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**Narratives and Counter-Narratives in Pharmaceutical
Patent Law Making: Experiences from 3 Developing
Countries.**

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**A thesis submitted to the School of Law, University of Warwick in
fulfilment of the requirement for the award of the degree of
Doctor of Philosophy**

**School of Law,
University of Warwick,
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Declaration

I hereby declare that, except where otherwise indicated, this thesis is entirely my own work, and that no part of it has been submitted for any other degree or qualification.

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It is good to rely upon others. For no one can bear this life alone.

Hölderlin

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Dedication

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Abstract

This empirical thesis explores the ways some Third World States use the patent regime as set out in the TRIPS Agreement to effect certain development and public health goals. It also investigates how non-state actors in these countries participate in patent law making, thereby creating narratives and counter-narratives that are challenging global norms on pharmaceutical patent protection.

To do this, the thesis takes the three different examples of Brazil, India, and Nigeria and tells the story of patent law making within each of them. Adopting a Third World Approach to International Law as a macro-theoretical guide and nodal governance theory as a supplement, the thesis maps the broad interpretations and contestations of international patent law within the Third World. In doing this, the thesis pays particular attention to the everyday life of international patent law through the examination of practices that unfold through the different sites and objects in which international law operates today.

In unpacking the patent law making in the aforementioned countries, the thesis posits that there is an emerging body of IP jurisprudence from the Third World that is expanding the aperture on norms governing pharmaceutical patent rules and medicines access discourse. In other words, the politics of international law making and implementation is shifting dramatically due to the confluence of different actors from various sectors in different forums in Brazil and India that are articulating counter-hegemonic pharmaceutical patent rules. The concomitant effect is not only the adoption of alternative pharmaceutical patent laws that are pro-human rights – especially pro-public health rights – in its articulation, but are also hermeneutic expressions of resistance against, and reform of, the international IP regime. In interrogating these narratives and counter-narratives that frame the global intellectual property regime in Third World forums, this thesis articulates successful counter-hegemonic discourses on patent law making and extrapolates lessons for Nigeria.

Abbreviations

A2M	Access to Medicines
ABIA	<i>Associação Brasileira Interdisciplinar De AIDS</i>
ABIFINA	<i>Associação Brasileira das Indústrias de Química Fina, Biotecnologia e Suas Especialidades</i>
ACTN	Advisory Committee for Trade Negotiations
AIDS	Acquired Immune Deficiency Syndrome
AMTC	Affordable Medicines and Treatment Campaign
API	Active pharmaceutical ingredient
ARV	Antiretroviral
ANVISA	<i>Agência Nacional de Vigilância Sanitária</i>
BRICS	Brazil, Russia, India, China, South Africa
BRL	Brazilian Real
CEME	<i>Central de Medicamentos</i>
CEO	Chief Executive Officer
CL	Compulsory Licence
CLS	Critical Legal Studies
CLT	Critical International Legal Theory
CSO	Civil society organisation
DCs	Developing Countries
DFID	Department for International Development
DNP+	Delhi Network of Positive People
DPCO	Drugs Control Prices Order
DSP	Dispute settlement procedures
EDL	Essential Drug List
EPW	Economic and Political Weekly
EU	European Union
FDI	Foreign Direct Investment
FMOH	Federal Ministry of Health (Nigeria)
FYP	Five-Year Plan

GAPA	<i>Grupo de Apoio à Prevenção à AIDS</i>
GATT	General Agreement on Tariffs and Trade
GFATM	The Global Fund to Fight AIDS, Tuberculosis and Malaria
GIPI	Inter-Ministerial Group on Intellectual Property
GTPI/REBRIP	Working Group of Intellectual Property of the Brazilian Network for the Integration of Peoples
HAART	Highly active antiretroviral therapy
HIV	Human Immune Deficiency virus
IDA	International Dispensary Association
IDMA	Indian Drug Manufacturers' Association
IEG	International economic governance
IMF	International Monetary Fund
INPI	<i>Instituto Nacional da Propriedade Industrial</i>
INR	Indian Rupees
IP	Intellectual Property
IPA	Indian Patent Act 1972
IPAA	Indian Patent (Amendment) Act
IPAB	Intellectual Property Appellate Board
IPC	Intellectual Property Committee
IPLB	Industrial Property Law of Brazil
IPR	Intellectual Property Right
ISI	Import substitution industrialisation
LDCs	Least Developed Countries
LGBT	Lesbian gay bisexual transgender
M&A	Mergers and acquisitions
MFN	Most Favoured Nation
MNC	Multi-National Companies
MSF	Médecins Sans Frontières
NACA	National Agency for the Control of AIDS
NAFDAC	National Agency for Food, Drugs, Administration and Control
NAIL	New Approaches to International Law
NAP	<i>Programa Nacional de Doenças Sexualmente Transmissíveis e AIDS</i>
NCE	New chemical entity
NDP	National Drug Policy

NDLEA	National Drug Law Enforcement Agency
NGN	Nigerian Naira
NGO	Non-Governmental Organisation
NHREC	National Health Research Ethic Committee Nigeria
NIEO	New International Economic Order
NME	New medical entity
NOTAP	National Office for Technology Acquisition and Promotion
NPPA	National Pharmaceutical Pricing Authority
NWGPL	National Working Group on Patent Laws
OECD	Organisation for Economic Co-operation and Development
OPEC	Organization of Petroleum Exporting Countries
OPPI	Organisation of Pharmaceutical Producers in India
PDA	Patent and Design Act
PhRMA	Pharmaceutical Research and Manufacturers of America
PLWHA	People living with HIV/AIDS
PMG-MAN	Pharmaceutical Manufacturers Group of Manufacturers Association of Nigeria
PPP	Public-Private Partnership
PSDB	<i>Partido da Social Democracia Brasileira</i>
RENAME	<i>Relação Nacional de Medicamentos Essenciais</i>
R&D	Research and development
SAP	Structural Adjustment Program
SPLT	Substantive Patent Law Treaty
SUS	<i>Sistema Unico de Saude</i>
TB	Tuberculosis
TRIPS	Trade-Related Aspects of Intellectual Property Rights
TWAIL	Third World Approaches to International Law
TWN	Third World Network
UK	United Kingdom
UN	United Nations
UNAIDS	Joint United Nations Program on HIV/AIDS
UNCTAD	United Nations Conference on Trade and Development*
UNDP	United Nations Development Program
UNGA	United Nations General Assembly

UNICEF	United Nations Children’s Fund
US	United States of America
USAID	US Agency for International Development
USD	US Dollar
USTR	US Trade Representative
VL	Voluntary Licence
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WTO	World Trade Organization

1.1 Background

In the last 20 years, intellectual property (IP) has become one of the key areas of conflict in the global political economy, thanks to the introduction of the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement),¹ which was concluded as part of the Uruguay Round of multilateral trade negotiations and came into force in 1995. The TRIPS Agreement ‘provides minimum standard for the protection of intellectual property rights (IPRs).’² As part of international law, the effect of the TRIPS Agreement on the development and lives of people in the Third World has been contentious. This is because the protection of IPRs as required by the TRIPS Agreement does not take into account the differences in the development levels and socioeconomic needs of developed and developing countries, and is usually implemented with no form of social security in place.

This empirical thesis seeks to explore Third World attempts to use the patent regime as set out in the TRIPS Agreement to effect certain development and public health goals, and to discover the ways these countries are challenging global norms in pharmaceutical patent protection. To do this, the thesis takes the three different examples of Brazil, India, and Nigeria and tells the story of patent law making within each of them. Using the Third World Approach to International Law (TWAIL) as a macro-theoretical guide, the thesis maps out the broad interpretations and contestations of international patent law within the Third World. Such contestations, however, and their significance in law making in the Third World are regarded as asymmetrical. This is because the presence of influential actors capable of mobilising knowledge, providing expertise, and participating in various forms of patent governance are uneven in these countries. In this regard, the thesis explicates the role and participation of these actors using nodal governance theory.

In unpacking the patent law making in the aforementioned countries, the thesis discovers the following. First, the innovative interpretation of global patent rules in

¹ World Trade Organization, ‘Agreement on Trade-Related Aspects of Intellectual Property Rights’ (World Trade Organization 1995) <https://www.wto.org/english/docs_e/legal_e/27-trips.pdf> accessed 26 March 2015.

² Jayashree Watal, ‘Developing Countries and the Protection of Intellectual Property Rights: Current Issues in the WTO’, *WTO Law and Developing Countries* (1st edn, Cambridge University Press 2007) 129.

the local forums of the countries under study was inspired by and made possible as a result of disappointment and disillusionment with the assertions of benefit and progress attached to instituting a *particular* form of patent regime. Second, the possibility of using patents to effect the twin goals of development and public health goals is likely when patent law is implemented in combination with other complementary policies such as public good protection strategies, enhancing local capacity in research and development (R&D), and healthy market competition. Third, the presence of local non-state actors is imperative in the cognitive shaping and innovative use of patent law as a tool for development and achieving public health objectives.

The discoveries and overall findings provided in this research form an original contribution to the discourse on patent law in Nigeria, as there is very few research explicating the effect of the absence of a local pharmaceutical manufacturing sector and civil society organisations in patent law making and structural reform. Furthermore, in exclusively focusing on law making in the Third World, this thesis unmask a competing narrative – a counter-narrative of sorts – to the current understanding of the international IP regime. Specifically – and this forms another contribution of this thesis – in successfully articulating and impelling a local counter-hegemonic discourse of global patent rules, the thesis shows that patent law making in Brazil and India is expanding the aperture on norms governing the pharmaceutical patent regime and access to essential medicines discourse. This in turn provides ways for governments of other Third World countries to exploit the residual flexibilities within the TRIPS Agreement.

The analyses in this thesis will appeal to law and policymakers interested in the intersection of contemporary IP global governance, development, socio-legal approaches, and critical international law. Lessons from Brazil and India as well as the suggestions in the conclusion could also assist Nigerian policymakers in shaping and instituting a patent regime that achieves the balance between IP protection, public health, and development. The rest of this introductory chapter orients the thesis as a whole by providing the context of this doctoral study, statement of the problem, aim and scope, methods and methodology and, finally, an overview of the thesis chapters.

1.2 Context of Study

A patent is a temporary exclusive right granted to the inventor of a product or process which is 'new' (or 'novel'), involves an 'inventive step' (or is 'non-obvious'), and is capable of industrial application (or 'useful').³ In its contemporary context, a patent is defined as 'a document, issued, upon application, by a government office which describes an invention and creates a legal situation in which the patented invention can normally only be exploited (manufactured, used, sold, imported) with the authorisation of the owner of the patent.'⁴ Patents are designed to reward inventors, encourage technical progress, and foster dissemination of information.⁵ According to May and Sell, a patent is an institutionalised bargain between the state and the inventor, where the 'State agrees to establish the legal mechanisms that ensure that the inventor can extract payment for their idea when others use it while the inventor allows the State to lodge the idea in its public records where it can be accessed by interested parties.'⁶ The development of a patent system can be grouped into three stages – the national phase, multilateral phase, and the global phase. These phases will be discussed briefly.

The National Phase

In their initial stages in 15th century Europe where they originated, patent customs were privileges rather than property rights as such, with links to strong development objectives such as assisting in the development of new industries by importation or through native invention.⁷ As such, it can be argued that patents were developed out of the realisation that there was a societal need to both recognise and protect a property right in invention to encourage local manufacturing and attain economic development objectives. According to legal historian Edward Walterscheid, the patent customs that originated from Venice (1421)⁸ and spread to England (1449), Germany

³ Frederick M Abbott, 'Intellectual Property, International Protection' (Florida State University - College of Law 2009) 2 ('Intellectual Property, International Protection').

⁴ *WIPO Intellectual Property Handbook* (2nd edn, WIPO 2004).

⁵ Carlos M Correa, *Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing* (1st edn, South Centre 2011) 1 <<http://apps.who.int/medicinedocs/documents/s21395en/s21395en.pdf>> accessed 20 May 2015; Abbott, 'Intellectual Property, International Protection' (n 3) 2.

⁶ Christopher May and Susan K Sell, *Intellectual Property Rights* (Lynne Rienner Publishers 2006) 8.

⁷ Edward C Walterscheid, 'The Early Evolution of the United States Patent Law: Antecedents (Part 2)' (1994) 76 *Journal of the Patent and Trademark Office Society* 850 ('The Early Evolution of the US Patent Law: Antecedents (Part 2)').

⁸ Walterscheid suggests that the earliest patentee of record is Filippo Brunelleschi, who received a monopoly patent from the city-state of Florence in 1421, after which 11 patents were granted 75 years prior to the official

(1484), France (1551), and Austria (1794) arose out of the desire of European rulers to encourage the development of new industries within their realms.⁹ To achieve these economic plans, patent customs then took two forms: importation of knowledge into the realm, which involved local artisans travelling abroad to learn a new trade (apprenticeship), or through invention within the realm.¹⁰ However, due to the reluctance of artisans to teach foreigners the secrets of the trade, the latter took precedence as the preferred method of encouraging local manufacturing over time. Thus, it can be argued that patents were privileges introduced to promote economic development rather than private property rights that prioritised trade and seen as a trade tool, as they are today.¹¹

Of course, many incentives were put in place to encourage local manufacturing such as financial grants, favourable tax treatment, sovereign protection, and bans on the emigration of skilled labour.¹² Ha-Joon Chang notes that many governments set up institutions of teaching (e.g. technical schools) and research (e.g. various non-teaching academies). They also established museums, organised international expositions ('expos'), bestowed new machinery to private firms, and set up 'model factories' using advanced technologies all in an effort to raise 'awareness' in advanced technology in a number of ways.¹³ In England, however, the grant of monopolies by the Crown became a popular practice. Known as *literae parentes*, the monopoly rights bestowed privileges upon individuals in furtherance of royal policies.¹⁴ The English Crown, recognising the costs and risks associated with the introduction of a new trade or industry, introduced patent monopoly for a limited period as a form of incentive to attract trade and manufacturing. Premised on the potential for substantial economic return to those taking such risks and incurring such expenses, patent monopoly provided a form of protection by eliminating competition

patent law enactment in 1474, and approximately 100 patents have been found in the Venetian archives, which were issued in the following 75 years.

⁹ *ibid.* Many of the other European countries established their patent laws in the other half of the 19th century — Russia (1812), Prussia (1815), Belgium and the Netherlands (1817), Spain (1820), Bavaria (1825), Sardinia (1826), the Vatican State (1833), and Sweden (1834). The United States (US) introduced patents in 1793.

¹⁰ Walterscheid, 'The Early Evolution of the US Patent Law: Antecedents (Part 2)' (n 7) 850; Ha-Joon Chang, 'Intellectual Property Rights and Economic Development: Historical Lessons and Emerging Issues' (2001) 2 *Journal of Human Development* 288.

¹¹ Edward C Walterscheid, 'The Early Evolution of the United States Patent Law: Antecedents (Part 1)' (1994) 76 *Journal of the Patent and Trademark Office Society* 669 ('The Early Evolution of the US Patent Law: Antecedents (Part 1)'); Srividhya Ragavan, *Patent and Trade Disparities in Developing Countries* (Oxford University Press 2012) 16.

¹² Walterscheid, 'The Early Evolution of the US Patent Law: Antecedents (Part 1)' (n 11) 669; Chang (n 10) 289.

¹³ Chang (n 10) 289.

¹⁴ Ragavan (n 11) 3.

and plagiarism. In response to these measures preventing technology outflows from advanced countries, the less advanced countries deployed all sorts of ‘illegitimate’ means to gain access to advanced technologies. Chang notes that many entrepreneurs and technicians in these countries were often involved in acts of ‘industrial espionage’ – the practice of spying to obtain information on new industrial technology – and sometimes with explicit sanction from the state.¹⁵

In an analysis of the evolution of the patent system, Walterscheid identified several parallelisms between the Venetian and English patent systems. For example, both the Venetians and the British used the custom of granting patent monopoly to introduce new art and lure artisans into their realms.¹⁶ In fact, the initial Venetian patent custom system was for the grant of ‘exclusive right to practice a particular art such as glass making, in return for its introduction into the Venetian city-state.’¹⁷ In England, on the other hand, the patent regime was created for the specific purpose of stimulating ‘the domestic production of both raw materials and a wide variety of manufactured goods.’¹⁸ Walterscheid contends that for the English Crown, the goal of the monopoly was to ‘attain economic self-sufficiency, thereby gaining in power and strength not only within its borders, but also relative to other states.’¹⁹ Under the reign of Queen Elizabeth I, the English patent custom took root and flourished. From 1561 to 1600, Queen Elizabeth I granted at least 51 monopoly patents for industries and inventions.²⁰ The acceptance of patents was crystallised in 1623, when Britain’s Statute of Monopolies transferred the right of granting monopolies from King James I to Parliament.²¹ This enactment was seen as an indication of the growing importance of trade within the country’s economy and the willingness to foster innovation, which eventually allowed a step forward into industrial production.²²

The spurt in the grant of monopoly in England was based on the belief that the Crown not only had the right but also the obligation to regulate commerce and industry, and to do so in a manner that encourages the creation of new native industries and trades.

¹⁵ Chang (n 10) 290.

¹⁶ Walterscheid ‘The Early Evolution of the US Patent Law: Antecedents (Part 1)’ (n 11) 701-02; see also Walterscheid, ‘The Early Evolution of the US Patent Law: Antecedents (Part 2)’ (n 7) 864.

¹⁷ Walterscheid, ‘The Early Evolution of the US Patent Law: Antecedents (Part 1)’ (n 11) 707.

¹⁸ Walterscheid, ‘The Early Evolution of the US Patent Law: Antecedents (Part 2)’ (n 7) 855.

¹⁹ *ibid* 856.

²⁰ *ibid* 853.

²¹ Petra Moser, ‘Patents and Innovation: Evidence from Economic History’ (2013) 27 *Journal of Economic Perspectives* 25.

²² Walterscheid, ‘The Early Evolution of the US Patent Law: Antecedents (Part 2)’ (n 7) 855.

As a result, English patents were primarily granted for the importation of new industry and the Crown granted many foreigners patent monopoly. Thus, for the English, the patent was seen as a tool to encourage manufacturing growth and to lure skilled workers to live in England. In exchange for the grant, the grantee agreed to not only ‘introduce the new art, trade or industry into England but also to practice or “work” it within the country.’²³ Thus, for both the Venetian and English systems, patents were introduced for national objective purposes, i.e. improvement of local industrialisation as part of the effort to further national economic development goals.

In addition to economic development policies, traditional patent policies were instituted to address welfare considerations. According to Srividhya Ragavan, the historic conception of patent rights developed amid strong notions of welfare or public good. Citing Thomas Jefferson’s letter that ideas should flow freely from ‘one to another over the globe for the moral and mutual instruction of man and improvement of his condition’, Ragavan contends that the welfare paradigm was one of the cornerstones of the American patent system, which was introduced in the United States (US) in 1790 based on a keen sense of national objectives and economic development. Like the British patent custom, the early American patent regime allowed the grant of ‘limited monopoly of 14 years to any applicant who invented or discovered any useful art’²⁴ as long as the invention is sufficiently useful and important. Further, the invention should be:

So particular and said invention so exact, as to not only distinguish the invention or discovery from other things before or known and used, but to enable a workman or other person skilled in the art to manufacture... to make, construct, or use the same, to the end that the public may have full benefit thereof, after the expiration.²⁵

In fact, the last line ‘...that the public may have full benefit thereof’ underscores the welfare objectives of patents in that monopolies are granted in exchange for ‘an enabled disclosure that could potentially benefit the progeny.’²⁶ For the American founding fathers, especially Thomas Jefferson, patents have as an end goal the service of society and as a result, they made policies that allowed everyone, including emigrants, to benefit from monopoly policies. However, it could be argued that

²³ Walterscheid, ‘The Early Evolution of the US Patent Law: Antecedents (Part 2)’ (n 7) 857.

²⁴ Ragavan (n 11) 11.

²⁵ *ibid.*

²⁶ *ibid.*

Jefferson's claim is quite rhetorical and that this welfarist concern is actually more parochial and nationalist and not for the loftier global circulation of ideas, in that the patent system reflected significant differential treatment between nationals and non-nationals as a way to privilege the former. This difference is even more apparent in terms of US copyright statutes. For that matter, even European nations also adopted various provisions for differential treatment between nationals and non-nationals. These laws, according to Chang, accorded very inadequate protection of the IPRs of foreign citizens.²⁷ For example, patenting of *imported inventions* by nationals was often explicitly allowed in Britain, Austria, and France, while patents were granted without any proof of originality in the US.²⁸

Other scholars such as Srividhya Ragavan contend that socio-economic realities and time shaped the evolution of early patent customs. The patent system, like all legal regimes, is susceptible to amendment based on national needs and requirements. History has shown that during adverse economic conditions, private rights tend to give way to government interventions to improve public rights and access to protected materials. So while early patents customs were engineered to be of benefit to the state, these monopolies were rescinded once perceived to not be of value to the realm.²⁹ Put differently, patents proliferated 'only when the economic climate remained conducive for research in order to appropriately channelize the early development and address public welfare concerns.'³⁰ Conversely, patents were abolished where economic conditions became unfavourable, especially in times of economic hardship. In those hard times, monopoly grant becomes limited and restrictions are placed on already granted monopolies. For instance, during the industrial depression in England and during the Great Depression in the US, patent grants were suspended.³¹ The various European capitals also abolished patents during periods of socio-economic upheavals. The Netherlands abolished its patent system in 1869 after the rise of the free trade movement, which viewed patents as a form of protectionism and rejected them as a restriction on trade.³² Germany followed in 1817 while Switzerland had no formal patent system until 1907.³³ This is due to, according to Srividhya Ragavan, the

²⁷ Chang (n 10) 290.

²⁸ Ragavan (n 11) 291.

²⁹ *ibid.*

³⁰ *Ibid* 33.

³¹ *ibid* 19.

³² Cicero Gontijo, 'Changing the Patent System from the Paris Convention to the TRIPS Agreement: The Position of Brazil' (2005) 26 Global Issues Paper 5; Chang (n 10) 291.

³³ Moser (n 21) 26.

‘disconnect between such times and the patent system and its objectives of social benefits as patented products become less accessible to even fewer people during the abnormal economic times.’³⁴

The Multilateral Phase – The Paris Convention

The push to harmonise IP law intensified as many countries started introducing local IPR laws and international commerce increased.³⁵ The argument for this push was couched on the need to guarantee uniform protection and recognition across territorial borders. Thus, in 1873, the Austrian government sent out invitations for an international conference on patents during the Universal Exposition held in Vienna that year.³⁶ This led to the adoption of the Paris Convention for the Protection of Industrial Property in 1883.³⁷ The Convention was signed by 11 countries – Belgium, Brazil, Ecuador, El Salvador, France, Great Britain, Guatemala, Italy, The Netherlands, Portugal, Serbia, Spain, Switzerland, Tunisia, and the US. Importantly, through colonisation, the patent rules of the Convention were transplanted directly from the metropolitan states to the colonial territories, even though these territories had not signed the Convention.³⁸ Such extension to the colonies, according to Ruth Okediji, was for purposes generally associated with the overarching colonial strategies of assimilation, incorporation, and control.³⁹

³⁴ *ibid* 19.

³⁵ Ulf Anderfelt, *International Patent-Legislation and Developing Countries* (Martinus Nijhoff 1971) 65-75.

³⁶ Surendra J Patel, ‘Intellectual Property Rights in the Uruguay Round: A Disaster for the South?’ (1989) 24 *Economic and Political Weekly* 981. According to Patel, the invitation for an international conference stemmed from a suggestion from the US and though the conference occurred in 1883, there were previous preparatory discussions in 1878 and 1880.

³⁷ World Intellectual Property Organization, ‘Paris Convention for the Protection of Industrial Property’ (1883) (Paris Convention). See also Gustavo Bravo, ‘From Paris Convention to TRIPS: A Brief History’ (2000) 445 *Journal Contemporary Legal Issues*; Pedro Roffe and Gina Vea, ‘The WIPO Development Agenda in an Historical and Political Context’, *The Development Agenda: Global Intellectual Property and Developing Countries* (1st edn, Oxford University Press 2008). The Paris Convention and the 1886 Berne Convention on copyright saw the creation of international bureaus (secretariats), which were merged in 1893 to form the United International Bureaux for the Protection of Intellectual Property (BIRPI). BIRPI was superseded by a new organisation, the World Intellectual Property Organization (WIPO), which was established by treaty in 1967. WIPO became a specialised agency of the United Nations (UN) in 1974. See Peter Drahos, *The Universality of Intellectual Property Rights: Origins and Developments* (1st edn, WIPO 1999) <http://www.wipo.int/edocs/mdocs/tk/en/wipo_unhchr_ip_pnl_98/wipo_unhchr_ip_pnl_98_1.pdf> accessed 22 March 2014 (*The Universality of Intellectual Property Rights*).

³⁸ Anderfelt (n 35) 119; see also GHC Bodenhausen, *Guide to the Application of the Paris Convention for the Protection of Industrial Property, as Revised at Stockholm in 1967* ((Colombettes 32) United International Bureaux for the Protection of Intellectual Property 1968).

³⁹ Ruth L Okediji, ‘The International Relations of Intellectual Property: Narratives of Developing Country Participation in the Global Intellectual Property System’ (2003) 7 *Singapore Journal of International and Comparative Law* 225 (‘The International Relations of Intellectual Property’).

The Paris Convention established ground rules with respect to patents, trademarks, and unfair competition.⁴⁰ Specifically, it established principles of national treatment, independence of patents, and patent priority rules among the signatories. The principle of national treatment allows for fairness and non-discrimination against foreign patent holders within a national territory,⁴¹ while independence of patents means that acts ‘taken by authorities with respect to a patent in one country will not affect the status of equivalent patents in other Paris Convention countries.’⁴² For example, if a judgement in one country considers an application or a patent to be invalid, that judgement does not have any impact on the treatment of the same application or patent in other member states. This rule, according to Frederick Abbott, reflects the fact that governments are distrustful of the possible motives of other governments in acting against their inventors.⁴³ Finally, the principle of patent priority means that an applicant who submits an application in one member state has a priority period (currently 12 months) to file an application in other member states, and no other application will be allowed within that 12-month period.⁴⁴

The Paris Convention is seen by many as the first international IP agreement that established a comprehensive system for patent protection across territorial borders.⁴⁵ This success stems in part from the number of countries that signed up to it, the length of its existence without substantial change, and its specificity. According to Cicero Gontijo, the Paris Convention did not try to harmonise national laws or establish the reciprocity principle for national treatment, thereby allowing countries to implement patent law to suit their specific interest and needs.⁴⁶ In a similar vein, Abbott notes that the fact the Paris Convention is non-specific helped in its longevity.⁴⁷ For example, it does not define a patent or the criteria used for granting a patent. Neither does it prescribe subject matter coverage nor set minimum or maximum terms of

⁴⁰ Abbott, ‘Intellectual Property, International Protection’ (n 3) 5; Bravo (n 37) 445; Fredrick M Abbott, Carlos M Correa, and Peter Drahos, ‘Emerging Markets and the World Patent Order – The Forces of Change’, *Emerging Markets and the World Patent Order* (1st edn, Edward Elgar 2013) 6.

⁴¹ Abbott, ‘Intellectual Property, International Protection’ (n 3) 5.

⁴² *ibid.*

⁴³ *ibid.*

⁴⁴ *ibid.*; Gontijo (n 32) 6.

⁴⁵ Abbott, ‘Intellectual Property, International Protection’ (n 3) 5; Gontijo (n 32) 6; Bravo (n 37) 445; Margrit Seckelmann, ‘From the Paris Convention (1883) to the TRIPS Agreement (1994): The History of the International Patent Agreements as a History of Propertisation?’ (2013) 14 *Journal der Juristischen Zeitgeschichte*; Bodenhausen (n 38).

⁴⁶ Gontijo (n 32) 7.

⁴⁷ Abbott, ‘Intellectual Property, International Protection’ (n 3) 5.

protection.⁴⁸ This allows for individuality of patent rules where countries adopt different standards of industrial property protection.⁴⁹

However, certain scholars view the Paris Convention otherwise. Surendra Patel, for example, contends that the Paris Convention serves the monopolistic interest of patent holders usually located in the West.⁵⁰ These misgivings were also voiced by Brazil (see Chapter 3) over a century later. In spite of its numerous revisions (1900, 1911, 1925, 1934, 1958, and 1967), the Paris Convention, according to Patel, remained ‘a rich man’s club’ that further strengthened the monopolistic rights of the patent holder.⁵¹ In a similar vein, Ruth Okediji notes that the patent law under the Paris Convention was merely for securing national economic interests against other European countries in colonial territories.⁵² Other scholars such as Dhavan et al. contend that the Paris Convention was engineered by the industrialised countries in order to secure import monopolies for the producer nations of the West so as to satisfy the needs of expanding capitalism.⁵³ This is because article 5^{quater} under the Paris Convention prohibits countries from revoking patents on the ground that the patented articles are being imported rather than locally manufactured.⁵⁴ As a result, a foreigner could obtain a patent monopoly with absolutely no associated obligation to produce the patented article or ensure its supply in the patent-granting country. This practice, Dhavan et al. argue, has the effect of retarding the industrial development of the importing country, since foreign monopoly grant blocks domestic producers.⁵⁵

In fact, this issue of patent monopoly was the main point of contention between developed and developing countries. This simmering discontent also explains why developing countries have sought the adjustment of the global patent regime at

⁴⁸ *ibid.*

⁴⁹ See Peter Drahos, ‘Developing Countries and International Intellectual Property Standard-Setting’ (2002) 5 *The Journal of World Intellectual Property* 768 (‘Developing Countries and International Intellectual Property Standard-Setting’).

⁵⁰ Patel (n 36) 981.

⁵¹ *ibid.*

⁵² Okediji, ‘The International Relations of Intellectual Property’ (n 39) 224-25.

⁵³ Rajeev Dhavan, Lindsay Harris, and Gopal Jain, ‘Conquest by Patent: The Paris Convention Revisited’ (1990) 32 *Journal of Indian Law Institute* 131.

⁵⁴ Article 5^{quater} states: ‘When a product is imported into a country of the Union where there exists a patent protecting a process of manufacture of the said product, the patentee shall have all the rights, with regard to the imported product, that are accorded to him by the legislation of the country of importation, on the basis of the process patent, with respect to products manufactured in that country.’

⁵⁵ Dhavan, Harris, and Jain (n 53) 132. See also Edith Penrose, ‘International Patenting and the Less-Developed Countries’ (1973) 83 *The Economic Journal*; Constantine Vaitsos, ‘Patents Revisited: Their Function in Developing Countries’ (1972) 9 *The Journal of Development Studies*; Owen T Adikibi, ‘The Multinational Corporation and Monopoly of Patents in Nigeria’ (1988) 16 *World Development*; AK Menescal, ‘Changing WIPO’s Ways? The 2004 Development Agenda in Historical Perspective’ (2005) *Journal of World Intellectual Property*; Peter K Yu, ‘A Tale of Two Development Agendas’ (2009) 35 *Ohio Northern University Law Review*.

various international and local forums. For example, Brazil pushed for a revision of the Paris Convention to reduce incidents of patent monopoly abuse of pharmaceutical patents by foreign multinational companies operating in the country at that time.⁵⁶ The push for patent reform in India was also borne out of the fact that many foreign pharmaceutical companies operating in the country at that time did not locally manufacture their patented invention or work their patent locally, but relied instead on the importation of the patented article whilst blocking indigenous companies that would normally manufacture locally.⁵⁷ Analyses of the patent regime in Nigeria also revealed that majority of the patents in the country were owned by foreigners who did not locally work the patented article.⁵⁸ This shows that developing countries have always been cognisant and wary of the asymmetrical effect of global patent rules and their tendency to favour the more economically powerful nations. It is this reservation about the impact on economic development that has animated (and continues to animate) contemporary discussion about patents in particular and IP in general.

