (ibid: 2287). The patent provisions in Dunkel’s second draft would however be adopted verbatim into the final TRIPS Agreement, thereby ‘legally’ de-legitimising any further demands by either of the parties concerned, ostensibly operating on principles based on equity and fairness.

#### 4.6 Conclusion: A Politics of 'Domination'

In order to account for the 'domination' aspect of Gramsci's concept of hegemony, the chapter traced the trajectory of the UR negotiations on patents by focusing on the key moments of the Round and their corresponding documents; locating the consensus formation strategies utilised by the core IPC jurisdictions, the GATT Secretariat, its DG, and the Chairman of the TRIPS negotiating group, within those key moments; and tracing the continuing conflict between the two camps in the negotiations as well as DC and IC reactions to the various proposals and strategies by the proponents of the GATT IP framework. Several strategies pointing towards domination were poignant in producing the parallels between the IPC's "Basic Framework" and the actual TRIPS accord assessed in Chapter II. Having already established in the last chapter that the hegemonic function was not exercised by virtue of the fact that the proponents of the GATT IP framework could not exert moral and intellectual leadership in the face of an unyielding developing world, the next step was to examine the kinds of strategies used in the making of patent provisions. The table below summarises the chronology of consensus formation strategies, together with corresponding implications and impacts.

**Table 4.1: A Chronology of Consensus Formation Strategies**

<b>Consensus Formation Strategy</b>	<b>Implication/s of Strategy</b>	<b>General Atmosphere &amp; Impact/s of Strategy</b>
October 1988 and US aggressive unilateralism: US imposes unilateral restrictions on Brazil's exports	To mobilise domestic unrest within Brazilian export constituencies; intended to increase fear in other opponents in order to force compliance with GATT IP regime.	Further opposition from DCs; Group Chairman, Ambassador Lars Anell, concedes a no-consensus scenario.
Anell appeals to the GNG for the future conduct of the negotiations to be made clear to all.	Anell appears to solicit demands by Ministers to force negotiators to 'cooperate'.	At Montreal, Ministers agree that future work should include substantive standards and enforcement provisions, cementing the IPC's agenda.
Informal consultation/Green Room	Exclusive and non-transparent	
India's Montreal proposal ignored by GATT Secretariat and working group Chair, Ozal	DCs reject Ozal compromise and endorse India's proposal	
Road to April 1989 TNC: increased use of informal consultations chaired by both Anell and then DG of GATT, Arthur Dunkel.	To promote agreement in remaining 4 areas, including IP, through asymmetrical contracting.	Exclusive and non-transparent.

Dunkel travels to Washington and Brussels in a bid to have the US and EC agree on a framework for Agriculture amongst themselves.	Once US and EC agreed on Agriculture, it would be forced on others; once Agriculture was resolved, the broad front of DC collaboration on several issues would dissolve.	DCs meet simultaneously in France and Geneva which results in a common position.
Dunkel ignores Third World Paper and produces his own text.	With support of informal Third World Group, Brazil amends Dunkel text.	
Secretariat's 'disinformation campaign': informs India that she was alone in opposing TRIPS.	To foment distrust among key DCs.	Relationship between India and Brazil dissolves.
India's GATT negotiator, Shukla (1984-1988), uprooted to India.	An important mobiliser for the South is unexpectedly uprooted.	
Further informal consultations.	DCs complain about lack of transparency during TNC meeting.	TNC Decision further cements IPC's agenda, agreeing to a mere 'consideration' of DC demands.
US utilises 'priority watch lists'.	Further warning signals to opponents to comply with US demands.	Further opposition from DCs; in June 1990, Brazil succumbs to US pressure and assumes 'observer' role in negotiations.
Further informal consultations		
Anell's first draft annexes DC draft proposal, while maintaining the contents of that of ICs in main body.	DCs oppose Anell draft for inherent biases.	
Anell commissions bilaterals as a means to 'exchange concessions and change positions'.	DCs were simultaneously seeking concessions in traditional areas in return for consensus in TRIPS.	
Anell tables series of informal documents on his own responsibility, committing no delegation, and pointing out that while brackets were to identify points for further negotiations, their absence does not mean consensus.	Use of language to pacify opponents.	ICs record no resistance to Anell's documents; DCs intensify opposition and Peru launches scathing attack. Despite Anell's rhetoric, his drafts would <i>become</i> the basis for further negotiation, the last of which was lifted verbatim into Dunkel's first Final Draft Act.
Escalation of informal consultations at '10+10', Quad and bilateral levels.	The basis of asymmetrical contracting to consolidate orthodox position.	
December 1991, Dunkel unveils second Draft Final Act, bearing similar identity to its contested predecessor. All bracketed text to which DCs attached importance had been removed.	Removal of brackets gave the false impression that differences in the group had disappeared.	Draft nicknamed DDT in India.
New TRIPS text becomes basis of Dunkel's 'arbitrated resolution' to issues undecided by the negotiators. Dunkel's latest draft "clearly meets and exceeds the initial negotiating mandate articulated in the UR" (Stewart, 1996: 2313), the patent provisions of which would be lifted verbatim into the TRIPS Agreement; and as seen in Chapter II, are identical to, or exceed the demands of the TDI.		

Unable to exercise moral and intellectual leadership because of the extent of the offensive mounted by developing countries against the Northern IP agenda, the architects of TRIPS resorted to a range of non-transparent and coercive strategies to ensure compliance. These strategies framed the making of the patent provisions of TRIPS as an instance of 'domination' in

Gramsci's hegemonic model, making TRIPS an expression, not of power, but of the failure of power (Arrighi, 1993: 149). Chapters three and four have therefore made the empirical case of institutional capture, less the classic Coxian moment of hegemony. They substantiate the last part of the first empirical hypothesis that the TDI secured its demands from TRIPS despite the high intensity of the conflict characterising the negotiations on patents; and together make an empirical contribution to Cox's extrapolation of Gramsci's concept of hegemony in critical IPE. While on the surface, the framers of the patent framework maintained the stability of the prevailing order (continuity), they simultaneously crafted the contradictions and points of conflict that would bring TRIPS into disrepute. Chapter V therefore goes on to challenge the legal form in general, and TRIPS in particular, as implicated in the politics of 'who gets what' before examining the renewed intensification of conflict in the post-TRIPS period.

## Chapter V

### Legitimacy and the TRIPS Agreement: Globalised Law as ‘Consent Without Consent’<sup>1</sup>

#### 5.1 Introduction

The thesis has hitherto focused on the first research question, examining the making of the global patent regime under TRIPS as a case study in institutional capture by the TDI, dominated by American industry. This was done by developing a theoretical framework in Chapter I which explains outcomes in international trade decision-making as a function of the prevailing historical structure; and then portraying an instance in which power is translated into action by comparing the IPC's patent demands for a GATT IPP, with the patent provisions in TRIPS. In order to explain the nature of decision-making, the UR negotiations relevant to patents were framed within Cox's extrapolation of Gramsci's concept of hegemony, that is, a combination of coercion and consent whereby the latter must prevail. The high intensity of the conflict characterising the negotiations meant that the proponents of a GATT IP framework could not exercise moral and intellectual leadership, and therefore had to resort to a range of non-transparent and coercive strategies to force DC compliance with industry's demands for a patent regime. The absence of moral and intellectual leadership in the making of patent provisions suggested that hegemony in TRIPS was tenuous at best.

Correspondingly, and by virtue of the legality of TRIPS, the current chapter examines the nature and function of law in the GPE and the ramifications for the study of IPE, particularly in the current climate characterising a “thickening of legality” (Shanker, 2003: 162) in global economic governance (Picciotto, 2003; 2005). The North/South polarization which characterised the negotiations, coupled with the pro-industry stance of the final agreement, forces one to

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<sup>1</sup> Noam Chomsky, *Perspectives on Power: Reflections of Human Nature and the Social Order* (London; New York: Black Rose Books, 1997), pp. 222-246.

problematise the role of law in the constitution of global society. At a very basic level, the constitution of the law propels an inquiry into the class asymmetries that define the GPE. As indicated in the 'Introduction', class does not simply apply to the sociologically-derived description of groups of individuals sharing common experiences or life chances or workplace relations (Burnham, 2002: 114). “The essence of class is social domination and subordination” (Cox, 2002: 3), specifically connoting the fissure between the globally powerful and the locally disenfranchised based primarily on legalised global intellectual property relations.

Law is usually construed as a legitimate authority, expressly separate from the whims of politics and the personal agendas of political leaders. It is understood primarily as a *neutral* and *objective* domain inhabiting a differentiated but superior space in a given society. The WTO has defined itself as a rules-based organisation, where decisions are achieved through consensus bargaining, conjuring up images of superiority based on rule of law notions. The acrimony and controversy that typified the negotiations force one to question the legitimacy of TRIPS as a genuine instrument of international law. It begs a reflection of law as a human social product, and having been produced in an historical context of capitalist dominance, is not class-neutral (Cutler, 2002: 236), and especially so when one considers TRIPS in the framework of monopoly capitalism (Richards, 2004: 15). Consequently, one cannot speak of the neutrality or objectivity of TRIPS, since the power dynamics that secured its conclusion bring any such notions into disrepute. From the narrative analyses of the last two chapters, the current chapter engages with the significance of a legal agreement ungrounded in the very attributes that demarcate the legal tradition, thereby setting the scene for what would follow in the post-TRIPS climate of a renewed and intensified conflict. Recalling the 'Contributions' enunciated earlier, this chapter also applies the dialectic concept of 'consent without consent' as a novel way of explaining coercive decision-making in the GPE while simultaneously intimating how a consensus (the legitimating mechanism of public international law) of TRIPS can be invoked.

## 5.2 Pharmaceutical Patents and the Relevance of Law for Critical IPE

In justifying the Coxian approach adopted in the thesis, Chapter I reviewed some of the basic premises and intellectual provenances of contemporary IPE, from which we recall Strange's provocation calling for a "radical desegregation" and dismantling of artificial disciplinary barriers separating international economics, politics and law: "these barriers needed to be overthrown, broken-up and done away with" (Cutler, 2000b: 160, taken from Strange, 1972: 63). The making of patents in the UR further augments Strange's challenge, particularly as it concerns the relevance of law for the study of critical IPE. To continue to neglect the co-constitutive nature of law in society, and therefore its productive and allocative functions, is to reproduce the precise framework that critical IPE seeks to transcend.

As Berry (2007: 4-5) reminds us, critical IPE's immediate origins can plausibly be traced to Susan Strange's directive that non-state structures do matter; that one of the principal and partially distinctive aims of critical IPE is to study 'globalisation' which is generally understood as a structural phenomenon; that critical IPE's long-term origins can obviously be traced to Karl Marx, whose work is widely credited with instigating a systematic focus in social science on the role and impact of socio-economic structures on political and ethical life; and that "critical IPE has developed an expertise on structure, whether the phenomenon in question is manifest locally or globally, in a particular sector, or is primarily social, political or economic in nature". Berry continues that in studying structure from a critical perspective, attention is inevitably directed to structural change. However, despite the law's ubiquity nowhere in Berry's account does he mention its structural significance for critical IPE. But as Gill (2002: 59) emphasises, "law is fundamentally a *productive* aspect of bourgeois society.<sup>2</sup> It is central to the constitution of the power of capital, the nature of the state and its separation from civil society". Consequently, the enduring decoupling of law from the remit of IPE reproduces and reinforces the hegemonic

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<sup>2</sup> See Cox (2002: 31) who overtime, expanded his production thesis to include the production of law. See also Strange (1994: 29) who includes legal processes in her production structure.

framework of private capital accumulation and undermines critical IPE's agenda towards structural transformation.

Nowhere is the contemporary significance of the constituent components of law, economics, politics and society, within the framework of a contiguous domestic-international sphere, more apparent than in the area of the trade-relatedness of intellectual property rights. Its significance is all the more acute in the contemporaneous transition from diplomacy to law (Weiler, 2000: 10) in the governance of international trade relations. As a consequence, law needs to be further scrutinised because it resides in one of the last bastions of uncritical scholarship in IPE. This is imperative especially since what is ultimately 'law' is inescapably wound up in facilitating the globalisation of a naturalised capitalism. One of the fundamental lessons from the TRIPS story is the extent of complicity of the law in the politics of who gets what (Cutler, 2002), suggesting that law is the pursuit of politics by other means (Picciotto, 2003b: 1) and that "politics and law are indissolubly intertwined" (Kahler, 2000: 661).

The relative absence of international law (IL) from IPE could be attributed to a long-standing myopia in its forerunner discipline, IR, as well as the prevalence of neoliberalism as the dominant discourse in the post-Cold War era. The dominance of realism in the inter-war era saw a blatant dismissal of international law as virtually irrelevant to matters of 'high' politics (Scott, 1994: 1), especially since efforts to create an international rule of law immediately after the carnage of WWI failed to deter international aggression. Essentially, the process of international politics has been accounted for by the concept of power, while international law is regarded as having no intrinsic significance (ibid). The dichotomy is no coincidence because the normative aspirations that formed the basis of post-WWI thinking was precisely what realists termed utopian/idealist, since it sought to create the world as it *should* be rather than explain the world as it *in fact* was. Realists therefore believed in the polarity of law and power, opposing one to the

other as the respective emblems of the domestic versus the international realm, normative aspiration versus positive description, cooperation versus conflict, soft versus hard, idealist versus realist (Slaughter-Burley, 1993: 207).

Secondly and arguably more important in explaining the law/politics dichotomy was an insistence on the very description of how the world *in fact* was. The persistence and ‘certainty’ accorded the condition of anarchy subsequently remained the overriding reasoning underpinning realist discourse. An anarchic international system has been specific not only to the timeless absence of political authority at the international level, but is also precisely that which sustains the permanence of conflict between states, a conflict instantiated through a chronic struggle for geo-strategic power. Within this essentially realist lens, international law can be aligned with power only insofar as it is considered a tool at the disposal of the most powerful (Scott, 1994: 2). Yet, international law and power are so frequently contrasted (*ibid*). If, as realists believe, IL is important only insofar as it is malleable to the whims of the most powerful, then it is ironic that it does not feature more prominently in their research agenda, except for the fleeting concern as to why states obey it; and the challenge to international lawyers to establish the ‘relevance’ of their discipline (Slaughter-Burley, 1993: 208), for the most part, maintaining scepticism about whether IL could mediate, constrain, or independently influence state behaviour (Haggard and Simmons, 1987: 491).

Ironically however, efforts veering at interdisciplinary collaboration began emerging in the height of the Cold War when realism was at its peak. For instance in 1979, Louis Henkin lamented that “the student of law and the student of politics ... purport to be looking at the same world from the vantage point of important disciplines. It seems unfortunate, indeed destructive, that they should not, in the least, hear each other” (Slaughter-Burley, 1993: 4n). In particular, Henkin sought to convince the realists that “law is a major force in world affairs”, while

persuading international lawyers to “think beyond the substantive rules of law, to the function of law, the nature of its influence, the opportunities it offers, the limitations it imposes” (ibid: 214). Henkin had effectively made the case for a more rigorous academic appreciation of the co-constitution of law and politics.

While Henkin was writing, a prominent group of scholars took on the challenge to resuscitate, at least in part, the relevance of IL in world politics by focusing on international regimes. One of the most influential formulations was put forward by Krasner, that regimes were “sets of implicit or explicit principles, norms, rules and decision-making procedures around which actors’ expectations converge in a given area of international relations” (Krasner, 1982: 186). He continued that principles are beliefs of fact, causation and rectitude; that norms are standards of behaviour defined in terms of rights and obligations; that rules are specific prescriptions or proscriptions for action; and that decision-making procedures are prevailing practices for making and implementing collective choice (ibid).

The suggestion generated from this ‘apparent definitional consensus’ (Young, 1986: 105) stems from the antiquated assumption that states are indeed the unitary, rational actors, since actors’ expectations invariably converge in a given area of international relations. Nothing in the above definition entertains the possibility that a regime may in fact be addressing the interests of private transnational actors, since ‘international regimes are those pertaining to activities of interest to members of the international system’; and that these involve activities which take place entirely outside the jurisdictional boundaries of sovereign states, or which cut across international jurisdictional boundaries, or which involve actions with direct impact on the interests of two or more members of the international community (Young, 1982: 277). More importantly, the definition remains mute with reference to the idea that what may appear to be a ‘convergence’ of expectations in an international regime, may be a packaged pretext arrived at

through the kinds of strategies commissioned through the highest levels of the GATT encountered in the last chapter.

Accordingly, Strange argues that regime analysis leads to a study of world politics that deals predominantly with the *status quo*, and tends to exclude hidden agendas and to leave unheard and unheeded complaints, whether they come from the underprivileged, the disenfranchised or the unborn, about how the system works (Strange, 1982: 480). She concludes that ‘the *dynamic* character of the “who-gets-what” of the international economy, moreover, is more likely to be captured by looking not at the regime that emerges on the surface but underneath at the bargains on which it is based’ (ibid: 496). This is a fundamental challenge because an analysis of the international patent regime under TRIPS which merely looks at the content of the TRIPS Agreement, simply could not capture the multiplicity of factors that worked in tandem in the making of the agreement – hence Henkin’s warning to look beyond the substantive rules of law. In a similar vein and referring to specific regime categories, Oran Young develops the concept of ‘imposed orders’ which are deliberately fostered by dominant powers or consortia of dominant actors... who succeed in getting others to conform to the requirements of these orders through some combination of coercion, cooptation, and the manipulation of incentives (Young, 1982: 284), a category of regimes that aptly captures the mix of strategies narrated in the last chapter, but which intentionally or otherwise, omits the role played by non-state intermediaries in regime formation, maintenance and consolidation.

Important in its own right, the regime framework developed in the late 1970s and 80s gave way to a more generalised focus on international institutions, in particular, a focus on neoliberal institutionalism which culminated in the neo-neo consensus (Lamy, 2001: 182-199) in IR theory. The approach builds extensively on realist foundations and starts from the premise that regimes are needed to overcome the problems generated by the anarchic structure of the international

system (Little, 2001: 306). In a classic institutionalist fashion, Keohane maintains that international regimes enhance the likelihood of cooperation by reducing the cost of making transactions that are consistent with the principles of the regime; that they create conditions for orderly multilateral negotiations, legitimate and delegitimate different types of state action, and facilitate linkages among issues within and between regimes; and that they increase the symmetry and improve the quality of the information that governments receive (Keohane, 1984: 8-10). Also emphasising its functionalist/rationalist dimension, international regimes would enhance compliance with international agreements in a variety of ways, from reducing incentives to cheat and enhancing the value of reputation, to “establishing legitimate standards of behaviour for states to follow”, and facilitating monitoring, which creates “the basis for decentralised enforcement, founded on the principle of reciprocity” (Slaughter-Burley, 1993: 219).

This synthesis in IR theory was useful from the vantage point that it somewhat ended a decades-long theoretical, arguably futile, debate about which perspective took better account of the discipline of international relations from epistemological, ontological and methodological viewpoints. However, it did not only mask the prevalence of the interplay of power in international institutions (Barnett and Duvall, 2005; Hurrell, 2005; Barnett and Finnemore, 1999, 2005; Gruber, 2005; Tooze, 2000), it also effectively de-emphasised law generally, and international law in particular, as a central and legitimate domain within the study of world politics, a de-emphasis that would filter through to IPE. To be sure, this may not have been a coincidence either, since the essence of regime analysis was to develop a scientific study, a “general theory” that would provide a nice, neat, and above all simple explanation of the past and an easy means to predict the future (Strange, 1982: 480). This epoch in IR theory would guarantee the preservation of the law/politics dichotomy, the natural corollary of which was the maintenance of law and power as unrelated, extreme opposites, and therefore out of the scope of IPE.

This phenomenon is also fundamentally linked to the liberal pretext that the fight for an international rule of law is a fight against politics, understood as a matter of furthering subjective desires; and that though some measure of politics is inevitable, it should be constrained by non-political rules (Koskenniemi, 1990), again implying the separability of the domains. This line of thinking can be traced at least as far back as the Enlightenment and its related assertions on the subjectivity of value, of which Hobbes and Rousseau can be hailed as two of the greatest exponents. In a classic liberal impulse to escape politics through law, Rousseau maintained that “a free people obey, but it does not serve; it has magistrates but not masters; it obeys nothing but the laws, and thanks to the force of laws, it does not obey men” (ibid). Rousseau, as did an earlier Hobbes (ibid), effectively gave law a life of its own, decoupling it not just from the social circumstances that were its necessary preconditions, but also from the lawmaking and law-executing ensembles behind which are real agents un-detached from a standpoint in space and time, a story captured in the last chapter.

Nonetheless, echoing Rousseau was the *Massachusetts Constitution of 1980* which provides that “the judicial shall never exercise the executive and legislative powers, or either of them; to the end [that Massachusetts’ government] may be a government of laws, and not of men”.<sup>3</sup> Within this formulation are principles believed to be intrinsic to the rule of law. It presupposes the ‘impartiality’ of the law, since legal standards are valid and applicable independently of the preferences of the judiciary, of the parties, or any particular state (Scott, 1994: 8, taken from Schachter, 1991: 34; see also Picciotto, 2005: 477). It presumes as factual that law is ‘rules’; that these rules are ‘neutral’; that the judiciary is ‘objective’; and that its prime task is to ‘apply’ rather than ‘make’ the rules (ibid, taken from Higgins, 1968: 58). Consequently, the ideology of international law presents legal norms, principles, rules and negotiating positions as not only distinguishable from non-legal political ones, but as somehow ‘more than’ or superior to them

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<sup>3</sup> See ‘Legal Formalism’, at <http://www.answers.com/topic/legal-formalism>.

(ibid). This is further illustrated through a reliance on the principle of ‘equity’ within the law. Legal equality has the propensity to further depoliticise the law because it legitimises the assumption that ‘international law does not operate in favour of any particular state or group of states’ (ibid: 9), components of which were encountered in the negotiations. Reacting to this worldview, critics have charged that the systematic application of an equal scale to systematically unequal individuals necessarily tends to reinforce systemic inequalities (Balbus, 1977: 577), a DC argument recurring throughout the texts of the UR negotiations. This was in fact the basis of Anatole France’s famous, ironic praise of “the majestic equality of the French law, which forbids both rich and poor from sleeping under the bridges of the Seine” (ibid).

These ‘taken for granted’ precepts point towards one crucial postulate that has dominated both legal scholarship and our social understanding of the law, that is, the absolute autonomy of the legal form. The thesis of autonomy suggests the independence of legal thought from material constraints (Collins, 1982: 63). This perceived autonomy of the legal form arguably circumvents an IPE inquiry into law as an intrinsically social category, with social origins and social consequences.

While this thesis in no way seeks to undervalue law as a category, it challenges, particularly in the context of international trade law, those seemingly unproblematic lenses through which we interpret and continue to explain our world. It therefore makes the case for the de-sectionalisation of international law, thereby making it (its origins, making, content, functions and impact) integral to the study of IPE. While for instance Gill makes a contribution to critical IPE with his analysis on new constitutionalism as “the *political/juridical form* specific to neoliberal processes of accumulation and to market civilization” (Gill, 2002: 399-423, 2003: 131-135), he focuses overwhelmingly on law as product, without paying sufficient attention to process. However, law may be more about process than about product since what legitimates law

and distinguishes it from other forms of normativity are the processes by which it is created and applied (Finnemore and Toope, 2001: 750).<sup>4</sup> The analysis of the making of the patent provisions in TRIPS unpacks the particular nature of judicial lawmaking, and the social forces at play that make legal output anything but apolitical, objective, neutral, superior, or autonomous. Since much of the IPE subject matter, particularly the critical tradition, centres on the prevailing structures of power and how established orders are maintained over time, it is imperative that the discipline takes stock of the “role of law in constructing and reproducing the foundations for global capitalism” (Cutler, 2002: 233).