Despite the fact that the Paris Convention was tilted in favour of developed countries, it was still regarded by certain countries, such as the US, as insufficient. Specifically, corporate interests in the US regarded the Paris Convention as ‘toothless’ due to the lack of enforcement mechanisms that led to, among other things, the frequent ‘disregard for the protection of non-nationals intellectual property outside most of developed countries and sometimes even between them.’⁵⁹ Moreover, the fact that the Paris Convention allowed countries to implement patent rules specific to them and created a patchwork system of disparate norms, rules, and levels of protection was also seen as problematic.⁶⁰ As a result, those who considered the Paris Convention unsuitable expended considerable resources in establishing patent rules at another point in time.

The 1960s to the 1970s is known as the decolonisation period for many former colonies located in Asia, Africa, and the Caribbean. As these countries gained their independence, they ‘became more assertive of their rights and aware of their international obligations.’⁶¹ Peter Yu writes that these countries were torn between

⁵⁶ See Ch 3, part 1.

⁵⁷ See Ch 4, part 1.

⁵⁸ See Ch 5, part 1.

⁵⁹ May and Sell (n 6) 4; Drahos, ‘Developing Countries and International Intellectual Property Standard-Setting’ (n 49).

⁶⁰ Okediji, ‘The International Relations of Intellectual Property’ (n 39) 316.

⁶¹ Yu (n 55) 470.

affirming and denouncing international obligations into which their former colonial rulers had entered on their behalf.⁶² Significantly, those willing to affirm their international obligation consider the extant standards to be too high and did not take into account specific economic conditions and technological gaps. For example, these countries found that the issue of patent monopoly under the Paris Convention hampered efforts to catch up with other developed countries.⁶³ As a result, many of these countries set about joining different multilateral organisations to suit their interests and where they can adjust international standards to favour them. According to Drahos, this process of forum shifting – of joining various multilateral agreements and international organisations – was adopted by many developing countries after mostly unsuccessful attempts in changing the rules against abuses of patent monopolies with the Paris Convention.⁶⁴

Many newly independent countries shifted the discussion of IP-related issues to other international forums like the World Intellectual Property Organization (WIPO), the United Nations (UN), and the UN Conference on Trade and Development (UNCTAD). Developing countries found these forums neutral due to the large presence of new decolonised countries and also because of the bloc voting and one-country-one-vote employed for consensus rule-making.⁶⁵ By shifting to these forums, these countries actively sought to recalibrate, revise, or reinterpret the Paris Convention to satisfy their needs.⁶⁶ According to Andrea Menescal, an intense and critical debate concerning abuses of patent monopolies by the Paris Union system and the prevalence of right-holders' interests in the Paris Convention was tabled at the UN.⁶⁷ As a result, Brazil (co-sponsored by Bolivia) submitted to the UN General Assembly (UNGA) in October 1961 a resolution entitled *The Role of Patents in the Transfer of Technology to Under-Developed Countries*.⁶⁸ The resolution highlighted, among other things, abuses and misuses of patent monopolies, the importance of co-operation in the field of applied science and technology for promoting the exchange of knowledge via transfer of technology from developed to developing countries, and

⁶² *ibid.*

⁶³ Roffe and Veal (n 37) 92.

⁶⁴ Drahos, 'Developing Countries and International Intellectual Property Standard-Setting' (n 49); see also Menescal (n 55); Laurence R Helfer, 'Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking' (2004) 9 *Yale Journal of International Law*.

⁶⁵ Helfer (n 64) 565-67.

⁶⁶ *ibid.* 564.

⁶⁷ Menescal (n 55) 765.

⁶⁸ *ibid.*; see also Roffe and Veal (n 37) 95.

the need for a ‘Development Agenda’ in the international patent system.⁶⁹ Though the final resolution presented to and adopted by the UNGA in December 1961 differed ‘considerably from the original Draft submitted’, as the initial resolution was vehemently opposed by developed countries,⁷⁰ it nonetheless showed emergent reformist narratives adopted by developing countries to change the multilateral architecture and to remedy colonial inequities.⁷¹

Certain scholars have linked the countermovement towards an equitable global IP regime and the demands made by Third World countries in the form of a New International Economic Order (NIEO) that also emerged around that time.⁷² The NIEO was spearheaded through UNCTAD and highlighted efforts by developing countries to assert greater control over technology transfer, multinational enterprises, and other economic activities related to economic development goals.⁷³ Menescal, for example, writes that the policy demands made by less developed countries, especially with regard to transfer of technology, is reminiscent of the draft resolution Brazil introduced before the UNGA.⁷⁴ Likewise, Susan Sell notes that the Development Agenda raised by developing countries animated the NIEO approach to patents.⁷⁵ Similarly, Okediji observes that the political similarities between the NIEO and the Development Agenda are powerful reflections of a deeply pathological process in the construction of IP relations between developed and developing countries.⁷⁶ Yet, decades later, the issue of an inequitable international patent regime still contours discussions on patents and their impact on development. As subsequent chapters will show, this countermovement and the reformist ideas have continued even within the

⁶⁹ *ibid* 767.

⁷⁰ Menescal (n 55) 765; Dhavan, Harris, and Jain (n 53) 162.

⁷¹ Roffe and Veal (n 37) 92.

⁷² Ruth L Okediji, ‘History Lessons for the WIPO Development Agenda’, *The Development Agenda: Global Intellectual Property and Developing Countries* (1st edn, Oxford University Press 2008) (‘History Lessons for the WIPO Development Agenda’); Yu (n 55); Susan K Sell, ‘Intellectual Property Protection and Antitrust in the Developing World: Crisis, Coercion, and Choice’ (1995) 49 *International Organization* (‘Intellectual Property Protection and Antitrust in the Developing World’); Susan K Sell, ‘The Quest for Global Governance in Intellectual Property and Public Health: Structural, Discursive, and Institutional Dimensions’ (2004) 77 *Temple Law Review* (‘The Quest For Global Governance’).

⁷³ United Nations General Assembly, ‘Declaration on the Establishment of a New International Economic Order’ (3201 (S-VI)) (United Nations 1974) <<http://www.un-documents.net/s6r3201.htm>> accessed 19 April 2015; D Otto, ‘Subalternity and International Law: The Problems of Global Community and the Incommensurability of Difference’ (1996) 5 *Social and Legal Studies*; Nils Gilman, ‘The New International Economic Order: A Reintroduction’ (2015) 6 *Humanity*; Okediji, ‘History Lessons for the WIPO Development Agenda’ (n 72).

⁷⁴ Menescal (n 55) 773.

⁷⁵ Sell, ‘The Quest for Global Governance’ (n 72) 372.

⁷⁶ Okediji, ‘History Lessons for the WIPO Development Agenda’ (n 72) 152.

new IP regime – the TRIPS Agreement – that replaced the Paris Convention.⁷⁷

The Global Phase – TRIPS Agreement

As developing countries shifted to other forums outside the Paris Convention in order to recalibrate the agreement, the US employed the same method to increase global IP rules and norms. For the US, bilateral agreements seemed to be the preferred approach in achieving high IP norms and standards outside of the WIPO and the Paris Convention. Furthermore, the US moved the issue of IP negotiations to the General Agreement on Tariffs and Trade (GATT)⁷⁸ – a forum in which it was the single most influential player – and it was this move that annihilated the dominance and reformist aspirations of developing countries.

Unlike the WIPO, the GATT was a negotiating forum where trade deals were not openly and freely negotiated.⁷⁹ This allowed some countries to drive a hard bargain in areas where they stood to benefit. Developed countries with their vast expertise had an unfair advantage over many developing countries that were dealing with substantial IP law making for the first time. Drahos points out that most developing countries did not have prior knowledge of IP or proposals to the TRIPS Agreement and were ill prepared for the negotiations.⁸⁰ He argued that many developing countries signed the TRIPS Agreement without prior knowledge of IP, thus reflecting ‘a high degree of ignorance amongst technology-importing countries as to the costs of increasing intellectual property protection.’⁸¹ This view is supported by Chakravarthi Raghavan, who writes that the reason the US chose the GATT as the location for introducing new issue areas to international trade is because Third World countries are at their weakest inside the GATT in terms of collective organisation and

⁷⁷ Even though it is beyond the ambit of this thesis, it is worth mentioning that other international agreements dealing with IP were also signed during the 20th century. These include the Madrid Agreement on trademarks and indication of source (1891), the Hague Agreement on designs (1925), the Rome Convention on performance (1961), the International Convention for the Protection of New Varieties of Plants, Acts of 1961 and 1991, the Patent Co-operation Treaty (1970), and the Treaty on Intellectual Property in Respect of Integrated Circuits (1989).

⁷⁸ Sell, ‘The Quest for Global Governance’ (n 72) 385.

⁷⁹ Drahos, ‘Developing Countries and International Intellectual Property Standard-Setting’ (n 49) 769.

⁸⁰ Peter Drahos, ‘Trade-Offs and Trade Linkages: TRIPS in a Negotiating Context’ (*Quaker United Nations*, 2000) <<https://www.anu.edu.au/fellows/pdrahos/reports/pdfs/2001tradeoffstradelinkages.pdf>> accessed 1 June 2015 (‘Trade-Offs and Trade Linkages’).

⁸¹ *ibid.*

bargaining.⁸² Sell, on the other hand, writes that the US ‘favoured GATT because it would permit them to link intellectual property protection to trade.’⁸³ The US negotiators anticipated better results owing to the large and attractive US market that could be used as negotiating leverage (see part II of Chapter 2 regarding the politics of the TRIPS Agreement negotiations).⁸⁴ At GATT, the US was able to push forward a higher IP standard than those contained in the Paris Convention.

The TRIPS Agreement is among the foremost international law frameworks that deal specifically with the aegis and utilisation of IPRs. It provides for a high global minimum standard for the protection of IPRs. According to May and Sell, even though the TRIPS Agreement does not determine national legislation, World Trade Organization (WTO) members should ensure that their national IP legislation adheres to the minimum level of protection for IPRs laid out in the TRIPS Agreement, thanks to the surveillance of adherence to various mechanisms and provisions such as the Trade Policy Review process.⁸⁵ With the aim of reducing distortions and impediments to international trade, the TRIPS Agreement was anticipated to not only promote effective and adequate protection of IPRs, but to also engender positive development goals through the transfer of technology from developed to developing countries, spurring local industrialisation in the latter.⁸⁶ Contracting developing country members also hoped that the TRIPS Agreement would increase much needed foreign direct investment (FDI) due to harmonised IP laws. Further, it was believed that a stronger global IP regime would not only ensure certainty and predictability, but would also stimulate more local research and development devoted to the special needs of developing countries that are not felt in technology exporting countries.⁸⁷

The TRIPS Agreement is currently the most comprehensive international agreement on IP matters as it introduced a strong compliance mechanism by judicialising dispute settlement among members⁸⁸ and by introducing the concept of non-discrimination in

⁸² Chakravarthi Raghavan, *Recolonization: General Agreement on Tariffs and Trade, the Uruguay Round and the Third World* (Third World Network 1990) 60.

⁸³ Sell, ‘The Quest for Global Governance’ (n 72) 385.

⁸⁴ *ibid.*

⁸⁵ May and Sell (n 6) 4.

⁸⁶ United Nations Conference on Trade and Development, ‘Report on the TRIPS Agreement and Developing Countries’ (United Nations 1996).

⁸⁷ *ibid.* 32.

⁸⁸ TRIPS Agreement, art 64.

all fields of technology for patent application.⁸⁹ In order to limit abuse and monopoly, it codified certain exceptions⁹⁰ and incorporated a set of procedural rules for issuing compulsory licences (CLs) for patents.⁹¹ To ensure that countries with different levels of IP effectively comply with the new regime and to support developing countries, the TRIPS Agreement allowed for tiered transition periods for gradual implementation of the agreement,⁹² and promised technical assistance⁹³ and technology transfer for least developed countries.⁹⁴ The TRIPS Agreement also allowed the use of CLs in many instances including public interest, abuse or anti-competitive conduct, or for non-commercial government use,⁹⁵ among others.

However, by limiting the use of CLs ‘predominantly for the supply of the domestic market of the Member authorising such use’⁹⁶ in Article 31(f), the TRIPS Agreement has come under considerable criticism. Compulsory licencing refers to the granting of patent without the consent of the patent owner.⁹⁷ Article 31(f) of the TRIPS Agreement is seen as problematic because it created situations of ambiguity and confusion. Certain countries could face difficulties when trying to utilise CLs as they do not have the local manufacturing capability, thereby creating significant restrictions on the quantities of drugs that can be imported.⁹⁸ This poses huge problems for developing or least developed countries that have little or no manufacturing capability, and severely limits access to medicines for the majority in poor countries.⁹⁹

⁸⁹ Pedro Roffe, Christoph Spennemann, and Johanna von Braun, ‘From Paris to Doha: The WTO Doha Declaration on the TRIPS Agreement and Public Health’ in Pedro Roffe, Geoff Tansey, and David Vivas-Eugui (eds), *Negotiating Health: Intellectual Property and Access to Medicines* (2006) 9.

⁹⁰ TRIPS Agreement, arts 13, 17, 26.2, 30, and 41-61.

⁹¹ *ibid*, art 31.

⁹² *ibid*, art 65.

⁹³ *ibid*, art 67.

⁹⁴ *ibid*, art 66.2.

⁹⁵ *ibid*, art 31 (a)-(l); see also Jerome H Reichman, ‘Comment: Compulsory Licensing of Patented Pharmaceutical Inventions: Evaluating the Options’ (2009) 37 *The Journal of Law, Medicine and Ethics*; Duncan Mathews, ‘Is History Repeating Itself? The Outcome of Negotiations on Access to Medicines, The HIV/AIDS Pandemic and Intellectual Property Rights in the World Trade Organisation’ (2004) 1 *Law, Social Justice and Global Development Journal* <<http://elj.warwick.ac.uk/global/04-1/matthews.html>> accessed 4 February 2015 (‘Is History Repeating Itself?’).

⁹⁶ TRIPS Agreement, art 31(f).

⁹⁷ *ibid*, art 31; see also Watal (n 2) 134.

⁹⁸ Frederick M Abbott, ‘The TRIPS Agreement, Access to Medicines, and the WTO Doha Ministerial Conference’ (2005) 5 *The Journal of World Intellectual Property* (‘The TRIPS Agreement, Access to Medicines, and the WTO Doha Ministerial Conference’). See also Mathews, ‘Is History Repeating Itself?’ (n 95).

⁹⁹ FM Scherer and Jayashree Watal, ‘Post-TRIPS Options for Access to Patented Medicines in Developing Nations’ (2002) 5 *Journal of International Economic Law* 925.

This situation would be further exacerbated by the HIV/AIDS epidemic that significantly affected many developing and least developed countries. To restore balance, WTO member states adopted the Declaration on TRIPS and Public Health (Doha Declaration) in 2001.¹⁰⁰ The Doha Declaration reaffirmed the rights of developing countries to protect the health of their populations as well as the right to interpret the TRIPS Agreement in a manner supportive to access to medicines for all.¹⁰¹ Significantly, the Doha Declaration states that ‘IP protection, as mandated by TRIPS, can be temporarily overridden to address public health issues and concerns as defined by States’ government.’¹⁰² The Doha Declaration also recognised the gravity of health issues facing many developing and least developed countries, especially those resulting in HIV/AIDS, malaria, and tuberculosis and reaffirmed that the TRIPS Agreement does not (and should not) prevent Members from taking measures to protect public health and promote access to medicines. Considering that many developing member states with insufficient or no manufacturing capacities in the pharmaceutical sector could face difficulties in effectively using CL, delegates to the Doha Ministerial Conference ‘instructed the Council for TRIPS to find an expeditious solution to this problem and report to the General Council by the end of 2002.’¹⁰³ The solution later came in the form of the August 2003 Decision on the Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health.¹⁰⁴

Despite these flexibility clauses, the implementation of the TRIPS Agreement, especially in Third World countries, has been contentious. This is because, as aptly pointed out by Joseph Stiglitz¹⁰⁵ and Thomas Pogge,¹⁰⁶ the protection of IPRs as required by the TRIPS Agreement does not take into account the differences in the development levels and socioeconomic needs of developed and developing countries,

¹⁰⁰ World Trade Organization, ‘The Doha Declaration on TRIPS and Public Health’ (2001) WT/MIN(01)/DEC/2 <https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_trips_e.htm> accessed 26 September 2016 (Doha Declaration); see also Duncan Mathews, ‘From the August 30, 2003 WTO Decision to the December 6, 2005 Agreement on an Amendment to TRIPS Improving Access to Medicines in Developing Countries’ (2006) *Intellectual Property Quarterly* (‘From the August 30, 2003 WTO Decision’).

¹⁰¹ Doha Declaration, para 4.

¹⁰² Valbona Muzaka, ‘Developing Countries and the Struggle on the Access to Medicines Front: Victories Won and Lost’ (2009) 30 *Third World Quarterly* 1344.

¹⁰³ Doha Declaration.

¹⁰⁴ ‘Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health’ (2003) WT/L/540 and Corr 1 <https://www.wto.org/english/tratop_e/trips_e/implem_para6_e.htm> accessed 26 September 2016.

¹⁰⁵ Giovanni Dosi and Joseph E Stiglitz, ‘The Role of Intellectual Property in the Development Process, with some Lessons from Developed Countries: An Introduction’, *Intellectual Property Rights: Legal and Economic Challenges for Development* (1st edn, Oxford University Press 2014) 5; Joseph E Stiglitz, ‘Economic Foundations of Intellectual Property Rights’ (2008) 57 *Duke Law Journal* 1694.

¹⁰⁶ Thomas W Pogge, ‘Human Rights and Global Health: A Research Program’ (2005) 36 *Metaphilosophy*.

and are usually implemented with no form of social security in place. This severely unjust agreement, they contend, imposes human rights violations on account of the avoidable mortality and morbidity it foreseeably produces. The resultant effects on developing countries currently confronted with numerous health issues such as HIV/AIDS, malaria, and tuberculosis include but are not limited to the unaffordability and unavailability of basic essential medicines for the majority who need it, as well as premature deaths and extreme poverty.

Apart from criticism from experts located in the Global North, many developing countries have often criticised the TRIPS Agreement even during the negotiating phase for many reasons. First, before the creation of the WTO, many developing countries in Africa, Asia, Latin America, and the Caribbean did not recognise IPR, most especially patents on pharmaceutical products. This is because on one hand, many of these countries have a common history of owning knowledge collectively, and the idea of profiting from an idea or invention to the exclusion of others for a specified period of time was new. According to Drahos, many of these developing countries were not culturally predisposed to accept higher IP norms due to their particular legal regime.¹⁰⁷

On the other hand, many of these countries did not recognise IPR, especially pharmaceutical patents, to ensure domestic accessibility and affordability of drugs. As will be seen in coming chapters, this welfare and developmental reason particularly orients the Indian and Brazilian patent regimes post-independence. Further, many of the countries in the Global South saw IP rules as a form of re-colonisation or economic imperialism,¹⁰⁸ especially as the IP regime under the TRIPS Agreement impairs their development by not only failing to give them access to knowledge but also by failing to protect *their* IPRs, especially in traditional knowledge and biodiversity.¹⁰⁹ This leads to asymmetric rent payments whereby developing countries pay IP rents to Western firms for their IP, but not receiving in return rents from Western firms on IPRs developing countries view as theirs.

¹⁰⁷ Peter Drahos, 'Global Intellectual Property Rights in Information: The Story of TRIPS at the GATT' (1995) 13 *Prometheus* 9 ('Global Intellectual Property Rights in Information').

¹⁰⁸ Raghavan (n 82).

¹⁰⁹ Dosi and Stiglitz (n 105) 2.

The implication of the above analysis can be summarised thus: IP regimes, specifically patents, are social constructs whose obligation is the promotion of the well-being of society, and thus should be tailored to the circumstances, history, and development objectives of each country in order to reap full benefits. Anything other than this skews this objective and impairs the utility of the IP regime.

1.3 Terminology

For purposes of this thesis, it is necessary to clarify the meaning of certain terms and explain the context for their use in this thesis.

Developed Countries

There are no definitions of ‘developed’ countries within the WTO. However, there are large and easily discernible differences in the size and state of economies, and the standard of living enjoyed by citizens of different countries. It is generally assumed that countries within the Organization for Economic Co-operation and Development (OECD) are considered to be developed countries. This is because each of these countries has completed the development process. In this thesis, the term is used to apply to certain countries possessing strong pharmaceutical industries such as the US, Japan, Canada, Switzerland, Germany, France, Sweden, and others. Other terms such as ‘the West’, ‘First World’, and ‘the Global North’ will also be used interchangeably to mean developed countries.

Developing Countries

The term ‘developing’ countries refers to those that have yet to achieve a significant degree of industrialisation even though the WTO provides no definition of the term. It uses the definition of ‘least developed countries’ provided by the UN to explicate the levels of development among ‘developing countries’. In this thesis, the terms ‘Third World’, ‘Global South’, and ‘subaltern’ are used interchangeably.

It is worth mentioning that the term ‘Third World’ has become controversial in recent times. Certain scholars posit that this term is defunct due to the collapse of the former Soviet Union and the Cold War politics that demanded that international systems be

divided into categories.¹¹⁰ However, such is not the view in this thesis. As B.S. Chimni aptly points out, too much is often made of numbers, variations, and differences in the presence of structures and process of global capitalism that continue to bind and unite.¹¹¹ He continues that even international law recognises the diverse set of countries with differences in patterns of their economies despite its practice of prescribing uniform global standards. This therefore validates the existence of the category 'Third World'.¹¹² For this research, the term is used in the sense of the analogy put forward by Karin Mickelson to define Third World as 'a chorus of distinctive voices that blend, though not harmoniously, in attempting to make heard a common set of concerns.'¹¹³ Due to the post-colonial lens adopted in the critical inquiry this thesis seeks to undertake, distinguishing between 'Third World' and 'First World' captures the oppositional dialectic between the European and the non-European, and identifies the plunder of the latter by the former.¹¹⁴

Local Pharmaceutical Industry

In this thesis, the term 'local pharmaceutical industry' refers to indigenous pharmaceutical manufacturing companies in developing countries. These companies are able to meet a certain percentage of the local demand for drugs within each country and contribute to the local economy to a certain extent. These companies usually focus their activities on the production and distribution of generic drugs.

Multinational Pharmaceutical Companies

The term 'multinational pharmaceutical companies' refers to pharmaceutical manufacturing companies in developed countries. These companies have strong research capabilities and engage in the advanced development of innovative medicines.

Non-State Actors

These are individuals and organisations that are not states and that participate in governance and law making at the global, regional, sub-regional, and local levels.

¹¹⁰ See RBJ Walker, 'Space/Time/Sovereignty', *Perspectives on Third World Sovereignty: The Postmodern Paradox* (St Martin's Press 1996) 15.

¹¹¹ See BS Chimni, 'Third World Approaches to International Law: A Manifesto' (2006) 8 *International Community Law Review* 5.

¹¹² *ibid.*

¹¹³ See Karin Mickelson, 'Rhetoric and Rage: Third World Voices in International Legal Discourse' (1998) 18 *Wisconsin International Law Journal* 360.

¹¹⁴ See Mukua Muthua, 'What Is TWAIL?', *The American Society of International Law Proceedings* (2000) 35.

They include individuals, private firms, civil society groups, social movements, trade associations, terrorist groups, and transnational corporations.

1.4 Statement of the Problem

Nigeria and many sub-Saharan African countries are presently confronted with numerous health burdens due to HIV/AIDS, malaria, and tuberculosis. Yet these countries face heavy financial and other complex burdens in meeting and tackling these health challenges. Although multiple factors affect affordability and adequate supply of medicines, this thesis seeks to focus on IP protection and how it affects socio-economic development.

In a world with increasing economic globalisation and interconnectedness, IPRs are wide-reaching, permeating virtually all areas of life, particularly in health, knowledge, agriculture, and human development. The result is ‘ever-increasing expansions on laws and customs protecting intellectual property.’¹¹⁵ However, Nigeria and other developing countries feel short-changed with the current IP regime. There is a general sense that the TRIPS Agreement has failed to deliver on many of its promises such as increased foreign investment, economic development, and technology transfer.¹¹⁶ Therefore, now more than ever, there is a need to carefully scrutinise the TRIPS framework and to think of new ways to make the IP system work.

Indeed, a lot has been written on the intersections within the TRIPS regime, specifically the patent system and access to medicines in Africa¹¹⁷ generally and in Nigeria¹¹⁸ specifically. While the TRIPS Agreement does pose a peculiar challenge

¹¹⁵ Edwin Hettinger, ‘Justifying Intellectual Property’ (1989) 18 *Philosophy and Public Affairs* 32.

¹¹⁶ Rochelle C Dreyfuss, ‘Intellectual Property Lawmaking, Global Governance, and Emerging Economies’, *Patent Law in Global Perspective* (1st edn, Oxford University Press 2014) 4.

¹¹⁷ Sisule F Musungu and Cecilia Oh, *The Use of Flexibilities in TRIPS by Developing Countries: Can They Promote Access to Medicines* (1st edn, 2006) <<http://www.who.int/intellectualproperty/studies/TRIPSFLEXI.pdf>> accessed 15 March 2015; Gabriela Chaves, Marcela Vieira, and Renata Reis, *Access to Medicines and Intellectual Property in Brazil: Reflections and Strategies of Civil Society* (1st edn, 2008) <http://www.scielo.br/pdf/sur/v5n8/en_v5n8a09.pdf> accessed 21 May 2015; Chan Park and Arjun Jayadev, ‘Access to Medicines in India: A Review of Recent Concerns’, *Access to Knowledge in India: New Research on Intellectual Property, Innovation & Development* (1st edn, Bloomsbury Academic 2011); James Thuo Gathii, ‘Approaches to Accessing Essential Medicines and the TRIPS Agreement’, *Intellectual Property and Information Wealth* (1st edn, Greenwood Publishing Group 2006) (‘Approaches to Accessing Essential Medicines’); Rochelle Dreyfuss and Cesar Rodriguez-Garavito, *Balancing Wealth and Health: The Battle over Intellectual Property and Access to Medicines in Latin America* (2014); Pedro Roffe, Geoff Tansey, and David Vivas-Eugui, *Negotiating Health: Intellectual Property and Access to Medicines* (2006); Scherer and Watal (n 99).

¹¹⁸ See AO Oyewunmi, ‘Health Access to Medicines and Intellectual Property Options for African Countries in Light of the WTO TRIPS Agreement’ (2013) 1 *Journal of International Law and Diplomacy*; Adebambo

for the Nigerian context, especially for the manufacture and importation of pharmaceutical goods, these noted scholars all agree that the level of patenting within Nigeria is low compared to other countries of somewhat similar socio-economic status. Therefore, patents alone cannot be held responsible for inadequate access to medicines.

Yet due to the intricacies of global trade, Nigeria and other developing countries cannot opt out of this multilateral trade regime without dire consequences. This raises important questions of what to do with the existing regime. This thesis addresses these issues and asks the following research questions:

1. How are patents conceptualised into law and policy vis-à-vis the TRIPS Agreement in Brazil, India, and Nigeria?
2. How do ideas regarding patents circulate? That is, what influences the way in which particular policy options get constructed – and, as an extension, how others get extinguished with regard to patent law and policy in the aforementioned countries?
3. How do non-state actors – private sector and civil society groups – challenge and/or influence this understanding and conceptualisation of patents into law and policy?

1.5 Research Aim and Scope

The aim of this thesis is to discover whether Nigeria could learn from Brazil and/or India on how to create and implement an IP framework, especially a patent regime that encourages, instead of hinders, development and public health management. It also aims to identify the key issues relevant to the implementation of development-oriented patent law and policy in the post-TRIPS period. As such, it employs a critical reading of the daily operationalization of international law in the subaltern forums of India and Brazil. That is, it provides a careful examination and extensive analysis of

Adewopo, 'Public Health, Access to Medicines and Role of Patent System In Nigeria' (2011) Nigerian Journal of Intellectual Property Law; Okechukwu Timothy Umahi, 'Access to Medicines: The Colonial Impacts on Patent Law of Nigeria' <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1975928> accessed 15 March 2015.

Brazilian and Indian pharmaceutical patent laws, even though Nigeria is ultimately its central focus.

Over the years, subaltern jurisdictions have become the battleground for the promotion of global ideals of human, social, economic, and environmental development. The struggles on access to medicines (A2M) have somewhat shifted from WTO forum disputes to local or national courts in the Third World. This is due to a prevailing perception in contemporary international legal discourse where the Third World has often been seen as the ‘other’. In this view, the Third World is usually the importer of international regulations, from the European civilising missions, International Monetary Fund (IMF) fiscal conditionalities, and the World Bank development programs, to many other such stipulations by donor states and organisations usually located in the Global North.

Within this narrative, international law discourses have the tendency to reduce the Third World to what Upendra Baxi calls the ‘geographies of injustice.’¹¹⁹ That is, the use of international law – be it in human rights, investment, trade, or others – as an instrument for social change, with its applications based on Eurocentric ideals to provide solutions to the needs and concerns of the Third World. One of the consequences of this is a reproduction of patterns of silence and the erasure of significant legal, institutional, and socio-political development and law making in the Third World.

This thesis, therefore, is an exercise in the quest for legal re-ordering of patent law in the Third World – a sort of unmasking of alternative approaches to patent law making and un-making. Such approaches are alternative in the sense that the IP law making engaged in this thesis moves away from the dominant European-US models to a development-oriented IP regime. Through an empirical study of the Brazilian and Indian patent regimes, this thesis maps out the broad interpretations and domestication of international law in the Third World, widening the aperture on international norms and rules governing IP whilst also being ‘TRIPS compliant’ in that challenges at the WTO have failed to materialise.

¹¹⁹ Upendra Baxi, ‘Geographies of Injustice: Human Rights at the Altar of Convenience’, *Torture as Tort: Comparative Perspectives on the Development of Transnational Human Rights Litigation* (Hart Publishing 2001) 197.

It also reveals how Third World countries such as Brazil and India are ascertaining how different IP regimes affect developing countries on one hand, and are adapting their patent law to fit their own unique environments on the other. In so doing, this thesis pays particular attention to how the local politics between the subaltern state, non-state actors, and transnational capital, as well as the fractions within subaltern states – often ignored in debates surrounding IPRs and their relation to access to health – are involved in the recalibration of global IP norms and discourses. In the discussions in coming chapters, the thesis also exposes some of the contradictions involved in this emerging subaltern jurisprudence on IP law. These contradictions are not surprising. While both Brazil and India are making huge strides in designing patent regime systems that best meet their needs, their respective regimes are still flawed as certain policies and actors inadvertently promote IP practices that impede development and public health management. These actions also do not mean failure of these regimes. Instead, it shows that the IP ecosystem is complex, does not exist in isolation, and the presence of various actors means it will continue to calibrate and recalibrate global IP regime.

Although Nigeria is ultimately the central focus of this thesis, Brazil and India play a very important role in the study for many reasons (see Table 1). First, both countries are similar to Nigeria in that they both have large populations and are demographically multi-ethnic with rich cultures. Secondly, these countries are important regional powers with the ability to influence the legal, political, and social cultures of neighbouring states. On the international scene, Brazil and India played very important roles at the Uruguay Round of negotiations and both countries have always been at the forefront of a development-oriented WTO, the fight for access to medicines, and South-South collaboration. Brazil and India are also hotbeds of social movements. This is apparent in the grassroots mobilisation for AIDS and treatment access movements. For socio-legal purposes, these countries provide useful fodder for competing theoretical ideas about social movements – identities, concerns, and emotional underpinnings. As will be seen in coming chapters, both the Brazilian AIDS program and the Indian patent regime are testaments to the strategic effort and coalition of social movements in these countries, especially in funnelling information and in producing knowledge.

	Brazil	India	Nigeria
Capital	Brasilia	Delhi	Abuja
Government Type	Republic	Republic	Republic
Population	204,369,000	1,267,401,849	178,516,904
Size of Economy	USD2.52 trillion	USD5.1 trillion	USD510 billion
GNI per capita	USD11,690	USD1,570	USD2,710
Gross Domestic Product	USD2.246 trillion	USD1.875 trillion	USD521.8 billion
No of Living With HIV	730,000	2,100,000	3,200,000
No of People on HIV Treatment	650,000	500,000	217,000
Net worth of Pharmaceutical sector	USD26.892 billion	USD12 billion	USD 1.28 billion

Table 1: Brazil, India, Nigeria: A Snapshot. Taken from the World Bank Open Data (<http://data.worldbank.org>), Joint United Nations Program on HIV/AIDS (UNAIDS) (<http://www.unaids.org/en/dataanalysis>) and the 2014 PricewaterhouseCoopers Report titled 'The Investment Opportunities in the Pharmaceutical Sector - Nigeria/Pakistan'.

1.6 Methodology

This thesis approaches its subject matter from the critical international legal theory (CLT) perspective. CLT challenges and overturns accepted norms and standards in legal theory and practice.¹²⁰ According to this school of thought, the failings in the international law project are not marginal or exceptional, but are endemic, consistent, and structural.¹²¹ As a result, this school of thought uses broad arrays of techniques to address separate but interrelated failings perceived in the international legal project to show the cruelty of the current systems of law.¹²² Though CLT constitutes various strands, its unifying stance is the need to rethink the foundations of international law and create space for an emancipatory and inclusive international legal project.¹²³ It is

¹²⁰ The critical international legal theory (CLT) is sometimes known as critical legal studies (CLS) or new approaches to international law (NAIL). CLS draws from different philosophical traditions such as Marxism, the critical theory of the Frankfurt School, and Post-Structuralism. See Roberto Mangabeira Unger, 'The Critical Legal Studies Movement' (1983) 96 Harvard Law Review; Nigel Purvis, 'Critical Legal Studies in Public International Law' (1991) 32 Harvard International Law Journal; Mark Tushnet, 'Critical Legal Studies: A Political History' (1991) 100 The Yale Law Journal; Anthony Carty, 'Critical International Law: Recent Trends in the Theory of International Law' (1991) 2 European Journal of International Law; Matthew Stone and others, *New Critical Legal Thinking* (Birkbeck Law Press – Routledge 2012); Alan Hunt, 'The Theory of Critical Legal Studies' (1986) 6 Oxford Journal of Legal Studies; Jason Beckett, 'Critical International Legal Theory' (2012) Oxford Bibliographies Online Datasets.

¹²¹ Hunt (n 120) 30-32.

¹²² Beckett (n 120).

¹²³ Hunt (n 120) 43; Beckett (n 120).

this rationale and its philosophical assumptions that underlie this research project. Hence, the thesis employs a reading and understanding of international law that is culturally constitutive and historically contingent. This form of engagement therefore enables the assessment of the adequacy of modern international law, which WTO laws is part of, for Third World countries.

Within CLT, this thesis specifically builds on the works of TWAIL. As will be seen in the next chapter, TWAIL is an intellectual movement devoted to providing an alternative narrative of international law that has developed to perpetuate the domination and subordination of the Third World. Within this oppositional space, TWAIL performs both deconstructive and reformatory functions.¹²⁴ As a deconstructive tool, TWAIL identifies, unpacks, and challenges the history, oppressive structures, and processes of international law.¹²⁵ As a reformatory tool, it reconstructs international law to be cognisant and responsive to the needs and aspirations of peoples of the Third World.¹²⁶

It is this particular understanding of *twailian* theory – the gradual unpacking, deconstruction, and inclusion of legal projects operating at the margins of the mainstream discipline – that underpins the critical engagement of this research with the IP regime and the access to medicine discourse.¹²⁷ Therefore, this research seeks to extrapolate a ‘Third World approach to IP law’ via a consideration of emerging counter-hegemonic rule-making in Brazil and India to deduce lessons for Nigeria. These successful domestic interventions, this research posits, are inadvertently changing the global IP regime by widening the aperture on norms as they relate to pharmaceutical patent laws, trade policies, and trade rules governing access to essential medicines. Therefore, by focusing on domestic jurisprudential experiences in detail, this research examines the ways international law ‘unfolds on the mundane and quotidian plane through sites and objects which appear unrelated to the international.’¹²⁸ That is, by focusing on domestic phenomenon that are not ostensibly

¹²⁴ James Thuo Gathii, ‘TWAIL: A Brief History of its Origins, its Decentralized Network, and a Tentative Bibliography’ (2011) 26 *Trade, Law and Development* 39.

¹²⁵ *ibid.*

¹²⁶ *ibid.*

¹²⁷ Chimni (n 111); Muthua (n 114).

¹²⁸ Luis Eslava and Sundhuha Pahuja, ‘Between Resistance and Reform: TWAIL and the Universality of International Law’ (2011) 3(1) *Trade, Law and Development* 103. Eslava and Pahuja suggest that TWAIL needs to expand its emphasis on materiality to think of international law as not only an ideological project that has material consequences but also as a material project itself. To contest international law’s shortcoming, Eslava and Pahuja contend paying attention to the ways in which international law constantly constitutes and reconstitutes what

international but in actuality is, the research expands *twailian* materiality by delving into ‘the everyday life of international [IP] law’¹²⁹ through the examination of practices that occur, not only through typical international legal IP practices, but also through many other sites and objects in which international law operates today.

Further, because this thesis reflects on the emergence of various narratives and counter-narratives on patent law making, a supplementary approach known as the nodal governance theory is adopted. This methodology is employed to delve into ‘deeper levels of understanding of the legal disconnect and discontinuities at play in [these] local spaces.’¹³⁰ Here, nodal governance analysis provides the lens to understand how ideas circulate among the complex web of actors in the local spaces of Brazil, India, and Nigeria. The identification of such networks is the first step towards developing an understanding of the strategies adopted by local actors to mobilise state government and address local problems.

1.7 Notes on Method

Much of the research for this thesis entails theoretical and contextual analysis of existing reports and documentation of the TRIPS Agreement, patents, and right to health laws in Brazil, India, and Nigeria. Thus, data collection for this dissertation included policy documents, news reports, statistics, archival materials, and ethnographic techniques. Policy documents were obtained from websites of governments and international organisations such as the WTO, WIPO, UN, UN Development Program (UNDP), UNAIDS, and others. Statistical data were obtained from Ministries of Health, especially the National AIDS Program websites, donor organisations such as the Global Fund to Fight AIDS, Tuberculosis and Malaria, World Bank, US Agency for International Development (USAID), and United Kingdom (UK) Department for International Development (DFID). News reports were sourced from leading press such as IP Watch, the Economist, Spicy IP, BRIC News, Economic and Political Weekly (EPW), and other online websites specialising in reporting access to medicines such as *Médecins Sans Frontières* (MSF). Other

people think of as places, subjects, and modalities of administration. This can be achieved by exploring the way that international law operates, including its daily functioning on the mundane, quotidian, and material plane.

¹²⁸ *ibid* 109.

¹²⁹ *ibid*.

¹³⁰ Scott Burris, Peter Drahos, and Clifford Shearing, ‘Nodal Governance’ (Temple University 2005); Scott Burris, Peter Drahos, and Clifford Shearing, ‘Nodal Governance’ (2005) 30 *Australian Journal of Legal Philosophy*.

materials used include secondary literature on TRIPS Agreement implementation in different jurisdictions, WTO dispute reports, health reports (such as the reports of the World Health Organisation's (WHO) Committee on Intellectual Property Rights, Innovation and Public Health and the UK Commission Reports on Intellectual Property Rights), case laws, and archive materials such as submissions to minutes of TRIPS Council meetings which can be easily accessed online.

Ethnography, specifically multi-sited ethnography, is the main research technique used to acquire new empirical material in the natural social setting. Multi-sited ethnography can be traced most notably to the works of anthropologist George Marcus. According to Marcus, social realities are created at multiple local sites and modern interlocking institutions.¹³¹ In this view, the global does not exist as an autonomous entity that is discursively bereft from the local.¹³² This is the allure of multi-sited ethnography as it allows the researcher to be involved in 'spatially dispersed fields through which the ethnographer moves – actually, via sojourns in two or more places, or conceptually, by means of techniques of juxtaposition of data'¹³³ Within this purview, the modality of multi-sited ethnography utilised for this thesis is partly about description and cultural differences of the Brazilian, Indian, and Nigerian patent cultures and partly in site in the sense of following people, connections, associations, and relationships across space. For this thesis, eight months were spent in the field: Brazil (May – June 2014), India (August – October 2014), and Nigeria (November 2014 – February 2015, and July 2016). A total of 58 interviews were conducted – 19 in Brazil, 17 in India, and 22 in Nigeria. Though exhausting and costly in terms of resources, this particular research method was used because it allowed for the 'objective study of social phenomena that cannot be accounted for by focusing on a single site.'¹³⁴

Key informant interviews were the main vehicle for obtaining in-depth knowledge of actors especially in policymaking circles and in understanding the social ties across the state-society interface. These key informants included policymakers, activists, government officials, academics, judges, and key players in the pharmaceutical

¹³¹ Mark-Anthony Falzon, *Multi-Sited Ethnography* (Ashgate 2009) 2.

¹³² *ibid.*

¹³³ *ibid.* 3.

¹³⁴ GE Marcus, 'Ethnography in/of the World System: The Emergence of Multi-Sited Ethnography' (1995) 24 *Annual Review of Anthropology* <https://www.ashgate.com/pdf/SamplePages/Multi_Sited_Ethnography_Intro.pdf> accessed 29 July 2015.

industry. However, the sampling was not random as some actors have already been identified from the background preparation prior to going into the field. Nevertheless, the snowball sampling method was employed in some cases.

The snowball method is a form of non-probability sampling technique for gathering research subjects through the identification of an initial subject who is used to provide the names of other actors.¹³⁵ In this method, existing respondents recruit future respondents from among their acquaintances and contacts.¹³⁶ This particular approach was used to contact exclusive groups such as top government officials and judges. Appendices 1 to 3 list all of the interviews conducted. Most of the interviews were conducted in English; however, 2 interviews in Brasilia (Brazil) necessitated the use of an interpreter. In those instances, a student interpreter from the University of Brasilia with background knowledge on the issues discussed was used. In most cases, the interviews were tape-recorded; a few interviews conducted with government officials in Nigeria were not recorded and notes were taken by hand. Interviewees in Brazil and India were generally more open to having their interviews taped. Due to institutional affiliations, some respondents have asked to remain anonymous.

Semi-structured interviews were used to interrogate the range of different respondents polled. In semi-structured interviews, the questions are not standardised, though an interview 'guide', which was later used as a code point for data analysis, was used as pointer towards topics that will be covered per interview (see Appendix 4). The utility of this interviewing technique is that it allows the use of conversation and discussion to gain insight and expert knowledge on [the research themes].¹³⁷ This is crucial as the exploratory and conversational nature of the interviews allowed for an understanding of the respondents' views on issues of access to medicine and tracked the mix of ideas that circulated among these key actors, thus enabling the generation of significant data.

There are many advantages to using this particular interview approach. For instance, the non-standardised nature of the questions allows interviewees to describe perceptions they would otherwise think irrelevant or that they usually feel inhibited

¹³⁵ Michael Lewis-Beck, Alan Bryman, and Tim Liao, 'Encyclopedia of Social Science Research Methods'.

¹³⁶ *ibid.*

¹³⁷ Nigel Newton, 'The Use of Semi-Structured Interviews in Qualitative Research: Strengths and Weaknesses' (*Academia.edu*) <https://www.academia.edu/1561689/The_use_of_semi-structured_interviews_in_qualitative_research_strengths_and_weaknesses> accessed 28 January 2014.

from mentioning in their normal social context.¹³⁸ This is because the face-to-face nature of the interview process helps in developing intimate, trusting, and empathetic relationships, which in most cases make respondents feel able to disclose the truth. Of course, there are weaknesses to this particular research approach, which include reduction in comparability,¹³⁹ perception of the interviewer by the interviewees,¹⁴⁰ and the validity of facts, i.e. interviewees may say what they think the interviewer wants to hear. In situations of questionable fact, clarification was made using data drawn from the aforementioned literatures.

In addition to qualitative interviews, specific local organisations dealing with issues on patent and its impact on health were utilised in order to gain inside knowledge, to understand the ideas circulating among key actors and the manner in which particular policy options get constructed – and, as an extension, how others get extinguished with regard to the patent regime and access to medicine. In Brazil, for instance, working with the Working Group of Intellectual Property of the Brazilian Network for the Integration of Peoples (GTPI/REBRIP) was of great help to the thesis. The same was true for working at the WTO office in Nigeria’s Federal Ministry of Trade, Industry and Commerce, and being a research fellow at India’s Centre for Study of Law and Governance at Jawaharlal Nehru University, Delhi.

Working at GTPI undoubtedly influenced the thesis’ views about Brazil’s health policies and patent regime. Nonetheless, an inquisitive disposition and a range of techniques were employed during interviews, including empathy towards understanding the concerns of AIDS patient groups or the realities faced by executives operating in a capitalist economic system. Furthermore, the data from the interviews were analysed using *NVivo*. *NVivo* is a comprehensive qualitative data analysis software package which can be used to organise and analyse interviews, field notes, textual sources, and other types of qualitative data including image, audio, and video files. Interview guides prepared prior to the fieldwork were used as codes to develop themes and demographic details.

Finally, not all of the target interviewees were interviewed, as some top government officials and executives denied interview requests out of lack of interest, or interviews

¹³⁸ *ibid.*

¹³⁹ Michael Quinn Patton and Michael Quinn Patton, *Qualitative Research and Evaluation Methods* (Sage Publications 2002) 40-41.

¹⁴⁰ Martyn Denscombe, *The Good Research Guide* (Open University Press 2007).

were cancelled due to busy schedules. For instance, the interview with the Indian Minister of Health and Commerce was cancelled as the date of the interview coincided with the visit of US President Barack Obama to India and the Minister's presence was requested in all meetings and related activities.

Other obstacles were also encountered. First, interviews in Nigeria had to be discontinued until an exemption certificate was received from the National Health Research Ethic Committee Nigeria (NHREC). The NHREC is tasked with advising the Federal Ministry of Health on ethical issues concerning research. It is also responsible for setting norms and standards for the conduct of human and animal research. Due to the fact that aspects of this research touched on issues such as antiretrovirals (ARVs), HIV/AIDS, and pharmaceutical procedures, official approval had to be obtained from the NHREC before continuing with the research. As a result, interviews had to be stopped for two weeks to complete the bureaucratic process. Second, initial interview requests sent to pharmaceutical companies during the Nigerian leg of the fieldwork were ignored. However, a pharmaceutical company executive responded to the 2014 interview request in May 2016 and agreed to be interviewed. This necessitated travelling back to Nigeria for a second round of interviews in July 2016. Fortunately, the pharmaceutical executive subsequently referred to three other pharmaceutical company executives who were subsequently successfully interviewed for the thesis.

1.8 Thesis Structure

This dissertation is divided into three sections – methodology, case studies, and insights or conclusions. The first section concerns the introduction and methodology (or the conceptual framework) employed in this study. Indeed, this introductory chapter, as already seen, performs a few initial but critical functions with respect to situating this study, the research questions, and the methods employed in the process of this research.

Chapter 2 maps out the terrain of the TWAIL and nodal governance theory. In doing so, it situates the harmonised regime of the TRIPS Agreement within the cultural context and historical contingency of international law as it relates to themes of

development and economic prosperity of Third World states. Nodal governance provides the lens for understanding and exploring local actor participation in patent law making and governance. Establishing the theoretical frame of reference for this thesis, this chapter employs a critical reading of the global IP framework and examines how the TRIPS framework has been inserted into the post-colonial development agenda and its continued use as a hegemonic political tool.

Chapter 3 begins the series of case study analyses. Focusing on Brazil, the chapter specifically centres on the intersection of Brazil's HIV/AIDS program and its patent law policies. It tells the story of how patent law and policies have been applied at the domestic level and how the A2M discourse has evolved in the wake of TRIPS implementation. The focus, then, is how local political dynamics and actors play into issues related to IPRs and medicine access. Though Brazil's overall application of IP standards has been comparatively mixed and uneven, the thesis argues that the prosaic implementation of pro-right to health policies even after the country phased fully into the TRIPS Agreement is a hermeneutic expression of resistance and reform of international law norms on patent law and medicine access discourse(s).

Chapter 4 continues with the series of case study analyses by critically investigating the Indian patent regime. India is often cited as an example of an 'innovative developing country' with a robust pharmaceutical sector and the capacity to carry out health innovations. This chapter analyses the government intervention policies that made these structural changes possible and examines how the growth of the sector is strongly linked to a wide range of factors which propelled Indian pharmaceutical firms on a path that spurred the growth of highly sophisticated generic drugs.

Chapter 5 focuses on Nigeria and maps the historical evolution of patent law in the country. After a schematic representation of the excruciating health burdens in Nigeria to help understand the critical situation and urgent actions required to tackle these multiple health emergencies, the chapter proceeds to examine the current patent law in Nigeria vis-à-vis the TRIPS Agreement to show how the latter interacts with laws, institutions, and actors at the domestic level. This chapter seeks to understand how issues of access to medicine are framed locally and the cognisance of policymakers of patent law as a development tool.

Chapter 6 concludes the thesis and focuses on the insights derived from the case studies. The individual and collective significance of the findings of the case studies are summarised and their benefits to the thesis are restated. The hope of this work is that the reader will understand that adroitly marketing the TRIPS Agreement as a trade tool inherently makes it unsuitable for development objectives, despite the inclusion of certain flexibilities. This necessitates the need for a conceptual recasting of the TRIPS-harmonised regime not based on the dominant European-US models but on a development-oriented IP regime embraced by both India and Brazil.

2. Theoretical Frameworks

Introduction

This chapter outlines the theoretical framework that underpins the thesis; that is, the relevant thinking that grounds this research. Within the context of this research, a theoretical frame helps connect the struggles of the jurisdictions under study, and provides insights into the various inequities inherent in the global patent system as they relate to the protection of pharmaceutical products and processes. Therefore, this chapter provides a particular perspective or lens within which this work is conducted.

This study was inspired by the desire to understand the interplay of the patent regimes in the Third World, specifically in Brazil, India, and Nigeria. That is, to excavate the history, origins, and impact of the implementation of the TRIPS Agreement vis-à-vis local actors and institutions in the Global South. To do this, the history of the TRIPS Agreement, its broad interpretations in the local forums of the Global South, and the ways in which such interpretations are changing international norms on patent law and medicine access discourse were explored. The belief was that unearthing these emerging critical legal trends within the Third World would serve as inspiration for Nigeria, and to a larger extent, other emerging economies in sub-Saharan Africa that are not only struggling with HIV/AIDS, but are also seeking to increase access to and the availability of essential medicines for their citizens. This goal informed the study's engagement with critical legal studies, specifically the TWAIL.

TWAIL argues that the current international legal framework is an imperial project.¹ That is, the colonial confrontation, which birthed international law and subsequently saw the subordination of non-European peoples and societies to the European imperial conquests, animates the current international law project.² As such, international regimes such as the TRIPS Agreement are nothing but a modern-day extension of this colonial engagement. Thus, the relevance of TWAIL to this thesis lies in its provision of the methodological and analytical lens for historicising and critiquing global patent law. More importantly, by engaging in the historiography of

¹ Antony Anghie, *Imperialism, Sovereignty and the Making of International Law* (New York, Cambridge University Press 2005) (*Imperialism, Sovereignty and the Making of International Law*).

² *ibid.*

international law, TWAIL provides the analytics for recognising the various on-going reform projects in the local jurisdictions of the subaltern which are expanding the aperture on patent norms and medicine access discourse.³ Sundhya Pahuja and Luis Eslava note that TWAIL ‘expands its emphasis on materiality to think of international law as not only an ideological project located in a particular material context, and with material consequences but also as a material project itself.’⁴ As such, it is pertinent to examine the way international law operates, including its daily functioning on the mundane quotidian level ‘by delving into the everyday life of international law, at domestic phenomena that is not ostensibly international.’⁵ By looking at the ‘*material*’ plane, TWAIL generates not only a form of new universality but also reveals ‘the numerous forms of resistance already at play in the struggle against the (post)colonial normative order now being institutionalised and administered across the world.’⁶

It is this call to delve to the mundane quotidian level that frames the study’s analyses of pharmaceutical patent regimes in Brazil, India, and Nigeria to find out how global patent law as it relates to medicine access is conceptualised, resisted, and reformed in legal and policy discourse within the confines of the TRIPS Agreement. Thus, it is in the historicising of international law and looking beyond the international to map the analytics of change happening within and without that TWAIL benefits this research. In other words, TWAIL provides the perspective to look at daily engagement and contestation of patent regimes in local forums of the Global South as not distinct from international law making but as part of it. It is only when the everyday engagement of international law in domestic forums of the Global South is placed in a historical context that these everyday actions are imbued with meaning and function.

In spite of the above benefits, TWAIL scholarship is methodologically and analytically insufficient for this thesis in two important dimensions. First, the erroneous assumption that Third World states have local actors to participate in the reform and resistance of international legal scholarship. In this context, ‘actor’ refers

³ See generally Luis Eslava and Sundhya Pahuja, ‘Between Resistance and Reform: TWAIL and the Universality of International Law’ (2011) 3 Trade, Law and Development (‘Between Resistance and Reform’); Luis Eslava and Sundhya Pahuja, ‘Beyond the (Post)Colonial: TWAIL and the Everyday Life of International Law’ (2012) 45(2), Journal of Law and Politics in Africa, Asia and Latin America - Verfassung und Recht in Übersee (VRÜ) (‘Beyond the (Post)Colonial’).

⁴ Eslava and Pahuja, ‘Beyond the (Post)Colonial’ (n 3).

⁵ Eslava and Pahuja, ‘Between Resistance and Reform’ (n 3) 103.

⁶ Eslava and Pahuja, ‘Beyond the (Post)Colonial’ (n 3).

to participants in local forums other than the state. This includes private sector interests such as pharmaceutical companies (transnational and indigenous firms), civil society groups, social movements, and donor organisations. By not exploring actor presence and agency, TWAIL ignores the impetus of actor politics and the politics of knowledge that govern actor involvement *within* and *between* Third World states. That is, *who* participates in this reform of and resistance against international (patent) law in the local forums of the Global South? *what* informs this participation? and *how* the knowledge about participation is produced? In fact, as shown in the analyses of patent law making as part of TRIPS implementation in the local forums of Brazil (Chapter 3), India (Chapter 4), and Nigeria (Chapter 5), there exists a vast difference in actor presence and participation among and within Third World states. Therefore, if Eslava and Pahuja's call to delve into the local is taken up, attention should be paid not only to the actor network, but also to the various roles played by – or contestation – between these local networks and the politics of knowledge, which structure engagement in reform and resistance vis-à-vis international law and scholarship in local forums.

The second limitation is that the *twailian* scholarship suffers from the notion that Third World states are automatically endowed with emancipatory capabilities because of their post-colonial status.⁷ That is, due to the 'problem space' they occupy – in this case, post-colonialism — TWAIL assumes that Third World states have the competency to engage in counter-hegemonic international law making. In other words, in calling for the refocus of attention to the local levels, TWAIL scholarship assumes the competency of such actors, where they exist, to participate in local counter-hegemonic international law making.

By 'competency', the thesis means the ability of actors to enrol support simultaneously at a number of different sites of law making and law enforcement (national, international, and transnational), and their ability to mobilise leading sources of expertise to reform, reconstruct, or dismantle patent regimes. An example of this is the ability of generic pharmaceutical companies in India to mobilise the government on patent issues and to collaborate with civil society groups to generate

⁷ Antonius R Hippolyte, 'Correcting TWAIL's Blind Spots' (2016) 18 International Community Law Review; Jayan Nayer, 'Between Hope and Despair: The Iraq War and International Law Futures?', *The Iraq War and International Law* (1st edn, Hart Publishing 2008) 320.

and produce expertise on key IP issues. As will be seen in Chapter 5 on Nigeria, not only is competency imperative in ensuring effective engagement, the willingness of such actors to engage in the long and arduous task of reforming and resisting international law is equally essential. As analyses in this thesis will show, Brazilian and Indian actors are willing and competent to engage in the reform of local patent law, whereas their Nigerian counterparts are generally unwilling to engage and are not unable to do so due to lack of capacity. In failing to acknowledge that not all developing countries are participating in the same way in international law making, TWAIL overlooks the asymmetries between and within the Third World.

Thus, by overlooking these important dimensions (actor presence, competency, and willingness), TWAIL ignores not only local histories and identities *between* and *within* the Third World but also how these asymmetries define which Third World state engages in reform and resistance vis-à-vis international law and scholarship, and who is excluded. In not addressing the local ecosystem of actor-participation, which includes looking into local presence, willingness, competence, and the politics of knowledge governance which frames this participation, TWAIL weakens its critical scholarship premise to connect to ‘the concrete experiences and claims found in local spaces’ that is central to its mission.⁸ In as much as TWAIL scholarship suggests focusing on the reform of and resistance against international law at the local forums, attention should also be paid to the presence and competence of local actors, their willingness to engage, and the politics of ‘knowledge’ that informs participation in order to bring about the desired change.⁹ In focusing in the ecosystem of non-state actor involvement, what is uncovered is not only the way such internal dynamics unfolds but also how it informs which Third World country’s participation in counter-hegemonic law making in local forums, as suggested by Eslava and Pahuja, as well as who is excluded.

Thus, while TWAIL benefits this research by providing the analytics for historicising and mapping change, it provides only a partial engagement. Understanding Third World engagement should also include exploring the local actor participation ecosystem. It is in exploring this ecosystem that the manner in how knowledge is

⁸ Asad G Kiyani, ‘Third World Approaches to International Criminal Law’ (2016) 109 AJIL Unbound.

⁹ Scott Burris, Peter Drahos, and Clifford Shearing, ‘Nodal Governance’ (2005) 30 Australian Journal of Legal Philosophy 31 (‘Nodal Governance’).

captured and repurposed by actors as they attempt to reform, reconstruct, or dismantle¹⁰ the patent regime is uncovered and understood. In addition, it reveals how actors coordinate actions in a variety of different sites at different ‘levels’ of the global regime and mobilise forms of counter-expertise from within and without the established legal regimes. This is important because it illuminates how and why actors mobilise in a particular locality and not in others. It is for this reason that this thesis draws from the nodal governance theory to supplement the *twailian* contribution and address the actor/knowledge gap.¹¹ Therefore, nodal governance is articulated here to not only emphasise the local capacity, but also how actors (nodes) in the local forums employ and deploy knowledge in ways that would promote their respective agenda while strengthening their collective capital.

Nodal governance puts forward the proposition that the dynamic interaction of key stakeholders in the patent regime relentlessly expands global IP systems by controlling the choice of words, meaning, and subsequent standard-setting processes.¹² Thus, it enables the understanding of microscopic processes that produce general outcomes by identifying actors involved in processes such as knowledge creation, capacity building, and resource mobilisation to manage a course of events.¹³ Nodal governance addresses the problem concerning the production, appropriateness, diffusion, exclusion, interpretation, and governance of knowledge that inform actor participation and competency, and subsequently, legitimacy. In other words, it illuminates how the participation of these actors shape this area of law by investigating the way they frame their ideas to theorise their interests and justify the change they seek. In applying nodal governance theory, this research shows the internal and messy mechanics of the local patent ecosystem – how knowledge and expertise is produced and framed, which actors intervene in policy debates and processes, what allowed such interventions, as well as what happens in the absence of these actors (Chapter 5). Therefore, nodal governance not only looks at local institutional arrangements but also the workings *within* and *between* actors engaged in the standard-setting processes in the local forums of the Global South.

¹⁰ *ibid* 47-48.

¹¹ See Clifford Shearing and Jennifer Wood, ‘Nodal Governance, Democracy, and the New “Denizens”’ (2003) 30 *Journal of Law and Society* 400 (‘Nodal Governance, Democracy and New “Denizens”’ (n 11) Governance, Democracy, and the New “Denizens”’), on the shift from a purely Westphalian state-centred governance of security and justice to one in which the state constitutes one of many actors.

¹² *ibid*.

¹³ Burris, Drahos, and Shearing, ‘Nodal Governance’ (n 9) 37.

The thesis draws upon Peter Drahos' study of the regulation of multi-national companies (MNCs) to understand how complex systems construct order, produce knowledge, and design governance systems that mimic or complement the ordering work of systems themselves.¹⁴ That is, nodal governance theory illuminates actors' mentalities, methods for exerting and mobilising influence, modes of governance employed, structure, as well as the dialectic relationships between and among actors.¹⁵ In addition, nodal governance enables the identification of actors involved in governance and the informal dynamics of power usually at play. Of particular significance to this thesis, nodal governance helps explain why pharmaceutical patents are relevant and used in legal and policy discourse in the local forums of Brazil and India but are absent in Nigeria. However, for all its benefit for this thesis, especially in understanding the nuts and bolts of patent ecosystems in local forums, the limitation of nodal governance lies in its inability to probe the structure, history, and processes of the (global) legal system within which it exists. Thus, in combining TWAIL and nodal governance theory to illuminate the materialisation of the international in the local, the thesis shows the gamut of legal, historical, political, and economic developments that bring about the internationalisation of pharmaceutical patent law in the local forums of Brazil, India, and Nigeria.

The remainder of this chapter is divided as follows: Part I focuses on TWAIL. Here, TWAIL is used as a resource to uncover the historical origins of international IP law and its continuities in the post-colonial. Thus, this section begins by identifying TWAIL as a theoretical position seeking to build a genealogy of the present through a careful analysis of the ways international IP law reproduces a renewed colonial order in the 20th century. In this section, the thesis shows how TWAIL informs and benefits the research. To do this, the thesis shows how the 'colonial hierarchy' is reproduced and reinforced in the politics of the Uruguay Round negotiations, the language on patents in the TRIPS Agreement, and the corollary medicine access debates. The third section concludes by exploring the methodological limit of TWAIL as it pertains to this thesis.

¹⁴ Peter Drahos, 'Intellectual Property and Pharmaceutical Markets: A Nodal Governance Approach' (2004) 77 Temple Law Review ('IP Nodal Governance Approach'); Peter Drahos and John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (2002) (*Information Feudalism*); John Braithwaite and Peter Drahos, *Global Business Regulation* (1st edn, 2000) (*Global Business Regulation*).

¹⁵ Burris, Drahos, and Shearing, 'Nodal Governance' (n 9) 34.