As such, it appears apposite that critical IPE should at least engage with the critical tradition in legal studies (CLS)<sup>5</sup> since both traditions focus on new and interconnected ways to understand power and oppression, how these shape everyday life and human experience, and how they can be transcended, albeit focussing on analytically distinct structures.<sup>6</sup> CLS members argue that law is neither neutral nor value-free, but inseparable from politics.<sup>7</sup> They attempt to debunk the law’s claims to determinacy, neutrality and objectivity, and argue that the law is a tool used by the establishment to maintain its power and domination over an unequal *status quo*.<sup>8</sup> From a “law is politics” thesis, scholars argue that the law is only an elaborate political ideology, which, like other political ideologies, exists to support the interests of the party or class that forms it.<sup>9</sup> In the TRIPS case study, the law advances the interests of the powerful (TDI) through the establishment of so-called *trade-related* intellectual property rights as an unassailable right (Cutler, 2002: 234). The law is a significant element in the deepening of neoliberal discipline and the expansion of private power (ibid: 236; Gill, 2002, 2003), and is thus deeply embedded in

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<sup>4</sup> The penultimate section will focus on questions of legitimacy.

<sup>5</sup> This conjoinment is proposed as a possibility for future research.

<sup>6</sup> CLS began in the US in the late 1970s and borrows from philosophers such as Marx, Engels, Gramsci; Horkheimer and Marcuse of the Frankfurt School; as well as poststructuralist thinkers Foucault and Derrida. Prominent CLS scholars include Morton Horwitz and Duncan Kennedy.

<sup>7</sup> See 'Critical Legal Studies: an overview' at: [http://topics.law.cornell.edu/wex/Critical\\_legal\\_theory](http://topics.law.cornell.edu/wex/Critical_legal_theory).

<sup>8</sup> Ibid, see also 'critical legal studies: <http://www.answers.com/topic/critical-legal-studies>

<sup>9</sup> Ibid.

politics: affected by political interests, power and institutions (Goldstein et al, 2000: 387). Crucially, since “the essence of private property is always the right to exclude others” (Cutler, 2000: 236, taken from Cohen 1927-8: 8-30), then law in general, and international trade law in particular, functions distributionally to determine “who gets what” and on what terms, and is thus, inescapably “political” (Cutler, 1999a: 285). The ultimate objective of CLS therefore, is to ‘delegitimate’ and ‘demystify’ the law, to undermine the law’s acceptance and to remove the cloak of mystery and awe that surrounds its functioning,<sup>10</sup> thereby complementing the research agenda in critical IPE. The next section looks at the contested nature of law in relation to the narrative analyses of previous chapters, before addressing the question of legitimacy in TRIPS.

### **5.3 TRIPS as Artifice: The Essentially Contested Nature of the Legal Form**

The making of the patent provisions in TRIPS has unveiled a remarkable story of the nature of the material content of international legal regulation, as well as the highly political nature of judicial lawmaking. It has also elucidated the social conditions in which the domination and regulation of social relationships assume a legal character (Beirne and Sharlet, 1980: 7), that is, the particular juncture at which the material interests of capital are threatened, characterised primarily as conditions lacking the rule of law. Accordingly, whenever, through the development of industry and commerce, new forms of intercourse evolve, the law has always been compelled to admit them among the modes of acquiring property (Cain and Hunt, 1979: 54). While global intellectual property relations are hardly a new form of intercourse, their origins in the GATT, as TDI-specific, can be so considered. There was a conscious, material requirement for the development of a trade-related conception of IPRs, and the law was made to admit this within the mode of acquiring property. The TDI and other high-tech industries encountered a moment of crisis, and the law was made to repel the crisis. The TRIPS narrative therefore points to the

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<sup>10</sup> Ibid.

malleability of the law, whereby the law was made to adapt to the requirements of global capital accumulation, exposing a legal framework that is anything but neutral.

This tendency towards malleability contradicts the rule of law doctrine<sup>11</sup> and exposes law (at the very least, international trade law) as an elaborate political ideology with a propensity to conceal power relations. In fact, the rule of law doctrine is as significant as it is paradoxical because it rests on a notion of impartiality that proscribes any real consideration of history and the precise circumstances that herald the need or desire for legal regulation. The law is what it is because an event in history provided the basis for its construction. As such, there cannot be a legal form detached from social circumstances, and from space and time considerations. While the law has to be made to adapt to changing circumstances, the prevailing question centres on the precise direction of the adaptations, and the parties whose interests they serve.

Consequently, the law's tendency towards malleability and its propensity to conceal the extent and reach of power in modern society, both point to its artificiality, particularly that which governs the rules of engagement for international trade and commerce. Artificiality here is composed of diverse assumptions, the debunking of which potentially leads to the demystification of the legal form. Several assumptions which define the international legal framework need to be unpacked when operationalising TRIPS as an artificial construct. These assumptions include the precise meanings of dualities or 'paired opposites' that have simultaneously been central to the work of critical IPE and CLS. These include the domestic/international divide, the public/private distinction, and the subject/object dichotomy. But probably the most fundamental of all assumptions, is the ideology of consensus which gives IL its thriving legitimacy.

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<sup>11</sup> At its most basic it means that no one is above the law. It follows from the idea that truth, and therefore law, is based on fundamental principles which can be discovered, but which cannot be created through an act of will. The core principle of the doctrine specifies that political power should be exercised according to rules announced in advance so that laws can be identified and applied impartially (Collins, 1982: 12).

As the name suggests, *international* law conforms to the domestic/international binary that informs the orthodox traditions in IR. While it would be incorrect to say that all domestic law functions in much the same way as all international law, it is nonetheless misleading to continue to analyse the international realm as if it were far removed from the domestic. The mere fact that the trade-relatedness of IPRs began as a domestic constituency concern in the United States provides justification for the examination of the international as an extension of the domestic, and not separate from it. If the globalisation of IPRs in the GATT/WTO was to be analysed simply from an international lens, it would misrepresent the richness of the dynamics, from conceptualisation to actual agreement, that were the basis of TRIPS. A strict ‘international’ analysis would also impair an inquiry into the points at which power and authority are located in the GPE. Indeed, there would be no power analysis, thereby prolonging the erroneous assumptions characteristic of liberal internationalist discourse encountered in Chapter I.

The debate would have been framed entirely within the realist lens of state power, thereby masking the role played by domestic constituencies (though transnational in character) as instantiated through the individual aspirations of Pfizer’s Edmund Pratt; Pratt’s teaming-up with other high profile CEOs and the formation of the IPC;<sup>12</sup> their various activities aimed at convincing the US government of the need to protect IP abroad under the auspices of the GATT; Pratt’s position at the helm of the President’s Advisory Committee on Trade Policy and Negotiations (ACTPN) providing actionable advice to Presidents Carter and Reagan, and their USTRs; the successful efforts of the IPC in bringing international IP partners as well as major governments onboard; the continuous advice from Pratt and his associates to the USTR during the Uruguay Round in formulating, representing and expanding the private sector demands for a

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<sup>12</sup> There were undoubtedly other important industries, as indicated in the make-up of the IPC (see for instance Matthews 2002 on the role of the International Intellectual Property Alliance, IIPA) however, since the research is concerned with the role of the pharmaceutical industry in TRIPS formation, an examination of the IIPA (which does not include pharmaceutical interests) did not make practical sense since the study does not purport to look at the entire TRIPS Agreement and all industries and countries involved in its formation.

GATT IP agreement. These citations, which were the roots of TRIPS, are further symptomatic of the inappropriateness of a state-centric ontology in IL which focuses on states as the sole, legitimate subjects of international law.

This state-as-subject ontology has its roots in the 1648 Treaty of Westphalia which ended the Thirty Years' War and established the interstate system. As Duncan Kennedy notes, the originality of 1648 is important to the discipline for it situates public international law as a rational philosophy, handmaiden of statehood, the cultural heir of religious principle (Cutler, 2001: 135, taken from Kennedy, 1988: 14). Westphalia established state sovereignty as the fundamental ordering principle of the states system, placing the state at the centre as the unambiguous locus of authority (ibid). For more than three centuries therefore, the state has maintained the status of *the* subject of international law and politics, something referred to as the 'problem of the subject' (ibid: 136). The problem of the subject involves the tendency to 'avoid confronting the question of who or what thinks or produces law' (ibid, taken from Schlag, 1991: 1640). Accordingly, on a surface examination of the making of the patent provisions in TRIPS, state parties think and produce law. The state as subject ontology therefore negates those crucial behind-the-scenes questions that aid in the process of law-formation, thereby performing a powerful conservative function that conceals the sources of power in the GPE.

Notwithstanding, the very meaning of IL is one based on a law among nations, a resolve which renders and sustains the invisibility of other actors (such as the TDI) despite their role in the initiation and formation of enforceable law. This invisibility functions as a facilitating mechanism for the continuing rise and power of capital, encountered in 'The Argument in Context', as it makes the reach of capital less detectable. The irony here is that despite the fact that TRIPS was formulated almost entirely by and for IP-based industries, the agreement itself is an agreement between *states*. While this potentially highlights the salience of the state in the 21<sup>st</sup>

century amidst debates about its defectiveness,<sup>13</sup> the irony is all the more powerful when one considers that TRIPS potentially represents the legal suppression of private power from public scrutiny. A law which requires *states* to ensure compliance of their domestic regulations with international obligations, while serving the interests of capital, acts categorically to conceal the nature of power and authority in the GPE. This is so because power and authority in the GPE are framed entirely in terms of publicness, as if private entities were not simultaneously endowed with tremendous power resources and capabilities, sometimes even more so than the state, as seen in Chapter I.

Herein lies yet another dualism (the public/private distinction) which further restricts the research agenda in international law and politics, a distinction that also finds its highly developed institutional expression in public conceptions of international law, as well as private conceptions of this law.<sup>14</sup> Despite the fact that TRIPS falls under the rubric of public international law, it simultaneously incorporates both institutional expressions of IL, a dialectic which further illustrates that “*there is no public/private distinction*” (Cutler, 1997: 265, taken from Klare, 1982: 1358-9). Noteworthy is the fact that international IPR matters were previously the domain of private international law, albeit with public law content, before the WTO came into being. IPRs became a public law concern when IPR-dependent industries failed to secure meaningful results in the pre-TRIPS regulatory context. The debate was then to be framed within the conventional, conservative state-as-subject discourse, thereby obscuring the significance of private authority in international affairs.

As Cutler reminds us, Westphalian-inspired notions of state-centricity and ‘public’ definitions of authority are incapable of capturing the significance of non-state actors such as TNCs and

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<sup>13</sup> See Chapter I, 7n.

<sup>14</sup> Public International Law (PIL) governs relations between states while Private International Law deals with the choice of law in private/non-state/apolitical matters when such matters arise in an international context. See Boyle 1996, 26-7 for some examples.

individuals, informal normative structures, and private economic power in the global political economy (Cutler, 2001: 133). In fact, the legal personality accorded to corporations at the international level is analogous to that of an individual, that is, they are the objects as opposed to the subjects of IL. Yet, as seen in previous chapters narrating the role played by high-tech industries for an international patent code under the GATT, while corporations may be objects at law (*de jure*), they are in fact, operating as subjects (*de facto*) (ibid: 137). The problem of the subject is therefore very definitely the problem of the disjuncture between law and politics, and between theory and practice (ibid). Despite its decision-making authority in the prevailing historical structure developed in Chapter I, and the very real implications of such authority, the transnational pharmaceutical corporation lacks “concrete presence in international law. Rather it is an apparition, reappearing in many different forms and contexts – its actuality sifted through the grid of state sovereignty into an assortment of secondary rights and contingent liabilities” (Johns, 1994: 893).

But arguably the most far-flung representations of the state-as-subject rationality are the ideology of consensus that legitimates the system, and the general rule that only states are formal participants in international negotiations. The dominant theory in international law is legal positivism, which identifies international law with positive acts of state consent (Cutler, 2000: 56). The consent rule generally is probably the most foundational element of legitimacy defining any legal or political order. For instance, within the democratic state, authority is traced to the consent of the governed, which is articulated through democratic processes under a doctrine of limited government (Cutler, 1999b: 64). Outside the state, liberal theories of international law craft the basis of obligation or authority upon the express or implied consent of states (ibid). However, despite being a maxim of alleged political fact, it has singularly little content of truth (Giddings, 1900: 259).

The WTO prides itself as a member-driven, consensus-based organisation. It insists that when WTO rules impose disciplines on countries' policies, this is the outcome of negotiations by WTO members.<sup>15</sup> While the organisation admits that reaching decisions by consensus among some 150 members can be difficult, it lauds that the main advantage is that decisions made by consensus are more acceptable to all members.<sup>16</sup> So embedded is this rule that Article IX of the Agreement establishing the WTO requires that only "where a decision cannot be arrived at by consensus, the matter shall be arrived at by voting". The assumption from the consensus rule is that the institution is intrinsically democratic, and by extension, high levels of social unity exist among actors. Deductions from consensus or unanimity decision-making further suggest that legislation will oblige the "organ to seek a formula acceptable to all" (Steinberg, 2002: 345, taken from Riches, 1940: 15) since legislation that makes any state worse off will presumably be blocked by that state (ibid). Moreover, the rules theoretically permit weak countries to block positive-sum outcomes that they deem to have an inequitable distribution of benefits (ibid).

What therefore explains the TRIPS outcome amidst such acrimony in the negotiations? On the face of it, TRIPS represents a consensus-based 'agreement', raising questions about the unproblematised nature of consensus at the WTO. By virtue of its positivist underpinnings, the consent rule represents an oversimplified gesture which omits more fundamental questions from enquiry. This is so because an emphasis on consensus provides the frame of reference for an enquiry into the status or non-status of law, that is, whether or not law exists. We know that law in fact exists by delving into the sources of law, where IL can be identified with reference to treaty provisions, custom or state practice, and judicial decisions.

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<sup>15</sup> See WTO's website at: [http://www.wto.org/english/thewto\\_e/thewto\\_e.htm](http://www.wto.org/english/thewto_e/thewto_e.htm)

<sup>16</sup>For an overview of decision-making at the WTO, see [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org1\\_e.htm#ministerial](http://www.wto.org/english/thewto_e/whatis_e/tif_e/org1_e.htm#ministerial)

However, the consent rule does not allow us to ascertain *how* consensus was reached. Establishing that there *is* consensus should never be sufficient measure to determine the existence of law. For instance, in well developed domestic legal systems, a consensus oriented paradigm has various validating facets, depending on whether consensually derived outcomes were the result of deception, coercion, and/or incapacity.<sup>17</sup> However, the consensus rule of the WTO is based on a peculiar ‘silence equals consent’ notion. Borrowing from GATT practice since 1959, “a decision by consensus shall be deemed to have been taken on a matter submitted for consideration if no signatory, present at the meeting where the decision is taken, formally objects to the proposed decision” (Steinberg, 2002: 345).<sup>18</sup> More broadly however, consensus implies that the consenting person, with full apprehension of the facts, has agreed to a certain conclusion or policy, through an act of individual reason (Giddings, 1900: 259). Consensus in international law in general, and WTO law in particular, remains unproblematic; its manufacture in the face of power remains uncritical.

Notwithstanding, English jurist John Austin (1790-1859) formulated that “the existence of law is one thing; its merits and demerits another. Whether it be or be not is one enquiry; whether it be or be not comfortable to an assumed standard, is a different enquiry” (Green, 2003: 1). Consequently, what the rule of consensus depicts at the level of WTO decision-making is a mere description that the law exists. It categorically eliminates any consideration of the kinds of corruptive/fraudulent strategies encountered in the last chapter aimed at manufacturing the necessary consensus to force compliance with TRIPS. The rule of consensus excludes any meaningful account of what strategies are used to achieve consensus, and whether a consensual outcome meant punitive welfare costs for some and overwhelming welfare gains for others. The consent rule points simplistically to the theoretical legitimacy of the law and an artificial

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<sup>17</sup>See entry from Legal Theory Lexicon, “Legal Theory Lexicon 042: Consent”, <http://legaltheorylexicon.blogspot.com/2004/11/legal-theory-lexicon-042.html>

<sup>18</sup>See also Narlikar, 2006.

conception of systemic unity. It points simply to the ‘fact’ that laws exist, but leaves no room for discussion about the law’s making, its impact and functions, its winners and losers, a prohibition which has the propensity to reify the legal apparatus, thereby acting to preserve it.<sup>19</sup>

So unyielding is this positivist dynamic in international trade law that in a June 2005 interview, the interviewee remarked that one cannot concentrate on economics and neglect/underestimate what is legal (Anonymous 1 interview). While this is significant and re-asserts a major thrust of this chapter, the respondent continued, referring to WTO law, that “at the multilateral level, there is a difference between passion and substance ... you have to get the substance right...the law is fundamental” (ibid). According to legal positivist orthodoxy therefore, what matters first and foremost is that the law exists. Referring to the African Group's public health demands in the Doha deliberations on TRIPS and Public Health<sup>20</sup>, the interviewee asserted “don’t come to us and say a million people are dying, so what? What is the substance?” (ibid). Anything outside what is immediately recognizable from the legal texts is “passion” or value-laden and therefore unworthy of consideration. Indeed, the fact that a policy is just, wise, efficient, or prudent is never sufficient reason for thinking that it is actually the law; and the fact that it is unjust, unwise, inefficient or imprudent is never sufficient reason for doubting it (Green, 2003: 1).

Responding to these claims an African Group respondent (Mauritian) exclaimed, “when people are dying by the millions, what does it touch if not passion?” (Palayathan, 2005 interview). He continued that “rules are at best, a way of life. They are a set of guidelines which tell us to agree on what to agree. Rules are made by human beings. The West makes rules that accommodate their interests so ‘they’ are more passionate than we are. We have changed society from barbarism to civilisation; from beheading, as this was also the law. If death tolls in Africa do not

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<sup>19</sup> See also Buchanan and Keohane (2006: 412-415) for more shortcomings of the consent rule.

<sup>20</sup> Although ‘TRIPS and Public Health’ is dealt with in the next chapter, some African Group interviewees were asked to respond to anonymous claims concerning the passion/substance dichotomy.

warrant a change in the law, then something is tragically wrong. TRIPS constitutes a set of standards, and changing the standard does not mean that we are constructing a rule-less society” (ibid). The Mauritian trade advisor was therefore making the case for acknowledging the intrinsically human/social origins of law, adopting a Vichian perspective that human institutions should not be thought of in terms of unchanging substances, but rather, as a continuing creation of new forms (Cox, 1981: 132). In a much ahistorical manner, the first respondent saw the law as *existing* because member-states consented to its formation, and paying attention to this fact was fundamental. For the Mauritian using history as a starting point, while the law does exist, it was in fact made by men and could well be transformed if human conditions so warranted.

The paradigm of consent therefore provides the system with an unexplained, mysterious legitimacy. As a consequence it preserves the character of the system, giving it a life of its own, far removed from the value-laden content that negatively defines politics. As Pashukanis argues, the usual analysis we find in any philosophy of law identifies the legal relationship as a will relationship, as a voluntary relationship between people in general (Collins, 1982: 61). But as the last chapter illustrated, achieving consensus could take on a variety of methods, including those framed within Gramsci's lens of coercion. In light of such methods, Steinberg concludes that “the GATT/WTO consensual decision-making process is organised hypocrisy in the procedural context” (Steinberg, 2002: 342).<sup>21</sup> Organised hypocrisy has been variously identified as patterns of behaviour or action that are decoupled from rules, norms, scripts, or rituals that are maintained for external display (ibid). In the context of the deliberations on patents in the Uruguay Round, these ‘decoupled patterns of behaviour or action’ are synonymous with the various strategies used to shore-up consensus over a strengthened international patent code.

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<sup>21</sup> Howse (2001: 359) argues that the consent of sovereigns provides a powerful basis for the legitimacy of the rules that constitute the WTO treaties. Buchanan and Keohane (2006: 414) contend that state consent confers legitimacy only when states are democratic.

We recall from Chapter IV the use of aggressive unilateralism by the United States against Brazilian exports and its compilation of ‘watch lists’ and ‘priority watch lists’ effected under its 1988 Trade Act; the widespread use of informal, closed consultations as the locales where deals were struck, forums which lacked transparency and for which there are no transcribed materials (one of the hallmarks of transparency); the strategic use of asymmetrically composed bilateral sessions to exchange concessions and change positions; Lars Anell's submission of texts on his own responsibility and committing no delegation, but which were the basis of the final agreement; the categorical elimination of bracketed language in Dunkel's final draft which represented the core interests of DCs; the GATT's ‘disinformation campaign’ tactically informing India of her isolation on TRIPS; and the unexpected uprooting of India's TRIPS negotiator at a crucial point in the Round.

We also recall that despite the fact that there was no consensus at the twenty-fifth hour of the Round, the final decisions implying consensus were reached by the GATT's DG, Arthur Dunkel, as an “arbitrated resolution to issues undecided by the negotiators” (Stewart, 1995: 2280, taken from Field, 1991). At this crucial moment, when there should have been a move to vote on the issues (as per Article IX of the Agreement establishing the WTO), the DG steps in with his ‘arbitrated resolution’. These citations point to a serious flaw in the law and its reliance on so-called state consent for legitimate expression. As Steinberg maintains, the procedural fictions of consensus and the so-called sovereign equality of states have served as an external display to domestic audiences to help legitimise WTO outcomes (Steinberg, 2002: 342).

In the face of these citations that are not publicly apparent, it is impossible to say that all parties *consented* to TRIPS. The fact that TRIPS was also signed by those countries mounting the greatest offensive against transnational capital's international IP agenda does not mean that the methods used to achieve consensus were *also* the subject of consensus, notwithstanding the fact

that the Uruguay Round package had to be accepted as a single undertaking. In the context of patents, we see a very different instrumentality of consensus emerging, one arrived at through a range of non-transparent and coercive strategies. As such, TRIPS in general, and its pharmaceutical-related patent provisions in particular, in their 1995 construct, did not contain the hallmarks of hegemony. At the time of ‘consenting’ to the UR package, in which TRIPS was a mandatory component, DCs were not convinced that the system being offered was in their best interest. In fact, it was the contrary. They maintained that the entire IP framework, on the eve of its endorsement in Marrakesh, had dealt them a grave injustice (MTN.GNG/NG11/27: 3-4). At no point in the texts of the negotiations could one comfortably argue that TRIPS was the result of an organically derived accord, that the countries of the South internalised the belief that intellectual property protection was the welfare-enhancing option in the pharmaceutical sector. They were never indoctrinated into this logic. The *sole* mention of a consensus being reached in the Round was the US delegate’s assertion of an “emerging international consensus” (MTN.GNG/NG11/14: 75, 81.1) on a 20-year patent term, a view which was shared exclusively by those countries representing the core IPC jurisdictions. TRIPS consensus was arrived at from a mixture of coercion, marginalisation, and an insistence that the agreements be accepted as an all-or-nothing package. It is partly in this context that TRIPS as an international legal instrument, represents a framework of ‘consent without consent’.

#### **5.4 Legitimacy and the TRIPS Agreement: A Framework of ‘Consent Without Consent’**

‘Consent without consent’ is a dialectical concept that speaks to the heart of democracy, as well as the making of the patent provisions in TRIPS reviewed in this work. Sociologist Franklyn Henry Giddings first used the expression to denote the terms of US military engagement in the Philippines. It described the 21 December 1898 “Benevolent Assimilation Proclamation” of US President William McKinley, which, *inter alia*, made it the duty of the commander of the forces of occupation ‘to announce and proclaim in the most public manner that *we come*, not as

invaders or conquerors, but as friends, *to protect* the natives in their homes, in their employments, and in their personal and religious rights' (McKinley, 1898). McKinley's desperation to establish the legitimacy of his operation by winning hearts and minds<sup>22</sup> showed further when he proclaimed that "it should be the earnest wish and paramount aim of the military administration to win the confidence, respect, and affection of the inhabitants of the Philippines by assuring them in every possible way full measure of individual rights and liberties which is the heritage of free peoples, and by proving to them that the mission of the United States is one of "Benevolent Assimilation" substituting the mild sway of justice and right for arbitrary rule" (ibid).

According to Giddings, what this meant was that "if, in later years", the colonised "see and admit that the perpetuation of the disputed relations was for their highest interest, it may be reasonably held that authority had been imposed with the consent of the governed"; "remembering that consent is an approval by reason and conscience, and not by mere submission, it is obvious that consent can only be given only when reason and conscience are brought face to face with experience" (Giddings, 1900: 266). Notwithstanding the colonial mindset which appeared to influence Giddings' writing, 'consent without consent' is "a law by which a higher civilization supplants a lower" and implies deferred consensus, to be given once subjects gained "full maturity of reason to understand and interpret" that the imposed order was in their best interest (ibid: 265-266).

A more recent highlight of this concept – which again draws attention to the primacy of the law for IPE – was a ruling of the US Sixth Circuit Court of Appeals against an appeal by workers who lost jobs when Ohio plants were moved to states with cheaper labour. The Court ruled that "states and counties in the United States compete with each other for companies contemplating

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<sup>22</sup> See Lukes, 2005 on power and the battle of hearts and minds.

relocation”, and labour laws neither “discourage such relocations” nor bar closing of unionized plants in favour of “a non-unionized plant in another part of the country”, as “contemplated” by NAFTA. Furthermore, Congress and the courts “have made the social judgement ... that our capitalist system ... will not discourage companies from locating on the basis of their own calculations of factors relating to efficiency and competitiveness. The rules of the marketplace govern. By so reflecting commercial interests, the institutions of government serve – according to current legal and economic theory – the long-term best interests of society as a whole. That is the basic social policy the country has opted to follow” (Chomsky, 1997: 237).<sup>23</sup>

According to Chomsky, “the country has opted to follow” no such course, unless we invoke the people’s ‘consent without consent’ (ibid). He continues that “with a proper understanding of the concept of ‘consent’, we may conclude that implementation of the business agenda over the objections of the public is ‘with the consent of the governed’, a form of ‘consent without consent’” (ibid). Consequently, so long as there is a gap between public preferences and public policy, one may consider that policy was decided with the best interests of society as a whole, thereby invoking ‘consent without consent’.

Looking closely at the story unfolding in previous chapters on the making of patent provisions in the GATT, one can similarly develop a framework of ‘consent without consent’. Amidst such high levels of resistance and opposition by the developing world against the very framework that was ‘agreed’ at the end of the Round, the only means through which the WTO could maintain that TRIPS was the result of consensus decision-making is to invoke a form of ‘consent without consent’. Indeed, the arguments aimed at setting the agenda for a GATT IP framework, as well as those expounded throughout the negotiations in favour of strengthened international patent rules, made the link between industry’s demands on the one hand, and benefits to society on the

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<sup>23</sup> Allen, et al., v Diebold, INC, 33F.3d 674 \*677, decided September 6, 1994.

other, as two sides of the same coin. Arguments were framed, not just in terms of what was best for business, but more importantly, what was fundamental for society.

Referring to the ‘Ideas and Institutions’ component of the prevailing historical structure developed in Chapter I, the TDI employed a conscious equalization strategy in the pre-Uruguay Round stages whereby it equalised its demands with the best interests of society, and what was good for the United States as a whole. We recall how industry was able to package policy ideas to convince Congress and the general public that certain policy proposals constitute plausible and acceptable solutions to pressing problems (Campbell, 1998: 380). In this case the US trade deficit was seen as one of its most urgent challenges – the solution to which lay in the proposals tabled by IP-dependent industries. By extension, we recall the scripture-like dynamism and embeddedness of the TAG rationality and its dependent PEG mechanism. The extent to which these dominate the growth agenda facilitated the TDI’s strategic manoeuvres to get IP on the US, then on the international trade agenda. It is on this basis that one can invoke ‘consent without consent’, because ultimately, what business wants is equivalent to what society needs.

We also recall some of the persistent debates in the Round which were drawn from similar interpretations, particularly those influenced by modernisation rationalisations. It was argued that proposals tabled by industrialised countries were conducive to the development of DCs because they allowed for greater security and predictability, and more attractive conditions for foreign investment and R&D (MTN.GNG/NG11/20: 32), all considered highly prized for developed and aspiring economies alike. It was maintained that the fact that some industrialised countries had not until recently provided full patent protection in certain sectors or were still in the process of doing so, did not establish that such policies were conducive to technological and economic development (ibid). Rather, “experience had shown the opposite, that in countries where patent protection had been increased, the industries concerned had been stimulated, and in countries

where patent protection had been reduced, the industries affected had suffered” (ibid). “The delay in extending full patent protection in certain sectors had been because it had taken time to learn from experience, the benefits of patent protection sufficiently to overcome sectoral interests that might be opposed to it” (ibid). And that “developing countries were now in a position to profit from the experience which had been gained at some expense in the industrialised world” (ibid).

The patronization notwithstanding, these arguments point towards a form of ‘consent without consent’ that is characteristic of democratic society, whereby decisions are taken because a particular group deems that particular decisions are in the best interests of society, despite society’s objection. In the case of the patent provisions under TRIPS, the final decisions were taken on the basis of Arthur Dunkel’s ‘arbitrated resolution’ because in his view, they were in the best interest of the developing world, a form of ‘consent without consent’.

‘Consent without consent’ is probably one of the most profound paradoxes confronting liberal democratic societies, past and present. It very plausibly explains the disjuncture that often exists between public preferences and policy outcomes. In fact, ‘consent without consent’ has always featured highly in the politics of property relations, an attribute which places TRIPS on parallel with some of the greatest historical documents (as well as the rationalisations in the making of these texts) such as the United States Constitution. The concept essentially captures one of the most enduring tensions within the liberal democratic tradition, that between the desire for limited forms of government on the one hand, and the overriding commitment to popular rule on the other (Heywood, 2003: 43). It highlights the fact that the basic democratic tenet of popular rule potentially hinders the realisation of other, similarly fundamental democratic ideals, such as those pertaining to individual rights and freedoms, such as the right to property. This is so because of the extent to which the will of the majority or greatest number potentially prevailed

over that of the minority (ibid: 44), thereby challenging basic individual rights and freedoms, a contradiction which has attracted considerable debate from some of the tradition's greatest thinkers.

French classical commentator Alexis de Tocqueville famously described this contradiction as constituting a "tyranny of the majority", and it is from this perspective that Alexander Hamilton termed the majority admired by democrats, the "great beast" (Chomsky, 1997: 229). To explain this concept using an historical example, Chomsky cites the experience of the UN and developing countries. He notes that the UN was a reliable instrument of US policy and was highly admired; but decolonization brought with it what came to be called the "tyranny of the majority", and from the 1960s, Washington was compelled to take the lead in vetoing Security Council resolutions, and voting alone or with a few client states against General Assembly resolutions (ibid: 235). It is at this juncture, where the tyranny of the "great beast" becomes a reality, that 'consent without consent' assumes much of its significance. Here, the need for responsible decision-making becomes paramount because of the likelihood of a subversion of the democratic process by the majority, or in the case of TRIPS, developing countries. According to Wilsonian democracy, what was needed to preserve stability and righteousness was an elite of gentlemen with "elevated ideals" (ibid: 232).

Walter Lippmann seconded this when he said that the intelligent minority of "responsible men" must control decision-making (ibid). This "specialised class" of "public men" is responsible for "the formation of sound public opinion" as well as setting policy, and must keep at bay the "ignorant and meddlesome outsiders" who are incapable of dealing with "the substance of the problem" (ibid). This may have been the motivation for Ambassador Anell's proposal to the GNG in November 1988 stressing the need for guidance from Ministers on the future conduct of negotiations to be made clear to all participants (MTN.GNG/NG11/11: 2); as well as the

anonymous interviewee above on the passion/substance dichotomy. In this vein, the public must be “put in its place”: its “function” in a democracy is to be “spectators of action”, not participants, acting “only by aligning itself as the partisan of someone in a position to act executively” (Chomsky, 1997: 232). More recently, Lasswell warned that the intelligent few must recognise the “ignorance and stupidity [of] ... the masses” and not succumb to “democratic dogmatism about men being the judge of their own interests” (ibid).<sup>24</sup> The masses must be controlled for their own good; and in more democratic societies, where social managers lack the requisite force, they must turn to “a whole new technique of control, largely through propaganda” (ibid), a directive which may have propelled the GATT Secretariat's disinformation campaign against India in the last chapter.

Of parallel or perhaps greater significance, were the views expressed by James Madison during the debates on the Federal Constitution. Expressing support for the intelligent few, he pointed out that “In England, at this day, if elections were open to all classes of people, the property of landed proprietors would be insecure” (Chomsky, 1997: 239). In an attempt to guard against majoritarian tyranny, a system of checks and balances was needed to make government responsive to competing minorities, but more importantly, there was a need to safeguard the propertied few against the propertyless masses (Heywood, 2003: 44), or “to protect the minority of the opulent against the majority” (Chomsky, 1997: 239). This line of thought is an extension of the Lockean construct almost a century earlier which contended that while the propertyless masses should be excluded from actual lawmaking, they were to be fully bound by laws which are intended to protect private property; “everyone was obliged” (Macpherson, 1980: xix). The famous unfettered liberalism of Hayekian thought later in the 20<sup>th</sup> Century also owes tribute to the earlier tradition, when he challenged the socialist tendencies of his time and proclaimed that “what our generation has forgotten is that the system of private property is the most important

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<sup>24</sup> See Robinson (1996b: 146) on a similar Henry Kissinger comment regarding the election of Chile's Allende in 1970; and Fukuyama (1997: 10) for his comment on the strange thoughts of people of Albania and Burkina Faso.

guarantee of freedom, not only for those who own property, but scarcely for those who do not” (Hayek, 1944: 78). In fact, this theme recurred throughout the negotiations, spelling out the universal benefits to be derived from a strengthened, GATT-administered system of international IP rules.

Notwithstanding, Madison further contended that “the senate ought to come from and represent the wealth of the nation” (Chomsky, 1997: 240). In the Madisonian Virginia Plan, the upper house was to “assure continuing protection for the rights of the minority and other public goods” (ibid). Similarly, he accorded “the people’s right to rule” the same importance as “the protection of the rights of property” (ibid). In resolving majoritarian tyranny, Madison, as well as his predecessors and advocates, gave precedence to the protection of the rights of minorities (propertied minorities) and accorded such rights a ‘public good’ status in much the same way that the story of IP unfolded. If the rights of the propertied class are protected, the greater interests of society are automatically served because essentially, those “without property, or the hope of acquiring it cannot be expected to sympathize sufficiently with its rights, to be safe depositories of power over them” (ibid: 241). In this case, in which the majority would have subverted the course of justice, protecting the rights of propertied minorities would in fact be the preservation of a fundamental public good. The Constitution which was to emerge from these debates was said to be “intrinsicly an aristocratic document designed to check the democratic tendencies of the period”, delivering power to a ‘better sort’ of people and excluding “those who were not rich, well born, or prominent from exercising political power” (ibid).

All these citations inform a framework of ‘consent without consent’ whereby decision-making in a given society is the real purview of the few who are supposedly endowed with reason and property, despite the objection of the public concerning certain policy orientations. These ‘responsible men’, who are inevitably unbending to ‘democratic dogmatisms’, are the only ones

capable of making sound policy for the universal good. ‘Sound’ policy however, must have its basis in the TAG rational model, and must rely on the PEG configuration for legitimate expression. The citations are also reminiscent of some of the debates encountered during the TRIPS negotiations on what should or should not constitute an appropriate patent regime. While there was no reference to the capabilities of ‘responsible men’ during the Round, the recurring theme admonished that DCs needed to understand that strengthened IP rules were the quintessential 21<sup>st</sup> century tools to secure investment and innovation opportunities. There was an apparent concerted effort aimed at demonstrating that there was no other alternative than to deliver on the demands of the TDI, packaged as a growth strategy that would benefit society.

Therefore, because the dominant framework necessarily informs the prevailing theory as practice, the imposition of policy cannot be judged on the basis of resistance to it, but on the deferred consensus that will ultimately legitimise it (Giddings, 1900: 265). As such, despite the uproar sustained by developing countries during the Round, at some point in the future when these countries recognise the contribution to growth from a TDI-specific global patent regime, they *will* admit that the Round ended fairly and will realise that the disputed relation was for their highest interest. Consequently, all those responsible for the particular formation of the patent provisions of TRIPS (from Pfizer’s Pratt, to DG Arthur Dunkel: the intelligent minority of ‘responsible men’) should invoke that their will was imposed with the consent of developing countries, a form of ‘consent without consent’ given when DCs attain “full maturity of reason to understand and interpret” (ibid) the relevance of minimum standards of protection in the pharmaceutical sector.

The problem with a policy based on ‘consent without consent’ is the sense of certainty with which it is delivered, despite its indeterminate character. Such policies are presented as the only sensible policies in the pursuit of efficiency and growth. However, one of the most fundamental

questions concerns the probabilities of success or failure of ‘policies of certitude’ (those derived from the prevailing theory as practice) intended for growth. What happens when such policies fail, when it is not possible to invoke ‘consent without consent’? As James Madison would later learn for instance, the “opulent minority” proceeded to use their new-found power much as Adam Smith had described, pursuing their “vile maxim”: “all for ourselves and nothing for other people” (Chomsky, 1997: 242, cited by Matthews, 1995: 358). By 1792, he warned that the Hamiltonian developmental capitalist state would be a government “substituting the motive of private interest in place of public duty”, leading to “a real domination of the few under an apparent liberty of the many” (ibid). Madison evidently rescinded on his earlier conviction that the protection of the rights of propertied minorities was *the* public good, gaining cognizance that there were real dangers when policies of certitude lacked meaningful balance. In spite of its ubiquity nonetheless, ‘consent without consent’ represents a deeply flawed understanding of legitimacy. Arguably, it has absolutely nothing to do with legitimacy, and is simply a nuanced way of saying that a particular policy is bereft of any level of legitimacy.

In the Weberian sense of the term, there tends to be greater adherence of subjects to the rule of law if the subjects perceive both the rule and the ruler as legitimate (Shanker, 2003: 155, taken from Weber, 1968: 31; Hurd, 1999: 381; Franck, 1990: 24; Buchanan and Keohane, 2006: 405; Cox, 2007: 525; Underhill and Zhang, 2008: 537).<sup>25</sup> The legitimacy of a rule, or of a rule-making or rule-applying institution, is a function of the perception of those in the community concerned that the rule, or the institution, has come into being endowed with right process (Franck, 1988: 711). In international legal parlance, the expression ‘right process’ encapsulates the rules’ literary structure; origins; internal consistency; reasonableness; utility in achieving stated ends and connection to the overall rule system; and the extent to which their origins and application comport with the international community’s “rules about rules” (ibid). Therefore, legal

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<sup>25</sup> See also, Mulligan, 2005; and Clark, 2005 for the historical evolution of thought on legitimacy.

legitimacy depends on agents in the system understanding why rules are necessary, and participating in constructing law enhances agents' understanding of its necessity (Finnemore and Toope, 2001: 749). Legal claims are legitimate and persuasive only if they are rooted in reasoned argument that creates analogies to the past, demonstrate congruence with the overall systemic logic of existing law, and attend to contemporary social aspirations and the larger moral fabric of society (ibid). In law, legitimacy is the justification of authority (the right to command or render an ultimate decision) – the authority, for example, of legislatures to prescribe legal rules or of courts to decide cases (Bodansky, 1999: 601).

“Legitimate authority” simply means “justified authority” and theories of legitimacy attempt to specify what factors might serve as justifications, such as tradition, rationality, legality, and democracy (ibid). Similarly for Habermas, “legitimacy means that there are good arguments for a political order’s claim to be recognised as right and just; a legitimate order deserves recognition. *Legitimacy means a political order’s worthiness to be recognised*” (Habermas, 1979: 178-9). “It represents a generalised perception or assumption that the actions of an entity are desirable, proper or appropriate within some socially constructed system of norms, values, beliefs and definitions” (Suchman, 1995: 574). It depends on a process of internalization by an actor of an external standard which satisfies variables existing at the intersubjective level (Hurd, 1999: 388). Legitimacy therefore is a contestable validity claim; the stability of an order of domination depends on its (at least) *de facto* recognition (Habermas, 1979: 178-9). At the very least and in spite of its contestability, accounts of legitimacy place considerable emphasis on non-coercive factors as conducive to rule-compliant behaviour (Franck, 1988: 710). When an actor believes a rule to be legitimate, compliance is not motivated by the simple fear of retribution, or by a calculation of self-interest, but instead by an internal sense of moral obligation (Hurd, 1999: 387). As such, a perceived absence of legitimacy broadly constitutes a democratic deficit (Moravcsik, 2004: 336-363; Keohane and Nye, 2003: 386-411), thereby

significantly reducing the 'compliance pull' of legalised orders (Finnemore and Toope, 2001: 749; Hurd, 1999: 387-8).

If we were to take the attributes of non-coercion, and a minimum of *de facto* recognition by the subjects of law that both the rule and the rule-making/rule-applying institution were justified, as hallmarks of a legitimate order, then the WTO and its patent provisions would fail the legitimacy test. And as Picciotto (2003b: 1) aptly framed it, “The WTO can't claim legitimacy merely because it acts through law, if the processes for making and applying those laws lack transparency, responsibility and accountability to the public”. To begin with, there appears to be broad agreement that the current functioning of international institutions such as the WTO does not meet democratic standards (Zurn, 2004: 261). Acknowledged democratic deficits include the lack of identifiable decision-makers who are directly accountable for wrong decisions made at the international level, as well as the inscrutability of international decision-making processes, and thus, the advantage executive decision-makers have over others in terms of information (ibid). Furthermore, particularly the primary actors in international politics, such as multinational business and major powers, are at best accountable to a fraction of the people who are affected by their activities (ibid).

More importantly, governments and citizens of DCs and LDCs have generally had a negative perception of TNCs, arguably the most important and influential actors in the global economy. Moreover, the GATT/WTO has been seen as a *status quo* institution, acting on behalf of transnational business and their governments. Many governments and citizens in developing countries still perceive TNCs as potential or actual agents of a neo-colonialist project aimed at exploiting their resources without adequate compensation (Koenig-Archibugi, 2004: 234), and as a result, the integrity of the WTO, which purportedly serves these entities, is thrown into disrepute as an institution with a built-in neo-liberal bias. In fact, poorer countries were highly

dissatisfied with the institution's predecessor, the GATT, because it was seen to favour the trading interests of industrialised countries (Griffin, 2003: 797). After agitation over a number of years, they were given UNCTAD, a weak, non-permanent body with no policymaking mandate (ibid). The WTO in effect, inherited a culture of disgruntled developing countries. Consequently, the level of anti-corporate and anti-WTO transnational activism in recent years – the ‘battle in Seattle’, the ‘failure at Cancun’ and the anti-globalisation movement – are all symptomatic of a global public perception of its intrinsic illegitimacy. As such, the WTO as the principal institution with a rule-making and rule-applying remit is at best, highly contested.

From this vantage point patent policy was already being negotiated in a climate of discontent, where more than half of the participants lay largely suspect of the motives of the trade institution. At the Punta del Este Ministerial launching the UR negotiations, Zimbabwe’s Minister of Mines stated that on the so-called new issues, including IPRs, “we are still to be convinced about the appropriateness and timing of negotiations on these issues, either in the GATT or in a new round”; and that in the preceding two weeks of the Punta del Este Ministerial, the Heads of State or governments of the Non-Aligned Movement recognised that GATT did not have jurisdiction over IP (MIN(86)/ST/61: 2-3).<sup>26</sup> In fact, DCs maintained the GATT-inappropriateness of IP throughout the negotiations, further supporting the “unjustified authority” of the institution in IP matters. Conversely, these countries expressly recognised the international IP conventions administered under WIPO as the legitimate authority.

To them, the Paris Convention had a long-standing pedigree, with an inclusive agenda that specifically addressed their development needs. These countries did not accept the automatic trade-IP linkage being proposed. As we are reminded, all “trade and...” linkages are constructed, in the sense that the decision to link trade to other issues is always a political decision and is not

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<sup>26</sup> At Punta del Este, there were also parallel proposals by Brazil and Argentina opposing the inclusion of IPRs in the Round. See Gervais, 1998: 10.

otherwise determined by the nature of things; that governments link trade concessions to the satisfaction of other, non-trade policy interests, either politically or legally, whenever they find such linkages useful to the achievement of their goals (Trachtman, 2002: 77). From this vantage point DCs remained unconvinced of the supposed neutrality of the trade-IP linkage and the stated possibilities for welfare enhancement. Instead, they believed that ICs were acting categorically in their interests and that of their pharmaceutical and other IP-dependent industries. Developing countries simply did not trust the motives of the industrialised countries. A typical argument saw the push for TRIPS as a double-edged sword: it would protect the patents of the US and other industrialised countries, but would also allow them to take out patents on age-old knowledge and practices in the Third World and then invoke 'free trade' to sell them back, at patent monopoly prices (Frank, 2004: 608). Therefore, the audience for whom the rules were intended accepted neither the rule-making/rule-applying institution, nor the justification upon which the rules were based.

When DCs realised that IP was fixed on the UR agenda, they fought to retain the letter of the pre-existing law, invoking their 'right' to legislate on intellectual property matters in accordance with their development and technological needs, a battle which had been brewing long before in WIPO (Bronckers, 1999: 548). Consequently, the compliance-pull from the point of view of the NITs depended upon what Peter Gerhart (2000: 361) calls the substantive validity of the international law obligation, that is, whether the obligation in question meets an articulated standard of welfare, lending credence to the assumption that legitimacy claims are closely linked to questions of justice and fairness, however defined. Gerhart maintains that analysis of a particular standard's substantive validity must specify, and defend, the measure of welfare that is being used to assess the standard. To do this, the analysis must articulate the goals of the standard and must explain why the goals are welfare-improving; it must explain how the measure meets those goals without unintended consequences or costs. Accordingly, actors will

more likely comply with laws they believe to be just than with laws they believe to be unjust; and laws that are substantively valid under widely accepted criteria are more likely to be obeyed than are laws perceived to be unsupported by justifications grounded in human welfare (ibid).

Gerhart uses the prisoner's dilemma analogy to shed light on the issue, in which each party is better off if the parties cooperate, but worse off if they do not. In the typical trade issue, the US needs Thailand to open its borders and Thailand needs the US to open *its* borders. But for IP issues, the problem ran only one way; it responded only to the interests of industrialised countries that would be the principal exporters of IP (ibid: 368). This dilemma provides an illuminating insight into the TRIPS story insofar as it explains the extent of the consensus formation strategies encountered in Chapter IV; as well as the insistence on an enforcement framework built extensively around changes to domestic law, criminalisation and punishment. The assumption therefore is that if the patent provisions in TRIPS were the result of a democratic process grounded in public interest justifications, their legitimacy would have been endogenously derived rather than a product of decree handed down by NETs. This is so because "subordinate actors need to be allowed, or at least encouraged, to believe that they are expressing their free will, not being coerced, are being treated as ends in themselves, not merely as means, and are respected as ontological equals, even in situations characterised by marked power imbalance" (Lebow, 2005: 556). Therefore, not only did TRIPS lack legitimacy in the eyes of those intended to serve it, they saw its claims as dubious and did not trust the new institution with jurisdiction over it.

Moreover, we recall the very real threat and use of coercive unilateral measures sanctioned under US trade law. The last chapter chronicled that on 20 October 1988, the United States unilaterally imposed increased duties on Brazilian exports in connection with an intellectual property issue (MTN.GNG/NG11/10: 27), and that throughout the Round, DCs complained bitterly about the

prospects of US Special 301 legislation and the extraterritorial powers it granted the USTR. Coupled with that, Brazil succumbed to US coercive unilateralism in June 1990 when its President announced that he would seek the legislation the US wanted (Drahos with Braithwaite, 2002: 136), effectively relegating Brazil's participation to that of 'observer' in the negotiations. On July 02, the increased duties were terminated by the USTR (ibid). What the story tells us is that DCs went along with TRIPS, not to make themselves better off, but to avoid being made worse off (Gerhart, 2000: 371).