Part II focuses on nodal governance theory. Here, nodal governance is used to generate insight into the dynamic power and influence of certain non-state actors to relentlessly expand global IP systems by exerting influence on the state structure to achieve their objectives. The section begins by unpacking the meaning of nodal theory – how nodes work, their principal categories, and the ways in which they influence changes in governance. In this respect, nodal governance is seen as a form of governance in which nodal networks are constantly reconstituting themselves to bring changes to a power relationship, either with the state or fellow nodal network.

This theory is then applied to the research to show its relevance in understanding actor participation in local ecosystems and how such participation generates new regulatory frameworks. Specifically, the thesis shows how a distinctive kind of nodal governance of big corporations (in this case, multinational biotechnology companies) emerged to push for greater global patent regulation by inserting the patent regime into the US' foreign policy. In so doing, the thesis shows how resources are mobilised and knowledge is captured and repurposed by corporate actors as they attempt to reform and reconstruct the patent regime to suit their collective objectives. Consequently, the thesis contributes to the understanding of the importance of local actor network and of complex interrelationships involved in the way patent knowledge is produced, contested, commercialised, and employed in the policy framework, and what happens in their absence. Therefore, the importance of this exercise is to show that participation in counter-hegemonic (international) patent law hinges not only on the presence of relevant actors, but also on the competency of such actors to mobilise in multiple sites and bring about compliance and changes in governance.

Part I: Third World Approaches to International Law

2.1.1 Theorising and Understanding TWAIL

TWAIL attempts to understand the history, structure, and processes of international law from the perspective of Third World states.¹⁶ This is grounded in the belief that international law is an imperial project.¹⁷ The colonial confrontation, which birthed international law and saw the subordination of non-European peoples and societies through European imperial conquests, still frames and influences international legal regimes as well as international economic governance (IEG) structures and institutions that operate within it.¹⁸ Overtime, international law has come to displace several national legal systems in importance and is having an unprecedented effect on the lives of ordinary people.¹⁹ That is, international law now plays roles that extend beyond adjudicating relations between states to adjudicating in local jurisdictions the global ideals of human, economic, political, and environmental development. As such, international law – its history, processes, and structures – cannot be neglected at a time when it is slowly becoming domestic law.²⁰ Therefore, a well-rounded study that fully incorporates the lived experiences of the global subaltern is imperative to make international law truly international and to animate its democratic emancipatory potentials.²¹

In response to and in dialectical opposition to this, TWAIL arose as a legal scholarship that furthers and includes the interests of the Global South in international law discourse. It aspires to ‘address the material and ethical concerns of Third World

¹⁶ BS Chimni, ‘The Past, Present and Future of International Law: A Critical Third World Approach’ (2007) 8 *Melbourne Journal of International Law* 1 (‘The Past, Present and Future of International Law’).

¹⁷ Anghie, *Imperialism, Sovereignty and the Making of International Law* (n 1).

¹⁸ Hippolyte (n 7) 3.

¹⁹ BS Chimni, ‘Third World Approaches to International Law: A Manifesto’ (2006) 8 *International Community Law Review* (‘TWAIL: A Manifesto’).

²⁰ Chimni, ‘The Past, Present and Future of International Law’ (n 16).

²¹ Though not a *twailian* per se but obviously sympathetic to TWAIL analysis, Martti Koskenniemi has pointed out that the international law project was initially created to be a force of good. The law was seen as a stabiliser of politics, a positive force meant to add something to politics. International law was created as a law of worldwide cooperation to further a shared end. This stems from the belief that if law takes over, things become better. However, this ideal was lost due to the expansion and specialisation within international law, what Koskenniemi calls the fragmentation of international law. This fragmentation has led to the reversal of established hierarchies in favour of structural bias in the relevant functional expertise. This is seen as a stumbling block to promoting a peaceful and just world. See Martti Koskenniemi, ‘The Fate of Public International Law: Between Technique and Politics’ (2007) 70(1) *The Modern Law Review* 1 (‘The Fate of Public International Law’). See also Martti Koskenniemi and Paivi Leino, ‘Fragmentation of International Law? Postmodern Anxieties’ (2002) 15 *Leiden Journal of International Law* 554. However, other scholars writing on public international law adopt a different hope for fragmentation. See also Gunther Teubner, ‘Global Bukowina: Legal Pluralism in the World Society’ in Gunther Teubner (ed), *Global Law Without a State* (Dartmouth, Aldershot 1997) 3.

peoples'²² by generating debate around questions of colonial history, power, identity, and the extent of the inclusion of Third World peoples in international law.²³ In doing this, it seeks to expose the messy and conflicting nature of international law – the power of international law to be both transformative as well as regressive.²⁴ This dialectical power tension has worked for or against the interests of Third World states as they seek to shape international rule-making processes.²⁵

TWAIL scholarship is far from uniform and has in no way followed a single line of enquiry.²⁶ The mission to question, unearth, and reform unites its smorgasbord of scholars who seek to reform or, where necessary, to retrench the rules of international law that are unjust to Third World people.²⁷ In so doing, they are unpacking the hypocrisies inherent in the international legal system, challenging its selective application, and offering crucial clues for its democratic reshaping.²⁸ As a result, TWAIL scholarship has included discussions on concepts of statehood,²⁹ international criminal law,³⁰ taxation,³¹ international criminal court,³² the role of social movement,³³ human rights,³⁴ the war on terror,³⁵ feminism,³⁶ international humanitarian law,³⁷

²² Chimni, 'TWAIL: A Manifesto' (n 19) 4.

²³ David Scott, *Refashioning Futures: Criticism after Postcoloniality* (Princeton University Press 1999) (*Refashioning Futures*); see also David Scott, *Conscripts of Modernity* (Duke University Press 2004) (*Conscripts of Modernity*).

²⁴ James Thuo Gathii, 'TWAIL: A Brief History of its Origins, its Decentralized Network, and a Tentative Bibliography' (2011) 26 *Trade, Law and Development* 37 ('TWAIL: A Brief History of its Origins').

²⁵ Antony Anghie and BS Chimni, 'Third World Approaches to International Law and Individual Responsibility in Internal Conflicts' (2003) 2 *Chinese Journal of International Law* 2 (1) 78; see also Antony Anghie, 'The Evolution of International Law: Colonial and Postcolonial Realities' (2006) 27 *Third World Quarterly* ('The Evolution of International Law').

²⁶ See Richard Falk, Balakrishnan Rajagopal and Jacqueline Stevens (eds), *International Law and the Third World: Reshaping Justice* (New York, Routledge 2008).

²⁷ Chimni, 'TWAIL: A Manifesto' (n 19) 468.

²⁸ Gathii, 'TWAIL: A Brief History of its Origins' (n 24) 37.

²⁹ Makau Muthua, 'Why Redraw the Map of Africa: A Moral and Legal Inquiry' (1995) 16 *Michigan Journal of International Law* ('Why Redraw the Map of Africa').

³⁰ Kiyani (n 8).

³¹ Jalia Kangave, '"Taxing" TWAIL: A Preliminary Inquiry into TWAIL's Application to the Taxation of Foreign Direct Investment' (2008) 10 *International Community Law Review* 389.

³² Parvathi Menon, 'Self-Referring to the International Criminal Court: A Continuation of War by Other Means' (2016) 109 *AJIL Unbound*.

³³ Balakrishnan Rajagopal, *International Law from Below: Development, Social Movements and Third World Resistance* (2003) (*International Law from Below*).

³⁴ Makau Muthua, 'Savages, Victims, and Saviors: The Metaphor of Human Rights' (2001) 42 *Harvard International Law Journal* ('Savages, Victims, and Saviors'); Balakrishnan Rajagopal, 'Counter-Hegemonic International Law: Rethinking Human Rights and Development as a Third World Strategy' (2006) 27 *Third World Quarterly* 971 ('Counter-Hegemonic International Law').

³⁵ Madhav Khosla, 'The TWAIL Discourse: The Emergence of a New Phase' (2007) 9 *International Community Law Review* 291.

³⁶ Vasuki Nesiah, 'The Ground Beneath her Feet: Third World Feminisms' (2003) 4 *Journal of International Women's Studies*; Mosope Fagbongbe, 'The Future of Women's Rights from a TWAIL Perspective' (2008) 10 *International Community Law Review* 401.

³⁷ Ntina Tzouvala, 'TWAIL and the "Unwilling or Unable" Doctrine, Continuities, and Ruptures' (2016) 109 *AJIL Unbound*.

urban law,³⁸ and Islamic contributions to the shared history of public international law,³⁹ to mention a few.

It is worth noting that the diversity found within TWAIL stems from certain distinct phases of scholarship, and each phase is characterised by a differing focus of TWAIL oppositions. The phases can be divided into TWAIL I, which focused on the decolonisation process and the role of powerful nations to use international law as a hegemonic force. Thus, the key feature of TWAIL I is the focus on statehood and the view that colonialism is a ‘system of totalizing degradation’⁴⁰ premised on a negative relationship between the coloniser and the colonised.⁴¹ This sentiment is echoed by Anghie and Chimni, who note that TWAIL I scholarship was closely aligned with the diplomatic initiatives undertaken by the newly independent Third World states who placed immense faith in the UN to cause the changes necessary to usher in a just world order.⁴²

TWAIL II, on the other, focuses on the roles and powers of international organisations in perpetuating Third World domination and marginalisation.⁴³ Thus, the distinct feature of TWAIL II lies in the examination of the global political economy by looking into the extent to which colonial relations shaped the fundamentals of international law.⁴⁴ The wide array of TWAIL scholarship on varying issues shows it has not only garnered a level of sophistication and complexity since its emergence in the decolonisation discourse, but it is also cognisant of contemporary concerns and contexts. This sophistication in its analyses of issues and recognition of contemporary context stems from an understanding of the manifold ways international economic relations are shaping Third World localities.⁴⁵ Nonetheless, in spite of this assortment of voices within, TWAIL scholarship remains committed to a

³⁸ Luis Eslava, *Local Space, Global Life* (2015) (*Local Space, Global Life*).

³⁹ Corri Zoli, ‘Islamic Contributions to International Humanitarian Law: Recalibrating TWAIL Approaches for Existing Contributions and Legacies’ (2016) 109 AJIL Unbound.

⁴⁰ Scott, *Conscripts of Modernity* (n 23) 95.

⁴¹ Edward Said, *Orientalism: Western Conceptions of the Orient* (1099th edn, 2003). Other binaries used to describe the dichotomy between the coloniser and the colonised which underpinned and legitimised the European colonising missions into Africa, Asia, Latin America, and the Caribbean include Civilised/Barbarian, Believer/Infidel, White/Black, or Advanced/Primitive. These binaries are still very much in use in politics today and are reflected in contemporary dualities such as Developed/Developing, Centre, or Core versus Periphery. See also Anghie, *Imperialism, Sovereignty and the Making of International Law* (n 1), who argues that the creation of the ‘other’ as uncivilised does not emerge from universal, but rather animates their formation.

⁴² Anghie and Chimni (n 25) 76.

⁴³ Khosla (n 35) 292.

⁴⁴ Anghie, *Imperialism, Sovereignty and the Making of International Law* (n 1) 81-84.

⁴⁵ Eslava, *Local Space, Global Life* (n 38) 7.

reading of international laws that historicises the ‘structure of modern colonial power’ as well as its reformation that incorporates the views and experiences of the often-ignored subaltern to recreate a just world order.⁴⁶

The TWAIL movement understands and recognises that international law privileges Europe and European knowledge and ideals.⁴⁷ It also recognises the trajectory of international law, from its colonial usage and how it was extended over time to the non-European world, which existed outside the realm of European international law,⁴⁸ as well as the exclusion of the rich body of doctrine and principle that originated from Third World legal systems in the larger body of international law.⁴⁹ Corri Zoli, for example, provides a persuasive argument regarding the role and contribution of Islam in the making of international law, especially the contributions of Islamic norms to international humanitarian law and the role of Muslim states in the early Geneva and Hague diplomatic conferences.⁵⁰ Thus, for TWAIL, dismantling the one-sided hegemonic Eurocentric narratives of international law involves teasing out encounters of difference along many axis – race, religion, class, gender, ethnicity, and economics, among others – and in interdisciplinary ways – social, theoretical, epistemological, and ontological.⁵¹

For this critical scholarship, historicising the relationship between the Third World and international law, and mapping the consequences of this relationship, is very crucial for two reasons. First, the Eurocentric story of international law is incomplete. To transform the present and future of international law from a state of subjection to emancipation, one should first understand the ‘problem-space’ in which the system occupies.⁵² Thus, an understanding that entails engaging in a reconstructed past and anti-colonial imagining to include often ignored experiences and forms of legal

⁴⁶ Gathii, ‘TWAIL: A Brief History of its Origins’ (n 24) 40.

⁴⁷ Ibiroko Odumosu, ‘Challenges for the (Present/) Future of Third World Approaches to International Law’ (2008) 10 International Community Law Review 468.

⁴⁸ Anglie, ‘The Evolution of International Law’ (n 25) 740.

⁴⁹ D Otto, ‘Subalternity and International Law: the Problems of Global Community and the Incommensurability of Difference’ (1996) 5 Social and Legal Studies 337; see also Obiora C Okafor, ‘Newness, Imperialism and International Legal Reform in Our Time: A TWAIL Perspective’ (2005) 43 Osgoode Hall Law Journal.

⁵⁰ Zoli (n 39); see also Upendra Baxi, ‘New Approaches to the History of International Law’ (2006) 19 Leiden Journal of International Law.

⁵¹ Gathii, ‘TWAIL: A Brief History of its Origins’ (n 24) 27-32.

⁵² The term ‘problem space’ is borrowed from David Scott who – though not a *twailian* – explains a problem-space to mean a language, an ensemble of questions and answers around which a horizon of identifiable stakes (conceptual as well as ideological-political stakes) hangs. In this respect, the context is not only the particular problems posed as such but also the particular questions that seem worth asking and the kind of answers that seem worth having. See Scott, *Conscripts of Modernity* (n 23) 4.

relations between autonomous communities is paramount.⁵³ An honest mapping of the origins and influences of the international legal system not only broadens one's perspective, but also has the potential to stimulate informed curiosity about the future of international law.⁵⁴

Second, a well-rounded re-interrogation and re-characterisation of the colonial past embedded in the international legal system is not only imperative but allows for the animation of its democratic emancipatory potentials.⁵⁵ This is especially pertinent as international law now plays roles that extend beyond adjudicating relations *between* states to *within* states. Overtime, international law has come to displace several national legal systems in their importance and is having an unprecedented effect on the lives of ordinary people.⁵⁶ For example, IPRs as encapsulated in the TRIPS Agreement can be seen as a direct regulation of property rights by international law or, in the words of Chimni, 'internationalization of property rights.'⁵⁷ That is, the specification, articulation, and enforcement of property rights through international law.⁵⁸ Therefore, the history of international law cannot be neglected at a time when it is slowly becoming domestic law manifesting itself in debates on health,⁵⁹ access to knowledge,⁶⁰ food security,⁶¹ environment,⁶² services,⁶³ and socio-economic development.⁶⁴ In essence, contemporary TWAIL scholars seek a 'kind of international legal scholarship that takes legal historiography seriously particularly in its relations between formerly colonial countries and their colonial overlord.'⁶⁵

It is this call for a historiographical engagement with international law that informs the chronological mapping of patent law in the countries under study in the coming

⁵³ JT Gathii, 'International Law and Eurocentricity' (1998) 9 *European Journal of International Law* 187 ('International Law and Eurocentricity'). See also Gerry J Simpson, *Great Powers and Outlaw States: Unequal Sovereigns in the International Legal Order* (2004).

⁵⁴ Anghie, *Imperialism, Sovereignty and the Making of International Law* (n 1).

⁵⁵ Sundhya Pahuja, *Decolonising International Law: Development, Economic Growth, and the Politics of Universality* (2011) (*Decolonising International Law*).

⁵⁶ Chimni, 'The Past, Present and Future of International Law' (n 16).

⁵⁷ Chimni, 'TWAIL: A Manifesto' (n 19) 8.

⁵⁸ *ibid.*

⁵⁹ The World Health Organization Framework Convention on Tobacco Control seeks to protect present and future generations from the devastating health, social, environmental, and economic consequences of tobacco consumption and exposure to tobacco smoke.

⁶⁰ WIPO Copyright Treaty; see also TRIPS Agreement.

⁶¹ The International Treaty on Plant Genetic Resources for Food and Agriculture is aimed at guaranteeing food security through conservation and sustainable use of plant varieties.

⁶² The UN Framework Convention on Climate Change, an agreement that attempts to reduce greenhouse emissions to combat global warming. See also the Kyoto Protocol.

⁶³ General Agreement on Trade in Services.

⁶⁴ Agreement on Subsidies and Countervailing Measures.

⁶⁵ Gathii, 'TWAIL: A Brief History of its Origins' (n 24) 40.

chapters. As will be seen, each chapter of the case study countries begins by genealogically tracing patent law in these countries. In doing so, it is then unsurprising to find that patent law was introduced in these countries via colonial conquests with negative implications. The reason for undertaking this historiographical exercise is to locate the particular kind of narrative which gave birth to patent discourse in these countries. This location helps in not only identifying what constitutes the conditions of possibility of the present, but provides a starting point from which to begin the process of revolutionary *re*-imagination and *re*-ordering. As will be seen, India presents a fitting example of where a post-colonial state engaged with and challenged the place of the past,⁶⁶ resulting in a re-imagined and re-ordered local patent regime reflective of its realities and need. Thus, in this instance, the past *became* the source of present obligations.⁶⁷

2.1.2 A Twailian Reading of the Global Patent Regime

Theorising the TRIPS Agreement and IP regime in general using TWAIL demonstrates that this critical scholarship is concerned about the effect of the inclusion of the Third World in the global IP framework. Particularly, *twailian* scholars are suspicious of how the provisions of the TRIPS Agreement have worked to further the hierarchy created by international law. In their view, the global IP regime is a post-colonial extension of the international legal framework that had legitimised colonialism. This is because the TRIPS Agreement is seen as a tool beyond the meaning of ‘international trade’ but is about the rights of foreigners and foreign enterprises and the derogation of national sovereignty to assure IP privileges and demands of the rich Global North while neglecting those of the poor Global South. In this sense, TWAIL benefits this research by using history to develop and map analytics of change occurring within international patent law.

TWAIL scholars show how current IP structures promoted under the veneer of ‘development paradigm’ and ‘technological transfer objectives’ enshrined in the

⁶⁶ The Ayyangar Committee Report, which will be discussed in detail in ch 4, laid the foundation of India’s patent regime. It is significant because it exhaustively engaged with the history and origins of patent law not only in India but in several other countries.

⁶⁷ Anne Orford, ‘The Past as Law or History? The Relevance of Imperialism for Modern International Law’ (2012) 2 Institute for International Law and Justice Working Papers 2.

TRIPS Agreement perpetuate North-South relations.⁶⁸ This is because the TRIPS Agreement is seen as an ideological project; ideological in the sense that it consists of a set of ‘*complexes of ideas* which tend to generate activities toward *maintenance of ideas of the existing order*.’⁶⁹ In this view, the complex ideas become the various components of IPR such as patents, trade secrets, geographical indications, industrial designs, copyrights, and layout designs, while the maintenance of ideas of the existing order becomes the universalization of the IP regime via its inclusion in bilateral, plurilateral, and investment agreements which lead to worldwide convergence on IP standards.⁷⁰ In this view, the concept of IPRs becomes an ideology coined to justify access to and control of Third World property rights, while the TRIPS Agreement *is* the legal conduit in which a particular idea of IP is restructured, protected, and operationalized.⁷¹

Reading the TRIPS Agreement with an unsuspecting eye would suggest a beneficial package or assistance to recipients mostly located in the South. However, the insidious aspect of the operationalization of this ‘ideology’ lies in its neutered language that masks the patterns of power inherent in the TRIPS Agreement. Commenting on this, Ngugi notes:

Whether the motive of the person is to maintain the existing order or to structure an impending change or evolution, the choice made is packaged as ‘universal’ and ‘scientific’ so that the claim that is applicable across board can be made. In other words, both discretion and indeterminacy is denied so as to mask the real motive of the person making the choice – which may be either to maintain an existing order that the person prefers or to change it in a particular direction. In other words, what enables the ideology to “reign” is the fact of manipulable interpretation as a result of indeterminacy. The complexes of ideas are “ideological” by denying or masking both the motive and the fact that the interpretation represents only a choice of interpretation.⁷²

In this sense, the ideological rendering of IP is the internationalisation of property rights where change in the form and substance of property rights is brought about through the intervention of international law.

⁶⁸ Chimni, ‘TWAIL: A Manifesto’ (n 19) 5.

⁶⁹ Joel M Ngugi, ‘The World Bank and the Ideology of Reform and Development in International Economic Development Discourse’ (2006) 14 *Cardozo Journal of International and Comparative Law* 12 (emphasis added).

⁷⁰ *ibid.*

⁷¹ *ibid* 10.

⁷² Ngugi (n 69) 13.

Further, the fact that the original ideas for a global patent protection framework historically came from the Global North, with minimal contributions from the Third World, also accentuates the *twailian* cynicism and scepticism.⁷³ In most cases, the transplant of IP laws to developing countries has been the outcome of empire building and colonisation. In fact, Okediji notes, Third World societies, principally in Africa and Asia, were swept under the aegis of the international IP system (under the Paris Convention) through the agency of colonial rule.⁷⁴ Under the Paris Convention framework, the modern global system was firmly secured and the Eurocentric notion and ‘definition’ of private property rights is regarded as the acceptable, legitimate, and relevant standard of protection. This legitimacy and relevance is then applied as ‘universal’ and extended to the Third World, thereby ignoring the inappropriateness of the TRIPS-specific notion of private property in those parts.

For many TWAIL scholars, the universalization of IP rules parallels the European colonial expansion and foregrounds a fundamental issue: the imposition on different contexts and realities of Eurocentric ‘ideals.’⁷⁵ It was during the colonial period in which the Western ways of life – religion, legal culture, neoliberal governance systems, and civilisation – were foisted on the colonies.⁷⁶ This is especially true in the realm of patent law as will be seen in the coming chapters.⁷⁷ The colonies were exposed to Western cultural-intellectual values, especially legal rules, which were represented as universally valid regardless of fit and relevance to local realities, and in so doing, denied, erased, or suppressed non-European subjectivity.

Of course, for some TWAIL scholars, the decolonisation processes of the 1950s and 1960s represented a ‘historical rupture’ that allowed the colonised to gain ‘freedom’

⁷³ Peter Drahos, ‘Developing Countries and International Intellectual Property Standard-Setting’ (2002) 5 *The Journal of World Intellectual Property* (‘Developing Countries and International Intellectual Property Standard-Setting’); Ruth L. Okediji, ‘The International Relations of Intellectual Property: Narratives of Developing Country Participation in the Global Intellectual Property System’ (2003) 7 *Singapore Journal of International and Comparative Law* (‘The International Relations of Intellectual Property’); Peter K Yu, ‘A Tale of Two Development Agendas’ (2009) 35 *Ohio Northern University Law Review*; Peris Jones, ‘When “Development” Devastates: Donor Discourses, Access to HIV/AIDS Treatment in Africa and Rethinking the Landscape of Development’ (2004) 25 *Third World Quarterly* 387.

⁷⁴ Okediji, ‘The International Relations of Intellectual Property’ (n 73).

⁷⁵ Martti Koskenniemi, ‘Histories of International Law: Dealing with Eurocentrism’ (Inaugural lecture delivered on 16 November 2011 on the occasion of accepting the Treaty of Utrecht Chair at Utrecht University, Utrecht University 2011) (‘Histories of International Law’).

⁷⁶ Makau Muthua, ‘What is TWAIL?’ (2000) *The American Society of International Law Proceedings* 35 (‘What is TWAIL?’); Koskenniemi, ‘Histories of International Law’ (n 75).

⁷⁷ See ch 3, 4, and 5 on Brazil, India, and Nigeria respectively.

from the hold of colonial politics and exploitation.⁷⁸ However, less obvious is the continued influence of colonialism even in the post-colonial. This is because, as Gathii notes, decolonisation did not imply complete self-determination, as even the process of decolonisation occurred within the Eurocentric notion of statehood – a concept on which the very regime of international law is built upon.⁷⁹ He further asserts that this Eurocentric idea of ‘statehood’ ignored the pre-colonial African concept of statehood that was based on the kingdoms.⁸⁰ Even upon independence, former colonies had no choice but to be ‘states’ in the Western tradition and thereby part of the existing international system. Today, international law’s key concepts such as ‘development’, ‘political economy’, ‘sovereignty’, and ‘nationhood’, which were formed in the imperial project, are continually reiterated and redeployed in the contexts and languages of contemporary legal and investment agreements.⁸¹ Indeed, international law in the 21st century has found its way home in a universal teleology of progressive humanitarianism⁸² and reflects the continuity of colonial law in the post-colonial. Put differently, key concepts developed and used to perpetuate colonial expansion have been assimilated in international state relations that decolonisation could not dismantle them.

Also, the fact that many of today’s advanced economies did not allow patents on chemical and pharmaceutical substances afforded them the opportunity to develop their technological process via imitation or otherwise. For example, chemical substances remained un-patentable until 1967 in West Germany, 1968 in the Nordic countries, 1976 in Japan, 1978 in Switzerland, and 1992 in Spain.⁸³ Pharmaceutical products remained un-patentable until 1967 in West Germany and France, 1979 in Italy, and 1992 in Spain,⁸⁴ while pharmaceutical products were also un-patentable in Canada into the 1990s.⁸⁵ This transplanting of Western legal regimes on countries in the Global South not only robbed them of opportunities which Western countries had,

⁷⁸ Balakrishnan Rajagopal, *International Law from Below* (n 33) 25-26.

⁷⁹ JT Gathii, *International Law and Eurocentricity* (n 53) 189; see also James Thuo Gathii and Brad R Roth, ‘Neoliberalism, Colonialism and International Governance: Decentering the International Law of Governmental Legitimacy’ (2000) 98 *Michigan Law Review* 1996, 2040-43.

⁸⁰ *ibid* 2043.

⁸¹ Gathii, *International Law and Eurocentricity* (n 53) 189; Gathii and Roth (n 79) 2041.

⁸² Koskeniemi, ‘Histories of International Law’ (n 75).

⁸³ Surendra J Patel, ‘Intellectual Property Rights in the Uruguay Round: A Disaster for the South?’ (1989) 24 *Economic and Political Weekly* 980.

⁸⁴ *ibid*.

⁸⁵ *ibid*.

but also hampered access to the information, knowledge, and technology needed for competitiveness, internal growth, and development.

The implication of this ‘universalization’ of IPR rules outside the West is important in many respects. First, as part of the WTO ‘single undertaking’, many countries that did not have a codified IP system accepted and harmonised a West-constructed IP regime. This harmonisation alters the local self-understanding by excluding and/or disrupting the rich body of legal doctrine and principle already in existence in the Third World. For example, many Third World countries have an IP system that supports openness, communal access, and custodianship in areas such as folklore, biodiversity, and indigenous prints and signs.⁸⁶ The IPR regime that the TRIPS Agreement advocates alters this crucial aspect of Third World culture by not only insisting on limited monopoly and secrecy via the institutionalisation of a system of corporate property rights, but also reduced the ability of Third World states to make autonomous policy choices regarding appropriate levels of IP.⁸⁷ These attempts to fit non-Western cultural forms into Western legal regimes in turn distort, disfigure, and destroy particular material context with material consequences.

Second – and this builds from the previous point – the nature and language of the ‘universalization’ process found in many international economic governance regimes obfuscates the real causes of poverty and underdevelopment. For example, many Third World countries argue that the IPR regime impairs development by not only failing to give them access to knowledge but also failing to protect *their* IP, especially in the area of traditional medicines.⁸⁸ Commenting on this, Dosi and Stiglitz note that the US has, on one hand, granted patents for traditional knowledge, which many countries in the Global South assert should not be patentable.⁸⁹ This protection therefore necessitates these countries paying large rents to Western firms for what they view as their *own* property.⁹⁰ The neem tree case provides a pertinent example.⁹¹

⁸⁶ Boatema Boateng, *The Copyright Thing Doesn't Work Here* (University of Minnesota Press 2011) 15-20.

⁸⁷ *ibid.*

⁸⁸ Giovanni Dosi and Joseph E Stiglitz, ‘The Role of Intellectual Property in the Development Process, with Some Lessons from Developed Countries: An Introduction’ in Mario Cimoli and others (ed) *Intellectual Property Rights: Legal and Economic Challenges for Development* (2014) 2.

⁸⁹ *ibid.*

⁹⁰ *ibid.*

⁹¹ The neem tree is native to India and the Indian subcontinent including Nepal, Pakistan, Bangladesh, and Sri Lanka. The neem tree possesses medicinal properties, especially its seed, which contains the chemical compound azadirachtin used in treating illnesses ranging from diabetes to ulcers. In 1985, a US trader sold the patents to a multinational chemical company. Since 1985, over a dozen US patents have been taken out by US and Japanese firms on formulae for stable neem-based solutions and emulsions and even for a neem-based toothpaste. At least

On the other, the US has not ratified the Convention on Biological Diversity due to pressure from pharmaceutical companies that fear it would provide ‘excessive’ protection for the IPRs for plants and animals found in the Third World.⁹² This is because many of the materials used in pharmaceutical manufacturing are derived from plants or animals in developing countries. Evidently, while companies should be rewarded for ‘discovery’, countries should not be punished for protecting their biodiversity – without which the discovery would not have been possible. This inconsistency leads to an asymmetric redistribution of property rights between the First and the Third Worlds. This redistribution generates widespread debt and poverty, and because it is not as explicit as, say, debt repayments, it disguises the real instances where IEG structures instigate poverty and ‘underdevelopment.’⁹³ This reveals, according to Dosi and Stiglitz, the double standards of the US in that it seeks an IPR regime that maximises the rents for its companies and minimises the rents that its companies might pay to others.⁹⁴

For TWAIL scholars, the TRIPS negotiations represent the globalisation of US-engineered IP rules and the forced inclusion of the subaltern into this US-led IP expansionism.⁹⁵ It is this narrative that problematizes the TRIPS Agreement and the global governance of IP for TWAIL. The reality of the Uruguay Round is that the negotiations were dominated by the US, European Union (EU), Canada, and Japan (known as the Quad).⁹⁶ This is in addition to instances of reluctance of many Third World countries to sign on to an international agreement with an IP strand.⁹⁷ For example, the Indian delegate pointed out the country’s concern regarding the IP component of the negotiations, particularly in the area of patents and the scope of

four of these are owned by WR Grace, three by another US company, the Native Plant Institute, and two by the Japanese Terumo Corporation. Civil society groups headed by Vandana Shiva brought the case of the neem tree patent to the European Patent Office, arguing that the grant of patent is akin to bio-piracy. On 10 May 2000, at the end of a five-year legal battle, the European Patent Office revoked the patent on the grounds that the process patented by the Americans lacked novelty. See Vandana Shiva, ‘The Neem Tree - A Case History of Biopiracy’ (*Third World Network* 2002) <<http://www.twn.my/title/pir-ch.htm>> accessed 28 May 2016.

⁹² Dosi and Stiglitz (n 88) 2.

⁹³ Ngugi (n 69).

⁹⁴ Dosi and Stiglitz (n 88) 4.

⁹⁵ Susan Sell and Christopher May, ‘Moments in Law: Contestation and Settlement in the History of Intellectual Property’ (2001) 8(3) *Review of International Political Economy* 468.

⁹⁶ Chakravarthi Raghavan, *Recolonization: General Agreement on Tariffs and Trade, the Uruguay Round and the Third World* (Third World Network 1990) 61; see also Peter Drahos, ‘Global Intellectual Property Rights in Information: The Story of TRIPS at the GATT’ (1995) 13 *Prometheus* (‘The Story of TRIPS at the GATT’); Sell and May (n 95).

⁹⁷ Drahos, ‘The Story of TRIPS at the GATT’ (n 96) 9.

patentability.⁹⁸ In a similar vein, the Brazilian contestation was on the ground that the inclusion of IP would negatively affect the country's technological transfer and industrialisation goals.⁹⁹ Meanwhile, the Nigerian delegate commented on the unsuitability of IP inclusion and the possible negative impact on Third World economies.¹⁰⁰ These examples demonstrate the *twailian* argument of unfair and unequal political structure, characterised by the dominance of the Global North over the Global South.

Added to this is the aggressive unilateralism of the US via threat of Section 301 and loss of market access, which proved effective in forcing many developing countries to accept the unfavourable terms of the TRIPS Agreement, especially in the area of pharmaceutical patents (Articles 27 to 31). The US Section 301 is a trade policy used by the US to initiate unilateral trade sanctions against countries it deems to not have sufficient IPR protection.¹⁰¹ Consequently, Section 301 allows the US to withdraw trade benefits or impose duties on goods from foreign countries with IP laws deemed insufficient by the US or countries that refused to amend their IP laws to reflect the US' domestic legal standards. According to Drahos, the US' use of Section 301 contributed to its insertion of IP matters into the GATT talks.¹⁰²

Thus, for TWAIL, the pressure exerted upon the Global South during the Uruguay Round to adopt legal rules fashioned by powerful states is intimately linked to 'the pressure exerted upon peripheral states during the nineteenth century to introduce reforms that would render them "civilised" and, hence, equal to Western state.'¹⁰³ Hence, TWAIL scholars are convinced that the TRIPS Agreement is a continuation and a renewal of colonial order in the post-colonial, and curbs the right of governments to intervene in the economy for the benefit of their people while expanding the 'space' for MNCs and governments of the Global North.¹⁰⁴

⁹⁸ Statement by Dr Subramanian Swamy, Union Minister of Commerce, Law and Justice, 'Multilateral Trade Negotiation: Ministerial Level Meeting in Brussels' (1990) MTN/TNC/MIN (90)/ST/46. See ch 4 on India for more details.

⁹⁹ Piragibe dos Santos Tarragô, 'Negotiating for Brazil', *The Making of the TRIPS Agreement: Personal Insights from the Uruguay Round Negotiations* (1st edn, World Trade Organisation 2015). See ch 3 on Brazil for more details.

¹⁰⁰ Senas J Ukanah, 'Statement at the Ministerial Level Meeting in Brussels' (1990) MTN.TNC/MIN (90)/ST/34 (1990). See ch 5 on Nigeria for more details.

¹⁰¹ Raghavan (n 96) 83-85.

¹⁰² Drahos, 'The Story of TRIPS at the GATT' (n 96) 11.

¹⁰³ Tzouvala (n 37) 3.

¹⁰⁴ Raghavan (n 96) 40.

Nonetheless, there are limits to these *twailian* anxieties. By solely focusing on the dialectics of North versus South and associated histories, TWAIL ignores the capability and psychology of states to determine and pursue actions for self-interest purposes. This is especially true if calculations of benefits seemingly outweigh the risk involved in engaging in IEG. For example, in analysing the politics and psychology of modern investment agreements, Lauge Poulsen finds that governments in developing countries typically overestimate the economic benefits of international agreements and practically ignore the risks.¹⁰⁵ Specifically, he notes that not only did developing countries' policymakers rely on inferential shortcuts when assessing the implications of agreements, such as those on access to Western markets, many saw them as little more than diplomatic tokens of goodwill which would be important signals for foreign investors but entailed no real liabilities or legal significance.¹⁰⁶ He cited an interview with a Ghanaian diplomat who mentioned that his country signed a bilateral trade agreement 'to push forward reform, keep politicians on their toes, to tell politicians to refrain from doing things, and to assure foreign investors.'¹⁰⁷ At the end of the day, as long as a reasonable case can be made that the treaty will provide economic or political benefits, many Third World countries will sign on to agreements even without the influence of more powerful countries.

Also closely related to the above point is the critical preference theory as put forward by Olu Fasan.¹⁰⁸ According to Fasan, *ex ante* preference plays a role in why countries sign up and voluntarily consent to international agreements, as opposed to being coerced into consenting.¹⁰⁹ Thus, a country is willing and open to engage with international legal rules if the rules reflect its economic and political preference(s). Citing South Africa as an example, Fasan notes that the country was broadly supportive of most of the Uruguay Round negotiations, including those on the TRIPS Agreement because the country saw TRIPS as 'a mechanism to lock in its unilateral domestic reforms that began in the early 1980s.'¹¹⁰ This is interesting as South Africa is currently not only a TRIPS opponent but is a counter-hegemonic actor in the

¹⁰⁵ See generally Lauge Poulsen, 'Bounded Rationality and the Diffusion of Modern Investment Treaties' (2013) 58 *International Studies Quarterly* 1-14.

¹⁰⁶ *ibid.*

¹⁰⁷ *ibid.* 3.

¹⁰⁸ Olu Fasan, 'Commitment and Compliance in International Law: A Study of the Implementation of the WTO TRIPS Agreement in Nigeria and South Africa' (2012) 20 *African Journal of International and Comparative Law* 191, 193.

¹⁰⁹ *ibid.*

¹¹⁰ *ibid.*

implementation of its TRIPS obligation. For example, South Africa was one of the first African countries to use the public health safeguards in the TRIPS Agreement to respond to the HIV/AIDS crisis when the South African government introduced the Medicines and Related Substances Act Amendment of 1997,¹¹¹ aimed at designing a new drug policy and making more affordable HIV/AIDS medicines available to the masses.¹¹²

Of course, many factors can be attributed to the switch in the behaviour and psychology of South Africa. First, the country's participation at the Uruguay Round was by the then apartheid government that was actively involved in maintaining the colonial order. Secondly, the devastation caused by HIV/AIDS and the corollary tuberculosis demanded a change in the South Africa-TRIPS relationship.¹¹³ Particularly, it was the damage caused by HIV/AIDS-related deaths in South Africa that triggered the worldwide campaign and conversation about the impact of the TRIPS Agreement on medicine access.¹¹⁴ Nonetheless, Fasan provides a potent argument on the psychology of state engagement with international law – a context lacking in TWAIL discourse. This is because most *twillian* analyses tend to ignore domestic policy preference and priorities, which appear to have more significant roles in influencing the behaviour and engagement of states with international economic governance.

One of TWAIL's core criticisms is that the very inclusion of areas traditionally thought to be beyond the ambit of trade is akin to the re-colonisation of the Global South by Western international institutions.¹¹⁵ Pertinent in this narrative is the argument that the overall legal and institutional rules of WTO are in essence a process of freeing transnational capital from spatial and temporal constraints and obligations through an effective system of cross-retaliation.¹¹⁶ Correspondingly, this sentiment reinforces the argument that the GATT/WTO rules are designed to serve mercantilist

¹¹¹ The Medicines and Related Substances Control Act as revised by the Medicines Amendment Act No 90 of 1997 can be found at <<http://www.info.gov.za/view/DownloadFileAction?id=70836>> accessed 7 August 2015.

¹¹² *ibid.*

¹¹³ Tshimanga Kongolo, 'Public Interest versus the Pharmaceutical Industry's Monopoly in South Africa' (2001) 4 *The Journal of World Intellectual Property* 611.

¹¹⁴ Médecins Sans Frontières, 'The Impact of Patents on Access to Medicines' (1997) <<http://www.msfaccess.org/content/impact-patents-access-medicines?>> accessed 28 February 2013.

¹¹⁵ BS Chimni, 'Political Economy of the Uruguay Round of Negotiations: A Perspective' (1992) 29 *International Studies* 135, 136 ('Political Economy of the Uruguay Round of Negotiations'). See also Raghavan (n 96).

¹¹⁶ Chimni, 'Political Economy of the Uruguay Round of Negotiations' (n 115) 147.

purposes that sustain the linkage between colonialism and international trade rules.¹¹⁷ By virtue of this, IEG regimes and corresponding institutions represent the coloniser while ostensibly claiming the virtues of neutrality, objectivity, and working towards the development of the Third World.¹¹⁸

Another associated insight of this critical scholarship is the perceived hypocrisy and double standard apparent not only within the TRIPS Agreement but in the politico-economic pressure that bear on Third World countries in the way they interpret their TRIPS obligations locally.¹¹⁹ Many scholars note that many prominent economic powers allowed the IP sector within their various countries to flourish by having weak IP laws.¹²⁰ It was only when these countries began to achieve technological breakthroughs that their preference for weak IP laws changed.¹²¹ Moreover, the calls to make IP protection global became stronger and more urgent with the rise of the emerging economies in Asia. Sell and May observe that it was only when owners and manufacturers of innovations saw the considerable advantages in IP monopolistic potentials that states increased support for stronger international protection.¹²² Therefore, the TRIPS Agreement was drafted and ratified to maintain the interests of Western powers, particularly the US. For this reason, the TWAIL movement believes that the global IP regime of protection and enforcement is a Western construct created to gain competitive advantage over emerging rival manufacturing centres in newly developing economies of the developing world.¹²³ As expounded by Sell and May, 'IP [is] an instrument of power and, once captured, the basis of further accumulation of power.'¹²⁴

¹¹⁷ See generally Surendra Raj Bhandari, 'From the Era of Colonialism to Globalization: Making Rules in the GATT/WTO' in Jin-Hyun Paik, Seok-Woo Lee and Kevin YL Tan (eds), *Asian Approaches to International Law and the Legacy of Colonialism: The Law of the Sea, Territorial Disputes and International Dispute Settlement* (1st edn, 2013).

¹¹⁸ Anghie, *Imperialism, Sovereignty and the Making of International Law* (n 1) 140.

¹¹⁹ Ha-Joon Chang, 'Kicking Away the Ladder: The "Real" History of Free Trade – FPIF' (*Foreign Policy in Focus*, 2003) <http://fpif.org/kicking_away_the_ladder_the_real_history_of_free_trade/> accessed 4 June 2013; Dosi and Stiglitz (n 88); see also Sell and May (n 95).

¹²⁰ Chang (n 119); see also Srividhya Ragavan, *Patent and Trade Disparities in Developing Countries* (2012) (*Patent and Trade Disparities in Developing Countries*); Srividhya Ragavan, 'Of the Inequals of Uruguay Rounds' (2006) 10 *Marquette Intellectual Property Law Review* ('Of the Inequals').

¹²¹ Chimni, 'Political Economy of the Uruguay Round of Negotiations' (n 115).

¹²² Sell and May (n 95) 486.

¹²³ Ruth L Okediji, 'Back to Bilateralism? Pendulum Swings in International Intellectual Property Protection' (2004) 1 *University of Ottawa Law and Technology Journal* 128 ('Back to Bilateralism').

¹²⁴ Sell and May (n 95) 468.

Other scholars note the coercion exerted by the US under its Trade Act of 1974 on countries whose IP laws are deemed to be unfriendly to US interests.¹²⁵ The Special 301 Report, prepared annually by the Office of the US Trade Representative (USTR), classifies specific countries based on the appropriateness of their IP laws vis-à-vis the US standard.¹²⁶ Countries found to have insufficient laws are put on the ‘priority watch list’ and are possible targets of US trade and investment sanctions. Since its existence, key Third World countries such as Brazil, Argentina, South Africa, and India have featured on the list.¹²⁷ India, for instance, has featured on this list since 1974 because of its Patent Act of 1970 and recently because of its Section 3(d).¹²⁸ Trade sanctions were initiated against Brazil over its informatics policy in 1985.¹²⁹ By placing countries on the Special 301 Report, the US creates pressure on these countries to increase IP protection beyond the TRIPS Agreement.

For TWAIL scholars, this unilateral and retaliatory measure by the US is reminiscent of the racism and cultural superiority that accompanied colonial conquests.¹³⁰ Importantly, it demonstrates the way powerful countries continue to deny the agency and legal innovations of non-Europeans, through a totalising discourse such as ‘best IPR practices’¹³¹ that seeks not only the total economic, political, and social transformation of ‘the other’ but also ignores the insights or advancement of ‘the other’. In most instances, the ‘best practices’ are ill-fitted to their domestic needs.

2.1.3 Limitations of TWAIL

Notwithstanding TWAIL’s utility as a relevant critical scholarship for unpacking the idiosyncrasies of modern international law and associated governance regimes, some structural shortcomings do remain. In fact, the empirical work that forms the core of this thesis sheds valuable light on the way things actually work on the ground and underscores even more of TWAIL’s limitations.

¹²⁵ Raghavan (n 96) 83-85. See generally Office of the United States Trade Representative, ‘The Special 301 Report’ (2016) <<https://ustr.gov/sites/default/files/USTR-2016-Special-301-Report.pdf>> accessed 29 April 2016 (‘Special 301 Report’).

¹²⁶ *ibid.*

¹²⁷ Raghavan (n 96) 84; Chimni, ‘Political Economy of the Uruguay Round of Negotiations’ (n 115) 143.

¹²⁸ *ibid* 83-84.

¹²⁹ *ibid.*

¹³⁰ Muthua, ‘Why Redraw the Map of Africa’ (n 29) 1127.

¹³¹ ‘Best IPR practices’ is the term used by the Report to applaud several countries seen by the US as acceptable to its interests. See generally The Special 301 Report (n 126).

TWAIL's dominant focus on unequal international legal structures and critique of colonial manifestation blinds it to the way Third World states 'play' the game of international law.¹³² Like Western states, many Third World states have become complicit in exploiting and playing the game of international law at the expense of both their citizens and IEG regimes. For example, Shalini Randeria has shown how certain Third World states, usually seen as weak against the forces of globalisation and international law, transpose the processes of globalisation into the national arena by capitalising on their perceived weakness.¹³³ The state is not merely a victim of neo-liberal economic structures and the constituting international legal framework but *is* an active participant, manoeuvring it nationally and locally. Thus, in playing this 'cunning' politics, they render themselves unaccountable both to their citizens and to international institutions.¹³⁴

In a similar vein, Parvathi Menon has shown how African states use international law and institutions to legitimise their actions and de-legitimise internal political 'others' (political opposition and rebel groups, in particular).¹³⁵ By employing the rhetoric of international humanitarian law, these states elevate internal issues to the status of 'international crisis', thereby opening up such issues to investigation and/or prosecution by the Office of the Prosecutor of the International Criminal Court.¹³⁶ Thus, these states do not only exploit international criminal law for their own political games, the law itself provides a legal cover for such exploitation.¹³⁷

The point here is this: the engagement of the Third World in the doctrinal and institutional terrains of international law is not one-sided. International law, as with all types of law, is a double-edged reality that can be advantageous to both the weak and the strong. However, by lacking awareness in the intelligent ways countries of the Global South 'play' the system, TWAIL scholarship not only denies them agency but also problematizes them in a way that resituates their engagement without contemporary resonance. Thus, the failure of TWAIL to recognise this substantive engagement with international law impinges on its self-proclamations as a

¹³² Menon (n 32).

¹³³ Shalini Randeria, 'Cunning States and Unaccountable International Institutions: Legal Plurality, Social Movements and Rights of Local Communities to Common Property Resources' (2003) 44 *European Journal of Sociology* 27.

¹³⁴ *ibid* 28.

¹³⁵ Menon (n 32).

¹³⁶ *ibid* 260.

¹³⁷ *ibid* 261.

‘transformative theory.’¹³⁸ In other words, Third World states are not merely passive objects in international law. By focusing on the historic exploitation and ‘othering’ of the Third World, TWAIL ignores the way seemingly powerless Third World countries exploit, to their benefit, the structural biases within international law. And in this exploitation, they repeat characteristics previously attributed to Western states.

Others have questioned TWAIL’s excessive focus on international law shortcomings. Rémi Bachand, for example, contends that the TWAIL discourse is incomplete and exhibits a number of gaps, which should be overcome to elevate TWAIL from a solely critical theory to a problem-solving one.¹³⁹ Jayan Nayer also questions TWAIL’s quest for renewal of international law, especially as such renewals have since dissipated.¹⁴⁰ He asserts that while it is understandable that TWAIL scholars strive to renew the vestiges of Third World ideological resistance in the early periods of post-independence international legal scholarship, ‘the experience of the past and the reasons for previous failures to realise the substantive transformation of international law impinges constantly on present imaginings, thus making the continued reliance on international law for the transformatory project less understandable.’¹⁴¹

However, Sundhuya Pahuja rejects the criticisms and instead notes the relevance of current TWAIL scholarship as a strategic engagement – an ambitious act of re-description – with international law in a way that rejects the violently transformative urge of the logic within which it is embedded.¹⁴² According to her, by adopting a neutered and totalising discourse such as ‘human rights’ and ‘development’, these concepts manage to locate themselves outside the realm of historical contingency and political decisions and are thus not open to questions and critique.¹⁴³ Thus, by delving into these concepts, TWAIL not only exposes the progressive narratives that usually accompany these descriptions to scepticism but reveals the power dynamics that render each of these of dubious benefit to ‘the wretched of the earth.’¹⁴⁴

¹³⁸ TWAIL vision statement.

¹³⁹ See Rémi Bachand, *Critical Approaches and the Third World: Towards a Global and Radical Critique of International Law* (1st edn) <<https://www.mcgill.ca/files/legal-theory-workshop/Bachand-3rd-world-critical-approaches.pdf>> accessed 15 April 2013.

¹⁴⁰ Nayer (n 7).

¹⁴¹ *ibid* 338.

¹⁴² Pahuja, *Decolonising International Law* (n 55) 41.

¹⁴³ *ibid* 38.

¹⁴⁴ José E. Alvarez, ‘Revisiting TWAIL in Paris’ (*Opinio Juris*, 2010) <<http://opiniojuris.org/2010/09/28/my-summer-vacation-part-iii-revisiting-twail-in-paris/>> accessed 15 September 2015.

Furthermore, Luis Eslava and Sundhuya Pahuja reject the nihilistic critique by noting the various forms of resistance and reform occurring daily as a material project.¹⁴⁵ They contend that TWAIL ‘expands its emphasis on materiality to think of international law as not only an ideological project located in a particular material context, and with material consequences but also as material project itself.’¹⁴⁶ It is therefore important to examine the way that international law operates, including its daily functioning on the mundane quotidian level.¹⁴⁷ Thus, the various forms of resistance and reform occurring daily at sub-national levels – spaces not normally associated with international law making but ‘are in themselves part of the political economy, of international law’¹⁴⁸ are recognised. To this end, Eslava and Pahuja suggest that TWAIL delves into the everyday life of international law at domestic spaces that are not ostensibly international but in actuality are such, i.e. local governments, courts, and other grassroots engagements. In so doing, this thesis shifts the focus away from international law as the only and legitimate site of reconstruction, as international law has the ‘tendency to draw our gaze to exceptional events and sites, often leaving aside what they consider ordinary or every day.’¹⁴⁹

Therefore, focusing on international law in this way serves to create technologies of *en-framing*, wherein international law acts as a ‘mechanism[...] through which the world is viewed, apprehended and constructed, according to parameters that are superimposed upon our surrounding realities.’¹⁵⁰ Consequently, understanding international law only in these terms – as an ideological project located in a particular material context and removed from local realities – only confirms its authority ‘to enframe certain events as superior and extraordinary, and therefore in need of international attention, while enframing many other events as daily, domestic, or lower level occurrences.’¹⁵¹

As a result, they argue for a different mode of approaching international law that focuses on its everyday operations in and through national and local norms,

¹⁴⁵ Eslava and Pahuja, ‘Between Resistance and Reform’ (n 3) 118.

¹⁴⁶ *ibid* 108-09 (emphasis added).

¹⁴⁷ *ibid* 103.

¹⁴⁸ Eslava and Pahuja, ‘Beyond the (Post)Colonial’ (n 3) 27.

¹⁴⁹ Luis Eslava, ‘Istanbul Vignettes: Observing the Everyday Operation of International Law’ (2014) 2 *London Review of International Law* 3 (‘Istanbul Vignettes’).

¹⁵⁰ *ibid*.

¹⁵¹ *ibid* 4.

administrative and spatial practices, and ordinary artefacts.¹⁵² That is, a mode of understanding international law in places that usually escape attention and yet regulate lives – the local forums, spaces, or jurisdictions.¹⁵³ This is because the language and tools of international law are felt in the daily lives of people. The spatial divide that previously existed between activities of nation-states in international forums and in the lives of ordinary people in local forums is increasingly getting blurred. In these blurred spaces, mass peoples' movements across the world are employing the language of human rights, or in the case of this research, the 'right to health' and 'access to medicines', to voice their dissatisfaction against the post-colonial state, international institutions, and MNCs, as will be seen in Chapters 3 and 4.

Moreover, local municipalities and courts are also playing insurgent roles. They do this by calibrating their geographical realities 'to ensure the inflow of international investment or compliance with an increasingly large set of development prescriptions.'¹⁵⁴ Patent application oppositions and radical legal actions against Third World states and pharmaceutical corporations in India and Brazil demonstrate this.¹⁵⁵ Thus, focusing on the everyday interpretation and application of international in these local spaces makes it possible 'to delineate the (post)colonial character of international law, and to work actively toward a meaningfully plural international normative order.'¹⁵⁶ Evaluating these multiple ways in which international law is crossing spatial divides and scales of governance shows that 'international law cannot be conceptualised today simply in terms of a restricted body of norms, or situated only in bureaucratic and institutional environments beyond daily life.'¹⁵⁷ Thus, in redirecting focus, it is easier to see the myriad ways the international unfolds in people's everyday lives and in domestic phenomena, which is not ostensibly international but in actuality is. This, according to Eslava and Pahuja, may be understood hermeneutically as expressions of resistance against and reform of colonialism within international law.¹⁵⁸

¹⁵² Eslava and Pahuja, 'Beyond the (Post)Colonial' (n 3) 28.

¹⁵³ *ibid.*

¹⁵⁴ Eslava, 'Istanbul Vignettes' (n 149) 27.

¹⁵⁵ Ch 3 and 4 on Brazil and India respectively, noting the participation of civil society groups in patent law making.

¹⁵⁶ Eslava, 'Istanbul Vignettes' (n 149) 25.

¹⁵⁷ *ibid.*

¹⁵⁸ Eslava and Pahuja, 'Beyond the (Post)Colonial' (n 3) 30.

2.1.4 Application of TWAIL to the Thesis

Having delved into TWAIL – understanding what it is about, its readings of global patent regime, and its weaknesses – the thesis now turns to explain how TWAIL is applicable in this instance. TWAIL is integrated in this thesis in two distinct ways.

First, it provides the historical lens to analyse and recognise the engagement of colonial patent laws in Brazil, India, and Nigeria. In this perspective, the imposition of colonial patent laws is seen as what it is – imperial conquest reflective of the needs of the European powers and devoid of any significant benefit for these countries.¹⁵⁹ This dynamic is further reproduced via the TRIPS system, which has created a new patent law universality and implementation despite principle objections of Third World countries to the inclusion of IP in the remit of international trade.¹⁶⁰ ‘Universality’ means that the TRIPS Agreement has not only established a uniform global IP regime and norms, but it also brought under international surveillance its implementation and enforcement. In juxtaposing these, TWAIL provides this thesis – and even the study of patent law in the Global South – with a new analytical framework that illuminates the ways in which imperialism has always underpinned patent law regime. Thus, engaging in a historiographic analysis of patent law as suggested by TWAIL is a start to seeing how, through the process of imperialism, non-European states were incorporated into a system of law that was essentially European.¹⁶¹

Second, TWAIL provides the analytical framework to understand the contestation of international law at the local forums of the Global South as part of the global project of reforming international law. As Eslava and Pahuja rightly note, the on-going resistance and contestation of international law at the local levels, especially in the Global South, are often overlooked as part of international law making. This is because international law and practices are usually understood to operate only in extraordinary places and through exceptional events. As a result, Third World engagement is seen as peripheral to the making of international law. It is in taking up Pahuja and Eslava’s call to delve beyond the international and recognise the various forms of resistance and reform occurring daily, especially in the Global South, that

¹⁵⁹ Anghie, *Imperialism, Sovereignty and the Making of International Law* (n 1) 71.

¹⁶⁰ Chimni, ‘Political Economy of the Uruguay Round of Negotiations’ (n 115).

¹⁶¹ Antony Angie, ‘LATCRIT and TWAIL’ (2011) 42 *California Western International Law Journal* 316.

TWAIL structures the thesis' analyses of pharmaceutical patent regime law making in the local forums of Brazil and India – and by extension, its absence in Nigeria.

In this perspective, local realities such as the inclusion of Section 3(d) in India's patent law, Brazil's *Agência Nacional de Vigilância Sanitária* (ANVISA) prior consent mechanism, right to health litigation, and even the use of CLs to ensure medicine access is then understood as part and parcel of the international legal order. These successful domestic interventions are inadvertently changing the global IP regime by widening the aperture on norms governing pharmaceutical patent laws and the discourse on access to essential medicines. Viewed in this light, the gradual and subtle reform of international legal regimes and norms as suggested by TWAIL is beginning to be seen in real examples, but it also imbues the 'ethos of "the international"' in norms, administrative process, spatial arrangements, artefacts of governance, and forms of subjectivity often considered in purely municipal terms.¹⁶²

However, in as much as TWAIL provides the lens to understand the engagement of international law in local forums of the Third World as acts of hermeneutical resistance against the structures of modern colonial structures, the theory is particularly inadequate as an encompassing framework for this thesis in two ways. First, TWAIL suffers from the assumption that Third World countries have local actors to participate in the reform of and resistance against international legal scholarship.¹⁶³ Third World states are not created equal and the mere fact of existing in the 'problem space' of post-colonialism does not mean *presence of actors* within the Third World states that would engage in the process of destabilisation and renewal of international law's history and operation. Actor presence here means the active participation of non-state actors such as the private sector (or in the case of this research, the local pharmaceutical manufacturing sector) or active civil society groups – actors that enable and promote counterhegemonic (international) law making in legal, public, and policy discourse. Thus, while there are Third World states endowed with the aforementioned actor presence, such as India with its robust pharmaceutical sector and Brazil's social welfare services and its politically active and informed citizens, there are also Third World states that, due to various factors, do not have these important capacities. As a consequence, these countries (such as Nigeria) are

¹⁶² Eslava, 'Istanbul Vignettes' (n 149).

¹⁶³ Eslava and Pahuja, 'Beyond the (Post)Colonial' (n 3) 30.

unable to engage in the resistance and reform of (international) patent law making, as will be seen in Chapter 5.

Further, in instances where Third World states are endowed with emancipatory capabilities, TWAIL assumes that such capabilities are *competent*. ‘Competency’ means the ability of these actors to enrol support simultaneously at a number of different sites of law making and law enforcement (national, international, and transnational), as well as their ability to mobilise leading sources of expertise to reform, reconstruct, or dismantle the patent regime. Therefore, not only should actors create and govern knowledge to allow for engagement, such actors should be competent enough to produce or create knowledge in the first place, as well as engage in its renewal. Using the case of Nigeria – as will be seen in Chapter 5 – while the country lacks some actors, i.e. pharmaceutical companies, the other relevant actors – civil society groups – have not been competent enough to produce expertise on patents nor cognitively shape legal and policy discourse on the patent issue. This is in stark contrast to Brazil (Chapter 3) and India (Chapter 4), where actors have managed to do this. This also explains the on-going legal innovations and contestations on patent issues in these forums.

In not recognising the competency of actors, TWAIL silences local experiences and history. Thus, while the thesis takes seriously this task of re-imagining and reforming the international patent regime, it is also cautious against any attempt to do so without seriously considering the questions of Third World actor-agency and competency to engage in the everyday operation of international law. It is this inability to reflect actor-agency and competency for effective and sustainable local engagement in reform and resistance vis-à-vis international law and scholarship that TWAIL is found to be limiting for the purposes of this thesis. The quest for a supplement will now be considered.

Part 2: Nodal Governance

2.2.1 Understanding Nodal Governance

The theory of nodal governance explains how a variety of actors operating within social systems interact along networks to govern the systems they inhabit.¹⁶⁴ It posits that governance in such systems is instituted ‘in nodes that mobilise the knowledge and capacity of members to manage the course of events.’¹⁶⁵ In this respect, nodal governance is a theory that focuses on the role of nodes in governance, especially the way such nodal links create concentrations of power for the purposes of exercising and/or influencing governance.

The idea of nodal governance was initially developed by Clifford Shearing and Jennifer Wood by building on the work of Friedrich von Hayek to explain multiple modes of governance in the changing governance landscape, wherein state governments constitute but one set of nodes.¹⁶⁶ According to Shearing and Wood, nodal governance theory recognises the interaction between state and non-state actors (node) as well as between nodes, and how these interactions extend ‘the existing activities of non-state agencies as well as the emergence of new forms of governmental activity outside of the State.’¹⁶⁷ In other words, the nodal framework provides an account of how a governing order emerges from the operation of highly complex systems.

A node can either be an actor within a network or a combination of one or two networks united for a common goal. Nodes take a variety of forms, from formalised institutional expressions (business corporations), voluntary groupings (non-governmental organisations or NGOs), to super-structures, i.e. combinations of representatives from different nodal organisations such as the Pharmaceutical Research and Manufacturers of America (PhRMA) or Indian Drug Manufacturers’ Association (IDMA).¹⁶⁸ A super-structural node, in other words, brings together one or more networks for the purpose of producing various kinds of action, such as lobbying the state for a favourable law or policy. Other examples of such super-

¹⁶⁴ Scott Burris, Peter Drahos, and Clifford Shearing, ‘Nodal Governance’ (Temple University 2005) (‘Nodal Governance, Working Paper Series’); Burris, Drahos, and Shearing ‘Nodal Governance’ (n 9) 31-33.

¹⁶⁵ *ibid* 33.

¹⁶⁶ Shearing and Wood, ‘Nodal Governance, Democracy and New “Denizens”’ (n 11); Jennifer Wood and Clifford D Shearing, *Imagining Security* (2007) (*Imagining Security*).

¹⁶⁷ Shearing and Wood, ‘Nodal Governance, Democracy, and the New “Denizens”’ (n 11) 403.

¹⁶⁸ Burris, Drahos, and Shearing, ‘Nodal Governance, Working Paper Series’ (n 164) 13. Burris, Drahos, and Shearing recognise a fourth group – an informal sector made up of people who operate outside of the first and second, such as criminal gangs.

structural nodes include the Brazilian Association of Fine Chemical Industry (*Associação Brasileira das Indústrias de Química Fina, Biotecnologia e Suas Especialidades* or ABIFINA) and the Pharmaceutical Manufacturers Group of Manufacturers Association of Nigeria (PMG-MAN). The role and influence of these nodes in relation to patent law making will be discussed in Chapters 3, 4, and 5, respectively.