The coercion story exposes an embarrassing aspect of international law that has been hidden behind the assumption that treaties are consensual (ibid). As Gerhart notes, if a contract in a domestic law system is not truly consensual in some fundamental sense, an independent institution, applying an independent metric of fairness, can relieve the offended party of the burdens of the contract (ibid). Unconscionable contracts are not enforced, nor are contracts arrived at through duress or undue influence (ibid). The high level of opposition and acrimony, as well as the kinds of justice-orientated, kicking-away-the-ladder arguments by developing countries in the Round, suggest that these countries never regarded the positions of the NETs as legitimate. Moreover, the kinds of consensus formation strategies we saw in the last chapter suggest that TRIPS was concluded under conditions of duress and undue influence, further exposing its legitimacy shortfall, but more importantly, highlighting its invalidity as a contractual product. As Templeman rightly notes, the TRIPS Agreement was obtained by the threat and reality of trade sanctions and the withdrawal of aid (Templeman, 1998: 604), thereby making any claims of an un-coerced, consensually-driven outcome tenuous.

## **5.5 Conclusion**

The unfolding of the TRIPS story in particular, and the making of the WTO in general, unveils the crucial juncture at which critical IPE must consciously incorporate legal dynamics as a

genuine component within its remit. The ‘thickening of legality’ in the GPE can be cited as arguably the most fundamental opportunity to heed Henkin’s counsel to realists that “law is a major force in world affairs”, and to international lawyers to “think beyond the substantive rules of law, to the function of law, the nature of its influence, the opportunities it offers, the limitations it imposes” (Slaughter-Burley, 1993: 214, taken from Henkin, 1979: 4-5). Nowhere else has the cogency of this insight become more apparent than in the current global dynamics of the trade-relatedness of pharmaceutical patents. IPE has enabled us to move beyond the frailty of many orthodox assumptions based on paired opposites; expanded the subject matter beyond a fixation with geo-strategic competition among states; and included an array of different issues, actors and processes within its mandate. In spite of these developments, IPE has not seriously considered the framework of law and its many assumptions on neutrality, objectivity and autonomy, thereby facilitating the facelessness and consolidation of prevailing power relations.

The making of the patent provisions in TRIPS has not only highlighted the profundity of the relationships between these differentiated domains in IPE, it has also underlined the inseparability of law and politics. Despite the liberal international proclamation that international law represents the necessary flight from politics, the TRIPS story has demonstrated that “politics continues even where there is law” (Abbott, *et al*, 2000: 404) and that the two domains have inherited an unfortunate separation, to the detriment of both academic enquiry and social understanding. Moreover, the separation acts categorically to reproduce the *status quo* as natural and inevitable. Scott argues that the ideology of international law upholds the power structure of the system by presenting itself in a way that blocks the evidence of the power structure and of its own relationship to that structure (Scott, 1994: 313). Moreover, the absence of an IL mandate within IPE effectively reinforces this evidence-blockage that Scott speaks of. Consequently, because the critical PE is concerned with demystifying prevailing structures of power, there should be conscious collaboration with the CLS movement, since the two have mutual agendas.

Similar to IPE's concern with political economy structures, CLS aims to demystify the law, which is itself part and parcel of the prevailing power structure, particularly as it pertains to the juridical conditions of an essentially contested global capitalism, that is, when the material interests of global capitalism are threatened, a legal framework is developed in order to bolster legitimacy, thereby alluding to the material content of international legal regulation. A GATT IP framework became a priority on the international trade agenda only when transnational high-tech capital perceived its interests to be threatened by particularly DCs which either encouraged so-called piracy or did nothing about it within their borders. This chapter has demonstrated that IL too is loaded with dual assumptions, pivotal of which are precisely those of interest to IPE, such as the public/private, objective/subjective, domestic/international constructions. In particular, we saw how the positivist insistence on the state-as-subject rationality, or public notions of state authority, cloak the *de facto* privateness of power and authority in the GPE.

Moreover, positivist underpinnings in IL that place paramount importance on state consent as a means of objectively formulating and identifying the law do not consider what it means to achieve consensus in international lawmaking. It is in the very real climate of coercion, that Steinberg challenges the WTO's consensus rule as "organised hypocrisy in the procedural context" (Steinberg, 2002: 342). In fact, the structure of the WTO's legal system and the content of its adjudicatory decisions reflect rationalist institutionalist assumptions that states are the primary actors in international politics and that they participate in the GATT to circumvent inefficient domestic trade policies (Slaughter, *et al*, 1998: 377, taken from Shell, 1995: 825). This legal system, however derived, is seen first and foremost, as objective. The most significant point of enquiry in legal positivism is the law's substantive content. Its merits and demerits, distributive dynamics and substantive validity are quite another matter.

Because TRIPS was vehemently opposed by developing countries throughout the UR, the agreement has always suffered a democratic deficit in the sense that the subjects of TRIPS did not perceive the rule (patents) nor the rule-applying institution (the WTO) as legitimate. Consequently, the only way in which the WTO could uphold that TRIPS was consensual would be to invoke the developing world's 'consent without consent', a dialectical concept which explains the fissure between public policy and public preferences on the basis that decisions are made, by the powerful, ostensibly in the best interest of society, despite society's objections. It implies a coercive assumption of superior judgement on the part of the architects of policy, that dissenters (at the time the policy is being negotiated), will mature in reason and appreciate that decisions were taken against their will. This concept also plausibly enlarges Gramsci's concept of hegemony because it explains a moment of interlock between coercion and consent in international trade decision-making. While consent to TRIPS had nothing to do with Gramsci's notion of moral and intellectual leadership, formal consent in international law is nonetheless a profoundly legitimating mechanism. By problematising it, one can arguably arrive at different levels of consensus which potentially enhance the explanatory power of the concept of hegemony. On the face of it, the countries mounting the greatest offensive against the patent framework in the UR formally consented to TRIPS and were among the signatories at Marrakesh. However, in heeding Strange's warning to look, not on the surface of regimes, but underneath on the bargains and hidden agendas on which they are based; the complaints from the underprivileged and disenfranchised about how the system works (Strange, 1982: 480), the consent story becomes partial at best, bearing in mind that Gramsci's consensual hegemony is more conceptual than actual.

However, because the justification for policy based on 'consent without consent' is not grounded in considerations of human welfare, compliance depends extensively on punitive enforcement. It is precisely as a result of the legitimacy shortfalls of TRIPS that the level of criticism and

widespread transnational activism have persisted so fervently against it. The next chapter examines the post-TRIPS context of renewed opposition and how African countries at the WTO have transformed themselves from obscurity in the UR, to centre-stage in the post-TRIPS period.

## Chapter VI

### **The Post-TRIPS Context and the Intensification of a Contested Terrain: the Rise of the African Group<sup>1</sup> (AG) at the WTO?**

#### **6.1 Introduction**

Because TRIPS was not grounded in human welfare considerations (from the point of view of the global public, DCs and many NGOs), and because of its trade-off in favour of the TDI and other transnational commercial interests, it failed to command legitimacy from its intended rule-takers. The attempt in the negotiations to present pharmaceutical patents as if they were the most natural of social relations was unsuccessful as the major opponents reflected on such views as historically contingent, highly sectional and self-interested. In effect, while IPRs were cast as a natural necessity for global prosperity, and an answer to the development woes of the South – by encouraging FDI investment, technology transfer, creating incentive structures for local inventors, and offsetting bilateral trade tensions (Matthews, 2002: 108-111; see also 'The Research Problem') – developing countries read them categorically as the pursuit of maximum material gain by high-tech industries, at the expense of the disenfranchised. The prevalence of 'consent without consent' in concluding the patent provisions of TRIPS magnified the distinction between power exercised through persuasion, and power that relied on coercion (Lebow, 2005: 551). The making of pharmaceutical patents is therefore appropriately captured as the expression, not of power, but of a failure of power (Arrighi, 1993: 149), because power must be masked to be effective (Lebow, 2005: 556). Unmasked 'power' has a greater propensity to stir upheaval because of its proneness to arousing sentiments of unfairness, asymmetry and injustice.

TRIPS' privileging of one set of demands on patents over 'the other' amidst such controversy and conflict in the negotiations meant that Dunkel's 'arbitrated resolution' to issues undecided by the negotiators, had the very real effect of disembedding TRIPS from global social control, thereby

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<sup>1</sup> While this grouping consists of all WTO members of the African Union, which consists of all African countries except Morocco, it will be limited to sub-Saharan African countries in the context of this research.

situating patent policy formation in the UR within the first phase of Polanyi's double movement. The disenfranchisement inherent in 'consent without consent' therefore represents global social disembedding, whereby the developing world is coercively subordinated to the utility maximising behaviour of monopoly capital. For Polanyi, embeddedness is the social control of economic relations through institutional means, where a link can be drawn between embeddedness and the social obligation to act in a morally dutiful manner (Watson, 2005: 153). The prevalence of coercive disembeddedness, (in spite of evidence of the probing and appeal of concessionary bargaining encountered in Chapter IV) therefore meant that there was no social obligation to act in a morally dutiful manner. While TRIPS contained some built-in flexibilities,<sup>2</sup> the usability of these by developing countries would be tested against the backdrop of precisely that which it purportedly addressed. Thus, the failure of power and the corollary legitimacy shortfall reignited an atmosphere of disgruntlement and acrimony against pharmaceutical patents, setting the terms of TRIPS' post-1995 trajectory.

While the battle against TRIPS had been brewing before its inception, it reached a climax in the infamous March 2001 patent-infringement case by 39 pharmaceutical companies against South Africa over a 1997 legislative amendment in its Medicines Act which appeared to grant the government unspecified power to issue compulsory licences and parallel importing contracts to its generic producers for HIV/AIDS pharmaceuticals (Shah, 2002; Bartelt, 2003; Gad, 2006; Sell, 2006). So horrified was global public opinion, the industry was forced to drop the case, taking with it, a series of weak legal claims (Abbott, 2002b: 471). This case would be the harbinger of the access to medicines campaign, but more damagingly, an intensified transnational public perception of the TDI as unconscionable profiteers of disease (Shiva 2001),

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<sup>2</sup> TRIPS contains some 'built-in' flexibilities which, while not derogations from the agreement, allow developing and least developed countries more flexibility in interpreting the terms of the agreement. These include transition periods; compulsory licensing; public, non-commercial use of patents; parallel importation; exceptions from patentability; limits on data protection. See for instance Musungu and Oh (2005) on the legislative incorporation of such flexibilities in developing countries. See also, Vandoren, 2002: 8-10; Matthews, 2006: 92; and Paragraph 5 of the Doha Declaration.

and of the NETs and the WTO as defenders of this pernicious dynamic (Wallach, 1999). The case therefore prised open the debate on the precise meaning of the flexibilities written into TRIPS; the content of its objectives and principles embodied in Articles 7 and 8;<sup>3</sup> the appropriateness of Article 31 in general, but 31(f) in particular, requiring that, subject to 31(b)<sup>4</sup>, any such use of a patent shall be authorised predominantly for the supply of the domestic market of a Member authorising such use. This stipulation effectively formed the crux of the conundrum for SSA since these countries did not have the manufacturing capacity to comply with a domestic supply requirement, familiarly called the 31(f) problem (Matthews, 2004: 78). The case would also propel the rise of the African Group at the WTO, with greater visibility and leadership in the post-TRIPS climate.

This chapter is primarily concerned with the post-TRIPS role of arguably, the most marginalised global economic actor at the WTO, the African Group, up until the December 2005 WTO Decision to amend the TRIPS Agreement.<sup>5</sup> This focus simultaneously addresses the second, third and fourth empirical hypotheses as well as the second part of the theoretical hypothesis. The chapter engages with the conflict triggered by the distributional implications of patents in TRIPS; the rise *and* role of the African Group in the post-TRIPS agitation and negotiation of the Doha Declaration<sup>6</sup>, along with the leadership of civil society. The purpose therefore is to weave through the role of conflict in change, and to continue to demonstrate the insightfulness of a Coxian IPE, in terms of pulling together Vico's class struggle and 'modification of mind' thesis, Gramsci's mental imagery that gives groups self-awareness, and the second phase of Polanyi's double movement: each intimating movement from a particular set of social relations which enable continuity in the prevailing historical structure, to alternative conditions which signal

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<sup>3</sup> See also Bartelt, 2003: 285-287.

<sup>4</sup> Art. 31(b) authorises the use of compulsory licenses in national emergencies and other circumstances of extreme urgency.

<sup>5</sup> Recall from the Introduction that the research spans the UR up to the 2005 Decision to amend the TRIPS Agreement.

<sup>6</sup> Formally the Doha Declaration on the TRIPS Agreement and Public Health.

human emancipation. This insight from Cox's framework for the thesis however, is the movement away from his notion of a rival structure which would signal a change in world order, to a more nuanced quasi-rival structure representing incremental changes in various aspects of world order.

## **6.2 AG Engagement in the Doha Negotiations on TRIPS & Public Health: Differentiating Uruguay**

As indicated in Chapter III, African countries did not participate in the TRIPS negotiations to any meaningful extent, however, arguably the most striking feature in the post-TRIPS scene, has been the engagement and leadership of the African Group with health issues (Drahos, 2002: 780-782; 2007: 17-18). At a TRIPS Council session on April 2-5, 2001, Zimbabwe's representative speaking on behalf of the AG, said that the AG wanted to bring an issue to the attention of the Council, an issue which had aroused public interest and was being actively debated outside the WTO, but one which the Council could not afford to ignore especially given the need to clarify the role of IPR protection in dealing with pandemics such as AIDS and other life-threatening diseases (IP/C/M/30: 229). He continued that although the TRIPS Agreement allowed developing countries the flexibility to apply patents in ways that still enabled the protection of the health of their people, recent legal challenges by the pharmaceutical industry and some Members, in national law and under the DSU, highlighted the lack of legal clarity on the interpretation and/or application of the relevant provisions of the TRIPS Agreement (ibid: 230). Moreover, "attempts had been made by some developed countries through bilateral and regional arrangements to get developing countries to apply "TRIPS-plus" measures, or to forego their rights"; and that "contrary to the principles and objectives of the TRIPS Agreement, the present model of intellectual property rights protection was too heavily tilted in favour of right holders and against the public interest" (ibid).

He alluded to the AIDS pandemic and other preventable diseases as “a human tragedy of mind-boggling dimensions and emergency proportions” (ibid) afflicting the sub-continent. He noted that the upsurge in a negative public image and public outrage over the price of AIDS pharmaceuticals was resulting in a crisis of legitimacy of the TRIPS Agreement (ibid: 231). Continuing, he noted that the AG initiative was in no way meant to undermine or discourage investment into R&D for new drugs; and that given the highly mutative nature of the AIDS virus as well as the resistance to conventional drugs by some new strains of STDs and other diseases, the case for continued and intensified R&D into new pharmaceutical processes could not be overstated (ibid: 232).

However, the challenges lay in Members addressing the question of affordable access to drugs in a manner that would be fair and equitable to all stakeholders; finding ways to avoid the abuse of patent protection through recourse to uncompetitive practices; seeking to provide legal clarity of the relevant TRIPS provisions which would allow for certain measures to enable the protection of health; seeking to realise the objectives and principles of the TRIPS Agreement, and restoring confidence in a rules-based multilateral trading system (ibid). The AG consequently proposed the convening of a “special session” of the TRIPS Council to address issues relating to TRIPS, patents and access to medicines, the outcome of which would feed into the preparatory process of the Fourth Ministerial Conference in Doha (ibid: 231). And while the question of affordable access to drugs went beyond the relationship between patents and prices (issues which were beyond the scope of the Council), ‘the TRIPS Council had to play its part to the full’ (ibid: 233).

The AG had therefore formalised the linkage between patents and healthcare at the level of the WTO. Noteworthy however, is that concern over the impact of the price of patented pharmaceuticals on people’s access to healthcare had been sustained by DCs (particularly Brazil and India) throughout the Uruguay Round and thus, was not exactly new to multilateral trade

talks. What is new is the fact that the issue was now being raised by African countries in a way that could not be ignored as occurred in the Uruguay Round. The AG was also raising the issue as part of the Doha Development Round which purported to place the needs and interests of developing and least-developed countries at the heart of its work programme (WT/MIN(01)/DEC/1). The novelty also lies in an African visibility in and of itself, a visibility unfamiliar to the negotiations on IPRs in the Uruguay Round; as well as an African agenda-setting motion in an organisation riddled with the kinds of power tactics encountered in previous chapters.

In response to Zimbabwe's presentation a US delegate stressed that for the year 2001, his country had the largest bilateral assistance programme on HIV/AIDS, amounting to approximately half a billion dollars in assistance; and that the US also had a domestic and international research budget on HIV/AIDS in excess of two billion dollars (ibid: 235). Pointing to the subject at hand he stated that the United States would raise no objection if countries availed themselves of the flexibilities afforded by the TRIPS Agreement, provided there was procedural compliance (ibid). However, his delegation was equally committed to a policy of promoting IPR protection, including for pharmaceutical patents, because of their critical role in the rapid innovation, development and commercialisation of effective and lifesaving drug therapies; financial incentives were needed to develop new medications; and 'no one would benefit if research on such products was discouraged' (ibid). He further emphasised that the cost of drugs was one aspect amongst many in addressing serious health problems and that countries also needed to stress education and prevention; urgent action in strengthening health management systems with regard to the means and methods of drug distribution; the training of care providers at all levels; and diagnosis and monitoring of complex therapies, all of which he said could only be accomplished through a partnership among governments, donors, multilateral organisations, civil society, philanthropic organisations and industry (ibid). "Intellectual

property could be an important factor in contributing to increased access, but drug therapies had to be part of a comprehensive approach” (ibid). Like the US, the EC stressed that the matter concerned more than only TRIPS issues, that many factors played a role (ibid: 243; see also Noehrenberg, 2003: 381; Cottier, 2003: 385).

Amongst other AG representatives voicing opinions at the meeting were South Africa and Kenya, both of which recalled that the AG had, in the preparatory process leading to the failed Seattle Ministerial Conference in 1999, called for a review of the TRIPS Agreement to exclude from patentability essential and lifesaving medicines so as to allow developing countries to have access to medicines at affordable prices (ibid: 238, 246). Moreover, while Kenya believed that members could freely exercise the options available to them under TRIPS to protect and gain access to lifesaving and essential medicines, “there had been pressure on some developing countries, including Kenya, not to use these options” (ibid: 246), testimony that bilateral coercive measures aimed against the use of TRIPS flexibilities also featured in countries other than the infamous South African experience a month earlier.

This April meeting ended with the Chairperson’s suggestion that the Council devote a full day ‘special discussion’ in the TRIPS Council meeting in June to discuss the interpretation and application of the relevant provisions of the TRIPS Agreement with a view to clarifying the flexibility to which Members were entitled under the Agreement; and the relationship between TRIPS and affordable access to medicines (ibid: 251). Perhaps equally relevant, at least symbolically, was the election of Zimbabwe’s Ambassador Boniface Chidyausiku to preside as Chairperson over the TRIPS Council for the following year (ibid: 253). Therefore, not only did the AG’s visibility increase in the period preceding the Doha Ministerial, coupled with their ability to steer the agenda of the Council in a way that would potentially benefit the Group as well as the entire developing world, but significantly also, an AG representative would preside

over the matter in its inaugural year. While this chain of events does not point to SSA as a power base *per se*, at the very least, it highlights a differentiated post-UR climate in which African countries participated.

At the following TRIPS Council meeting, June 20 was reserved for the special discussion on TRIPS and access to medicines in which a total of 44 delegations opined on the matter, of which seven were from the AG, with Zimbabwe speaking on behalf of the AG, and Tanzania on behalf of least-developed countries (IP/C/M/31). Prior to this meeting, the EC, and a contingent of 17 DCs including the AG, both tabled a communication to the TRIPS Council which formed the basis of their presentations. Similar to US exhortations at the April meeting, the EC's paper listed HIV/AIDS and general development-related initiatives undertaken by the European Commission as EU responses to public health crises around the world (IP/C/W/280: 2-5). Addressing DCs' concern about the TRIPS Agreement and essential access, it nonetheless maintained that in the view of the EC and its member states, the Agreement's objectives, principles and purpose (set out in Articles 7 and 8), special transitional arrangements and other provisions give these countries a sufficiently wide margin of discretion in implementing it (*ibid*: 8).

The paper contended that while it has been charged that Article 31 is hedged around with too many procedural restrictions for it to be of use for developing countries who might wish to resort to compulsory licences in order to obtain access to patented medicines at affordable prices, 'procedural safeguards are important to guarantee legal security' (*ibid*: 11). In terms of the need for legal clarification of the appropriate TRIPS provisions such as what constitutes a "national emergency" and "circumstance of extreme urgency"; and the need to ward off expensive litigation because of legal uncertainties, the communication made a welcome contribution in stating that the level of HIV/AIDS infection reported in some developing countries would appear

to be very good reason for describing it as a national emergency or circumstance of extreme urgency (ibid: 12). In relation to 31(f) the submission concurred with the argument that this provision is sometimes said to prevent a small country that has no production facilities of its own from obtaining cheap medicines from abroad under a compulsory licence, stating “this is an important argument as the Agreement does not appear to offer legal certainty on the issue” (ibid: 13). Generally however, the EC believed that TRIPS “represented a delicate balance between the interests of right-holders and consumers” (ibid: 16).

From another lens the DC paper (IP/C/W/296) had moved from examining the particular consideration of TRIPS and access to medicines, to the more general TRIPS and Public Health, thereby extending the remit of the negotiations to consider all public health ramifications of patents and paving the way for future talks on the issue to be open-ended. In this document, the sponsors listed a number of global public policy initiatives linking trade agreements and public health, such as the May 2001 World Health Assembly’s “WHO Medicines Strategy” Resolution calling for further evaluation of the impact of international trade agreements on access to, or local manufacturing of, essential drugs, and of the development of new drugs (ibid: 11). Other significant illustrations were, the May 2001 XI Summit of the Heads of State and Government of the Group of Fifteen (G-15) in Jakarta (ibid: 13); the April 2001 57<sup>th</sup> Session of the United Nations Commission on Human Rights which adopted Resolution 2001/33 on “Access to Medication in the Context of Pandemics such as HIV/AIDS” (ibid: 9); the March 2001 lawsuit brought by 39 pharmaceuticals against SA contextualising the reality of the issue; but also very important was the impetus from reputable civil society organisations such as Medecins Sans Frontières, Oxfam and Consumers International. From this end therefore it was impossible for the TRIPS Council to ignore the issue which had generated such momentum at the international level.

These countries alluded to various elements that relate TRIPS to public health issues, not least its preamble which recognises the underlying public policy objectives of national systems for the protection of IPRs; as well as the special needs of LDCs in respect of maximum flexibility in the domestic implementation of laws and regulations in order to enable them to create a sound and viable technological base (ibid: 15); and the objectives<sup>7</sup>, and principles<sup>8</sup> embodied in Articles 7 and 8. In relation to the objectives and principles of TRIPS, the sponsors cited Article 31 of the 1969 Vienna Convention on the Law of Treaties, that “a treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose” (ibid: 17-23).

The document also made the case for an interpretation of Article 6 of TRIPS as permissive of an exhaustion regime premised on parallel importation (ibid: 24-27); for a more permissive interpretation of Article 31, and in particular, that nothing in the TRIPS Agreement should prevent members from granting compulsory licences to supply foreign markets (ibid: 28-34), thereby directly countering the 31(f) problem. While these countries believed in the virtues of policies based on differential pricing, such policies were insufficient and should not prejudice the right of members to avail themselves of parallel importation and compulsory licensing (ibid: 35-37). The proposal also categorically called for an extension of the transitional arrangements embodied in Articles 65.4 and 66.1 (ibid: 41). It was obvious therefore, that DCs were now of the impression that, if/once clarified, the TRIPS Agreement could be used to their advantage in a way that had not been deemed possible in the immediate post-Uruguay Round context.