Regardless of type, a node has four essential characteristics: first, it should have a way of thinking (mentalities) that cognitively shapes how individuals and organisations see the world and act accordingly.¹⁶⁹ It is in these mentalities and purposes that nodes differ greatly from each other in terms of goals and legal conduct. Second, it should have a set of processes (technologies) for applying and exercising influence over the course of events at issue.¹⁷⁰ Third, it should also have resources to support and mobilise the operation of the node and fuel its influence.¹⁷¹ Fourth, there should be a system (institutions) that enables the directed mobilisation of resources, mentalities, and technologies over time.¹⁷²

Thus, to be a governing node, according to this theory, a node should have some institutional form, even if temporary. It need not be a formally constituted or legally recognised entity, but it should have sufficient stability and structure to enable the mobilisation of resources, mentalities, and technologies over time. The lobbying tactics of the IDMA in India in the wake of the amendment of the Indian Patent Act provides an example of a successful governing node, as the group had the stability and structure to mobilise its mentalities, resources, and technologies over time to achieve a tempered patent regime for India. Conversely, in Brazil and Nigeria, the super-structural nodes of ABIFINA and PMG-MAN were not able to participate in patent law-making because both groups, though formally recognised by the state, did not have sufficient stability and structure to enable the mobilisation of resources, mentalities, and technologies over patent-related matters due to various domestic economic factors.

All nodes are not created equal, and the grouping and structure of each node affects

¹⁶⁹ Burris, Drahos, and Shearing, 'Nodal Governance' (n 9) 12.

¹⁷⁰ *ibid.*

¹⁷¹ *ibid.*

¹⁷² *ibid.*

its arrangement or interface with the state.¹⁷³ For example, the relation of the state with big corporations, voluntary groups, or a super-structural node, though non-linear in nature, is often one of cooperative arrangement and sometimes contestation. For example, IDMA's lobby of the Indian Parliament, urging them to oppose an IP dimension to GATT in order to protect public health and the pharmaceutical sector, highlights a corporative nodal relationship. On the other hand, the civil society protests in Brazil on access to HIV medicines are an example of contested nodal engagement with the state.

Notwithstanding which side of the interface prevails, the capacity of a node to exert influence and the potency of its influence depends on the resources available for exerting influence, technologies in use, as well as the institutional structure.¹⁷⁴ In other words, the ability of the nodal network to enrol such resources and governing technologies at a number of different sites to mobilise the state and others to comply with its direction also affects the effectiveness of its influence. For example, a small NGO can mobilise resources to exert influence at one site such as the local, municipal, or national levels of governance. The ability of social movements in India to petition government by writing amicus curiae briefs is an example. However, because these groups are usually limited by financial capacity, they are unable to exact influence simultaneously and at multiple sites.

A business corporation could simultaneously exert influence at a national and local level. For example, 12 US corporations, according to Susan Sell, were primarily responsible for the lobbying that brought the TRIPS Agreement into being.¹⁷⁵ It was intense lobbying activity from these companies, particularly in the US, that laid the foundations of linking IP protection to trade in the multilateral context.¹⁷⁶

Super-structural nodes, on the other hand, can channel their resources to exert simultaneous influence at the local, national, and international levels. An example of this is the role of the PhRMA in influencing the USTR to include IP as part of the US

¹⁷³ Shearing and Wood, 'Nodal Governance, Democracy, and the New "Denizens"' (n 11) 415.

¹⁷⁴ Peter Drahos, 'Intellectual Property and Pharmaceutical Markets: A Nodal Governance Approach' (2004) 77 Temple Law Review 409 ('Intellectual Property and Pharmaceutical Markets').

¹⁷⁵ Susan K Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights* (Cambridge University Press 2003) 1 (*Private Power, Public Law*). These companies include Pfizer, IBM, Merck, General Electric, DuPont, Warner Communications, Hewlett-Packard, Bristol-Meyers, FMC Corporation, General Motors, Johnson & Johnson, Monsanto, and Rockwell International.

¹⁷⁶ Sell, *Private Power, Public Law* (n 175) 137.

foreign policy as well as its presence during the Uruguay Round negotiations.¹⁷⁷ It is this ability of the super-structural node to engage simultaneously at multiple sites that makes it powerful compared to the NGO or business corporation.

While the relationship between the state and a node differ, relationships between and among nodes also differ. This intra-node relationship takes different forms such as dialogue, democratic bargaining, or contestation of ideas.¹⁷⁸ As a result, nodes are constantly reconstituting themselves by regulating other nodes that are accessible to them through networks.¹⁷⁹ According to Burris, Drahos, and Shearing, the pervasiveness of nodes not only influences the way knowledge is produced and diffused in a given system, but also informs how resources relevant to regulation are focused to bring about social action.¹⁸⁰ In other words, nodal governance facilitates understanding of how nodal networks produce the results they have by providing insight into who is able to participate and who is excluded, how knowledge is produced and disseminated, as well as the resources available for mobilisation purposes.¹⁸¹ In the next section, a case study of the TRIPS Agreement is presented to show how the nodal governance theory helps explain how a nodal network played a larger role in the formation of US trade policy and led to the globalisation of the private interests of its member corporations.

2.2.2 Nodal Governance and the Pharmaceutical Patent Regime

The inclusion of IPR in the Uruguay Round of multilateral trade negotiations did not happen by chance. It involved the dynamic influence and participation of American MNCs, especially pharmaceutical and biotechnology companies, that first actively shaped the national legislation on IP and, by corollary, the foreign trade policy of the US government.¹⁸² This raises the question of how and why did a group of private

¹⁷⁷ Drahos, 'Intellectual Property and Pharmaceutical Markets' (n 174) 411.

¹⁷⁸ Peter Drahos and Ruth Mayne, *Global Intellectual Property Rights: Knowledge, Access and Development* (Palgrave Macmillan 2002) 164 (*Global Intellectual Property Rights*).

¹⁷⁹ Burris, Drahos, and Shearing, 'Nodal Governance' (n 9) 15.

¹⁸⁰ *ibid.*

¹⁸¹ Burris, Drahos and Shearing, 'Nodal Governance, Working Paper Series' (n 164) 15.

¹⁸² Drahos, 'Intellectual Property and Pharmaceutical Markets' (n 174); Sell, *Private Power, Public Law* (n 175); Drahos and Mayne, *Global Intellectual Property Rights* (n 178); Susan K Sell and Aseem Prakash, 'Using Ideas Strategically: The Contest Between Business and NGO Networks in Intellectual Property Rights' (2004) 48 *Int Studies Q*; see also Duncan Matthews, *Trade-Related Aspects of Intellectual Property Rights: Will the Uruguay Round Consensus Hold?* (1st edn, Centre for the Study of Globalisation and Regionalisation (CSGR), University

sector actors succeed in establishing, locally and internationally, a maximalist IP agenda. Nodal governance theory proffers insight on how these private companies were able to secure US government compliance with emerging global IPR standards that, in turn, constitute today's international patent law regime.

Having developed a large portfolio of R&D for innovation in the chemical, power machinery, electrical, petroleum, and rubber industries, thanks to the massive corporate research laboratories, these companies needed IPRs and licences to protect their investment.¹⁸³ This is because the owners and manufacturers of innovations saw the considerable advantages in IP monopolistic potentials of patents such as exclusive foreign market access, sustained competitive advantages, and economic rents from patents.¹⁸⁴ These companies sought to institute locally as well as within all significant markets a regulatory agenda for largely uniform patent rules that made it cheap to obtain patents, maximise the scope of patentable subject matter, and minimise state control over the use of patented technology.¹⁸⁵

In fact, the need for IP protection was especially important in the pharmaceutical sector as these companies saw countries like India and Brazil – with ‘weak’ IP laws but budding pharmaceutical sectors – as threats to their revenue and market access. Understandably, these companies saw the considerable advantages in IP monopolistic potentials of patents such as exclusive foreign market access and sustained competitive advantages as a way to protect their R&D investment. The very nature of IP, specifically patents and its ensuing monopoly, gives its owner strong protection over the exploitation of a patented invention. This temporary monopoly allows the inventor to set the terms of use and the price for access to the invented product. Thus, with the increase in the value of knowledge relative to other assets, companies are bound to protect not only this asset but also laws that may impact the value of and access to this asset.¹⁸⁶ With this goal in mind, new tactics were needed to develop a global network of universal patent standards while solving the problem of free riding

of Warwick 2002)
 <<http://www2.warwick.ac.uk/fac/soc/pais/research/researchcentres/csgr/research/workingpapers-copy2/2002/wp9902.pdf>> accessed 10 May 2015; Peter Drahos and John Braithwaite, ‘Intellectual Property, Corporate Strategy, Globalisation: TRIPS in Context’ (2002) 20 *Wisconsin International Law Journal* (‘Intellectual Property, Corporate Strategy, Globalisation’).

¹⁸³ Drahos and Braithwaite, *Information Feudalism* (n 14) 49.

¹⁸⁴ *ibid* 47.

¹⁸⁵ Peter Drahos, ‘“IP World”—Made by TNC Inc.’ in Gaëlle Krikorian and Amy Kapczynski (eds) *Access to Knowledge in the Age of Intellectual Property* (1st edn, 2010) (‘“IP World”—Made by TNC Inc.’).

¹⁸⁶ Peter Drahos and John Braithwaite, ‘Who Owns the Knowledge Economy? Political Organising Behind TRIPS’ (The Corner House 2004) 3 <<http://www.thecornerhouse.org.uk/resource/who-owns-knowledge-economy>> accessed 13 March 2016 (‘Who Owns the Knowledge Economy, Corner House Report’).

– a situation where those who benefit from a good or service do not pay for them.

The process of linking IP with trade policy was spearheaded by Pfizer, a global pharmaceutical company with interest and investments in Third World countries such as India.¹⁸⁷ Pfizer's investment in many developing countries had 'sensitized it to the threat to international markets that generics posed for the pharmaceutical research-and-development industry'.¹⁸⁸ According to Drahos, Pfizer cognitively shaped and influenced fellow pharmaceutical manufacturers regarding the value of trade-based IP through lobbying, giving talks, and delivering white paper presentations at business forums like the National Foreign Trade Council and the Business Round Table.¹⁸⁹ In these processes, Ed Pratt – CEO of Pfizer at that time – was able to delineate the links between trade, IP, and investment as well as the importance of linking the IP regime to the GATT and making it enforceable under the GATT dispute resolution procedures.¹⁹⁰

In this context, Pfizer plays the role of a quintessential node with a foreknowledge and particular mind-set of thinking of IP (mentalities); it employed a set of technologies in the form of giving speeches and white paper presentations to apply and exert influence over the course of events at issue. All these were possible due to the resources and institutional structure of the company, which allowed it to mobilise support in the media and industry and resulted in policy from the government. In other words, Pfizer was able to extract support within the nodal network of fellow pharmaceutical companies and influence other networks of biochemical and technology companies to create ever-widening circles of influence that brought more networks (software, film, and music sectors) into the cause of exporting the US IP standard to the wider world.¹⁹¹ The combined influence of these nodes developed governmental support for strengthening the global protection of IP.¹⁹²

Furthermore, Pfizer was able to achieve compliance from the US through the creation of the Advisory Committee for Trade Negotiations (ACTN).¹⁹³ The ACTN was set up by the US Congress in 1974 as a unique public-private forum to ensure that the

¹⁸⁷ *ibid* 5.

¹⁸⁸ Drahos, "'IP World'—Made by TNC Inc.' (n 185) 206.

¹⁸⁹ Burris, Drahos, and Shearing, 'Nodal Governance' (n 9) 42; Sell, *Private Power, Public Law* (n 175) 48.

¹⁹⁰ Burris, Drahos, and Shearing, 'Nodal Governance' (n 9).

¹⁹¹ Duncan Mathews, *Trade-Related Aspects of Intellectual Property Rights: Will the Uruguay Round Consensus Hold?* (1st edn, Centre for the Study of Globalisation and Regionalisation (CSGR), University of Warwick 2002) 5; Drahos and Braithwaite, *Information Feudalism* (n 14) 65-71.

¹⁹² Sell, *Private Power, Public Law* (n 175) 1.

¹⁹³ Drahos and Braithwaite, *Information Feudalism* (n 14) 72.

private sector was represented in US trade policies.¹⁹⁴ Simply put, the ACTN was structured to allow direct engagement of the US business sector during trade negotiations. The ACTN was not only an open access interaction between business and the bureaucratic centre of trade policy, it also played a strategic role in the design of US policy on IP issues.¹⁹⁵ In 1972, Pfizer's CEO Ed Pratt became the chairman of the ACTN.¹⁹⁶ With Pratt as chairman, the ACTN began constructing a new trade and investment agenda.¹⁹⁷ He also represented the private sector and was an adviser to the US official delegation at the Uruguay Round trade talks in his capacity as chairman of the ACTN.¹⁹⁸ By bringing foreknowledge on IP to the table, Pratt was able to frame the contours of national IP legislation as well as add it into the already existing US foreign trade template.¹⁹⁹ As far as the ACTN was concerned, folding IP standards into US foreign trade policy, first in bilateral agreements and then in multilateral agreements like the GATT, was the single best way in which to spread those standards.²⁰⁰

During this period, the ACTN worked closely with the USTR to shape the services, investment, and IP trade agenda of the US.²⁰¹ Crucially, the ACTN established a Task Force on Intellectual Property whose recommendation formed the backbone of the US strategy for IP. It advised the US to have a long-term objective of placing IP into the GATT as well as in unilateral and bilateral agreements.²⁰² In doing this, the ACTN signified it would pull every lever at its disposal in order to obtain the right result for the US on IP.²⁰³ Consequently, the US amended its trade laws to reflect this new IP universalization goal. Particularly, it revised Section 301 of the Trade Act of 1974 to address unfair practices on IPRs in various countries.²⁰⁴ This provision allowed the US to withdraw trade benefits or impose duties on goods from foreign countries with poor IP laws or countries that refused to amend their IP laws to standards that are acceptable to the US.²⁰⁵ For example, the USTR initiated Section 301 of the Trade Act

¹⁹⁴ *ibid.*

¹⁹⁵ Drahos, 'The Story of TRIPS at the GATT' (n 96); Braithwaite and Drahos, *Global Business Regulation* (n 14) 62.

¹⁹⁶ Drahos and Braithwaite, *Information Feudalism* (n 14) 67.

¹⁹⁷ *ibid* 72; Drahos and Braithwaite, 'Who Owns the Knowledge Economy, Corner House Report' (n 186) 15.

¹⁹⁸ Sell, *Private Power, Public Law* (n 175) 50.

¹⁹⁹ Drahos and Braithwaite, *Information Feudalism* (n 14) 72.

²⁰⁰ Drahos and Braithwaite, 'Who Owns the Knowledge Economy, Corner House Report' (n 186) 15.

²⁰¹ Drahos and Braithwaite, *Information Feudalism* (n 14) 91.

²⁰² Drahos, 'The Story of TRIPS at the GATT' (n 96).

²⁰³ Drahos and Braithwaite, *Information Feudalism* (n 14) 116.

²⁰⁴ Braithwaite and Drahos, *Global Business Regulation* (n 14) 62.

²⁰⁵ Peter Drahos, 'Trade-Offs and Trade Linkages: TRIPS in a Negotiating Context' (*Quaker United Nations*, 2000) <<https://www.anu.edu.au/fellows/pdrahos/reports/pdfs/2001tradeoffstradelinkages.pdf>> accessed 1 June 2015 ('Trade-Offs and Trade Linkages').

against Brazil in 1988.²⁰⁶ This imposed a 100 per cent tariff on imports of Brazilian products such as paper, consumer electronics, and agricultural products.²⁰⁷ In fact, the effective use of Section 301 gave the US the needed leverage in dealing with the problem of poor IP laws and could be credited for the successful inclusion of IP rules at the GATT.²⁰⁸ In another example, the US included the protection of IP as an investment activity in the Bilateral Investment Treaty program that it signed with many developing countries in the 1980s.²⁰⁹ If anything, the significance of including IP as part of the US foreign policy and successfully pushing forward legislative changes show how a node (Pfizer) mobilised the government to achieve its goal. The levers of a very personal self-interest thus shaped a macro outcome.²¹⁰

To successfully include IP into the multilateral framework of the GATT, the ACTN had to move beyond the perimeters of US governance to bring in other possible like-minded stakeholders into its mentality of a trade-related IP regime. To do this, the USTR set up the Quadrilateral Group (Quad) of countries consisting of the US, EU, Japan, and Canada with the purpose of developing a consensus for the Uruguay Round of multilateral trade negotiations.²¹¹ In the nodal governance context, the Quad is a super-structural node of like-minded countries which sought to promote their interests in IP at the global forum. Pertinently, it summoned combined resources of the Quad countries and nodal network access of business organisations within each to pressure their governments to include IP in the next round of trade negotiations.²¹² During the Uruguay Round, the Quad developed the impetus for particular decisions and the negotiating positions of developed states.

In addition to setting up the Quad, Pratt – together with John Opel, the then Chairman of IBM – also created the Intellectual Property Committee (IPC). Like the Quad, the IPC was another super-structural node and consisted of a coalition of 13 major US corporations, namely Bristol-Myers, DuPont, FMC Corporation, General Electric, General Motors, Hewlett-Packard, IBM, Johnson & Johnson, Merck, Monsanto, Pfizer, Rockwell International, and Warner Communications.²¹³ According to Burris,

²⁰⁶ Drahos and Braithwaite, *Information Feudalism* (n 14) 104.

²⁰⁷ *ibid.*

²⁰⁸ Drahos, 'The Story of TRIPS at the GATT' (n 96); Braithwaite and Drahos, *Global Business Regulation* (n 14) 62; Raghavan (n 96) 84; Chimni, 'Political Economy of the Uruguay Round of Negotiations' (n 115) 143.

²⁰⁹ Drahos, "'IP World' – Made by TNC' (n 185) 207.

²¹⁰ Drahos and Braithwaite, *Information Feudalism* (n 14) 113.

²¹¹ *ibid.* 118-20.

²¹² Drahos, 'Trade-Offs and Trade Linkages' (n 205) 14.

²¹³ Burris, Drahos, and Shearing, 'Nodal Governance' (n 9) 45.

Drahos, and Shearing, the IPC was dedicated to the inclusion of a comprehensive agreement on IP in the GATT negotiations with the stated objective of activating its nodal networks in Europe in order to achieve a European buy-in of a trade-linked globally enforceable IP regime.²¹⁴ These objectives were achieved in 1988 when the Quad released a suggested draft text of an agreement on IP, which eventually formed the backbone of the TRIPS Agreement.²¹⁵

The above analysis illustrates how and why IP language was conceptualised and included in the US trade policy discourse. The technical design of American IP strategy also underscores the power of nodal governance (pharmaceutical companies and big corporations) in reforming the global IP regime to suit collective objectives. In cognitive terms, by bringing foreknowledge on IP to the table, mobilising resources at multiple sites, and utilising institutional networks, these companies became a super-structural node that no government could ignore. These companies conceived the idea of linking the IP regime to the trade regime and successfully marshalled government support to bring it to pass, consequently enrolling and activating a strong global IP regime in the TRIPS Agreement.

2.2.3 Application of Nodal Governance to the Thesis

The story of global IP law, which was formalised in the TRIPS Agreement, shows how owners of large IP portfolios achieved the goal of IP globalisation by deploying and enrolling multiple nodal networks to produce action. The TRIPS Agreement case study and the empirical findings²¹⁶ underpin the critical observations of nodal governance and its relevance for this thesis.

First, nodal governance brings insight to the inner workings of local law making and governance – the actors, governance, knowledge capacity, and resource availability. Explicitly, it shows the ‘circuitry of power in societies where information networks have become a dominant organisational form’.²¹⁷ This is shown in the role and activities of Pfizer in mobilising support among like-minded organisations (nodal network). It was the concentration of power from these networks that successfully gave rise to the ACTN and the IPC – super-nodes that ‘give their constituent nodes

²¹⁴ *ibid* 46.

²¹⁵ Drahos and Braithwaite, *Information Feudalism* (n 14) 115-17.

²¹⁶ See ch 3, ss 3.3 and 3.4; ch 4, ss 4.2 and 4.4, and ch 5, ss 5.3 and 5.4.

²¹⁷ Burris, Drahos, and Shearing, ‘Nodal Governance’ (n 9) 46.

highly effective regulatory access to the people and governmental nodes that had to be regulated.²¹⁸ Those super-structural nodes in turn activated other private and public assemblages in the US, Europe, Canada, and Japan at the Uruguay Round negotiations. This shows not only the *presence of actors* but also the power dynamics between actors to channel available resources and bring about the desired outcome.²¹⁹ Thus, all actor(s) should first be present for such actors to be able to access people and governmental nodes that had to be regulated. If actors were not present, there would not have been a nodal network to activate and access. As will be seen in coming chapters, the presence of actor networks in the form of pharmaceutical manufacturers and dynamic NGO networks has been key in advancing a particular agenda on patents in Brazil and India. Employing the nodal governance theory in analysing the actions of these non-state actors reveals how these groups embedded themselves in a spirit of resistance against a new global IP regime. In the process, they demanded and achieved a public interest and human rights-oriented IP regime in their respective jurisdictions.

Second, it shows the importance of decentred (i.e. between state and local governance) but competent performance in activating both private and public assemblages within the state structure. Pratt, as head of the ACTN, was able to bring and activate other nodal networks.²²⁰ In doing so, he was able to enlist not only the influence of CEOs of fellow companies with large portfolios but more financial resources.²²¹ Knowledge, capacity, and resources thus became focused and concentrated. While NGOs in Brazil and India lack the economic muscle of big corporations in the US, they have been able to adroitly market their activism by employing human rights principles (right to health in Brazil and right to life in India) to mobilise government action and contest transnational corporate power. Generic pharmaceutical companies were able to use similar tactics in the run up to India's Patent Act amendment to facilitate efforts with a similar result from the Indian government.

Third, mentalities matter. Big corporations in the US were able to frame their way of thinking to cognitively shape how the US government approached its foreign trade policy. According to Susan Sell, the big corporations displayed impressive framing

²¹⁸ *ibid* 47.

²¹⁹ *ibid*.

²²⁰ *ibid*.

²²¹ *ibid*.

skills in presenting their case to the government and their foreign counterparts, not merely by making the link between IP and trade, but also by the very terms they used to describe their position.²²² As Chapters 3 and 4 will demonstrate, on-going contestations in Brazil and India over IP rights have been framed as ‘right to health’ and ‘right to life’, respectively. These have proved to be effective counter-framing to the highly protectionist IP maximalist agenda.

2.3 Summarising the Theoretical Frameworks

The aim of this chapter was to show the conceptual theoretical framework that underpins the thesis. The assessment of the TRIPS Agreement illustrates the extent to which the international economic law framework has continued to ascribe universalism borne out of Western philosophical persuasions. Particularly, in using TWAIL, the thesis has been able to delve into and critique the Eurocentric foundations of modern IEG to show that the system has continued to perpetuate a world of deep injustice characterised by violence, exploitation, and inequality.

In order to rectify international law injustices, TWAIL has suggested looking instead at the prosaic life of international law manifesting in the local forums. This is because processes of reforming and resisting are on-going in these forums that ostensibly might not look as being part of the international legal system but in actuality is. In calling to focus on the local as part of the international, TWAIL theory envisions a new ‘praxis’ of (the new) universality by mapping the numerous forms of resistance already at play in the struggle against the (post)colonial normative order now being institutionalised and administered across the world.

However, the suggestion of focusing on the various forms of reform and resistance vis-à-vis international law at the local forums falls afoul of the assumption that Third World states automatically have the requisites needed. Particularly, TWAIL ignores the questions of who, why, and how to participate in reform and resistance *vis-à-vis* international law and scholarship. To rectify this lacuna, the thesis drew from the nodal governance theory to show how non-state actors engage in governance through nodal networks to produce change. In highlighting how governance processes are facilitated, it shows how power and participation is constituted and who is excluded in

²²² Sell, *Private Power, Public Law* (n 175) 51.

the process. Thus, in combining TWAIL and nodal governance theory to illuminate the materialisation of the international in the local, the thesis shows the gamut of legal, historical, political, and economic developments that demonstrate the internationalisation of pharmaceutical patent law in the local forums of Brazil, India, and Nigeria.

In the subsequent chapters, these theoretical frameworks will be put in context to show their practical relevance. Starting with Brazil, the next chapter examines the structure and implementation of patent law. This is important because it shows that the country is not strictly adhering to the patent regime of Western countries, but is instead adapting patent law to its own unique environment. Thus, it provides a real life example of Third World resistance and reformation of global patent law. It also focuses on the actors involved in counter-hegemonic law making, bringing attention to the nodal governance of civil society activism and the very nature of these networks themselves.

3. Brazil

Introduction

Brazil represents the first, and so far, exemplary model in the implementation of a programme of universal and free access to ARV drugs. The country is often cited¹ as an exemplary model of a developing country that has successfully tackled and contained the HIV/AIDS epidemic. The importance of Brazil's AIDS treatment programme extends far beyond the Brazilians that have received ARV treatment, which – according to the Director of the National AIDS Programme Fabio Mesquita – is estimated at around 350,000 recipients.² It has shown that it is possible to offer free and universal access to ARV in a resource-limited country. In doing so, Brazil changed the narrative on health, human rights, and access to medicines discourse.

The success of the Brazilian government's HIV/AIDS programme, as this chapter explains, did not happen in a vacuum. It was the result of domestic and international political processes that emerged from the re-democratisation process of the 1980s. This re-democratisation process that included the emergence of new political parties, the creation of a new Constitution, a freer press, active social movements, the on-going Uruguay Round negotiations, and the explosion of the HIV/AIDS epidemic at the time provided the recipe that produced Brazil's contemporary AIDS treatment institutions.

This chapter focuses on the intersection of Brazil's HIV/AIDS programme and pharmaceutical patent regime. It traces the development and implementation of a socially conscious patent law and pharmaceutical policies. It also maps the roles of

¹ Jane Galvão, 'Brazil and Access to HIV/AIDS Drugs: A Question of Human Rights and Public Health' (2005) 95 American Journal of Public Health 1110 ('Brazil and Access to HIV/AIDS Drugs'); Paulo R Teixeira, Marco Antônio Vitória and Jhoney Barcarolo, 'Brazilian Experience in Providing Universal Access to Antiretroviral Therapy' in Jean-Paul Moatti and others (eds), *Economics of Aids and Access to HIV/AIDS Care in Developing Countries; Issues and Challenges* (ANRS 2003); Guillaume Loup and others, 'The Brazilian Experience of "Scaling Up": A Public Policy Approach' in Benjamin Coriat (ed), *The Political Economy of HIV/AIDS in Developing Countries: TRIPS, Public Health Systems, and Free Access* (Edward Elgar Publishing 2008); Lynnette Johnson Williams, '2003 Gates Award for Global Health - Brazilian National AIDS Program' (*Bill and Melinda Gates Foundation*, 2003) <<http://www.gatesfoundation.org/Media-Center/Press-Releases/2003/05/Brazilian-National-AIDS-Program>> accessed 28 May 2015.

² Fieldwork interview with Fabio Mesquita (Brasilia, 2014) (transcript on file with author). The programme hopes to add another 100,000 by the end of 2014. The Joint UN Programme on HIV/AIDS (UNAIDS) puts the number at 355,000. See UNAIDS, 'The Brazilian Response to HIV and AIDS' (2015), <http://www.unaids.org/sites/default/files/country/documents/BRA_narrative_report_2015.pdf> accessed on 15 February 2016.

various actors in the making of the AIDS programme – their motivations, challenges, and how they influenced these policies. That is, the way key actors – particularly civil society – captured and framed the state’s understanding and application of patents for health and economic development purposes. In examining the Brazilian context, the thesis finds that patents are not just seen strictly as private rights, but also as legal rights with a social function that should be balanced with public interests. This stems from the constitutionalization of a universal right to health and the subsequent institutionalisation of a universal public health system. In doing so, patents are jointly understood and conceptualised by both the state and non-state actors as not only an impediment to the legal commitment to universal health care, but also a tool for achieving this social function embedded within the constitutional framework. It is this understanding that shapes the interests of policymakers, drives them to implement a socially-conscious patent regulatory system, and informs civil society activism and engagement with patent law. Likewise, the country also demonstrates that the significance of the active presence of domestic political actors and institutions are the most important determinant in the understanding, conceptualization, and direction of law and policy.

The analysis on Brazil puts the TWAIL theory in perspective by establishing links between the past and the present in the development of a patent regime and why the country took certain positions and supported certain arguments at different times. In examining the genesis, character, and dynamics of patent law in Brazil, the *twailian* perspective provides the analytics for recognising the materialization of patent law and access to medicines litigation in the local jurisdictions of Brazil as part of ongoing wider reform projects in the subaltern, which are expanding the aperture on norms governing patent and medicine access discourse. In this light, the post-colonial political behaviour is not only an ideological project located in a particular material context with material consequences, but also a material project itself.³ In other words, the politics and activism surrounding the development of the AIDS programme and subsequent reform in patent law are not an isolated incidents happening in a local space but is part of a larger network of resistance already at play in the struggle

³ Luis Eslava and Sundhya Pahuja, ‘Between Resistance and Reform: TWAIL and the Universality of International Law’ (2011) 3 Trade, Law and Development (‘Between Resistance and Reform’); Luis Eslava and Sundhya Pahuja, ‘Beyond the (Post)Colonial: TWAIL and the Everyday Life of International Law’ (2012) 45(2), Journal of Law and Politics in Africa, Asia and Latin America - Verfassung und Recht in Übersee (VRÜ) (‘Beyond the (Post)Colonial’).

against the colonial normative order now being institutionalised and administered across the world.⁴

As the chapter develops, the dynamic activism of social movement and civil society groups, which originated during the authoritarian military regime, becomes prominent. The success of the AIDS programme is largely due to the involvement of these social movement groups in producing expertise and knowledge regarding AIDS as well as in employing human rights principles in treatment campaigns. It was this human rights-based approach that produced cumulative and long-term effects on law and policy. Employing nodal governance insights, the thesis shows how social movements, in collaboration with the government, secured pharmaceutical autonomy for the Brazilian population. By strategically using ideas and networks, these groups were able to form strong domestic coalitions that exploited critical junctures in domestic politics to produce positive impacts on health, law, and the economy. Thus, the nodal governance perspective shows how nodes (social movement) activate their nodal network to interpret their interests, recruit allies, and convince the state of not only the justness of their cause but also of its constitutionality.

The remainder of this chapter is therefore structured as follows: the first section looks at the development of the patent regime in Brazil from the colonial period to the present. In doing so, the section shows how patent laws, originally intended by the colonial powers to be exploitative in practice, was changed by the Brazilian state to make them work for the country's welfare and developmental needs. The second section examines Brazil's industrial property law and delineates the roles of – and sometimes dialectic relationship between – the Brazilian Patent Office (*Instituto Nacional da Propriedade Industrial* or INPI) and the Brazilian National Health Surveillance Agency or ANVISA. This is important as it demonstrates that the creation of ANVISA is an attempt by the Brazilian state to recapture the discourse on patents from a strictly exclusive private right point of view, without regard to consumers and the public, to one that balances private rights with social responsibility. It is argued in this chapter that these everyday intimacies across spatial divides and scales of governance show how international law – in this case, Brazil's

⁴ Eslava and Pahuja, 'Beyond the (Post)Colonial' (n 3).

obligation under the TRIPS Agreement – can be reconceptualised beyond a ‘restricted body of norms, or situated only in bureaucratic and institutional environments.’⁵

The third section focuses on the right to health by analysing three inter-related incidents, namely the generic drugs policy, the HIV/AIDS programme, and the CL for the ARV drug *Efavirenz*. Tracing these incidents help to cognitively map the local politics of the construction of particular policy options. Importantly, it exemplifies the tension faced by developing country governments as they seek to balance social justice with economic issues. The third section deals with local actors influencing law, policies, and institutional agenda. Though some scholars contend that the confluence of various actors ‘renders the Brazilian state weak on a fundamental level as it is captive to a wide array of distributional coalitions,’⁶ it is posited in this chapter that such confluence has played an important role in shaping public policy responses to the AIDS epidemic and in articulating a counter-hegemonic patent discourse. As a result, these actors have concomitantly influenced the government in adopting alternative policy norms and IP rules that are advocacy-orientated and pro-human rights in their articulation. The fourth section assesses how local actors participate in patent law making while the fifth section looks at Brazil’s norm and agenda-setting at the international level by linking IP discourse with a development-related approach. In doing so, the country linked public interests, socio-economic needs, and changing realities at the local level to the international IP framework, concomitantly providing an alternative to existing IP framework and unwittingly furthering a *twailian* agenda in the reform of the global IP regime. The sixth section summarises the Brazilian context.

By and large, this chapter explores how Brazil developed a health-oriented patent examination system. Specifically, by predicating the engagement of the pharmaceutical patent regime to a right to health frame, the Brazilian state implemented a specific normative approach in which patent rights are balanced with socio-economic and technological development and the public interest. The participation of civil society enhanced the synergy between the drug sector and the patent system. This contributed to the development of a wider policy framework reflective of local social and economic conditions and priorities. As such, it provides

⁵ Eslava and Pahuja, ‘Between Resistance and Reform’ (n 3) 125.

⁶ Bruno M Salama and Daniel Benoliel, ‘Pharmaceutical Patent Bargains: The Brazilian Experience’ (2010) 18 *Cardozo Journal of International and Comparative Law* 637.

an example of how Nigeria can recalibrate its own patent policy in a manner compliant with the TRIPS Agreement while being responsive to its own socio-economic realities.

3.1 Historical Evolution of the Patent Regime in Brazil

Colonial Encounters

Brazil has always had an extensive engagement with the patent regime. The Portuguese Crown first introduced patent law in the country in 1809 through a royal decree by King Joao VI, thereby making Brazil the fourth country in the world to have a patent regime. It was also a founding member of the Paris Convention for the Protection of Industrial Property in 1883, which established the three pillars of the current patent system, i.e. independence of patents and trademarks, equal treatment of nationals and foreigners, and priority rights.⁷ The imperial Constitution of 1824 provided inventors exclusive rights of ownership over their discoveries or products and guaranteed a temporary exclusive privilege or compensation for any loss from popularization.⁸ That is, it allowed for compensation of the inventor in case of proliferation without the inventor's permission.

Other laws such as the Law of 28 August 1830 provided for patents only for Brazilian nationals and allowed for the exhaustion of patents that have not yet been locally exploited after a period of two years.⁹ The aim of these colonial IP laws was not to encourage innovation, as there was not only little to no local industrial activity ongoing at that time but also little scientific progress in the fields of chemistry and physics.¹⁰ Rather, these laws were based on the experiences of early 19th century Europe, which was dominated by the principle of territoriality or the belief that protection does not extend beyond the territory of the sovereign that granted the rights

⁷ Maria Auxiliadora Oliveira, Gabriela Costa Chaves, and Ruth Epsztejn, 'Brazilian Intellectual Property Legislation' in Jorge A. Bermudez and Maria Auxiliadora Oliveira (eds), *Intellectual Property in the Context of the WTO TRIPS Agreement: Challenges for Public Health* (2nd edn, Oswaldo Cruz Foundation 2004) 152 ('Brazilian Intellectual Property Legislation').

⁸ Cícero Gontijo, 'Changing the Patent System from the Paris Convention to the TRIPS Agreement: The Position of Brazil' (2005) 26 *Global Issues Paper* 17-18.

⁹ *ibid.*

¹⁰ Oliveira, Chaves, and Epsztejn, 'Brazilian Intellectual Property Legislation' (n 7) 152.

in the first place.¹¹ This principle is largely grounded on protecting colonial interests and territorial sovereignty.¹² Thus, the patent law at that time was not enacted to enhance indigenous innovation, as it was of little industrial importance. Rather, it was enacted to protect the interest of the Portuguese monarchy in exploiting Brazilian natural resources and to prevent any activity in the colony that might hinder or jeopardise such exploitation.¹³

Post-Colonial Interventions

In the beginning of the 20th century, Brazil enacted various industrial property statutes, notably Decree 16.264/23 of 1923 Law, which created the Industrial Property Office and regulated both patents and trademarks.¹⁴ However, socio-economic structural anomalies and the deepening economic crisis at the time shifted public sentiments regarding the utility of an IP system, and created local resistance over the international patent system. This ‘wind of change’ against the support for an IP system that secured the protection of patent holders’ rights can be attributed to the Brazilian dissatisfaction with the Paris Union as well as to the development ideas circulating among the government and policymakers at that time, such as the import substitution industrialisation (ISI) policy¹⁵ – an economic and trade policy that advocates the local manufacturing of goods to spur domestic industrialisation and reduce dependency on foreign imports.

The Brazilian dissatisfaction with the Paris Union stemmed from the high incidence of patent monopoly abuse, especially by multinational pharmaceutical companies operating in Brazil.¹⁶ According to Menescal, foreigners dominated Brazilian applications without locally working any of the patent particles. This is not surprising

¹¹ This principle was embedded in the Paris Convention. See Paris Convention for the Protection of Industrial Property, as amended (1979) 828 UNTS 305, art 4*bis*.

¹² Peter Drahos, ‘The Universality of Intellectual Property Rights: Origins and Developments’ (1st edn, 1999), <http://www.wipo.int/edocs/mdocs/tk/en/wipo_unhchr_ip_pnl_98/wipo_unhchr_ip_pnl_98_1.pdf> accessed 22 March 2014) 5 (‘Universality of Intellectual Property Rights’).

¹³ Edith Penrose, ‘International Patenting and the Less-Developed Countries’ (1973) 83 *The Economic Journal* 769; Jorge A Bermudez and others, *The WTO TRIPS Agreement and Patent Protection in Brazil: Recent Changes and Implications for Local Production and Access to Medicines* (Oswaldo Cruz Foundation, Rio de Janeiro 2002) 52. For the ‘anti-developmental’ nature of the IP regime during this period see AK Menescal, ‘Changing WIPO’s Ways? The 2004 Development Agenda in Historical Perspective’ (2005) *Journal of World Intellectual Property*; Peter O’Brien, *Developing Countries and the Patent System: An Economic Appraisal* (1974) 2 *World Development* 27-36.

¹⁴ Graziela Ferrero Zucoloto, Patrick Alves and Dea Guerra Fioravante, ‘Intellectual Property and Socio-Economic Development: Country Study Brazil’ <http://www.wipo.int/edocs/mdocs/mdocs/en/cdip_11/cdip_11_inf_3.pdf> accessed 11 May 2015; see also Bermudez and others (n 13) 53.

¹⁵ Rex A Hudson, ‘Import-Substitution Industrialization, 1945-64’ (1998) in Rex A Hudson (ed), *Brazil: A Country Study*.

¹⁶ Menescal (n 13) 764.

as this was the practice adopted by many pharmaceutical foreign firms in the Global South to dominate the market and control local competition. To resolve the issue of patent abuse, the country set up a special ‘inquiry commission’ (*Comissao Parlamentar de Inquerito*) in 1961 to analyse the domestic abuses of patent monopolies by foreign pharmaceutical corporations. The Commission found incidents of abuse in the form of ‘restrictive practices in licensing agreements and the payment of high royalties including royalties for expired patents, which led to the high cost of medicines in Brazil.’¹⁷ The culmination of the Brazilian frustration with the existing international patent system pushed the country to denounce at the UNGA in October 1961 the ‘imbalance between the national and the foreign sector of his country’s economy due to patents and royalties.’¹⁸ As a result, Brazil and Bolivia submitted a draft resolution on the need for a ‘Development Agenda’ for the international patent system. The resolution stated, inter alia, the importance of cooperation in the field of applied science and technology for promoting the exchange of knowledge,¹⁹ the application of international patent rules in ways that are cognizant of the legitimate claims of patentees and the economic development needs and requirements of underdeveloped countries,²⁰ the effects of patents on the economies of underdeveloped countries, and the characteristics of the patent legislation of underdeveloped countries in light of economic development objectives.²¹ By presenting the issue of patent abuses at an international forum such as the UN, Brazil and other countries from the South were not only seeking to revise domestic law but were also seeking to forcibly change multilateral trade rules.

While the local discontent with the international patent system was gaining momentum, the ISI policy was also circulating among government circles in Brazil and in most parts of the developing world. The ISI is an economic policy adopted by economically less developed countries to stimulate local industrialisation by establishing domestic production facilities to manufacture goods which were formerly imported.²² ISI stems from the dependency theory, which viewed global economic structures as antithetical to Brazilian (and most areas of the less developed world)

¹⁷ *ibid.*

¹⁸ *ibid.*

¹⁹ *ibid.*

²⁰ *ibid.*

²¹ *ibid.*

²² Werner Baer, ‘Import Substitution and Industrialization in Latin America: Experiences and Interpretations’ (1972) 7 *Latin American Research Review* 95.

economic advancement aspirations. The weakness of the Brazilian export markets, coupled with the global depression of the 1930s and the disruption of world trade during the war, gave impetus to the wave of local populist movements that demanded a policy of reducing dependency on the world market. Baer, for example, notes that the interruption of shipping and the decline of non-military production in Europe and the US during the First World War created severe shortages of imported manufactured goods in Latin America and raised the relative prices of goods such as textile, medicines, food products, and other light consumables.²³ Continued importation of finished goods and exportation of raw material through the 1940s, which became especially precarious during the Second World War, led to the local realisation that the economic structure would not be conducive to long-term development of the Brazilian economy.²⁴ Thus, it was after the Second World War in 1945 that ISI became a deliberate economic policy of the Brazilian government.

In fact, the situation of dependency was more pronounced in the pharmaceutical sector due to the penetration of foreign capital, unsuccessful policy interventions, as well as the absence of a strong local chemical industry.²⁵ Flynn, for example, recounts the growth and development of Brazilian pharmaceutical research laboratories, which were established in the 1920s and 1930s and resembled their European and US counterparts.²⁶ However, these local firms started to decline ‘as the government began providing incentives to attract foreign investors.’²⁷ To rectify this, the government introduced from 1945 to the 1980s a series of ISI policies to boost not only the sector but local industrialisation as a whole. These policies included cheap loans from the government, high import tariffs to discourage importation, and construction by the government of infrastructure especially designed to complement industries, including the development of an upstream petrochemical industry, on which the production of medicines is dependent.²⁸ The government believed that implementing these policies would not only shield the pharmaceutical sector from international competition, but

²³ *ibid* 97.

²⁴ *ibid*.

²⁵ Matthew B Flynn, *Pharmaceutical Autonomy and Public Health in Latin America: State, Society and Industry in Brazil's AIDS Program* (2014) 71 (*Pharmaceutical Autonomy and Public Health*).

²⁶ Matthew Brian Flynn, *Pharmaceutical Governance in Brazil: Globalization, Institutions and AIDS* (2010) 51 (*Pharmaceutical Governance in Brazil*).

²⁷ *ibid*.

²⁸ Baer (n 22) 71; Fabienne Orsi and others, ‘Intellectual Property Rights, Anti-AIDS Policy and Generic Drugs: Lessons from the Brazilian Public Health Program’ in Jean-Paul Moatti and others (eds), *Economics of AIDS and Access to HIV/AIDS Care in Developing Countries: Issues and Challenges* (Agence Nationale de Recherches sur le Sida 2003), 122.

would also increase industrialisation by forcing international firms to locally manufacture as importation is forbidden. This would lead to transfer of technology to the Brazilian economy in the long run. The government also believed that it would lead to local production, including production of intermediates and active principles, which would make the country self-sufficient.

The impact of these policies was mixed and, it has been argued, insufficient. On one hand, it resulted in the development of the Brazilian pharmaceutical industry by enhancing industrial and technological capabilities, particularly the production of intermediates and active principles as well as the development of an upstream petrochemical industry.²⁹ However, the period also saw the increased involvement of foreign capital in the sector. For example, foreign investment in the pharmaceutical sector rose from USD113 million in 1971 to USD646 million in 1979 despite the ban on importation.³⁰ In analysing this phenomenon, Elize Massard da Fonseca suggests that the monetary policies adopted during that time opened up the pharmaceutical sector to foreign capital. This policy, she contends, provided favourable exchange rates for firms importing capital goods to establish new factories in Brazil.³¹ For the purpose of this study, it is important to note at this point that ISI should be seen as part of a wider transformation in development theory – another expression of Southern thinking that included the intermingling of concepts such as unequal exchange, centre-periphery, development of underdevelopment, delinking, and others.³² This change in discourse and politics reflects – at the time – emergent concerns of a post-colonial predicament of many developing countries, both in terms of industrialisation and global trade policy.

Thus, it was the combination of global IP discontent and circulating ISI ideas that provided the impetus for Brazil to first enact Law Number 7.903/1945 in 1945, which included the novelty concept and removed product patent protection for medicines, food, and chemicals.³³ In addition, the country enacted Law Number 1.005/1971 in

²⁹ Orsi and others (n 28) 122.

³⁰ Gary Gereffi, *The Pharmaceutical Industry and Dependency in the Third World* (Princeton University Press 1983) 229.

³¹ See Elize Massard da Fonseca, 'Reforming Pharmaceutical Regulation: A Case Study of Generic Drugs in Brazil' (PhD thesis, University of Edinburgh, 2011) 110.

³² There were many Marxist influences to this theory and useful background can be found in various entries in Tom Bottomore and others, *A Dictionary of Marxist Thought* (2nd edn, 1985). See Arturo Escobar, *Encountering Development: The Making and Unmaking of the Third World* (2004).

³³ Law No 7.903/1945; see also Salama and Benoliel (n 6) 639; Srividhya Ragavan, *Patent and Trade Disparities in Developing Countries* (Oxford University Press 2012) 58; Christopher S Mayer, 'The Brazilian Pharmaceutical

1969 and Law Number 5.772/71 in 1971, both dealing with patents.³⁴ The former, which enacted the new Industrial Property Code, removed food, chemical, and pharmaceutical substances, materials, products, and medicines from the list of patentable materials, while the latter prohibited the patenting of processes for food, chemicals, and medicines.³⁵

According to Orsi et al., these laws allowed local pharmaceutical companies to engage in large-scale reverse engineering of drugs without any legal restriction or repercussions, thus allowing a number of firms and laboratories to acquire synthetic capability formulae.³⁶ The ideas underpinning these laws – similar to those underpinning the Indian Patent Act of 1970 (as will be seen in the next chapter) – would spur the development of the industrial sector, as the government believed that the elimination of patent protection would create stronger domestic industries.³⁷ Reducing the incidence of high poverty and the high cost of medicines were some of the compelling reasons for implementing patent policies suitable for the country's needs at that time. Within a decade after the removal of patent products and processes, the 10 largest national pharmaceutical companies increased their market share by 10 per cent.³⁸ However, it is also arguable that the lack of patent protection discouraged foreign companies from further increasing their presence in the market.

Further, the military regime created the Central Medicines Agency (*Central de Medicamentos* or CEME) under the Office of the President in 1971 to regulate the production and distribution of drugs by pharmaceutical laboratories subsumed or linked to various government ministries.³⁹ The CEME was tasked with the responsibility of developing policies for the sector and of leading the public procurement of medicines from public and private laboratories in order to develop the country's pharmaceutical and technology base. To complement the CEME mandate, the government also enacted policies to attract investments so as to build up the fine

Industry Goes Walking from Ipanema to Prosperity: Will the New Intellectual Property Law Spur Domestic Investment?' (1998) 12 Temple International and Comparative Law Journal 37; Bermudez and others (n 13) 52.

³⁴ See Law No 5.772/71 and Law No 5.772/71.

³⁵ Bermudez and others (n 13) 52.

³⁶ Orsi and others (n 28) 122; see also Maurice Cassier and Marilena Correa, 'Patents, Innovation and Public Health: Brazilian Public-Sector Laboratories' Experience in Copying AIDS Drugs' 90-107 <<http://www.lepublieur.com/anrs/ecoaids7.pdf>> accessed 6 May 2015.

³⁷ Mayer (n 33) 379; Ragavan (n 33) 59.

³⁸ Gereffi (n 30) 229.

³⁹ Jorge AZ Bermudez, Maria Auxiliadora Oliveira, and Egleubua Andrade de Oliveira, 'Expanding Access to Essential Medicines in Brazil: Recent Regulation and Public Policies' in Jorge A Bermudez and Maria Auxiliadora Oliveira (eds), *Intellectual Property in the Context of the WTO TRIPS Agreement: Challenges for Public Health* (2nd edn, Oswaldo Cruz Foundation 2004) 129.

chemical industry that produces specialised chemicals for active pharmaceutical ingredients (APIs) and their intermediates, as well as for fertilizers in order to reduce dependency on imported APIs for pharmaceutical and chemical production.

This historical reflection of Brazil's engagement with the patent regime at the local and international level – leading the Global South in seeking to transform global IP rules – illustrates the country's comprehension of the patent system as a policy tool for the development of the state. This should also be viewed within the larger context of the development aspirations percolating at that time. While the reform in patent law did have a direct link to the pharmaceutical sector, the legislative change is indicative of a more general transformation of the development aspirations of post-colonial societies that lent to looking at things differently, some of which pertained to particular policy interventions for certain industrial sectors such as pharmaceuticals.

It is this view – of balancing private rights and pursuing development goals – that underpinned Brazil's participation at the Uruguay Round, which was launched at that time. This explains why the country opposed the inclusion of IP in the global trade mechanism (with India, as discussed in the next chapter) in the Group of Ten. According to Piragibe dos Santos Tarragô, Brazil's chief TRIPS negotiator during the Uruguay Round from 1987 to 1993, the country considered the protection afforded by the Paris Convention sufficient and thus did not see the reason for a new agreement on IP.⁴⁰

Crucially, Brazil (along with a number of developing countries including India and Nigeria) insisted on the inadequacy of the GATT to host negotiations on IPRs and maintained that the treaties on IP were fundamentally about the protection of rights, whereas the GATT essentially concerned trade in goods.⁴¹ On patent, dos Santos Tarragô notes that Brazil was not only concerned about patent protection in the area of pharmaceuticals and biotechnology, but was also concerned about the ability 'to grant compulsory licences to acquire manufacturing capacity whenever the patent owner made use of its monopolistic rights to serve the market only by importation.'⁴² This is because, for the country, the ability to develop structures and institutions in

⁴⁰ Piragibe dos Santos Tarragô, 'Negotiating for Brazil', *The Making of the TRIPS Agreement: Personal Insights from the Uruguay Round Negotiations* (1st edn, World Trade Organization 2015) 241.

⁴¹ *ibid.*

⁴² *ibid.* 247.

order to promote and foster technological and scientific development was of utmost importance.

Thus, during the negotiations, the Brazilian delegation endeavoured to keep for the government the maximum flexibility to apply CLs, should it be needed, to meet its requirements of public health, combat abusive practices, and encourage local manufacturing. However, various factors (discussed in the next section) – which included change in the domestic government – changed the Brazilian staunch opposition against the inclusion of IP. Brazil became more amenable to accepting patents for pharmaceuticals and adopted a tactical approach at the Uruguay Round.⁴³ Though the country did not succeed in opposing the inclusion of IP into the jurisdiction of the WTO, it succeeded in including considerable flexibilities to safeguard its national interest and give governments some latitude of policy space in implementing development policies and in defending the public interest. As will be seen in coming sections, it appears that this idea – of balancing patent right with development goals – still circulates among its policy circles.

Global Experience

With its accession to the WTO in 1995 and the attendant implementation of the TRIPS Agreement, Brazil began – as part of its obligation to the TRIPS Agreement and the Single Undertaking – to recognise IP protection for all pharmaceutical products and processes. This period also coincided with the neoliberal efforts of the government at that time, which aimed to open up the Brazilian economy, stem hyperinflation, and jumpstart the country's sluggish economic growth. Thus Law 9.279/96 (Industrial Property Law of Brazil or IPLB), which came into effect in 1996, not only changed key aspects of previous industrial property law but implemented higher standards than those required by the TRIPS Agreement. However, even though the IPLB is protected by the Brazilian Constitution, it is secondary to Brazil's social interests and technological and economic development. Specifically, Article 5, XXIX of the Constitution reads, 'the law shall ensure the authors of industrial inventions of a temporary privilege for their use, as well as protection of industrial creations, property

⁴³ Fieldwork interview with Pedro Paranagua (Brasilia, 2014) (transcript on file with author).

of trademarks, names of companies and other distinctive signs, viewing the social interest and the technological and economic development of the country.’⁴⁴

The new industrial property law as it relates to the TRIPS Agreement and the politics surrounding its implementation is interesting in many ways as it points to, in the words of Chimni, the integral role played by the ruling elites in Third World states that ‘seek to establish the global rule of transnational capital on the pretext of pursuing “national interests.”’⁴⁵ Though Brazil had the option of waiting until January 2005 to phase-in fully into the TRIPS regime, it did not use this transition period. Instead, it not only changed its industrial property code eight years earlier but also implemented some TRIPS-plus provisions. This raises important questions, chiefly: why did Brazil not utilise the full transition period like India and China? Further, why did it include TRIPS-plus provisions in its industrial property code? The answers hinge on the internal and external dynamics at play during this period.

Internally, various local compulsions were at play. Brazil was going through neo-liberalization policies under the leadership of Fernando Collor de Mello (1990-1992), which aimed at improving the Brazilian economy. Stressing the need for ‘modernization’, Collor de Mello rapidly liberalised the economy by drastically reducing tariffs, privatising public assets, removing price controls on medicines, and abandoning industrial policies.⁴⁶ The implementation of these neoliberal reforms officially ended the ISI economic policy. As a result, tariffs on APIs and fine chemicals fell from 65 per cent to 20 per cent, while the privatisation of State petrochemical firms led to the closure of several upstream plants that had been established to produce APIs.⁴⁷

The neoliberal structural reforms continued with the subsequent presidencies of Itamar Franco, who replaced Mello after the latter’s impeachment, and Fernando Henrique Cardoso, who won by popular vote in 1995 and was a self-proclaimed

⁴⁴ Constitution of the Federal Republic of the Brazil (1988), art 5, XXIX (Brazilian Constitution).

⁴⁵ BS Chimni, ‘Third World Approaches to International Law: A Manifesto’ (2006) 8 *International Community Law Review* 7 (‘Third World Approaches to International Law’).

⁴⁶ David Trubek, Diogo Coutinho, and Mario Schapiro, ‘Toward a New Law and Development: New State Activism in Brazil and the Challenge for Legal Institutions’ (2012) *World Bank Legal Review*, Legal Studies Research Paper Series Paper No 1207, 283; Flynn, *Pharmaceutical Governance in Brazil* (n 26) 54.

⁴⁷ Fieldwork interview with Reinaldo Guimarães (Rio de Janeiro, 2014) (transcript on file with author); Flynn, *Pharmaceutical Governance in Brazil* (n 26) 54.

advocate of the aforementioned development theory.⁴⁸ The period under the Cardoso government was also the period that the Brazilian Social Democracy Party (*Partido da Social Democracia Brasileira* or PSDB), centrist in its political and economic stance, was in power. Under a PSDB government, Brazil continued to move away from the *dirigiste* policies of the developmentalist period, embracing many of the neoliberal prescriptions favoured by the Washington Consensus.⁴⁹ Under the Cardoso government, there was a shift in the consciousness of Brazil's ability to be a global player on one hand, and a general idea circulating among policymakers that the implementation of the TRIPS Agreement earlier than planned would bring in FDI.⁵⁰ That is, a new thinking where Brazil positions as a regional leader, a respected spokesman for the developing world, and an increasingly important partner for the US and the EU. Thus, policymakers believed that embracing IPR internally would not only be a positive step towards Brazil's economic liberalization but would also improve the image of Brazil as a modern economy. This, it was hoped, would attract foreign companies that would set up manufacturing plants in Brazil and reduce the country's dependence on technology imports.⁵¹

Another internal factor that allowed Brazil to phase into the TRIPS Agreement earlier was the weakened position of local generics at the time the IPLB was passed. With trade liberalization and the removal of the ISI policy that protected local manufacturers, many petrochemical raw material firms were privatised while the local firms that remained could not compete with their foreign counterparts that flooded the market.⁵² In the view of Reinaldo Guimarães, Vice President of the association representing the indigenous pharma-chemical industry (ABIFINA), over 1,500 production lines of local generic pharma-chemical companies were shut down due to the commercial opening of the Brazilian economy.⁵³ This view is reinforced by Orsi et al., who observed that the trade liberalization of the 1990s negatively affected the Brazilian pharmaceutical sector as the 'privatisation of petrochemical raw material firms reinforced the phasing out of the production of synthetics intermediates in

⁴⁸ In his memoir, Cardoso details how he combined principle and pragmatism to transform a harsh military dictatorship into a hopeful modern democracy, and how his background in sociology influenced his administration's major economic and social development achievements. See Fernando Henrique Cardoso and Brian Winter, *The Accidental President of Brazil* (2006).

⁴⁹ Trubek, Coutinho, and Schapiro (n 46) 283.

⁵⁰ Fieldwork interview with Richard Parker (Rio de Janeiro, 2014) (transcript on file with author).

⁵¹ Fieldwork interview with Guimarães (n 47).

⁵² Cassier and Correa (n 36) 123.

⁵³ *ibid.* Incidentally, the then Vice President of ABIFINA Nelson Brasil was an important negotiator in the National Congress but was totally defeated in the final voting of the law at Congress.

which the sector has competitive edge.’⁵⁴ The few drug manufacturers that remained in the market moved to less competitive areas, subsequently concentrating their production on low value-added commodities. In this environment, Brazilian firms could not compete in scale and technology with imported drugs distributed locally by specialised international traders.

The weakened position of local manufacturers meant that the sector could not mount any concerted sensitization campaign against the possible adverse impact of the TRIPS Agreement on Brazil’s indigenous generic pharmaceutical sector. Commenting on this, Reinaldo Guimarães notes:

The growth of neo-liberal ideologies such as Thatcher and Regan influenced Brazil in the 1990s. We had in Brazil a huge commercial opening without any kind of protection of our pharmaceutical companies. It was difficult for our members because many closed down and laid off workers. We were too weak to influence the government on TRIPS. In India, by contrast, trade liberalisation proceeded at a slower pace with policies in place to support local pharmaceutical sector. India also used the 10-year transition period, within the 2 years of signed of TRIPS, Brazil passed the Patent Law which simply ignored the domestic industrial policy and domestic companies. Our current VP who incidentally was the VP in 1996 was an important actor in the discussion of patent law at that time. His name is Nelson Brasil and was an important negotiator for local drug manufacturers in the national congress but him, his friends and allies were totally defeated in the final forum of the law. The impact of that decision can be seen even till present time. Today, India is a player in the international pharmaceutical market while Brazil is not.⁵⁵

This domestic economic configuration explains the muted role of Brazilian drug manufacturers in the lead-up to the country’s harmonisation with the TRIPS regime.

In addition, the inaction of various civil society groups, particularly the health and AIDS activists, also explains why Brazil phased into the TRIPS regime quickly. Brazilian civil society groups were focused on internal politics and the re-democratisation process especially after the corruption scandal that led to the impeachment of President Collor. The crisis was that Collor, a conservative populist, implemented an incredibly corrupt government that carried out graft and embezzlement. In this crisis situation, it appeared that the young democracy (and the

⁵⁴ Cassier and Correa (n 36) 123.

⁵⁵ Fieldwork interview with Guimarães (n 47).

re-democratisation) process was going to come apart. This led to protests by civil society groups that were active in the democratic transition and had fought for the democratic process in previous years. In an interview with Richard Parker, the current president of the Brazilian Interdisciplinary AIDS Association (*Associação Brasileira Interdisciplinar De AIDS* or ABIA) who was in Brazil at the time, he notes:

A lot was going on internally at time. It was also the period in Brazil that the internal political process and the threat to re-democratisation was so important and so central at that point in time. The crisis that was opened up by fact that Collor's, a populist conservative man was elected president, and then implemented this incredibly corrupt government left all Brazilians who defended democracy in a crisis situation because it appeared that the democracy and re-democratisation process was going to come apart. And so everybody, including activists in the AIDS world such as Herbert D'Souza who was the founder of ABIA and a major figure in the movement were all preoccupied with the corruption of Collor government. Specifically, they were focused in creating a social movement and civil protest asking for the impeachment of Collor. It was Herbert D'Souza who walked up to the Congress to deliver the letter asking the Congress to open impeachment proceedings against Fernando Collor when civil society groups marched in Brasilia. So the point is that our leadership and organisations like ABIA was totally focused on what needed to be done to try to save democracy and the re-democratisation process in Brazil. In another time without that focus, we might have been thinking about things like TRIPS Agreement but at that time, that was the furthest thing from our mind.⁵⁶

This view is supported by Amy Nunn, who writes that IP regulations on access to AIDS medicines were largely unaddressed by the AIDS movement and treatment activists as they had not recognised the importance of the law for access to treatment because they were more focused on 'federal AIDS bureaucracies and moving trials through the judiciary rather than working with Congress.'⁵⁷ This preoccupation of both the civil society groups and the pharmaceutical sector explains why the new IP legislation – with very little TRIPS flexibilities designed to protect consumers and curtail industry abuses – was implemented.⁵⁸ As will be seen in the next sections, Brazilian civil society groups and AIDS activists have tried to rectify this by actively engaging with the law.

⁵⁶ Fieldwork interview with Parker (n 50).

⁵⁷ Amy Nunn, *The Politics and History of AIDS Treatment in Brazil* (Springer 2008) 85.

⁵⁸ Cassandra M Sweet, 'The Political Economy of Pharmaceutical Production in Brazil', *The New Political Economy of Pharmaceutical: Production, Innovation and TRIPS in the Global South* (1st edn, Palgrave 2013) 48; Flynn, *Pharmaceutical Governance in Brazil* (n 26) 55.

Externally, international politics brought to bear on Brazil. The country was under pressure from the US to change its IP laws since the early 1980s. Specifically, the US adopted trade restrictive measures towards Brazil, combining multilateral pressure in the GATT and Uruguay Round negotiations and bilateral actions.⁵⁹ In 1988, for example, the US initiated the Section 301 of the Trade Act – a unilateral action and contradictory to the ethics of the GATT/WTO – after the USTR found the pharmaceutical patent law ‘unreasonable’.⁶⁰ In initiating this trade sanction, the US imposed a 100 per cent tariff on imports of Brazilian products such as paper, consumer electronics, and agricultural products – about USD40 million worth of annual imports from Brazil.⁶¹

The use of Section 301 was indeed an extremely timely threat as the Brazilian economy was vulnerable and was going through economic upheavals, such that the loss of millions of dollars’ worth of export revenues hit home.⁶² This is especially so as many of Brazil’s political elite had interests in the agriculture export industry and with the US being one of the main destination markets, they were therefore particularly susceptible to US trade threats.⁶³ Consequently, many senators and deputies believed that implementing the TRIPS Agreement would not only improve trade with the US but would also ease trade sanctions. In fact, Piragibe dos Santos Tarragô notes that the threat to Brazil’s agricultural exports was very influential in breaking down Brazil’s opposition to IP negotiations.⁶⁴

Although these sanctions were suspended in 1990 after a visit from US President George Bush, the message was clear that the US would not tolerate any form of opposition to its foreign trade policy objectives. Importantly, the use of trade threats against Brazil explains the latter’s capitulation at the Uruguay Round after leading the

⁵⁹ See Michelle Ratton Sanchez Badin, ‘Developmental Responses to the International Trade Legal Game: Cases of Intellectual Property and Export Credit Law Reforms in Brazil’, *Law and the New Developmental State: The Brazilian Experience in Latin American Context* (1st edn, Cambridge University Press 2013) 260.