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<sup>7</sup> Article 7 “Objectives” states that the protection and enforcement of IPRs should contribute to the promotion of technological innovation and the transfer and dissemination of technology, to the mutual advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.

<sup>8</sup> Article 8 “Principles” states that members may adopt measures necessary to protect public health and nutrition, and to promote the public interest in sectors of vital importance to their socio-economic and technological development, provided measures are consistent with TRIPS provisions.

Building on this June submission, Zimbabwe again spoke on behalf of the AG at the Council's special session, proposing that members aim to reach a common understanding that asserts and confirms the balance in the TRIPS Agreement: that recognises the importance of patent protection; and that provides that governments may adopt all appropriate measures to protect the health and lives of their people (IP/C/M/31: 4). This common understanding is precisely "the guarantee that governments need to enable them to adopt measures without fear of litigation (either at the national or WTO level)" or the apprehension that bilateral pressures will be applied on them (ibid). The AG therefore proposed that members issue a special declaration on the TRIPS Agreement and access to medicines at the Ministerial Conference in Doha, affirming that "nothing in the TRIPS Agreement should prevent members from taking measures necessary to protect public health" (ibid). Consequently, the Doha Ministerial Declaration should adopt a moratorium on dispute settlement (with immediate effect) to allow members to take measures to protect public health (ibid: 6). In addition to pressing for further consideration of their suggestions in the June 19 document, the AG representative echoed a similar observation we saw in the last chapter, expressed by the Mauritian trade advisor, that improvements to the TRIPS Agreement are required to take into account recent developments and problems that have arisen since the implementation of the agreement (ibid). He added that the seriousness of these problems were not anticipated at the time the agreement was negotiated and concluded, and that, with the benefit of hindsight, members are now in a position to improve upon TRIPS and thus be able to contribute more effectively to dealing with the crisis of AIDS and other infectious diseases (ibid)<sup>9</sup>.

Building on their June 12 submission, Ambassador Trojan<sup>10</sup> from the European Communities re-emphasised that "we have always insisted and continue to insist, that intellectual property

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<sup>9</sup> See also Abbott, 2002: 43-44 on the emergence of the HIV/AIDS pandemic as unforeseen during the initial negotiations.

<sup>10</sup> Name gleaned from Tanzania's presentation, IP/C/M/31: 30.

aspects are only one among many aspects to be considered and cannot be dissociated from the global problem of access to health” (ibid: 7). “We remain strongly committed to the TRIPS Agreement because we consider that intellectual property provides an essential stimulus for creativity and innovation. These rights need to be adequately protected in order to encourage investment in research and development into new medicines, and we need the R&D-based pharmaceutical industry to have those new medicines” (ibid). Consequently, “downgrading the level of current IP protection should certainly not be the aim of this exercise” (ibid).

Similarly, a US representative reiterated its country’s April 2-5 position, contending that “we must recognise that even if enough drugs to treat every single HIV-infected person were provided free of charge, an adequate infrastructure to deliver them and monitor their use does not appear to exist in many areas most in need” (ibid: 34). “We believe that participants in our discussion today should keep in mind that the TRIPS Agreement – its obligations and flexibility – is, at most, one element of the equation. To deal with serious health problems, countries need to stress education and prevention as well as care and treatment if health crises are to be eliminated” (ibid). He continued with the recurring theme we saw in previous chapters that countries with strong patent regimes are more effective in attracting investments and market entry by innovative companies (ibid: 36). In this context, he urged participants to refer to two documents on the WTO’s website (“WTO Fact Sheet: TRIPS and Pharmaceutical Patents” and “Technical Note: Pharmaceutical Patents and the TRIPS Agreement”) as aids to understanding the balance struck by the TRIPS Agreement. “We encourage Members to refer to these documents as useful explanations of the Agreement *and to avoid documents circulated by other individuals and organizations that lack the WTO’s expertise*” (emphasis added) (ibid), thereby insinuating that the counter-movement was not only wrong, but also misguided. There was only *one* interpretation, that which is consistent with the norms of the prevailing historical structure.

In a very matter-of-fact way, India's Ambassador Narayanan<sup>11</sup> argued that while it may be perfectly legitimate to discuss the various factors that impact on access to medicines and healthcare – such as infrastructure and the availability of medical personnel – as well as the various national and global initiatives/funds set up to address pandemics such as HIV/AIDS, the purpose of the current exercise was to examine public health and access to medicines in the context of the TRIPS Agreement (ibid: 21). Therefore, it was not within the Council's remit to examine such issues, and time spent debating them, unquestionable but unbecoming, would only serve to detract from the issue at hand (ibid). The issue was more appropriately captured as one concerning the impact of trade policy/law on people's access to healthcare in the poorest countries. He further contended that rather curiously, Article 8 of TRIPS reflects that the protection of public health and nutrition is a fundamental principle governing the agreement, it grants members the right to adopt measures necessary to protect such, yet, such measures must be consistent with the provisions of the agreement (ibid: 22). A principle which, *inter alia*, incorporates an element of exception, cannot be tested against the yardstick of consistency (ibid), a point seconded by Tanzania on behalf of LDCs (ibid: 29), but opposed by the United States in the subsequent formal meeting of the Council (IP/C/M/33: 162).

At the subsequent September meeting, the Indian delegate further argued that it would be unacceptable for his delegation if the current exercise resulted in a reduction of TRIPS flexibility; that the same applied to any preambular or "comfort" language simply restating the TRIPS wording; and that the scope of the text to be developed "should concern TRIPS and public health and should not be limited to addressing issues concerning the tragic HIV/AIDS crisis alone" (ibid: 150), concerns upheld by the Brazilian contingent (ibid: 157-8). However, this meeting saw increasing calls by delegations of 'defenseurs', including the EC (ibid: 154, 220), Switzerland (ibid: 179), Canada (ibid: 205-6) and Japan (ibid: 234), to stick to the mandate

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<sup>11</sup> Name gleaned from Tanzania's presentation, IP/C/M/31: 29.

which called for an examination of “TRIPS and affordable access to medicines”, as opposed to “TRIPS and Public Health”, since an expansion of the scope of the discussions ‘would eventually fail to reach any concrete result’ (ibid: 179). The interesting observation from this insistence is the parallel it draws with events in the TRIPS sessions of the Uruguay Round. We recall a similar level of opposition in Chapter III when DCs insisted that the Negotiating Objective be limited to the trade-relatedness of IP and not the whole gamut of substantive IP issues, suggesting, in the least, that when a party feels that particular negotiations threaten its interests, there is a decisive push to limit the scope of the agenda.

In what can be characterised as a hallmark of the US negotiating position, the United States delegation recited that the rights of innovators and creators were balanced by obligations such as, in the case of patents, the obligation to disclose their inventions clearly, so that others skilled in the relevant art could practice the invention and build upon it. Such disclosure often resulted in improvements or new uses of existing technology and sometimes the creation of new technologies. Rather than impeding access to medicines therefore, patent regimes actually met the objectives of Article 7 by contributing to the promotion of technological innovation and to the transfer and dissemination of technology. In his delegation’s view, the objectives of the TRIPS Agreement as outlined in Article 7 should indeed be used to interpret the provisions of the agreement, bearing in mind that the provision stated what “protection and enforcement of intellectual property rights” should do. “Obviously, where the standards of such rights and enforcement were not met through full implementation, the objectives would not be met either” (ibid: 161). In the US view therefore, the objectives of the agreement would be realised *only* after full implementation of its provisions, a spectrum of the ‘chicken/egg’ sequence in diametric opposition to AG and DC demands.

The AG and other DCs nonetheless found support within IC quarters also, with Norway assuming the role as champion of the DC cause. As did developing countries before him, a Norwegian delegate articulated that it was clear that all other provisions of TRIPS had to be read and interpreted in light of Articles 7 and 8 (ibid: 172). He therefore expressed disagreement with the US position, contending that the objectives and principles were particularly important for the interpretation of Article 31 (ibid). Furthermore, with respect to Article 31(f), ‘Norway could not accept that Members with small domestic markets or low technological skills, pursuing legitimate national public health goals, be placed in a disadvantaged position as to the possible use of Article 31 (ibid: 173).

Another highlight of the meeting however, was a proposal for a draft Ministerial Declaration on TRIPS and Public Health, again presented by Zimbabwe on behalf of the AG along with 19 others (ibid: 175). The draft was sectionalised into preambular language highlighting the context in which the proposal was made, such as the inability of large segments of DC populations to access medicines at affordable prices, the mounting international public opinion regarding the potential implications of the TRIPS Agreement on the availability and affordability of essential medicines and other healthcare products, the lack of adequate R&D into medicines for the prevention and treatment of diseases of relevance to DCs; and a 14-point section on operational language restating much of the demands in the aforementioned June paper, particularly stressing the textual inclusion that “nothing in the TRIPS Agreement should prevent Members from taking measures to protect public health” (IP/C/W/312). The US along with Australia, Switzerland, Japan and Canada followed with a draft Ministerial text containing only preambular language (IP/C/W/313). In the words of the Indian delegate, “it was a most conspicuous omission not to refer to patents when listing the factors to be addressed for improving access to medicines” (IP/C/M/33: 218) leaving one to conclude that these countries were convinced that TRIPS was not part of the problem, as they had so frequently reiterated.

However, the Fourth Session of the Ministerial Conference in Doha in November 2001 heralded a separate “Declaration on the TRIPS Agreement and Public Health” (WT/MIN(01)/DEC/2) specifically calling for the need for TRIPS to be part of wider national and international action to address public health problems; *agreeing* that while TRIPS did not prevent members from taking action to protect public health, it nonetheless needed to be interpreted and implemented in a manner supportive of members’ right to use the provisions in the agreement which provide flexibility in dealing with public health problems. Paragraph 5 ruled that each provision of the agreement had to be read in view of its objectives and principles; that each member had the right to grant compulsory licences and the freedom to determine the grounds upon which such licenses are granted; that each member had the right to determine what constitutes a national emergency or other circumstance of extreme urgency, it being understood that public health crises can be understood as such; and each member should be left free to determine its own exhaustion regime without challenge, subject to MFN and NT provisions. Paragraph 6 of the declaration, in recognising that members with insufficient or no manufacturing capacity in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the agreement, called on the Council to find an expeditious solution before the end of 2002. Lastly, paragraph 7 reaffirmed commitments towards technology transfer to LDCs; provided that LDCs were not obliged to implement, apply or enforce provisions relating to pharmaceutical patents until 1 January 2016, without prejudice to further extensions.

This declaration appeared to give the ‘demandeurs’ precisely what they hoped for – at least in terms of problem identification from the point of view of the AG and to find an expeditious manner to resolve the domestic manufacturing implications of Article 31(f) – responding positively to the spate of global public opinion mounted against the multilateral trading system in general, and in particular, the impact of representations of HIV/AIDS in Africa and an overarching TRIPS. Significantly, paragraph 5 of the declaration recognises the impact of

patents on access to medicines, and explicitly permits Members to make use of flexibilities available within the agreement for the protection of public health (Gopakumar, 2004: 100). By recognising the seriousness of the public health difficulties facing developing and least developed countries, Ministers place decisions made in the declaration at a high level in the hierarchy of norms should there be a conflict between rules (Abbott, 2002b: 490).

Noteworthy however, while the declaration exemplifies a “significant breakthrough” and has interpretative value for TRIPS, it has not altered the agreement (Vandoren, 2002: 8; Vandoren and Van Eeckhaute, 2003: 780). In fact, Eric Noehrenberg, Director of Intellectual Property and Trade Issues at the International Federation of Pharmaceutical Manufacturers Associations<sup>12</sup> maintained, “I think it is a very good point to realize that the Doha Declaration... did not add anything new; it did not weaken TRIPS... it did not change any of its obligations” (Noehrenberg, 2003: 379). There is also the view that perhaps, the declaration is merely political, and legally weak (see Charnovitz, 2002; Garcia-Castrillon, 2002). Notwithstanding, the declaration represents the case of a weak coalition making a gain that an observer would not have predicted given the power resources of the US-led coalition (Drahos, 2007: 19). The AG did not only manage to initiate and steer the debate on the issue at the WTO (Kongolo, 2003: 373), it remained engaged throughout, chaired the discussions in their inaugural year, presented the drafts, and secured most, if not all of its demands in the related Doha Ministerial Declaration. What remains unexplained however, is what precisely lay behind this reinforced negotiating performance by the AG, especially against the backdrop of obscurity in the Uruguay Round.

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<sup>12</sup> This is the negotiating arm of the TDI in Geneva. Noehrenberg is responsible for negotiations regarding intellectual property and trade issues between the global, research-based pharmaceutical industry and the major international organizations involved in these issues, including the WTO, WHO, the World Bank and WIPO. See [www.ifpma.org](http://www.ifpma.org).

### **6.3 A Post-Uruguay Round Trajectory and the Capacity Momentum: Explaining AG Reinforcement**

One of the most fundamental drawbacks faced by DCs in the GPE is their inability to bargain on a level playing field with their industrialised counterparts. An important structural issue putting many such countries at a disadvantage is the lack of resources, capacity and/or expertise for effective deliberation (Kapoor, 2004: 529; Abbott, 2002b: 479). Most small delegations do not have the appropriate resources either in Geneva or in their capitals to service the negotiating process and thereby participate meaningfully in what could be meetings of primary importance for their national interests (Sampson, 2000: 1100).<sup>13</sup> During the UR of MTNs only about ten DCs actually sent IP experts to the TRIPS negotiations, and in most cases, TRIPS negotiators were from national trade ministries lacking any specialisation in IP (Matthews, 2002: 44; 2004b: 3). Despite the presence of some trade officials however, there is the chronic problem of absent participation.

Indeed, we saw testimony of this in previous chapters narrating the Uruguay Round negotiating experience, in which SSA countries were mere spectators in the unravelling of issues of vital importance to them. Although it may be inaccurate to assume that non-evidence of participation is necessarily causally related to capacity constraints, it remains highly suspect that adept delegations would take a back seat in negotiations where so much is at stake. What is certain, however, is that developing countries generally, are characterised by problems of scarcity, limited economies of scale due to small market size, minimal demand or supply power, and inadequate infrastructural networks (Narlikar, 2003: 11). As a result of such structural limitations which adversely affect capacity in international negotiations, DCs (SSA in the current context) have had to manufacture capacity by way of alliance formation through the African Group. According to Narlikar, since the weak have few sources of 'internal balancing'

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<sup>13</sup> See also Blackhurst, *et al* (2000: 497-503) for a sense of the human resource deficits in SSA's Geneva contingents; as well as other difficulties.

(inherent capabilities) they must rely on 'external balancing' arrangements (ibid: 10-11) to achieve some measure of success in international negotiations.

The African Group at the WTO<sup>14</sup> has its roots in the Organisation of African Unity/African Economic Community (OAU/AEC). The treaty establishing the AEC was signed in 1991 and came into force on 12 May 1994 (ibid: 191) at precisely the time when the GATT-WTO transition was taking place. At a meeting in Harare in 1998, the trade ministers of the OAU/AEC took a key decision on the need for coordination in the formulation of a positive agenda for the forthcoming Seattle Ministerial Conference (ibid, taken from Luke, 2000). This AEC directive can be seen as the crucial Vichian-Gramscian moment constituting Vico's modification of mind, that is, a group's self-understanding and attitudes towards a common reality of marginalisation (Cox, 1981: 132; 2002: 45; Berry, 2007: 16); and Gramsci's mental imagery which gives groups self-awareness and understanding of where they stand and how they must act for their emancipation (Cox, 2002: 29). Consequently, the African Group established a Permanent Delegation of the OAU in Geneva to convene meetings and collaborate research, and its 41-state strong WTO membership has defended common positions in WTO talks since 1999 (Sell and Odell, 2003: 15). The group's presence was felt at least towards the end of the failed Seattle Ministerial when it issued a joint statement about its refusal to join the Seattle consensus by virtue of being marginalised and excluded. It declared:

“There is no transparency in the proceedings and African countries are being marginalised and generally excluded on issues of vital importance to our peoples and their future. We are particularly concerned over the stated intentions to produce a ministerial text at any cost including the cost of procedures designed to secure participation and consensus... We will not be able to join the consensus required to meet the objectives of the Ministerial Conference.”<sup>15</sup>

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<sup>14</sup> This designation has nothing to do with the African Group as one of the 5 geopolitical regional groupings at the UN.

<sup>15</sup> Quoted in Narlikar, 2003: 192.

There appears to be an unequivocal 'modification of mind' on the part of the AG, impelling it to take a stance against the kinds of coercive strategies encountered in Chapter IV, a reality unsubstantiated in the UR. Coupled with this AG's newfound visibility in the Seattle context, it would team up with an unsurprising ally that would help bolster the capacity requirements for more effective participation in the TRIPS and public health talks slated for the Doha Development Round. The AG's ally would be the gamut of advocacy organisations and networks subsumed under the banner of civil society, such as Medecins Sans Frontières (MSF), Health Action International (HAI), Oxfam, Consumer Project on Technology (CPTech), amongst others, in a movement that would be called 'the access campaign'. Further, events in world politics would render the moment ripe for the level of activism in the post-TRIPS landscape, engendering what one may call "a new politics of confrontation" (Narlikar and Hurrell, 2006).

The process of post-TRIPS pharmaceutical activism began gathering momentum months after the WTO came into being in 1995. In October 1995, directors of US-based CPTech wrote a letter to the then-USTR Michael Kantor indicating that there were many different, legitimate views concerning patents and healthcare and that the USTR had been too narrowly focused on protecting the interests of US-based international pharmaceutical companies (Nader and Love 1995; Halbert, 2005: 88), a viewpoint upheld in the 'The Argument in Context'. A year later, HAI organised the first major NGO meeting on TRIPS and healthcare in Beilefeld, Germany, at which Love presented a paper on drug pricing and compulsory licensing (Sell, 2003: 147-8). This meeting would bring together a diverse group of interested people who would form the core of the access campaign. Later in 1998, Zimbabwe's Minister of Health, Dr. Timothy Stamps, asked Bas van der Heide of HAI to produce a draft resolution for a WHO "Revised Drug Strategy" (ibid). HAI and CPTech were already collaborating on comments for the FTAA negotiations and incorporated language from this process, stressing the priority of health

concerns over commercial interests (ibid). The WHO's Executive Board approved HAI's resolution, reportedly because the United States was not on the board that year (ibid). The draft resolution, which provided guidance for developing countries and explicitly endorsed some of the precise practices that PhRMA had been fighting through the USTR, was greeted with the characteristic resistance from PhRMA, the US and EC governments (ibid). However, in May 1999, the WHO's World Health Assembly (WHA) unanimously enacted resolution WHA 52.19 (ibid: 149). Significantly also, in addition to the ensuing support that was already being enlisted through UNDP, WHO and the World Bank, when MSF won its Nobel Peace Prize in October 1999, it donated the proceeds to the access campaign (ibid).

Earlier in 1996, Brazil reverted to a pre-TRIPS Paris Convention understanding and passed a patent law stipulating a local working requirement within three years of grant, as constitutive of the working of a patent to ensure sustainable access (Sell and Odell, 2003: 12). Brazil threatened compulsory licenses in the absence of this working requirement and was subsequently able to negotiate substantial price reductions for HIV/AIDS drugs from Roche and Merck (ibid), a point the Brazilian delegate reiterated at the aforementioned special session of the TRIPS Council in June (IP/C/M/31: 10). In February 2000, PhRMA petitioned the USTR to launch an infringement case against Brazil in the WTO for alleged violation of Article 27(1) of TRIPS which provides that importation satisfies working requirements. Brazil countered with evidence that US law was in violation of TRIPS precisely on the same grounds, for example, under Article 204 of the US Patent Code, small businesses and universities must manufacture their inventions "substantially in the United States"; while Article 209 establishes a local working requirement for federally owned patents (Sell and Odell, 2003: 13, taken from Viana, 2002: 312). Brazil subsequently filed a request for WTO consultations with the US over US law, and the case was dropped in June the following year (ibid) coinciding with the Council's special session.

While all crucial events surrounding post-TRIPS activism cannot be sufficiently delineated, two would stand out as decisive push factors in what was to follow. Arguably the more important of the two began in South Africa in December 1997 when the then President Nelson Mandela signed the South African Medicines and Medical Devices Regulatory Authority Act (Medicines Act) which allowed the Minister of Health to revoke patents on medicines and to allow for broad-based compulsory licensing to manufacture generic versions of HIV/AIDS drugs (Sell, 2002: 182; Sell, Odell 2003: 9; Bartelt, 2003: 291-4; Gad, 2006: 217-8; Halbert, 2005: 87) to facilitate access in the wake of the pandemic. Article 15C of the Act permitted parallel importing so that South Africa could take advantage of the discriminatory pricing policies and import the cheapest available patented medicines (ibid). In February 1998, 42 members of the Pharmaceutical Manufacturers of South Africa (mainly local licensees of global PhRMA) chose to sue Nelson Mandela, challenging the Act's legality in Pretoria High Court, and maintained that the Act was unconstitutional because it violated constitutional guarantees of property rights (ibid). They further argued that the Act violated TRIPS by authorising uncompensated compulsory licensing (ibid).

PhRMA also recommended in a February submission to the USTR that South Africa be named a "Priority Foreign Country" and argued that the country's Act posed a direct challenge to the achievements of the Uruguay Round (ibid, taken from PhRMA, 1998: 10-11). The USTR responded by placing South Africa on the "Watch List" and urged the government to repeal its law (ibid). In June 1998 the White House announced a suspension of South Africa's duty-free treatment under the GSP (ibid). Referring to a similar Thai predicament after Thai authorities planned compulsory licensing of AIDS drug ddI (although US trade sanction threats forced Thailand to abandon such plans), Vick (1999) commented that compulsory licensing permitted under TRIPS "was intended as a lifeline. But in practice, any country reaching for this lifeline

has been handcuffed by US trade negotiators” (Sell, 2003: 151), highlighting the spurious nature of TRIPS flexibilities supposedly designed to facilitate access in difficult circumstances.

Furthermore, the aggrieved TDI would garner tremendous support from the United States administration, particularly from the then Vice President Al Gore who was also a Democratic contender for the 2000 Presidential campaign, and understandably keen to be counted in PhRMA’s campaign contributions. As a result of his PhRMA-friendliness, a US advocacy group, ACT UP, took up South Africa’s cause and repeatedly interrupted Gore’s campaign appearances in the summer of 1999 with noisemakers and banners that said “Gore’s Greed Kills” (ibid: 152). These had quite an impact on live television, with near immediate results. The Clinton administration withdrew two years of objections to South Africa’s Medicines Act in June, the same week that Gore declared his intent to run for president, and AIDS activists began tormenting his campaign (ibid: 152-3, taken from Gellman, 2000). On 17 September 1999, the US removed South Africa from the USTR watch list shortly after Gore’s private meeting with the country’s succeeding president, Thabo Mbeki (ibid: 153).

In November 1999, on the eve of the Seattle WTO Ministerial, the access campaign held a conference in Amsterdam and produced an “Amsterdam Statement” which called on the WTO to establish a working group on access to medicines and to endorse the use of compulsory licenses of patents under Article 31; allow exceptions to patents under Article 30 that would redress export constraints to import markets with insufficient manufacturing capacity (ibid: 153). In Seattle, President Clinton signalled a major change in US policy and on May 10, 2000, he issued an Executive Order stating that “the United States shall not seek, through negotiation or otherwise, the revocation or revision of any intellectual property law or policy of a beneficiary sub-Saharan African country, as determined by the president, that regulates HIV/AIDS pharmaceuticals or medical technologies” (ibid: 154). This understandably incensed the TDI

because since Clinton's initial announcement at Seattle in 1999, the global industry had been working with UNAIDS to reduce prices of AIDS drugs for selected African countries (ibid), a move MSF criticised as a cynical attempt by industry to undercut countries availing themselves of compulsory licensing and parallel importing options (ibid). In February 2001 however, USTR Robert Zoellick of the Bush administration announced that the Clinton order would be upheld (ibid: 155).

This period saw a series of additional plummeting drug prices, as well as production deals between NGOs and generic producers, in which India's Cipla contracted to sell a three-drug HIV/AIDS cocktail to MSF at \$350 per person per year, down from its initial \$10,000 (ibid: 156). The successes continued to drum-roll, and the PhRMA-led lawsuit against South Africa which was scheduled to start on March 5 – became a high profile event marked by protesters, grim images of dying mothers and babies, street demonstrations and extensive media coverage – was subsequently withdrawn (ibid: 157).

A related, critical environmental factor was the tragic pre-Doha terrorist attacks that beset America on September 11, 2001 (9/11) ushering in a fury of snap reactions which appeared to go against the grain of the precise TRIPS Article that sparked the controversy in the first place. In what was presumed to be another terrorist attack, powdered anthrax had been sent through the mail killing several postal and media workers (Sell and Odell, 2003: 18). Several leaders in the US and Canada discussed issuing compulsory licenses for ciprofloxacin (Cipro) to ensure adequate emergency supplies of the drug (ibid; see also Drahos, 2007: 486-8). Ultimately however, these countries negotiated steep drug discounts with Bayer, the patentee, just as Brazil had done with Merck and Roche (ibid). The highlight of this example is that compulsory licensing was at least contemplated in the terrorism hype following the 9/11 attacks to attend to what was potentially an *American* crisis.

All this highlights, among others, provided the apposite environmental cocktail that would enable the African Group to assume ownership of an issue that significantly affected its members. One notable reference point was Ambassador Boniface Chidyausiku<sup>16</sup> of Zimbabwe who described his encounter as “an exhilarating experience – navigating among the interests of PhRMA, worried that changes to TRIPS would open a floodgate” (Chidyausiku interview, August 2005). “I was convinced that part of the reason why prices were so high was because of the monopolies bestowed on patent owners. And because I knew we were up against the big cats, I had to reach out to all the expertise I could get”. Chidyausiku explained that “the NGO community helped a lot, including Third World Network/TWN, MSF, Frederick Abbot from the Quakers United Nations Office, and Carlos Correa from the South Centre” (see also, Abbott, 2002b: 478; Drahos, 2007: 18). This was also substantiated by Cecilia Oh, then of TWN, who said that “many workshops, conferences and meetings were organised by several key actors: TWN, the Quakers office, and South Centre, which provided negotiators with a forum to speak” (Oh interview, August 2005; see also Drahos, 2007: 18).

Chidyausiku continued, “a very active team in the African Group played a pivotal role as we felt we had a duty”. “We started to raise government interest at the capital level and there were huge awareness campaigns in Nairobi, Zambia and other places” in Africa. “We were ready, did our homework”. “A number of sources were consulted, we outsourced from civil society, and papers were written by negotiators in Geneva”. “The African Group demonstrated that we had the capacity to absorb, and we did”. This method of civil-society-outsourcing demonstrates that the AG was aware of its own ‘internal balancing’ constraints even as a group, and that to gain additional capacity and effectiveness, there was a need to move away from older ‘demandeur’ methods of rhetorical claims for distributive justice. Indeed, coalitions today place considerable emphasis on constructing their proposals and demands on the basis of research rather than the

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<sup>16</sup> Encountered earlier as the succeeding Chair of the TRIPS Council when the issue became formalised at the level of the WTO.

rhetoric of distributive justice (Narlikar, 2003: 195). In addition, as highlighted above, civil society had already gained a foothold on the issue of TRIPS and access to medicines, and it made sense to align with credible agents in the access campaign.

Similarly fundamental is the acknowledgement that in the past five to eight years, the knowledge level in DC delegations has risen exponentially, and while knowledge does vary and some delegations are overwhelmed with portfolios, the expertise does exist (Oh interview, August 2005). Indeed, “our peculiar problems do not prevent us from becoming experts by default” (Palayathan interview: June, 2005), a point contradicted by a former AG negotiator from Senegal, who stated that “technical capacity is lacking dramatically” in the AG (Samb interview, June 2005). This critic was not alone, as a similar off-the-record indictment was offered by a Secretariat staff member, that while members of the AG were big players in the TRIPS and Public Health negotiations, they possess “limited knowledge of substance” (anonymous 1). At risk of stating the obvious, the representative maintained that, by contrast, US negotiators have good resources, “people know what they’re talking about” (ibid).

Nonetheless, Chidyausiku confirmed that another aspect of the AG’s success, in collaboration with other DCs such as India, Brazil, CARICOM (Caribbean Common Market), and Bolivia, was the fact that the group was united. “Africa has managed to develop alliances everywhere”. And “one of our greatest strengths is our unity and togetherness”. This view attests to Narlikar’s analysis above that because DCs have few sources of internal balancing, they must rely on external balancing arrangements for any measure of success in international trade negotiations. The crucial aspect of this strength-in-numbers thesis is the WTO’s institutionalisation of consensus decision-making, problematised in Chapter IV. While we saw the downside of this method against the backdrop of the kinds of strategies used by developed countries and the GATT Secretariat to achieve consensus during the UR, DCs can in fact gain considerably if they

stick together as a group, simply because they number well in the majority of the organisation's membership.

In fact, Chidyausiku substantiated that many attempts at the age-old method of 'divide and rule' sought to destabilise the Group's apparent solidarity. He confirmed that selected African trade ministers were brought to Washington to try to create divisions in the Group. Amongst those selected were ministers from Kenya, Botswana and Nigeria. "But", he continued, "we had developed such a powerful position in Geneva at that time, that such tactics did not work". He also provided testimony of the 'carrot' approach cloaked in the African Growth and Opportunity Act (AGOA) of the United States which formed part of the aforementioned Executive Order by President Clinton. He maintained that AGOA "was intended to have precisely the same meaning as the GSP in US trade law Section 301, whereby the continuation of benefits would be tied, in the long run, to implementation of IP as per America's wishes".

The other explanatory factor contributing to the Group's success according to Chidyausiku was the ingrained belief that "technical capacity development should be the responsibility of national governments, and not developed country governments and the WTO Secretariat". Indeed, "there is no way that your adversary can train you to be better than him". He believed that "it has become an industry at the WTO where donors send Secretariat staff to developing countries to talk about implementing WTO agreements. It is not about capacity building that can help developing countries. It is simply about implementation of the Northern agenda and is therefore, not in our best interest". We saw a similar argument in the third chapter concerning the UR politics of the appropriateness or lack thereof of special and differential treatment for developing countries in the area of IP. These kinds of arguments also attest to the fact that developing countries remain very wary of the motives of the trade organisation, continuing to see it as a mediator of Northern interests, and therefore, bereft of legitimacy. Chidyausiku's account also

portrays the AG as having the necessary self-awareness and an understanding of where they stand, as they speak of their common marginalisation, exclusion and weakness; and how they must act for their emancipation, in terms of alliance formation, teaming-up with global civil society, information outsourcing, and a determination that the UR method of 'consent without consent' would not be repeated.

In addition to this Gramscian portrayal, Chidyausiku's testimony also points to a dynamic which encapsulates 'society's self protective response' inherent in the second phase of Polanyi's double movement. The implications of pharmaceutical patents on access to medicines in the developing world, and particularly the devastatingly circumscribing impacts of Art. 31(f) fuelled civil society's activism, which animated the AG's 'self protective response' to bring pharmaceutical patents under social control. That is, to resist the dominant intellectual property discourse which places IP into a false dichotomy – absolute protection or no protection at all – in favour of a moralised alternative which privileges life over property (Halbert, 2005: 88-9). What is common in all these accounts is how a surge in conflict and contestation over social relations deemed unjust and unconscionable by the counter-society (peopled by the marginalised and the excluded, by those who are intellectually alienated from established order in thought, behaviour and institutions, and by those deprived of the possibility of satisfying their material needs according to the prevailing norms of social order [Cox, 2002: xvi]), created the necessary conditions towards a transformative dynamic. However, the conflict does not end here, and neither does the visibility of the African Group.

#### **6.4 The Post-Declaration Phase: Paragraph 6 Negotiations & The TRIPS Amendment**

While the counter-society, which includes the AG, can claim victory up to the point of the Doha Declaration and the 'modification of mind', it is worth re-emphasizing that the 'declaration' or 'launching' phase of any negotiation represents only the initiation of a process between opposing

sides. Also, paragraph 6 negotiations were still impending at the drafting of the declaration. Recalling the UR, the Punta del Este Declaration included the demands of virtually all interested parties to the negotiations. Yet, the political processes which ensued to shore-up consensus at the end of the Round ensured that many of the concerns of the developing world were negotiated out. Therefore, the justice-speak content of ‘declaration’ documents do not automatically result in what demandeurs (particularly from the developing world) see as a just outcome. The essential question therefore concerns the negotiating process itself and the methods by which the content of the declaration endures or dissolves during the negotiations.

Negotiations in the aftermath of the Doha Declaration centred on finding a solution to Paragraph 6 which recognised that WTO members with insufficient or no manufacturing capacity in the pharmaceutical sector could face difficulties in making effective use of compulsory licensing under the TRIPS Agreement. Until then, “the assumption was that there *is* domestic manufacturing capacity” (Ntwaagae interview, June 2005), an assumption which rendered pointless TRIPS flexibilities (Bartlet 2003: 296). For much of this phase, negotiations centred on the nature of a Paragraph 6 solution that was palatable to the diverging interests in terms of the substantive components such a solution would entail, as well as the legal mechanism to implement it. Solutions negotiated were three-fold: an amendment of the TRIPS Agreement; a waiver of Article 31(f); and an interpretation of Article 30 (Gopakumar, 2002; Abbott, 2002c; Matthews, 2006).

As in the Uruguay Round, negotiators were pitted against each other in the typical North/South configuration, only this time, the persistence and participation of the African Group was arguably as proficient as that of the NETs as well as that of the stronger DCs. The negotiations saw ICs maintain a *status-quo* or problem-solving approach, one aimed at quick-fixing, thereby attending only to the immediacy of serious health crises in poorer DCs. This method focused on

the need to first seek accommodation from right holders “in order to be assured of a supply of quality products at the lowest possible prices” (IP/C/M/35: 81); “the best way to expedite the delivery of medicines to the populations in need at strongly reduced prices was through reduced-pricing offers by the right holders. Therefore, it was crucial to enable the patent holder to make a proposal to rapidly solve the problem by offering sustainable voluntary licences and strongly reduced pricing offers” (IP/C/M/36: 13). There was no attempt in such suggestions to seek ways of technology transfer or other long-term solutions that would enable domestic capabilities to deal sustainably with the problem of disease which, as we saw in the first chapter, has an impedimental impact on growth and development. In fact, a UNAIDS representative present at the meeting spoke of the falling annual per capita growth rate in half the countries of sub-Saharan Africa, highlighting that in countries with a high agricultural dependency, AIDS alone had claimed some seven million agricultural workers since 1985 (ibid: 124) with devastating impacts on economic growth and livelihoods.

The major NETs, particularly the US, went as far as to seek a limitation on disease coverage, arguing that “the Council should focus on fashioning a solution to improve access to pharmaceuticals to treat these diseases referred to in the Declaration” (IP/C/M/35: 82; Abbott, 2005b: 327-334); and to prevent diagnostic equipment from being included (Jawara and Kwa, 2004: 247; Matthews, 2006: 94), thereby pre-empting any expanded use of the solution should other epidemics emerge in the future. Conversely, developing countries were in favour of language that related coverage to HIV/AIDS, malaria, tuberculosis and other infectious epidemics of comparable gravity and scale, including those that may arise in the future (JOB(02)/217: 1). In fact, the scope of disease to be covered by the solution was a major sticking point in the negotiations. So persistent was the US on this issue that on 25 October 2002, then Assistant USTR for Africa, Rosa Whitaker wrote a letter to sub-Saharan African trade ministers urging them to instruct their representatives in Geneva to accept the US position, which is in the

interest of African countries (reprinted in Jawara and Kwa, 2004: 250-252). The letter went as far as to *inform* capitals' trade ministers that "sadly, while HIV/AIDS has taken its greatest toll in sub-Saharan Africa, most of the region's representatives to Geneva are not attending meetings related to this issue or engaging in the debate" (ibid: 250). If the Whitaker letter referred to non-attendance and non-engagement of AG representatives at formal TRIPS Council meetings, the minutes of the meetings would appear to be a gross fabrication. More accurate however, this hitherto marginalised group was engaging in a way that proved impossible in the Uruguay Round.

This insistence on limiting the scope of disease was precisely why the US – supported only by Japan – did not join the consensus on the 16 December 2002 draft on the "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health".<sup>17</sup> A US delegate subsequently indicated that her delegation was willing to join the consensus on all parts of the draft, except the one on the scope of disease (IP/C/M/38: 34), to the dismay of most other members of the negotiations including the EC (ibid: 60), and Switzerland (ibid: 62). Botswana's Ambassador would later note that the differences from American colleagues were as a result of pressure from their pharmaceutical industry (Ntwaagae interview, June 2005) a point reiterated by South Africa once the negotiations were restarted in February 2003 (IP/C/M/39: 71). The US would subsequently retort that "all delegations in the Council had constituents which they represented, and even independent governments were arguably in the Council to represent their constituents" (ibid: 87).

With this in mind, the IC focus also saw an overwhelming concentration on safeguarding the interests of right holders against diversion of pharmaceuticals from intended jurisdictions, and sought to litter the solution with conditionalities aimed at circumventing diversion; and arguably,

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<sup>17</sup> Hereinafter the Motta text, after the then Chairman of the TRIPS Council.

aimed at creating disincentives for potential users of any negotiated solution. These moves were criticised by DCs, notably the AG. Zimbabwe's delegate for instance, cautioned that while trade diversion was a legitimate concern, "the current attempt was to address an unbalanced situation and therefore, one should be careful not to create more imbalances by hedging any envisaged solution with terms and conditions that might turn out to be more burdensome than what was currently in the TRIPS Agreement" (IP/C/M/35: 88). At another formal session, a WHO representative reminded participants that the basic health principle to be followed was that the people of a country without manufacturing capacity to produce a needed product, should be no less protected by compulsory licences and other provisions and safeguards in the TRIPS Agreement, nor face greater procedural hurdles compared to people in a country capable of producing the product (IP/C/M/37: 5), in effect, making the case for differential rules/requirements aimed at mitigating incapacity.

Nonetheless, because of the persistent fear of diversion and an insistence that TRIPS represented a carefully negotiated balance, ICs decided to opt out of a negotiated solution, thereby absolving it from any single undertaking, and launching another debate into beneficiary countries of a paragraph 6 solution (Matthews, 2004b). While it is understandable that NETs were not the intended recipients of a paragraph 6 solution, their decision to opt out as exporting countries did not bode well with NGOs (Matthews, 2004b), and DCs which maintained that it was disappointing if the solution did not necessarily include ICs as exporters since this would significantly restrict the potential supply of pharmaceutical products (IP/C/M/36: 154). Brazil also expressed grave concern about the message the TRIPS Council would send if it talked about using a mechanism in which developed countries were not part of the solution (IP/C/M/36: 187). Nonetheless, the US maintained that "the countries that would be potential suppliers of needed pharmaceuticals under a solution should be developing or least-developed countries that had the capacity to produce the needed pharmaceuticals" (ibid: 137), ignoring the fact that only a

handful of such countries have some measure of capacity in the sector, of which, South Africa was the only country in SSA. In a most expedient manner, a US delegate noted that “a solution could only provide or facilitate technology transfer if developed country Members were not included as exporters” (ibid), implying that the US did not look favourably on the prospect of being a sponsor of technology transfer to DCs.

Adopting the ‘other’ worldview in the ‘aftermath’ negotiations, DCs maintained an interest in the long-term sustainability of any paragraph 6 solution. This perspective focused on precisely some of those issues which were negotiated out of the UR, such as ways to facilitate technology transfer; and building domestic manufacturing capacity and a sound base in medical technology. Therefore, we see the recurrence of legitimacy concerns to the extent that issues that were, from the point of view of DCs, craftily excluded from the UR, were precisely those that would resurface to challenge TRIPS, further suggesting how unsettled such issues were. The essence of the AG’s position was summed up by Zimbabwe that ‘it was critical for every country to have the opportunity to improve its manufacturing capacity where adequate and to establish capacity where none existed. Africa does not see itself, and others should not see Africa, as only a market for their products’ (IP/C/M/36: 24), a point reiterated in virtually all DC statements.

This emphasis on long-term sustainability led the NITs to reject what the US thought was a perfect solution, that is, one based simply on a moratorium/waiver on dispute settlement, a point capitalised from the AG presentation at the June 2001 Special Session (IP/C/M/31: 31). The US reasoned that an agreement on a moratorium would not require an amendment to TRIPS and the application of the solution could be overseen by the Council; “it is worth considering whether a dispute settlement moratorium would not in fact be the most expeditious solution and the one least prejudicial to the rights and obligations of Members under the TRIPS Agreement” (IP/C/M/35: 85). Kenya, on behalf of the AG, maintained that solutions like moratoria and

waivers were not durable because they did not address the lack of manufacturing capacity in countries, especially those in Africa (IP/C/M/37: 25).

Instead, DCs led by the AG (IP/C/M/35: 74), India (*ibid*: 97), and Brazil (*ibid*: 119), proposed that Article 31(f) be scrapped since it was the source of the problem, a point rejected by ICs, although the EC did initially envisage a solution which would carve out an exception clause to Article 31(f) (*ibid*: 69). DCs also envisaged a solution on the merits of an authoritative interpretation of Article 30, a proposal encountered in the 1999 “Amsterdam Statement” of the ‘access campaign’.<sup>18</sup> In this context, the production, sale and export of the product would be considered as limited exceptions authorised under Article 30 (*ibid*: 74; see Vandoren, *et al*, 2003: 783; Matthews, 2006: 94-5). But probably more original in the context of an AG-specific demand, was a proposal in which the phrase ‘domestic market’ as used in Article 31(f), would under certain circumstances mean the combined market of members that have formed, or were in the process of forming, a customs union of free trade area (IP/C/W/351: 4-5).

This, according to the AG would function in much the same way as ‘domestic industry’ in footnote 1 to Article 2 of the Agreement on Safeguards, where domestic industry is interpreted to include the combination of industries at the regional level where members have formed a customs union (*ibid*). Kenya’s representative substantiated that this interpretation of regional domesticity would “assist in dealing with domestic markets that were too small to support viable production, or to utilize production capacity at the desired levels” (IP/C/M/36: 5). She added that this would also promote regional supply centres for pharmaceutical products, a critical issue for poor member countries (*ibid*).

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<sup>18</sup> See Section 6.3. See also Drahos, 2007: 21.

While much headway was made under Mexico's Motta chairmanship especially in terms of the Motta text that was agreeable to most participants, it was not until Singapore's Ambassador Menon assumed chairmanship that consensus was finally reached in late August 2003 on an Agreement on TRIPS and Public Health. Menon was appointed chair at the end of the February 18-19, 2003 formal session. At his first formal meeting as chair 4-5 June 2003, he indicated that he had been in touch with many delegations on a bilateral basis or in small groups in order to brief himself on their positions and concerns and to gauge the scope for finding a way to resolve the outstanding problem (IP/C/M/40: 27). During such consultations, delegations "stressed their resolve to finding a multilateral solution prior to the Cancun Ministerial Conference" (ibid) less than three months away. The EC corroborated this and added that the Motta text "remained the best basis for a deal because it was fair and balanced" (ibid: 28), signalling another instance in which the EC (a major IPC jurisdiction) diverged with the US on this particular issue; and suggesting that the NGO backlash throughout the negotiations had manifested itself, at least outwardly, in a more DC-friendly EC.<sup>19</sup> This meeting ended with no breakthroughs, however, most delegations voicing concerns spoke notably of their disappointment with the current impasse, and the need to reach consensus before Cancun.

This deadlock was followed by months of informal contact between the United States and developing countries, and even direct contact between the pharmaceutical industry and certain developing countries,<sup>20</sup> which proved useful in clarifying positions (Vandoren, *et al*, 2003: 781; Matthews, 2006: 96). Reports subsequently began to appear that the US was prepared to abandon its earlier insistence that a paragraph 6 solution cover only specific diseases, shifting its focus from disease coverage, to limitations on eligibility aimed at low-income DCs and LDCs, together with safeguards against the risk of diversion (Matthews, 2004b: 10). Finally in a formal

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<sup>19</sup> See Vandoren, 2002: 12, on the role of the EU as arbiter of all interests in the negotiations. Jawara and Kwa (2004: 247) however contend that while the EC pandered to civil society critics, it was primarily concerned with protecting its corporate interests.

<sup>20</sup> Recall Chidyausiku's testimony about 'divide and rule' and 'carrot' strategies encountered earlier.

session on 28 August 2003, Menon confirmed that after several informal consultations with various groups of delegations, he was now in a position to seek the Council's approval of the draft Decision on the "Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health" contained in document JOB(02)/217 (IP/C/M/41:1-2). Furthermore, he proposed that the Council approve forwarding, along with the draft Decision, the text of the statement contained in document JOB(03)/177 to be made by the Chairman of the General Council prior to the adoption of the Decision, both of which were agreed by the Council (ibid: 2).

This latter document alluded to the 'good faith' basis of the Decision and some 'best practices' aimed at circumventing diversion (Vandoren, *et al*, 2003: 781; Matthews, 2004b: 11), and its reading was a condition by the US to agree to a temporary waiver (Shashikant, 2005). Finally on August 30, 2003, two crucial weeks before Cancun (one week after members agreed to extend transitions for pharmaceutical patents for LDCs), the General Council adopted the Decision, thereby providing a temporary waiver of Members' obligations under Article 31(f) of TRIPS, of the type originally proposed by the US during the paragraph 6 deliberations, until such time as that article is amended (Matthews, 2004b; Gopakumar, 2004: 104). The Decision which contains burdensome procedural requirements such as measures to prevent trade diversion, and notification requirements (see Vandoren, *et al*, 2003: 786-90; Matthews, 2006: 101-103), took the form of three temporary waivers: two relating to Article 31(f) and one to Article 31(h). Taken together, the waivers allow WTO members, either acting individually or in regional groupings, to grant compulsory licenses with a view to exporting pharmaceutical products to countries with insufficient or no manufacturing capacities, without the requirement for the payment of double remuneration to the right holder in the importing and exporting countries (Matthews, 2006; 98).

In a joint statement, MSF and Oxfam (2003) contended that the deal was intended to offer comfort to the US and the Western pharmaceutical industry,<sup>21</sup> and offers little comfort for poor patients. Drahos (2007: 21) also argues that an Article 30 solution would have been preferable for developing countries because it would have recognised that states may limit the right of the patent holder for certain purposes, and that the Article 30 principle of a limitation of rights could potentially be used to create new exceptions and limitations on patent rights. In its simplest form, an Article 30 solution could have seen WTO members simply agreeing that in cases where a country lacked manufacturing capacity and needed medicines, Article 30 would permit the creation of an exception to the restriction posed by Article 31(f) of TRIPS (*ibid*), and over time, a state practice over this exception would have emerged. Consequently, the rule-intensive solution which prevailed will be more costly for DCs (*ibid*: 22). Moreover, while the General Council Chairperson's Statement does not have any legal status, problems may arise in the future should any national or international dispute settlement mechanism use the statement as a tool to interpret the decision (Gopakumar, 2004: 105; see also Matthews, 2006). This of course remains to be seen, however, all was not lost for the African Group as its proposal on regional groupings made paragraph 6 of the Decision. The Decision allows countries that are Members of certain regional groupings to further export products, which have been produced or exported under a compulsory license, to other Members of that regional grouping, thereby promoting economies of scale (Voandoren, et al, 2003: 790). Also, paragraph 7 of the Decision at least recognises the desirability of promoting technology transfer and capacity-building in the pharmaceutical sector in order to overcome the problem initially identified in paragraph 6, and encourages eligible importing and exporting Members to use the system set out in the Decision in a way which would promote this objective (*ibid*: 791).

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<sup>21</sup> See also Rwanda's statement in IP/C/M/47: 185 corroborating this.

Subsequently, TRIPS Council negotiations centred on paragraph 11 of the Decision which required WTO Members to agree to an amendment to the TRIPS Agreement as a follow-up to the temporary waivers of Articles 31(f) and (h) (Matthews, 2006: 105). A waiver/amendment battle ensued, in which the AG in particular and DCs in general, were in favour of an amendment, while particularly the US sought to maintain the waiver position. The WTO Secretariat, which sees itself as a “moderator between different interests” (Kampf interview, June 2005), cautioned that in terms of real life application the waiver and amendment are the same (ibid). In a similar vein, the then TRIPS Council Chair maintained that “it is not true that the lives of African people are at stake as they can make use of the waiver agreement” (Choi interview, June 2005). Mauritius’ negotiator retorted that generic producers have to be enticed into production and the waiver is not a mechanism which entices them because waivers are under annual review (Palayathan interview, June 2005). “Legally, a waiver is subject to annual review according to Article IX of the WTO Agreement, therefore, if the WTO is all about certainty and predictability, how would you invest in a waiver climate?” (ibid). Seconding this, Rwanda’s delegate argued that while it is true that African countries may benefit from a waiver by importing cheap drugs, it is difficult to convince a foreign investor, from India for example, to invest in Africa simply because a waiver is not predictable (Bizumuremyi interview, July 2005). The provisions of the waiver can change in the amendment process and this may have a negative impact on business (ibid).

The first proposal for an amendment pursuant to paragraph 11 of the Decision came from the AG. At the 1-2 December 2004 meeting, Chaired by Choi's predecessor, Hong Kong's Miller, Nigeria, on behalf of the AG, introduced document IP/C/W/437 and recalled that Members had agreed that an amendment would be based, where appropriate, on the Decision (IP/C/M/46: 106). In this regard, the appropriateness of particular elements should be understood to refer to those elements in the Decision that were necessary to ensure that the amendment is legally

predictable, secure and economically and socially sustainable. He said that the AG proposal aimed to provide the basis for such an amendment. It was proposed to amend Article 31 of the TRIPS Agreement by adding a second paragraph to the Article, so that the current text of Article 31 would become Article 31(1) and the amendment text would become Article 31(2). The proposed amendment would be based on the Decision with modifications, as appropriate (ibid). Nigeria then delineated what should be retained or removed from the Decision, and what was redundant because the TRIPS Agreement already dealt with it (ibid: 107-110).

In response, the EC noted that the Decision could already be used effectively by Members, and that 'the amendment process should be a purely technical exercise, faithfully transposing the Decision into TRIPS language without re-opening of substance' (ibid: 115). The US delegate maintained that it was essential that the amendment preserve the entire Decision, and it needed to include an express reference to both the Decision and the Chairman's Statement, and "what might seem like surplusage to some delegations, was essential to others". "The Chairman's Statement was an essential part of the agreement of 30 August 2003 and there would have been no agreement without it" (ibid: 118). Kenya responded that the AG proposal was based on paragraph 11 of the Decision and had not deviated from it; that the AG had taken from the Decision what had been appropriate to include in the TRIPS Agreement, without disturbing the equilibrium; that TRIPS set minimum standards, and the Group had not seen the sense in disturbing that part of the equilibrium. "Besides, the amendment would be part of the TRIPS Agreement, and there should be no risk that the amendment could somehow be interpreted as eliminating the application of previously existing provisions" (ibid: 120). Regarding the Chairman's Statement, he stated that there was a need to clarify that the statement was not intended to form part of the amendment because it would negate the solution mandated in the Doha Declaration, and did not encourage technology transfer, which went against the principles and objectives of TRIPS (ibid: 122).

At the subsequent meeting (IP/C/M/47), the Council considered three communications, including one from Rwanda on behalf of the AG (IP/C/W/440) and one from the United States (IP/C/W/444). This AG communication comprised legal arguments in support of its earlier proposal for an amendment IP/C/M/437, which had considered modifications, where appropriate, to the Decision, and which in turn, was criticised by the EC and US delegations. This new communication considered WTO jurisprudence on the legal status of footnotes (IP/C/W/440: 3-6); justifications for modifying the 30 August Decision (ibid: 6-11); and the Chairman's Statement (ibid: 12-13). Speaking on behalf of the AG, Nigeria told the Council that modifications in the AG proposal were based on the fact that the purpose of some provisions would have already been served or would be redundant in the context of an amendment – such as the preamble, paragraph 8 on annual reviews, and paragraph 11 on amendment – (IP/C/M/47: 107). Nigeria's representative continued that the proposed elimination of paragraph 4 on re-exportation was because the patent holder would have sufficient avenues to prevent re-exportation of the product manufactured under system, and that the Chairman's Statement “should not be part of the amendment because it was not part of the Decision. Making it part of the amendment text, including through a footnote would elevate its legal status” (ibid: 109-10).

The AG was particularly incensed about this, and in an interview with the author, Nigeria's delegate opined that in an attempt to dilute the waiver decision, the US insists that the Decision incorporate the Chairman's Statement maintaining, *inter alia*, that the system should not be used commercially, thereby strengthening its legal status (Buba interview, June 2005). In its submission, while the US maintained that “the United States does not seek to elevate the legal status of the Statement”<sup>22</sup> (IP/C/W/444: 11), it nonetheless continued that “it is certain that the solution would not have been reached without the Chairman's Statement. To preserve the consensus, the principles included in the Statement must be preserved. The Statement made the

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<sup>22</sup> The EC went further in a July 2005 proposal that there was a 'legal relationship' between the two. See Matthews, 2006: 110.

consensus solution possible by addressing and resolving questions concerning aspects of the Decision that were unclear or were not addressed. It thus is an essential part of the solution, and provides value for all WTO Members. If elements of the consensus are eliminated, it will be difficult or impossible to transform the solution into an amendment” (ibid: 12).

Speaking on behalf of the AG, Rwanda's delegate argued at length before the Council that “the African Group and many other developing and least-developed countries had not been entirely happy with this solution and this had been made very clear during the TRIPS Council meetings. The Group had agreed to this "interim solution" on the precise understanding that it was only an interim solution, while discussions to find a permanent solution would continue. This understanding was reflected in paragraph 11 of the Decision which stated: "The TRIPS Council shall initiate by the end of 2003 work on the preparation of such an amendment with a view of its adoption within six months, on the understanding that the amendment will be based, where appropriate, on this Decision". The ordinary meaning of the sentence "the amendment will be based, where appropriate, on this Decision" indicated that it had never been the intention of Members to use the entire Decision as the amendment. Only those parts of the Decision that were appropriate were to be used” (ibid: 184).

She also noted that “the reading of the Chairman's Statement, when the Decision was adopted, had been more of an attempt to provide comfort language to assuage the concerns of some pharmaceutical industries that generic manufacturers would gain a strong foothold in the pharmaceutical market. During the informal TRIPS Council meetings, some developing and least-developed countries' delegates had expressed their reservations over the content of the statement, which was a clear indication that this statement had never been intended to form any part of the permanent solution” (ibid: 185). Some however argue that the statement is wholly complementary to the Motta text, that it does not affect it in any respect, and cannot be read as

creating new conditions. “The Perez Motta text remains the only valid legal text, setting out the conditions for the use of compulsory licences for export” (Vandoren, *et al*, 2003: 781). Rwanda's delegate nonetheless maintained that “the main reason why those countries with reservations had agreed to go along with the Chairman's Statement had been because they had felt an urgent need to make a contribution to the success of the Cancún Ministerial Conference. WTO Members might recall that there had been a strong feeling at that time that a solution, even if it was an interim one, had to be concluded before the Cancún meeting so that the meeting could focus on other issues and thus have a better chance of success. It had been felt by all that a Chairman's Statement would help facilitate a quick conclusion of an interim solution. But it had also been the understanding that this would only be an interim solution, and that a permanent solution would require more careful consideration, taking into account all the aspects, including how the mechanism chosen could be operationalized in practice” (IP/C/M/47: 186).

She then clarified that “in line with the context in which the Chairman's Statement had come into being, the Decision that had been agreed to in document IP/C/W/405 did not make any reference to the Chairman's Statement. It was only later that a footnote referring to the Chairman's Statement had been added, without the express consent of Members. Indeed, the African Group was puzzled as to how that footnote came to be added and that it wished to have a clarification on this.<sup>23</sup> Moreover, it had to be put on record that it had been added without the consent or consensus of Members. Thus, the African Group which made up a large portion of the WTO's Membership could not and would not accept an interpretation of paragraph 11 that said that the Decision and the Chairman's Statement in its entirety should form the amendment” (ibid: 187). She recalled Members' commitment in the Doha Declaration to interpret and implement the TRIPS Agreement “... in a manner supportive of WTO Members' right to protect public health and, in particular, to promote access to medicines for all”. Consequently, 'the African Group was

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<sup>23</sup> See IP/C/M/47: 219 for clarification by the Secretariat. See also, Mathews, 2006: 107.

not convinced that the Decision together with the Chairman's Statement as it stood at that time would fulfil the commitment to protect public health and promote access to medicines for all. Indeed, concerns had been raised by policy makers in African countries that the "interim solution" as it presently stood could pose problems and obstacles to the realization of the goal of access to affordable medicines for all" (ibid: 188), a position also supported at the African Regional Workshop on Patents and Access to Medicines (ibid: 189-191).

The US delegation nonetheless continued to express dismay at the AG's omission of key safeguards from the Decision to ensure the proper functioning of the solution, such as notification and diversion (IP/C/M/47: 122), followed by the EC (ibid: 125-8), Canada (ibid: 136), Japan (ibid: 142-143), Switzerland (ibid: 151-153), while developing countries largely supported the AG proposal (Matthews, 2006: 108). The US remained adamant that the Decision in its entirety should be preserved, including the Chairman's Statement (IP/C/M/47: 210; IP/C/M/48: 143; IP/C/M/49: 12), supported by other developed countries (Matthews, 2006: 109) with the exception of Norway (IP/C/M/48: 128). The EC continued to maintain that the transposition of the waiver into an amendment should be a technical exercise (IP/C/M/48: 132), with Kenya rebuffing that while the EC maintained such, the European Communities had been working for a long time on their proposal, indicating that the preparation of an amendment was not an easy task (ibid: 135).

Conflict and lack of progress in the negotiations persisted (see Matthews, 2006: 110). In a manner reminiscent of the Uruguay Round and the Rosa Whitaker letter encountered earlier, Kenya informed the Council in October that his delegation had recently been accused of blocking consensus on the issue and that he hoped that the delegation that had given this message to his Minister would bear witness to what had been stated (IP/C/M/49: 14). The Southern leaders of the UR Brazil and India, both expressed concerns about exclusion at that

meeting (ibid: 33; 35), prompting the Chairman to undertake to ensure full transparency in the process of consultations (ibid: 37), and a 29 November 2005 complaint by Brazil that it had been altogether excluded from consultations (ibid: 40). Nonetheless, in this period, press reports began to surface that the AG and the US were close to agreement (Matthews, 2006: fn. 96), a revelation which reportedly incensed other DCs (ibid: 111). On the same day as Brazil's complaint, a draft text of the permanent amendment, in the form of an Art.31 bis and an annex, began to circulate (ibid).

This draft then became the subject of joint criticism by a 54-strong NGO contingent on 03 December 2005. The group criticised the draft as a “bad deal on medicines”, arguing that the proposals are flawed and that poor countries should not accept a permanent amendment that has not been shown to work in practice.<sup>24</sup> The statement noted that although the African Group proposal for an amendment had received much support, developing countries were instead being pressured to agree on an amendment that included the entire 30 August 2003 Decision and a re-reading of the Chairman's Statement because “the US and the EU are desperate to deflect attention from their lack of movement in agriculture and their anti-development proposals in NAMA and services”.<sup>25</sup> Nonetheless, on 06 December 2005, the General Council took the Decision to directly transform the 30 August 2003 waiver into a permanent amendment of TRIPS<sup>26</sup>, exactly one week prior to the start of the Hong Kong Ministerial Conference. The amendment was reported to have been ‘rushed through’ under curious circumstances in which the Chair of the General Council, Ambassador Amina Mohamed of Kenya, made personal appeals to delegations to agree on amending TRIPS (Shashikant, 2005). Following this appeal, it was proposed to delegations that the basis of the amendment would be the Decision in its entirety and a re-reading of the Chairman's statement, with no reference whatsoever to the

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<sup>24</sup> Statement is available at: <http://www.cptech.org/ip/wto/p6/ngos12032005.html>, along with names of all signatories.

<sup>25</sup> Ibid; see also Matthews, 2006: 111.

<sup>26</sup> See Matthews, 2006: 113-4 on the content paragraphs 1-5 to the new Art.31 bis; the new annex and its appendix.

statement in the amendment, a proposal which was accepted by the AG (ibid), and secures one of its key objectives (Matthews, 2006: 112). According to reports, a request was made by the Chairs of the General Council and the TRIPS Council that there be no statement by any delegation (not even to thank or congratulate the Chairs) before or after the adoption of the decisions at both the Councils (Shashikant, 2005) further clouding decision-making at the WTO.

Perhaps it is this cloud that has propelled the AG and others to refrain from accepting the change. The 01 December 2007 deadline to accept the amendment has since been extended to 31 December 2009 (WT/L/711), and only Mauritius from the AG has thus far accepted. Noteworthy however, on 17 July 2007, Rwanda became, and still is, the first country to inform the WTO that it would use the 30 August 2003 Decision (as per paragraph 2(a) of that Decision) to attend to AIDS-related public health needs (IP/N/9/RWA/1). On 04 October 2007, Canada made the first notification from any government that it has authorised a company to make a generic version of a patented medicine for export to Rwanda under the terms of the 30 August 2003 Decision (IP/N/10/CAN/1). These developments will surely test the appropriateness of the Decision for public health. Nonetheless, the conflict and contestation that ultimately led to the Doha Declaration, the 2003 Decision, and then the 2005 Amendment, however imperfect, cannot be discounted.

### **6.5 Conclusion: A Quasi-Rival Structure?**

Throughout this chapter we see a strikingly differentiated 'Africa' from its initial disengagement and obscurity in the TRIPS UR negotiations, to the leadership of the African Group in the post-TRIPS period. Africa's non-participation in the UR negotiations was particularly distressing especially since the issue of pharmaceutical patents are so significant in the context of the disease burden on the sub-continent, and particularly in relation to the devastating reality of the HIV/AIDS pandemic. The chapter has shown the continuing class struggle between the forces of

the global economy and those who are largely excluded from the gains from the prevailing structure; and the precise Vichian 'modification of mind' or Gramscian 'mental imagery' moment in which African countries, by virtue of a common incapacity and marginalisation, decided in 1998 to collaborate (in the form of the African Group) in the area of international trade policy at the WTO, and then to steer the issue of TRIPS and public health thereafter. Arguably the single most important issue in the post-TRIPS period and the role of the AG, is the focusing effect of the South African court case and the transnational attention and activism it drew. The African Group is arguably the most legitimate contemporary example of a 'modification of mind' against the backdrop of its 'absence' in the UR.

However, recalling Chidyausiku's testimony above, there is little doubt that the rise in influence of the African Group has been enabled by the partnership with civil society NGOs (Drahos, 2002: 781; 2007: 18; Abbott, 2002b: 578). We recall also from the 'Theoretical Framework' Cox's insight that the struggle for change will take place primarily in civil society (Cox, 1997: 112), thereby providing a conceptual reference point for the empirical picture portrayed earlier. While the African Group remained engaged throughout the post-TRIPS process, it is arguable whether it could have participated on a similar level had civil society NGOs not taken on the issue of access to medicines,<sup>27</sup> beginning with CPTech's October 1995 letter to then-USTR Mickey Kantor.

Cox (2002: 102) notes that civil society<sup>28</sup> has become the comprehensive term for various ways in which people express collective wills independently of (and often in opposition to) established

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<sup>27</sup> It is important to note that while civil society NGOs have been around for a while, most neglected multilateral trade issues, hence their disengagement during the UR. See Scholte, *et al*, 1999; Robinson, 2000 for insights on civic interest in the WTO.

<sup>28</sup> The political literature on civil society is vast and this conclusion does not attempt to be representative.

power, both economic and political.<sup>29</sup> He contends that civil society is not just an assemblage of actors, i.e. autonomous social groups. It is also the realm of contesting ideas in which the intersubjective meanings upon which people's sense of 'reality' are based and can become transformed and new concepts of the natural order of society can emerge. "In a 'bottom-up' sense, civil society is the realm in which those who are disadvantaged by globalisation of the world economy can mount their protests and seek alternatives" (ibid). Moreover, civil society inhabits the more expansive terrain of the counter-society, which is peopled by the marginalised and the excluded, by those who are intellectually alienated from established order in thought, behaviour and institutions, and by those deprived of the possibility of satisfying their material needs according to the prevailing norms of social order (ibid: xvi). Consequently, disadvantaged by the globalisation of pharmaceutical patents by virtue of their distributional implications for the African continent, civil society NGOs and the African Group challenged the prevailing TRIPS order in search of an alternative that was responsive to the needs of the poor, in a way that could not have been substantiated in the UR.

The engagement of civil society NGOs; the patent-infringement lawsuit against South Africa in March 2001; the subsequent rise of the African Group as a legitimate expounder in the midst of the gravity of the HIV/AIDS pandemic; the transnationalisation<sup>30</sup> of the access to medicines issue and its coverage in the media; but more importantly, the high intensity of the conflict between the forces of the global economy (including the TDI, the US and the WTO) and the counter-society (peopled by the marginalised in terms of thought and material capabilities), were a compelling cocktail that seriously challenged the prevailing historical structure and its mode of decision-making. As Oh notes, "it was the first time developing countries were the 'demandeurs' of a particular issue and saw it through" (Oh interview, August 2005), pointing to the blocking

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<sup>29</sup> See Cox (1999: 396) for a view on the malign side of civil society, such as for instance, xenophobic movements; and Cox (2007: 521) on civil society's vulnerability to being manipulated, subverted and co-opted.

<sup>30</sup> Cox (1991: 191) contends that the taming and civilising of the dominant structure presupposes social and political forces that are global in their reach.

power of those whose interests are served by the current institutional arrangements, and the probability of DC success in pursuing an agenda against the forces of the global economy.

Consequently, while the widespread and deep-seated contestation and conflict led to changes to the multilateral rules governing pharmaceutical patents, it is important to frame this success within the proper context. Importantly the development does not constitute a change in world order in the sense that the counter-society did not fundamentally alter the structure of the GPE. In speaking of historical structures – material capabilities, ideas, institutions – Cox contends that individuals and groups may move with the pressures, or resist and oppose them, but they cannot ignore them. 'To the extent that they do successfully resist a prevailing historical structure, they buttress their actions with an alternative, emerging configuration of forces, a rival structure' (Cox, 1981: 135), ultimately signalling a change in world order, however 'ambitious' (Cox, 2002: 102). The successive victories embodied in the Doha Declaration and parts of the 30 August 2003 Decision cannot be said to constitute a rival structure in terms of toppling the prevailing power structure, even though the counter-society did manage to 'shake' this structure and significantly sensitise global public opinion.

Instead of Cox's rival structure, the story depicts a more nuanced quasi-rival structure covering a particular aspect of social life. The post-TRIPS moment is not a change in world order, but a change in an aspect of the current order that appears to respond to the conditions of the world's poor. Conceptually, the quasi-rival structure simultaneously represents the dynamics of continuity and change in the GPE because it explains how some forms of emancipation can emerge without necessarily unravelling the prevailing order. It probes the possibility of whether a succession of quasi-rival structures via the counter-society can be sufficiently numerous to eclipse the prevailing world order structure. This possibility will be dependent on successive

modification(s) of mind, the nature of conflict these engender, the preparedness of the counter-society, and perhaps divergences between the major jurisdictions.

## CONCLUSION

### 1. The Synthesis

The overarching thread of the thesis is subsumed under Cox's historicist insight that each successive historical structure generates the contradictions and points of conflict that bring about its transformation (Cox, 1995: 35). To begin with, the thesis examined the making of the patent provisions in TRIPS as a case study in institutional capture by private interests, specifically focusing on how and why the TDI was able to secure all of its demands for pharmaceutical patents under TRIPS. It analysed this both empirically and theoretically, firstly, by developing a theoretical framework that explains continuity in the GPE, that is, the identification and explanation of material structures that constrain action in different historical periods (continuity); then empirically, producing a narrative analysis of the UR negotiations to determine the nature of the decision-making that led to patent-formation in TRIPS. In explaining 'who gets what' in international trade decision-making, Chapter I did several things. It was able to corroborate the first part of the first hypothesis, that the TDI was a key player in the making of the international patent code inscribed in the original TRIPS Agreement. It did this by looking at the role of the industry in the history of TRIPS, primarily at the initiation of Pfizer's then CEO, Edmund Pratt; the leadership of the IPC, the majority of which membership consisted of pharmaceutical manufacturers; the President's ACTPN with Pfizer's Pratt at the helm during two consecutive presidential terms, and more generally, the federal advisory committee system that legally sanctions a decision-making space for sectional/private interests in US politics.

By applying Cox's historical structures framework to examine the role social, cultural and economic forces play in constituting and reconstituting the prevailing order, Chapter I also confirmed the first part of the theoretical hypothesis, that Cox's historicism, which first examines the factors that sustain and consolidate prevailing structures, or continuity in the GPE, provides

the best analytical means of making sense of the making of patent provisions under TRIPS. While the mercantilist and liberal perspectives summarised could provide some conceptual insights, they were insufficient in and of themselves, in explaining the dynamics involved in the making of patent provisions in TRIPS. Notwithstanding, the Coxian framework deployed does embrace a prevailing-theory-as-practice discourse that gives liberalism more explanatory purchase than mercantilism. It shows how the prevailing structure of meaning, within the 'ideas and institutions' component of Cox's historical structures, both favoured the TDI structurally, as well as provided the conceptual frame within which the TDI could package its demands. The analysis placed the TDI in a favourable position in the prevailing power structure by virtue of the TAG rationality and PEG mechanism (supported by the institution of private property, global market institutionalism and the role of the US as global economic superpower) which form the basis and meaning of this power structure. It also demonstrated that corporate/industry actors are pivotally aware that structures impact on outcome, and therefore, by consciously equalising their demands with the intersubjective meanings (the range of norms, values, language, symbols and institutions) that constitute the prevailing order, such actors were favourably placed to influence the TRIPS process.

By confirming this aspect of the theoretical hypothesis, Chapter I also makes an important contribution to critical IPE by developing an additional dimension to the three-pronged categories of forces (material capabilities, ideas and institutions) that interact in Cox's prevailing historical structures framework. While these forces compellingly illustrate the projection of the TDI's power in the making of the patent provisions in TRIPS, the decision-making authority of private interests under the US Federal Advisory Committee system proved fundamental in enabling pharmaceutical and other high-tech interests to capture the TRIPS process. Significant were the President's Advisory Committee on Trade Policy and Negotiations (ACTPN) which is the advisory system's direct channel to the President; and the Industry Trade Advisory

Committee for Intellectual Property (ITAC-15) which reports directly to the ACTPN. Both committees seat high-level executives from the pharmaceutical industry as well as their trade associations and legal representatives. Section 135 of the Trade Act of 1974 requires the USTR to consult and seek the advice of trade committees before entering into trade agreements; on the operation of trade agreements once entered into; and on matters arising in connection with the development, implementation and administration of US trade policy,<sup>1</sup> thereby making trade advisory committees effective decision-making ensembles in American politics. In the context of the research this component added explanatory weight to the Coxian framework deployed, and provided a lens through which Cox's historical structures can be enlarged in IPE depending on the issue under investigation.

The 4-dimensional historical structures framework developed in Chapter I explains the synchronic study of existing power relations in a given historically located limited totality (Cox, 1981: 137). Therefore, notwithstanding the fact that this framework theorises 'continuity' in the GPE, this is not synonymous with fixity. Rather, continuity suggests reinforcement or consolidation of the prevailing structure, and intimates that the TDI was well-placed, structurally and materially, to secure its demands from TRIPS, an advantage chronicled in Chapter II. By juxtaposing the supply of concrete decisions on patents in TRIPS with the demands for such contained in a 1988 industry proposal for a GATT framework on IP, the second chapter – linked to the first – portrayed actual decisions as testimony of the TDI's influence, and the way in which power is translated into action. It showed that the TDI got more than what was articulated in its 1988 proposal, making TRIPS an overwhelming victory for the industry. While for instance it has been variously concluded that industry got what it wanted from TRIPS (Sell, 1998, 2003; Drahos, 2002; Devereaux, 2006), Chapter II went further by systematically verifying industry's gains with a comparison between its demands in the 1988 joint-industry proposal, with the actual

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<sup>1</sup> See USTR online at: [http://www.ustr.gov/Who\\_We\\_Are/List\\_of\\_USTR\\_Advisory\\_Committees.html](http://www.ustr.gov/Who_We_Are/List_of_USTR_Advisory_Committees.html)

supply of decisions relating to patents in TRIPS. By so doing, the chapter simultaneously proved the second aspect of the first empirical hypothesis, that (linked to the first part of the hypothesis that the TDI was a key player in the making of the patent provisions in TRIPS), the TDI ensured that its interests were fully inscribed in the original agreement, thereby substantiating institutional capture.

Chapters three and four then looked at the nature of the TDI's TRIPS victory by documenting the composition and extent of conflict in the TRIPS negotiations. To conceptualise this conflict, and to determine some of the contradictions of the prevailing framework, these chapters framed the negotiations in the context of Cox's extrapolation of Gramsci's concept of hegemony in critical IPE. Hegemony in critical IPE is an analysis of power which necessarily captures a combination of consent (moral and intellectual leadership) and coercion (domination). To the extent that the former is in the forefront, hegemony is said to prevail. Chapter III therefore examined the high intensity of the conflict characterising the TRIPS UR negotiations on patents (Hypothesis I) and concluded that on the basis of Gramsci's hegemony, TRIPS was non-hegemonic because the framers of the patent framework did not command moral and intellectual leadership. Throughout the negotiation, DCs expressed indignation, asserting that the patent framework proposed by the industrialised countries on behalf of the TDI and other high-technology industries, was morally indefensible by virtue of their underdevelopment. This indignation and the corollary offensive mounted against the entire Northern patent agenda, meant that the framers did not command the essential condition required for hegemonic consolidation, thereby unveiling a crucial contradiction.

However, the high intensity of the conflict presented in Chapter III merely inferred that TRIPS depended on coercion and domination to be concluded. Since Gramsci's framework of hegemony constitutes a combination of consent and coercion, it was insufficient to simply substantiate the

absence of the former. Accordingly, and to further probe the question of points of conflict and contradictions in the present, Chapter IV examined the range of non-transparent and coercive strategies, used to shore-up consensus over patent policy in the negotiations, as belonging to 'domination' on Gramsci's yardstick of hegemony. Such strategies included US coercive unilateralism; the GATT Secretariat's 'disinformation campaign'; the pervasive use of informal/'green room' consultations; and asymmetrical contracting. These strategies were aided by crucial GATT intermediaries, including the Secretariat and its then DG, Arthur Dunkel; as well as the Chairman of the Negotiating Group on TRIPS, Ambassador Lars Anell of Sweden.

So incensed were DCs by the manner in which the negotiations were unfolding, that in a November 1990 formal GATT session, Peru's Julio Menoz launched one of the most scathing criticisms of the Northern IP agenda which appeared to have been set without the approval of the developing world. Prefiguring Hypothesis II of this thesis, Munoz criticised the entirety of Anell's draft accusing it of not taking adequate account of the special needs and problems of developing countries (MTN.GNG/NG11/27:3). He expressed concern that all the emphasis in the draft was on the provision of rights for IPR owners, and little account was taken of their obligations, or of the underlying public policy objectives of national IP systems (ibid). Despite the fact that Anell had submitted this draft to the GNG on his own responsibility and committed no delegation, it would be copied verbatim into Dunkel's draft texts. Later, with the removal of bracketed language that represented the core of developing countries' demands, this draft would become the actual TRIPS Agreement on the basis of Dunkel's 'arbitrated resolution' to issues undecided by the negotiators (Stewart, 1995: 2282).

The roles played by these intermediaries essentially cemented the extent of capture by industry of the patent provisions of TRIPS and demonstrated how structures are maintained over time with the dedication of agents (continuity). This chapter therefore made the case that TRIPS was

concluded on the basis of Gramsci's domination, further intimating the contradictions and points of conflict in the prevailing historical structure that reveal the shakiness of its underpinnings.

This absence of hegemony and the consequent dependence on coercion and domination to obtain the acquiescence of DCs further equipped the study with a conceptual lens through which to examine the legal form – since TRIPS is an instrument of public international law – and its role in the politics of 'who gets what' in the GPE. The thesis therefore made a case for critical IPE to consciously admit the study of law, particularly its international economic counterpart, into its remit, since law – its functions, the nature of its influences, the opportunities it offers and the limitations it imposes – is as much implicated in the consolidation and maintenance of global power relations, an inquiry which informs a critical IPE framework of analysis. The study proposed that a good starting point presented itself in the form of a conjoinment between critical IPE and critical legal studies (CLS) since both traditions engage with structural origins and their transformation. Critical IPE could certainly benefit from an infusion of the kind of legal analysis in CLS.

The thesis also demonstrated that the prevailing historical structure – with its attendant politico-economic, juridico-legal, material-ideational and institutional configurations – was not sufficient to sustain the permanence of the TRIPS package primarily because of the legitimacy shortfalls that permeated it. The consensus formation strategies that defined the transition from resistance to acquiescence were subsumed under the framework of 'consent without consent', a dialectical concept intimating a novel way of explaining coercive decision-making in the GPE. It speaks to a form of deferred consensus and implies a coercive assumption of superior judgement on the part of the architects of policy, that dissenters (at the time the policy is being negotiated), will mature in reason and appreciate that decisions were taken against their will. In a powerful exposition of this concept, the US Sixth Circuit Court of Appeals ruled that "the rules of the

marketplace govern. By so reflecting commercial interests, the institutions of government serve – according to current legal and economic theory – the long-term best interests of society as a whole” (Chomsky, 1997: 237). In much the same way, the study located the making of the global pharmaceutical patent regime within the framework of ‘consent without consent’ because of the extent to which it represents a fissure between global public preferences and global public policy, even while maintaining that it serves the global public interest. In effect, the only way the WTO could maintain that the patent provisions in TRIPS were the result of consensus decision-making is to invoke the developing world's 'consent without consent'.

The problem with a reliance on this kind of consensus for public policy is its inherent legitimacy deficit, and a consequent proneness to subversion attempts. Indeed, while the TDI satisfied the various criteria of a hegemonic framework from the vantage point of the prevailing power structure, it stopped short of total hegemony precisely because those for whom the global patent system was being devised, were not convinced of the welfare-enhancing arguments put forward by the framers of the regime. In the beginning of the negotiations, when the link between trade and IP was being constructed, it was an attempt at ideological acceptance of the virtues of patent protection from the point of view of the global pharmaceutical industry. It was only after developing countries opposed all areas of the TRIPS negotiations that the more ancient strategies aimed at compliance were unveiled, hence the prevalence of ‘consent without consent’. The concept also plausibly enlarges Gramsci's concept of hegemony because it explains a moment of interlock between coercion and consent in international trade decision-making. While consent to TRIPS had nothing to do with Gramsci's notion of moral and intellectual leadership, formal consent in international law is nonetheless a profoundly legitimating mechanism. By problematising it, one can arguably arrive at different levels of consensus which potentially enhance the explanatory power of the concept of hegemony in critical IPE.

All such contradictions – consent without consent; legitimacy shortfalls; the absence of hegemony – and the high intensity of the conflict characterising the negotiations (which build on the central thread of the thesis articulated in the opening sentence), made TRIPS prone to challenges, thereby generating a second research question. Consequently, the thesis examined how, why and under what circumstances the TRIPS capture by the TDI was, in some measure, successfully challenged by arguably the weakest global economic actor, the African Group at the WTO.

The TRIPS trade-off in favour of the TDI and other high-tech industries, despite some built-in flexibilities, meant, not only that the outcome resulted in a disaffected Global South, but importantly also, that there was no social obligation on the part of DCs to act in a morally dutiful manner. Coupled with that, and arguably an even greater contradiction, were the distributional implications of patents, particularly how they impacted on poor countries' access to public health (Hypothesis II). This was magnified in the wake of the March 2001 lawsuit by 39 pharmaceutical companies against South Africa over a 1997 legislative amendment in its Medicines Act which appeared to grant the government unspecified power to issue compulsory licences and parallel importing contracts to its generic producers for HIV/AIDS pharmaceuticals (Shah, 2002; Bartelt, 2003; Gad, 2006; Sell, 2006). South Africa, the most HIV/AIDS-indebted country, made history when transnational civil society NGOs (which had been engaging with the 'access to medicines' cause at least as early as October 1995 with CPTech's letter to USTR Mickey Kantor) seized the opportunity with more intensified global campaigns aimed at sensitising global public opinion to the dangers of pharmaceutical patents for access to essential drugs, with a view to altering the *status quo* (Hypothesis III).

These emboldened calls for change further energised the African Group at the WTO, formed in 1999 upon recognition of a common marginalisation and incapacity, and a need to bolster

collaboration in international trade policy. Arguably the most legitimate propounder by virtue of the HIV/AIDS pandemic on the continent, the African Group (AG) was responsible for formalising the issue of access to public health at the level of the WTO, and asserted itself as a key player in the post-TRIPS agitation and negotiation of the Doha Declaration on the TRIPS Agreement and Public Health; the Paragraph 6 negotiations leading to the 30 August 2003 Decision; and the subsequent Paragraph 11 negotiations leading to the 06 December 2005 Decision to Amend the TRIPS Agreement (Hypothesis IV). Because the issue of 'access to medicines' had gathered unprecedented momentum, and especially so since the 2001 lawsuit, the prevailing power structure could not simply ignore the African Group or the spate of global public opinion that demonised the WTO, the major economic powers, and the TDI. While in the UR the demands of the developing world were successfully negotiated out of the round through 'consent without consent', the post-TRIPS climate of renewed and morally-charged conflict, framed as a contest between good and evil in what was nominally a 'development' round, could not be ignored. This is not to say that some of the strategies used in the UR were abandoned in the post-TRIPS period. In fact, Kenya's negotiator testified that while Kenya believed that members could freely exercise the options available to them under TRIPS to gain access to important life-saving medicines, "there had been pressure on some developing countries, including Kenya, not to use these options" (IP/C/M/30: 246). What therefore made the AG 'succeed'?

The rise in influence of the AG and its subsequent success in challenging TRIPS was attributed, theoretically (the second part of Hypothesis V) to a Vichian-Gramscian moment in Coxian IPE, constituting Vico's modification of mind, or a group's self-understanding and attitudes towards a common reality of marginalisation (Cox, 1981: 132; 2002: 45; Berry, 2007: 16); and Gramsci's mental imagery which gives groups self-awareness and understanding of where they stand and how they must act for their emancipation (Cox, 2002: 29). This was most apparent by the fact

that there was no African Group during the Uruguay Round. It was conceived in 1998 after OAU trade ministers took the decision to collaborate on trade policy for the forthcoming Seattle Ministerial Conference (Narlikar, 2003: 191). After a statement denouncing the lack of transparency at the failed Ministerial, the AG went on to command a level of leadership and prominence in the post-TRIPS context at a similar level of engagement as the NETs in the negotiations.

We also recall Chidyausiku's account from Chapter VI, that the AG's rise to prominence had been greatly enhanced by its partnership with civil society NGOs. Moreover, as Cox maintains, the struggle for change will take place primarily in civil society (Cox, 1997: 112). In a 'bottom-up' sense, civil society is the realm in which those who are disadvantaged by the globalisation of the world economy can mount their protests and seek alternatives (Cox, 2002: 102). Civil society also inhabits the more expansive terrain of the counter-society, which is peopled by the marginalised and the excluded, by those who are intellectually alienated from established order in thought, behaviour and institutions, and by those deprived of the possibility of satisfying their material needs according to the prevailing norms of social order (ibid: xvi). Consequently subsuming the second phase of the research is Cox's intimation of the second phase of Polanyi's double movement which turns our attention to society, towards identifying those crisis points in societies that are likely to mobilise people into resistance and to generate social movements seeking an alternative future (Cox, 1997: 107).

The contradictions recounted earlier, as well as the distributional implications of pharmaceutical patents on the poorest countries, provided the apposite crisis points which mobilised people into resistance, generating social movements seeking meaningful change that placed life before pharmaceutical profits. While it has been substantiated that the AG experienced a 'modification of mind' that propelled it towards an ownership of the issue of patents and access to medicines at

the level of the WTO, it is arguable whether the group would have made as many inroads had transnational civil society NGOs not simultaneously become involved with trade issues in general, and the access issue in particular. Nonetheless, the progress made by the group in a seemingly enduring power structure cannot be discounted by virtue of the fact that it at least managed to get a rethink of a power-riddled TRIPS.

Notwithstanding, while there is undoubtedly some degree of transformation in the post-TRIPS era, it has to be properly contextualised. While Cox rationalised in terms of a rival structure transcending a prevailing historical structure (Cox, 1981: 135) – a change he calls 'ambitious' (Cox, 2007: 102) – this study takes a more nuanced approach and instead invokes a quasi-rival structure on the basis of incremental gains. This is so because the successes recorded by the AG do not constitute a change in world order, the premise of a rival structure. Instead, there were changes to certain aspects of world order which signalled movement that is responsive to the needs of the poor. The concept simultaneously engages dynamics of continuity and change in the GPE because it explains how some forms of emancipation can emerge without necessarily unravelling the prevailing world order structure. This novel concept therefore probes the question of whether sufficient forms of emancipation based on incremental gains can emerge to eclipse the prevailing order.

Overall therefore, the thesis has substantiated all four empirical hypotheses articulated in the opening pages of the 'Introduction', and has demonstrated that the Coxian approach to the dual dynamics of continuity, and change through conflict, provided the thesis with the best analytical means of making sense of the making and remaking of the international patent code under TRIPS. The thesis derives its contributions to knowledge precisely from this theoretical application, beginning with Cox's historical structures (a term he borrows from Braudel), 3-dimensional framework. In explaining continuity, the thesis supplements this approach with a

fourth dimension located in decision-making authority, thereby adding explanatory weight to the framework being deployed. Moreover, by employing Cox's extrapolation of Gramsci's concept of hegemony to contextualise the nature of conflict and contradictions in the making of pharmaceutical patents, the thesis provided an empirical contribution to this subject in critical IPE. In analysing the 'domination' aspect of Gramsci's hegemony, the thesis also developed the dialectical concept of 'consent without consent' as a novel way of explaining coercive decision-making in the GPE, thereby plausibly enlarging Gramsci's concept of hegemony in IPE by the way in which it combines coercion and consent.

The contradictions and points of conflict analysed in the thesis enabled it to substantiate Cox's insight that such components prefigure change in the GPE. By looking at the post-TRIPS climate of agitation and re-negotiation of patent provisions in TRIPS, the thesis also provided an empirical contribution of change through the counter-society and the Africa Group. However, while Cox ambitiously theorised in terms of change in world order, the thesis advanced the more nuanced but novel concept of a quasi-rival structure on the basis of incremental gains in the counter-society. The thesis also demonstrates a detailed analysis of UR and post-TRIPS negotiating documents, and corroborates, through systematic analysis, some conclusions that have been reached in the IP literature, such as for instance, that African countries played no meaningful role in the TRIPS negotiations, and that the pharmaceutical industry got what it wanted out of TRIPS.

## **2. Implications of the Study for Future Research**

As indicated in the 'Introduction' and 'The Synthesis' above, the thesis makes several contributions to the field of IPE, all of which potentially inform a future research agenda. One such area is the contribution to multidisciplinary, and particularly the focus on bringing law and the legal form into the remit of critical IPE. Aside from the natural sciences, the legal form has

enjoyed a special place in the domain of un-criticality. While the sub-discipline of critical legal studies has opened the debate into the supposed 'objectivity' assigned to law, there is still more to be done to open up the legal form to sustained criticality. This research dealt with a small part of this cloud cloaking social enquiry by looking at TRIPS (a legal mechanism) that was anything but neutral. Bringing the legal form into IPE is fundamental, not only because of the false disciplinary boundary it will debunk, but also, its potential in abetting a demystification of our 'learned' social understanding of the law's objectivity, precisely that which actively maintains unsatisfactory social arrangements.

This is not inconsequential since the critical tradition invites us to reflect upon the social construction and effects of knowledge and to consider how claims about neutrality can conceal the role knowledge plays in reproducing unsatisfactory social arrangements (Linklater, 1996b: 279). When a social construct (as in the case of a legal framework) carries the banner of neutrality/objectivity, it becomes naturalised and gives rise to notions of 'immutability' in social practice since there is generally no impetus to alter social relations construed as unbiased. As Linklater rightly suggests, notions of inalterability support structured inequalities of wealth and power, which can in principle, be recast (*ibid*). This kind of critique has been one of the main contributions of the critical approaches to international studies, and bringing 'law' in, particularly its international economic counterpart, would serve to enhance this research agenda.

In fact we saw notions of objectivity recurring throughout the research. The first was the manner in which trade-related IPR protection was framed, in the period leading up to the Punta del Este Ministerial, as the answer to innovation and growth, as it would provide the right mix of incentives that would benefit all of society. The arguments had a clear rational logic, and it often appeared that the pharmaceutical industry was operating out of sheer altruism. All of society would benefit. Another crucial instance of the objectivity paradigm was the discussion on

consensus decision-making at the GATT/WTO, a notion which appears to take equal account of the interests of all parties to a negotiation. Yet, at the very least, consensus decision-making means that parties *present* at a meeting show no objection to the issue being decided. No account is taken of delegations without the necessary material capabilities and expertise to participate effectively in negotiations such as those in SSA during the Uruguay Round.

Moreover, as we saw in Chapter V, there was no real consensus over TRIPS even though it was supposedly consensual. A layperson, aware of the consensus decision-making apparatus of the WTO could ask, why would sub-Saharan African countries seek to overturn TRIPS if they *consented* to it? These are just two amongst numerous examples of the infiltration of notions of objectivity that permeate social reality, which, if taken as ‘given’ can serve to maintain unsatisfactory social arrangements. The research therefore opens up possibilities for a more sustained emphasis on uncovering such ‘incontestable’ tendencies usually cloaked in ‘beneficial to all’ language, but which serve the interests of particular groups in society. It invites us to consider/uncover the many such standards which are not given but made, not imposed by nature but adopted by convention by the members of a very specific community (Neufeld, 1995: 42-43).

Another contribution with implications for future research, as well as theoretical substantiation, hinges on the replicability of this research for other areas of social enquiry. While this study was specific to international trade decision-making, its theoretical framework and methodological approach can easily be replicated to study other issue areas. In other words, the life of this research does not end with an analysis of the making and remaking of the global pharmaceutical patent regime. Coxian historicist insight – that each successive historical structure generates the contradictions and points of conflict that bring about its transformation – has the attribute of transferability and can be used to investigate essential winner-loser arrangements and their

transcendence in the GPE. This is significant as a corollary to the project against the objectification of social life alluded to above, as it specifically rejects any attempt aimed at re-presenting the world as it is. By seeking to understand the dynamics of social relations, embodied in the domains of ideas, institutions, material capabilities, and decision-making authority, we can provide robust explanations of the nature of the present order and the way in which it came into being, as the starting point of an inquiry into the potentials for progressive social and political transformation (Devetak, 1996: 248).

The research therefore invites us to ponder Cox' framework in search of additional parameters through which to interpret social relations that are deemed unsatisfactory and unjust for some, but beneficial for others. While this study was able to locate decision-making in American politics as an essential mechanism in the 'who gets what' scenario in the GPE, this may not necessarily be the case if one were to examine the trajectory of other WTO Agreements. There may well be other mechanisms that improve the explanatory capacity and applicability of Cox's work, a point which draws our attention to the socially inappropriate agendas which claim that "we add to knowledge primarily when we render reality more intelligible by seeking generalisations of empirical validity" (Neufeld, 1995: 51, taken from Holsti, 1985). This is not to say that theoretical projects *should* have no generalisable quality. It is the insistence that this be mandatory in valuations of what counts as reliable knowledge that detracts from the social purpose of scholarly investigation in the social sciences.

By remaining cognizant that social environments are not fixed in place and time, there will be more enhanced prospects of not just re-presenting and explaining reality, but also in understanding how unacceptable social arrangements can be transcended. Applying and verifying a Coxian criticality for instance, has real practical policy implications. This research has shown how an unsatisfactory socio-economic, politico-legal arrangement was imposed from

above, and how this very imposition became the basis for a threats-from-below initiative. It therefore begs further investigation into the dynamics that enable systemically weak actors to at least partially determine their course of development in a power-riddled GPE. Furthermore, the incremental gains made by these actors cannot be seen as inconsequential in terms of explanations of the broader world order structure. While these gains may not eclipse world order structures, they do result in emancipatory changes. Therefore, such gains need to be consciously captured within the explanatory framework, and for this reason, the prospects of quasi-rival structures need to be further operationalised.

## List of Interviewees

Charles T. Ntwaagae	Ambassador and Permanent Representative of the Republic Of Botswana to the United Nations, the WTO and other International Organisations in Geneva. Monday, 13 June 2005. Face-to-face interview.
Roger Kampf	Counsellor, Intellectual Property Division, World Trade Organisation. Monday, 13 June 2005. Face-to-face interview.
Falou Samb	Trade Policy Officer, Agency for International Trade Information and Cooperation, Geneva. Former Senegalese Trade Negotiator in Geneva. Monday, 13 June 2005. Face-to-face interview.
Hyuck Choi	Chairman of the WTO's TRIPS Council. Ambassador and Permanent Representative of Korea to the WTO, Geneva. Monday, 13 June, 2005. Face-to-face interview.
Anonymous 1	Face-to-face interview, WTO, Monday June 13, 2005.
Falou Samb	Trade Policy Officer, Agency for International Trade Information and Cooperation, Geneva. Former Senegalese Trade Negotiator in Geneva. Tuesday, 14 June 2005. Face-to-face interview.
Siva Palayathan	Trade Adviser, Permanent Mission of Mauritius to the UN and other International Organisations in Geneva. Tuesday, 14 June 2005. Face-to-face interview.
Maigari Buba	Trade Adviser, Permanent Mission of Nigeria to the WTO, Geneva. Wednesday, 15 June, 2005. Face-to-face interview.
Edward Bizumuremyi	Trade Expert, Permanent Mission of Rwanda to the WTO, Geneva. Friday, 15 July 2005. Telephone Interview.

Cecelia Oh

Department of Technical Cooperation for Essential Drugs  
And Traditional Medicine, World Health Organisation.  
Former Researcher with the Third World Network.  
Monday, 08 August, 2005. Telephone interview.

Boniface Chidyausiku

2001 Chair of the TRIPS Council; Ambassador and  
Permanent Representative of Zimbabwe to the United  
Nations in New York. Monday, 08 August, 2005.  
Telephone interview.

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