⁶⁰ Chakravarthi Raghavan, *Recolonization: General Agreement on Tariffs and Trade, the Uruguay Round and the Third World* (1990) 84.

⁶¹ *ibid.*

⁶² Mathew Flynn, ‘Corporate Power and State Resistance: Brazil’s Use of TRIPS Flexibilities for its National AIDS Program’ in Kenneth C Shadlen, Samira Guennif, and Georgina Alenka Guzman Chavez (eds), *Intellectual Property, Pharmaceuticals and Public Health: Access to Drugs in Developing Countries* (Edward Elgar Publishing 2011) 154 (‘Corporate Power and State Resistance’); see also Sweet (n 58) 49; see also Monica Steffen Guise Rosina, Daniel Wang, and Thana Cristina De Campos, ‘Access to Medicines: Pharmaceutical Patents and the Right to Health’, *Access to Knowledge in Brazil: New Research on Intellectual Property, Innovation and Development* (1st edn, Yale Law School 2008) 183.

⁶³ Flynn, *Pharmaceutical Governance in Brazil* (n 26) 55.

⁶⁴ dos Santos Tarragô (n 40) 245.

Southern resistance (with India, see next chapter) against the inclusion of IP rules in the global trade regime.

It was these externalities that prepared the ground for the full implementation of the TRIPS Agreement when it was finally introduced to the Brazilian Congress the following year.⁶⁵ Mapping the politics surrounding the implantation of the TRIPS Agreement has indeed shown how the interests of a transnational ruling elite have come to influence the shaping of global policies and law on one hand, and the obvious dialectic between struggles in Third World countries and the external forum on the other hand.⁶⁶

3.2 Unpacking the Industrial Property Law of Brazil

As mentioned earlier, the IPLB allows for patents on all pharmaceutical processes and products, consistent with Article 27 of the TRIPS Agreement. Section 1 of Chapter 2 provides conditions for patentability and patentable objects in Brazil. Though the IPLB does not provide an explicit list of patentable matters, the INPI Guidelines for the Examination of Patent Filings in the areas of Biotechnology and Pharmaceuticals, as well as the ANVISA Subject Matter Guideline on what is held patentable in Brazil, provide the parameter for patentable objects.⁶⁷

According to the INPI guidelines, the INPI authorises the following: synthetic processes of preparation of chemical compounds,⁶⁸ biological or enzymes processes,⁶⁹ natural biological processes,⁷⁰ new uses, and subsequent pharmaceutical uses.⁷¹ This means that the new law allows the patenting of chemical products (as processes were already patentable) and all sorts of food and pharmaceutical inventions. Article 8 stipulates that an object is patentable only when it meets ‘the

⁶⁵ In April 1991, the recently elected President Fernando Collor de Mello initiated the first attempt to change Brazil’s industrial property law by sending Bill 824/1991 to Congress and requesting for its urgent appreciation, but the discussion was suspended due to the political moment, specifically the corruption scandal that led to the impeachment of President Collor.

⁶⁶ Chimni, ‘Third World Approaches to International Law’ (n 45) 7.

⁶⁷ Maristela Basso and Rodrigues Edson Baes, *Intellectual Property Law in Brazil* (2010); see also Denis Barbosa, ‘The New Brazilian Patent Law’ (unpublished, Denisbarbosa.addr.com 1997) <<http://denisbarbosa.addr.com/papers.htm>> accessed 8 June 2014.

⁶⁸ Basso and Baes (n 67) 60.

⁶⁹ *ibid.*

⁷⁰ *ibid.*

⁷¹ *ibid.*

requirements of novelty, inventive activity and industrial application.’⁷² INPI authorises applications that involve first use, i.e. new use of products already known outside the medical field as medicine and second use (i.e. claims involving a subsequent medical use for a product already known as a medicine). Specifically, novelty is determined by comparing the invention to be patented with the existing ‘state of the art’ that comprises material accessible to the public by means of written or oral description, use, or any other means in Brazil or abroad.⁷³ Article 10 lists non-patentable objects, which include but are not limited to discoveries, scientific theories, mathematical methods, abstract concepts, surgical methods, all or parts of living beings, and biological material found in nature, to mention a few.⁷⁴ These non-patentable items are generally in conformity with European standards and those in other developing countries such as India.

The IPLB includes certain flexibilities intended to mitigate the adverse effect of rights conferred to patent holders with a view of restoring balance between private rights (IP) and social justice (economic and social rights.) These flexibilities include CLs, Bolar exceptions, experimental use, parallel imports, and health sector participation in examining pharmaceutical patent applications. Specifically, Articles 68 to 74 allow for the issuance of a CL if the ‘rights resulting are exercised in an abusive manner or if the patent is used in abuse of economic power.’⁷⁵ The abuse should be determined in a court or administrative court decision. The provisions further provide instances for the grant of a CL, which include failure to exploit the patented product within Brazil (local working requirement),⁷⁶ failure to satisfy the needs of the local market,⁷⁷ dependent patents,⁷⁸ and in situations of national emergency or public interest.⁷⁹ Compulsory licencing is also possible in case of dependent patents, that is, when a new invention that amounted to a substantial technical progress as compared to a prior one cannot be worked by reason of the prior patent’s scope of claims.⁸⁰ In cases of national emergency or public interest, the President of Brazil may grant a CL via an Executive Order. Paragraphs 2 and 4 of Article 68 specify conditions for parallel

⁷² IPLB, art 8.

⁷³ *ibid*, art 11, para 1; Ragavan (n 33) 130.

⁷⁴ IPLB, art 10, para 2.

⁷⁵ *ibid*, art 68, para 1(1).

⁷⁶ *ibid*, para 1(2).

⁷⁷ IPLB, art 68.

⁷⁸ *ibid*, art 70, para 1.

⁷⁹ *ibid*, art 71.

⁸⁰ Barbosa (n 67).

importation, which allows for the importation of patented products by third parties provided it has been introduced in the market directly by the patent holder or with his consent.⁸¹

The IPLB also allows for the participation of the health sector in the examination of pharmaceutical patents. To interpret this rule, Law 10196/2001 was added as Article 299c to Brazil's IP legislation, which instituted the 'prior consent' (*Anuência Prévia*) mechanism.⁸² The inclusion of the prior consent mechanism altered Brazil's IP regime; whereas INPI was previously solely responsible for patent examination and approval, the new law divided this competence between INPI and ANVISA.⁸³ To carry out this role, ANVISA – located at the Ministry of Health and responsible for the sanitary safety and quality assurance of pharmaceutical drugs – is empowered to grant patents for pharmaceutical products and processes on public health security grounds.⁸⁴ Under this arrangement, when an application for a pharmaceutical patent is filed, INPI first analyses whether it meets patentability and formal requirements, as determined by the IPLB. The application is then forwarded to ANVISA for a separate examination that the patent will not negatively affect public health. It is only after this rigorous examination that ANVISA grants its 'prior consent' for the issuance of a patent certificate.⁸⁵ Each examination is determined on a case-by-case basis, as ANVISA does not have a codified guideline on when to grant the prior consent.⁸⁶ However, ANVISA examiners refer to INPI regulatory guidelines to test whether the patent is new (novelty) and inventive in its applicability even though it is a lot stricter than INPI in its examinations. In this light, ANVISA aims to balance private rights (patent applications) with the state's social contract of ensuring security, well-being, development, and equality.⁸⁷

In addition, ANVISA considers the decisions of various patent offices in the US, Europe, and developing countries on similar issues. But most importantly, each

⁸¹ IPLB, art 68, para 3.

⁸² Rosina, Wang, and De Campos (n 62) 191.

⁸³ Rodrigues Edson Beas Jr and Bryan Murphy, 'Brazil's Prior Consent Law: A Dialogue Between Brazil and the United States over Where the TRIPS Agreement Currently Sets the Balance Between the Protection of Pharmaceutical Patents and Access to Medicines' (2006) 16 Albany Law Journal of Science and Technology 427.

⁸⁴ Rosina, Wang, and De Campos (n 62) 191; Beas Jr and Murphy (n 83).

⁸⁵ ANVISA Resolution 45, art 1.

⁸⁶ Fieldwork interview with Monica Caetano (Rio de Janeiro, 2014) (transcript on file with author).

⁸⁷ *ibid.* See Carlos M Correa, *Pharmaceutical Innovation, Incremental Patenting and Compulsory Licensing* (South Centre 2011) <<http://apps.who.int/medicinedocs/documents/s21395en/s21395en.pdf>> accessed 20 May 2015 (*Pharmaceutical Innovation*).

technical evaluation and final decision is based on how such patent application would affect the public health interest.⁸⁸ So while INPI is responsible for examining the legal sufficiency of patent applications, ANVISA is dedicated to protecting and promoting 'public health' in Brazil, similar to the US Food and Drug Agency.⁸⁹ Once an application is given the ANVISA consent, it is then sent to INPI for approval. On occasions when ANVISA does not grant its consent, the patent application is not authorised even with input from INPI.⁹⁰ This effectively means that ANVISA has veto power in the grant of pharmaceutical patents.⁹¹

Given the importance of medicine access, this particular role of ANVISA is a measure to protect patients as it prevents the granting of frivolous patent rights (ever-greening). It has been suggested that the 'prior consent' prerogative of ANVISA provides the Ministry of Health with an instrument to influence patent examination, making it difficult to get private rights of exclusion over knowledge for pharmaceuticals.⁹² In fact, according to Peter Drahos, the Brazilian model of double examination of pharmaceutical patents presents, from a social welfare point of view, one way in which developing countries can improve the quality of examination in a sector of vital national importance.⁹³ Therefore, by preventing patent abuse through the set-up of a rigorous process of examination, ANVISA becomes the 'gate-keeper' that not only serves to restrain term extension but also halts the grant of patent rights to inventions that are neither new nor inventive but are instead revised versions of known molecules. Importantly, the prior consent law reflects a novel use of its bureaucratic framework to roll back rights to the minimum required under the TRIPS Agreement and serves as a means for the Brazilian government to take control of the sensitive field of pharmaceuticals.⁹⁴

⁸⁸ Fieldwork interview with Caetano (n 86).

⁸⁹ Ruth L Okediji, 'Legal Innovation in International Intellectual Property Relations: Revisiting Twenty-One Years of the TRIPS Agreement' (2014) 36 *University of Pennsylvania Journal of International Law* 241.

⁹⁰ *ibid.* See also Basso and Baes (n 67) 79.

⁹¹ Beas Jr and Murphy (n 83) 427.

⁹² Kenneth Shadlen, 'The Politics of Patents and Drugs in Brazil and Mexico: The Industrial Bases of Health Policies' (2009) 42 *Comparative Politics* 47; see also Renata Reis, Veriano Terto Jr, and Maria Cristina Pimenta, *Intellectual Property Rights and Access to ARV Medicines* (ABIA 2009) 25; see also Eduardo Da Gama Camara Jr, 'Prosecution of Pharmaceutical Patents in Brazil: Tensions Between the Brazilian Patent Office and ANVISA - Intellectual Property - Brazil' (*Mondaq.com*, 2013) <<http://www.mondaq.com/article.asp?articleid=253068>> accessed 20 May 2015.

⁹³ Peter Drahos, *The Global Governance of Knowledge: Patent Offices and their Clients* (Cambridge University Press 2010) 249 (*The Global Governance of Knowledge*).

⁹⁴ Da Gama Camara (n 92) 244.

There have been some controversies regarding ANVISA's competence to examine and approve patent applications, and this contestation of ANVISA's role is divided between health activists and academics on one hand and pharmaceutical companies on the other. From the point of view of the former, the participation of ANVISA in the examination of pharmaceutical patents is consistent with Article 8 of the TRIPS Agreement, which stipulates that states may formulate or amend laws or adopt regulations necessary to protect public health.⁹⁵ In this view, the interests of the public, usually ignored in IP decisions, are represented and protected. Further, it has also been argued that the role of ANVISA promotes the development of new technologies that will allow the national industry to also develop, thus benefiting Brazil's social needs.⁹⁶

Many pharmaceutical patent-holding companies – usually led by foreign pharmaceutical firms – on the other hand, argue that ANVISA's role should be limited to evaluating the quality and safety of medicines. In 2004, for example, INPI rejected Roche's patent application for an ARV *Valcyte* (*valganciclovir hydrochloride*), citing ANVISA's prior consent refusal. Roche subsequently sued INPI on the ground that ANVISA is not competent to examine the requirement of inventive activity, novelty, and industrial application due to lack of legal knowledge. In light of this, Roche averred the role of ANVISA is inconsistent with the TRIPS Agreement.⁹⁷ The court ruled that the second substantive examination by ANVISA is unconstitutional and violates Brazil's TRIPS obligation. The court agreed ANVISA was not competent to examine the requirements of inventive activity, novelty, and industrial application on pharmaceutical patents due to lack of specific legal foresight on the matter.

Also, in *Aventis Pharma SA v INPI/ANVISA*, the French pharmaceutical company Aventis sued INPI after it rejected the former's patent application for its anti-cancer

⁹⁵ Under Article 8(1) of the TRIPS Agreement, states may formulate or amend laws or adopt regulations necessary to protect public health and to promote the public interest in sectors of vital importance to their socio-economic and technological development. Article 8(2) allows for countries to take appropriate measures, provided that they are consistent with the provisions of the TRIPS Agreement, that may be needed to prevent the abuse of intellectual property rights by right holders or the resort to practices which unreasonably restrain trade or adversely affect the international transfer of technology.

⁹⁶ Reis, Terto Jr, and Pimenta (n 92); Correa, *Pharmaceutical Innovation* (n 87) 6.

⁹⁷ *F Hoffmann-La Roche AG v INPI/ANVISA* (2004) Vara Federal do Rio de Janeiro, Ordinary action 2004.5101506840-0 (Vara Federal do Rio de Janeiro); see also Basso and Baes (n 67) 79.

drug *Taxotere*, due to ANVISA's denial of the prior consent.⁹⁸ In this case, the court ruled that patent rights are not absolute and should meet a certain set of social requirements in order to be granted. The court decided that access to medicines is a constitutionally recognised right in Brazil and as a result, sustained the prior consent mechanism.⁹⁹ However, in spite of the presence of ANVISA, a study by Carlos Correa found that six per cent of pharmaceutical patents were granted by INPI without being analysed by ANVISA.¹⁰⁰ This raises concerns on whether all pharmaceuticals applications are really going through examination by both bodies.

3.3 The Constitutional Right to Health

One of the most important and significant structural reforms occurred in the health sector in the form of the inclusion of the right to health in the new Brazilian Constitution of 1988. The new Brazilian Constitution established health as a human right for all Brazilian citizens. Specifically, Article 6 lists various rights, including right to health, as social rights,¹⁰¹ while Article 196 explicitly provides for the scope of the health rights, stating:

The health is the right of all and the responsibility of the State, to be guaranteed by means of social and economic policies aimed at reducing the risk of illness and other hazards, and at the universal and equal access to actions and services for its promotion, protection and recovery.¹⁰²

The right to health law as articulated in the Constitution has both tangible and intangible characteristics. Intangibly, it provides for individual and trans-collective rights. Individually, the right to health gives a person the right to demand a given provision (in this case, health care) from the state. The *Rosa Vieira v Municipality of Porto Alegre* case¹⁰³ provides a good example. In this case, Dina Rosa Vieira – HIV-positive, poor, destitute, and unable to afford the cost of ARV treatment – brought a case against the Municipality of Porto Alegre for failing to provide medication for the

⁹⁸ *Aventis Pharma SA v INPI/ANVISA* (2005) 38th Federal Court of Rio de Janeiro, 2004.51.01.513854-1 (38th Federal Court of Rio de Janeiro).

⁹⁹ *ibid.*

¹⁰⁰ Correa, *Pharmaceutical Innovation* (n 87) 7.

¹⁰¹ Brazilian Constitution, art 6.

¹⁰² *ibid.*, art 196.

¹⁰³ *Rosa Vieira v Municipality of Porto Alegre* (2000) Supreme Federal Tribunal, Rio Grande do Sol, No 271286 (Supreme Federal Tribunal, Rio Grande do Sol) <<http://www.globalhealthrights.org/health-topics/health-care-and-health-services/dina-rosa-vieira-v-municipality-of-porto-alegre/>> accessed 28 May 2015 (Rosa Vieira case).

treatment of AIDS. The first instance court ruled in favour of Vieira on the grounds of right to health and life enshrined in the Constitution. The Municipality of Porto Alegre appealed the decision to the Supreme Court. The Supreme Court upheld the decision of the first instance court, specifically noting:

The subjective right to health represents the undeniable judicial prerogative guaranteed to the general public by the Constitution of the Republic (article 196). This translates as a constitutionally mandated right, and ... proscribes that, the Public Authority, whomever constitutes such position and has the power to implement appropriate social and economic policies must provide and guarantee its citizens, including those carrying the HIV virus, universal and equal access to pharmaceutical assistance and medical-hospital access.¹⁰⁴

This means that the right to health is an individual entitlement which the state is mandated to satisfy and not a mere declaration. It is not just a formal recognition from the Brazilian state or a consumer right as provided for in many Latin American Constitutions such as in Argentina. Rather, it is an essential right that should be integrally respected and fully guaranteed. Importantly, the case shows that the right to health is an inalienable consequence of the right to life, and the state should ensure that social and economic policies are implemented to guarantee universal and equal access to health services to its citizens.¹⁰⁵ This right therefore qualifies as a 'judicial prerogative that involves a citizen's power to demand that the State implement positive obligations imposed on it by the constitutional order.'¹⁰⁶

Trans-individual right, on the other hand, can be either collective or diffusive in nature. It is a collective right, in the sense that members of a particular group with an established legal relationship can obtain protection on behalf of the entire group, such as when a group of HIV-positive soldiers obtain a legal ruling that prevents discrimination based on their HIV status. This collective right thus covers not only defendants in this particular case, but all future persons that might be HIV-positive from being discriminated against. In this way, there can be 'no satisfaction or loss in

¹⁰⁴ *ibid.*

¹⁰⁵ Fieldwork interview with Pedro Vallardi (Rio de Janeiro, 2014) (transcript on file with author). For broader discussion on right to health in Brazil, see also Teixeira, Vitória, and Barcarolo (n 1) 69-88; Richard G Parker, 'Civil Society, Political Mobilization, and the Impact of HIV Scale-Up on Health Systems in Brazil' (2009) 52 *Journal of Acquired Immune Deficiency Syndromes* S49-S51; Octavio Luiz Motta Ferraz, 'The Right to Health in the Courts of Brazil: Worsening Health Inequities?' (*Health and Human Rights*, 2013) <<http://www.hhrjournal.org/2013/08/29/the-right-to-health-in-the-courts-of-brazil-worsening-health-inequities/>> accessed 28 May 2015 ('The Right to Health in the Courts of Brazil'); Alan Berkman and others, 'A Critical Analysis of the Brazilian Response to HIV/AIDS: Lessons Learned for Controlling and Mitigating the Epidemic in Developing Countries' (2005) 95 *Am J Public Health* 1162-72; Kurt Weyland, *Democracy Without Equity* (1996).

¹⁰⁶ Rosa Vieira case.

the group's representation except such as affects all members.'¹⁰⁷ On the other hand, the right to health is diffusive in nature when a group with undetermined membership but whose membership is derived from de facto circumstances share benefits from said right.¹⁰⁸ For example, it can be argued that the *Rosa Vieira* case is diffusive in nature in the sense that other destitute HIV-positive individuals also benefit from free HIV treatment. This ruling therefore provides not just a singular protection but also a collective jurisdictional protection for other persons in similar circumstances.

Analysis of right to health cases by Rosina et al. found that even though consequences of court decisions apply to all, most judges consider the right to health on a case-by-case basis and not collectively, and interpret the right to health and the principles of the Unified Health System (*Sistema Unico de Saude* or SUS) as the individual's right to any health-related expense.¹⁰⁹ This has led to tensions between universal access to health care and limited state resources. Octavio Ferraz contends that the right to health litigation is worsening Brazil's already pronounced health inequities and is thus detrimental to health equity. This is because 'the criterion for privileging litigants over the rest of the population is not based on any conception of need or justice but purely on their ability to access the judiciary, something that only a minority of citizens possess.'¹¹⁰ Many health activists disagree with this view. In an interview, Marcela Viera, the coordinator of the GTPI/REBRIP, argues that ensuring right to life is justice in itself because allowing people to die when there is a cure for an illness is unjust.¹¹¹ In a similar vein, Renata Reis points out that the idea behind the right to health is the bridging of income disparities in Brazilian society by extending preventive measures as well as basic services to the poor.¹¹² However, a recent study of court decisions has shown signs that judges are rethinking this approach, as the financial impact of high drug costs has become increasingly unsustainable. According to Rosina et al., there is a shift in judicial thinking, as the 'court started to deny some petitions for access, in light of public budgetary considerations.'¹¹³

¹⁰⁷ Roger Rauup Rios, *Legal Responses to the HIV/AIDS Epidemic in Brazil* (2003) <http://www.columbia.edu/itc/hs/pubhealth/p8725/all_week_8_articles.pdf> accessed 21 May 2015.

¹⁰⁸ *ibid.*

¹⁰⁹ Rosina, Wang, and De Campos (n 62) 172.

¹¹⁰ Ferraz, 'The Right to Health in the Courts of Brazil'; see also Octavio Luiz Motta Ferraz, 'Between Usurpation and Abdication? The Right to Health in the Courts of Brazil and South Africa', SSRN Journal ('Between Usurpation and Abdication')

¹¹¹ Fieldwork interview with Marcela Viera (Rio de Janeiro, 4 June 2014) (transcript on file with author).

¹¹² Fieldwork interview with Renata Reis (Rio de Janeiro, 13 June 2014) (transcript on file with author).

¹¹³ Rosina, Wang, and De Campos (n 62) 191.

Tangibly, the right to health requires the state to provide free health care – medicines, medical technology, and medical treatments – for all who need it. In response to this new law mandating free health care for all, the Congress passed the Health Act of 1990 which created the SUS, to offer free comprehensive health care to the entire population, irrespective of employment, status, or access to other forms of health insurance.¹¹⁴ Regulated by Law 8080/90 and 8142/90, the SUS aims to provide comprehensive, universal, and preventive health services to all Brazilians.

The creation of the SUS is based on three important principles of integrality, universality, and equality.¹¹⁵ *Universality* means that no citizen can be excluded from SUS coverage and each citizen is entitled to the satisfaction of one's health needs with the most advanced treatment available, irrespective of costs.¹¹⁶ This principle of universality enables *equality* of access by ensuring that there is no discrimination in the provision of public health services and products to Brazilian citizens, whilst *integrality* provides for full health care coverage, from the most basic to the most complex health care needs. These three principles define the Brazilian state's promotion of health as a fundamental social right,¹¹⁷ such that at least 80 per cent of the population depend solely on the public health care system.¹¹⁸ It provides health care free of charge with universal access, based on the principle of equity and community participation, to 200 million inhabitants. There is no other country that provides free health care to that many users, and even in the few where there is a universal health system, the population is fewer. In line with constitutional obligations, Ordinance 3.916/98 created the National Policy on Medicines and directed the Ministry of Health to issue a list of essential medicines – the *Relação Nacional de Medicamentos Essenciais* (RENAME). Importantly, the ordinance was aimed at guaranteeing access to affordable, safe, and quality medicines.

The impact of the codification of the right to health is especially prominent in the government's response to the HIV/AIDS epidemic. The first case of AIDS in Brazil was reported in 1982 and over time, São Paulo has become the epicentre of the

¹¹⁴ Jane Galvão, 'Access to Antiretroviral Drugs in Brazil' (2002) 360 *The Lancet* 1862, 1863 ('Access to Antiretroviral Drugs in Brazil'). See also Galvão, 'Brazil and Access to HIV/AIDS Drugs' (n 1) 1112.

¹¹⁵ Ferraz, 'Between Usurpation and Abdication' (n 110) 34.

¹¹⁶ *ibid.*

¹¹⁷ A Nunn, E Da Fonseca, and S Gruskin, 'Changing Global Essential Medicines Norms to Improve Access to AIDS Treatment: Lessons from Brazil' (2009) 4 *Global Public Health* 133.

¹¹⁸ Jose Serra, 'The Political Economy of the Brazilian Struggle Against AIDS' (2004) <<https://www.sss.ias.edu/files/papers/paper17.pdf>> accessed 21 May 2015.

epidemic due to the concentration of key gay movements. As a result, São Paulo emerged as the key constituent that capably handled the AIDS epidemic, having set up the official response programme as early as 1984.¹¹⁹ In an interview with Veriano Terto Jr. – one of the founders of ABIA – it was stated that the initiative of São Paulo in starting non-discriminatory universal access programmes not only convinced the Brazilian government that AIDS can be treated and contained, but gave impetus to the demand of health activists for the national implementation of a similar programme.¹²⁰ As a result, other state governments and even the federal government borrowed heavily from the response to the epidemic developed in São Paulo. In fact, the first nationwide programme was established in 1986 in the form of the Brazilian National STD and AIDS Programme (*Programa Nacional de Doenças Sexualmente Transmissíveis e AIDS* or NAP) two years before the constitutionalization of the right to health in 1988.

The NAP initially focused on epidemiological surveillance, medical assistance, release of non-discriminating and prevention messages to patients and to the general public, as well as limited dispensation of drugs to treat opportunistic infections.¹²¹ It created awareness of the new infection whilst monitoring its spread among the population, but not treatment of the disease itself. This particular response by the government – of monitoring and creating awareness instead of treatment and prevention – meant that the disease exploded especially in the urban areas and among vulnerable groups such as sex workers and injecting drug users. The proliferation of HIV/AIDS from a few cases in 1983 to a full blown epidemic in 1993 triggered protests from civil society organisations (CSOs) made up of HIV/AIDS patients groups, academics, human right groups, health professionals, lesbian, gay, bisexual, and transgender (LGBT) groups, and religious organisations. Anchoring their agitation on anti-discrimination practices and the constitutional right to life and health, these protests pressured the government to adopt progressive AIDS policies and provide free ARV to all those in need. These AIDS activists voiced their

¹¹⁹ Fieldwork interview with Veriano Terto Jr (Rio de Janeiro, 2014) (transcript on file with author); See also Richard Parker, *Building the Foundations for the Response to HIV/AIDS in Brazil: The Development of HIV/AIDS Policy, 1982 - 1996* (2003) 147. For a fascinating and rich literature on AIDS activism from a variety of different angles – some of which come from the sociology of science / STS literature and illuminate interesting points about expertise, lay intervention, and the multiple roles of pharmaceutical companies and regulators, see Steven Epstein, *Impure Science: AIDS, Activism, and the Politics of Knowledge* (1996).

¹²⁰ Fieldwork interview with Terto Jr (n 119).

¹²¹ Galvão, 'Access to Antiretroviral Drugs in Brazil' (n 114) 1862; Guido Carlos Levi and Marco Antonio A Vitória, 'Fighting Against AIDS: The Brazilian Experience' (2002) 16 AIDS 2372.

frustration by petitioning the judiciary, mobilising street campaigns, and using mass media.¹²² According to Terto Jr., these social movements played a critical role in producing knowledge and expertise by conceptualising AIDS-related policies such as treatment programmes, providing templates on how the state should manage AIDS treatments, using rights-based discourse to establish novel conceptions of citizenship and social solidarity, and pursuing legal action against insurance companies which refused to fund *azidothymidine* (AZT) treatment.¹²³ It was the ability of these diverse social groups – with very real differences in class and economic status – to develop a countervailing response to the stigma surrounding homosexuality and HIV that made the movement powerful and forced the government to take notice.

In 1996, the government enacted Law 9313/96 – also known as the Sarney Law, named after the Congressman Jose Sarney who introduced the bill. Law 9313/96 guarantees free access to ARVs for AIDS treatment for all people in Brazil living with HIV/AIDS.¹²⁴ Specifically, Article 1 thereof stipulates:

HIV-infected people and/or people living with AIDS are entitled to receive, at no cost, all medicines necessary for their treatment, from the Unified Health System and the Executive Branch of the Government through the Ministry of Health will standardize which drugs are be used for each stage of the disease and will procure the drugs through the SUS.¹²⁵

The law therefore formalised and centralised ARV drug policy at the Ministry of Health. It also placed no restriction on the expenditure of the treatment to be borne by the government.¹²⁶ The NAP is self-funded by the Brazilian government as it gets its funds from the national, state, and municipal budgets. According to Amy Nunn, by deliberately excluding means test and regulatory clauses and including the words ‘free of charge’, the Congress via the Sarney Law signed a blank cheque for the AIDS treatment.¹²⁷ The law also helped structure the purchase of ARV medicines for the NAP by decentralising the procurement and distribution of HIV and other essential medicines. This legislation has been suggested to be the most important health reform

¹²² Galvão, ‘Brazil and Access to HIV/AIDS Drugs’ (n 1) 1112.

¹²³ Fieldwork interview with Terto (n 119).

¹²⁴ Nunn, Da Fonseca, and Gruskin (n 117) 134.

¹²⁵ Nunn (n 57) 89.

¹²⁶ Lei 9.313: Dispõe Sobre a Distribuição Gratuita de Medicamentos aos Portadores do Hiv e Doentes de AIDS (1996).

¹²⁷ Amy Nunn and others, ‘The Impacts of AIDS Movements on the Policy Responses to HIV/AIDS in Brazil and South Africa: A Comparative Analysis’ (2012) 7 *Global Public Health* 89.

implemented for the NAP as it helped scale up generic production of pharmaceutical products in Brazil.¹²⁸

The provision of free ARV turned the tide in favour of Brazil in the fight against HIV/AIDS.¹²⁹ For example, the free distribution of ARV led to a 50 per cent decline in AIDS mortality from 1996 to 2002.¹³⁰ There were also substantial reductions of around 80 per cent in hospitalisation and treatment associated with opportunistic infections within that time frame.¹³¹ This, according to estimates, resulted in cost savings close to USD1 billion for the Brazilian government.¹³² Other scholars note that the free distribution of ARV changed public perception of the disease as those who have not yet been diagnosed decided to get tested on the basis of information about the effectiveness of the drugs and their availability free of charge.¹³³ As of December 2013, of the 718,000 people with HIV/AIDS in Brazil, 350,000 are on ART.¹³⁴ Thus, it can be argued that this particular policy of universal access led to the stabilization of the number of new cases, and the enhancement in quality of life of people living with AIDS.¹³⁵ At the time of writing, the budget of the NAP from the federal government is estimated at BRL1.4 billion (USD600 million), which is exclusive of the state and municipal contribution to the AIDS programme.¹³⁶

The approval of Law 9313/96 occurred at an interesting junction in Brazilian politics. Parallel to the enactment of the Sarney Law, the Congress approved Law 9.279/96, changing the industrial property law and allowing for patents on pharmaceutical processes and products. Thus, the government approved a bill that mandated the national health system's provision of free ARV to HIV/AIDS patients on one hand, and implemented a new TRIPS-compliant industrial property law on the other. The introduction of the new industrial property law raised prices of the same drugs the government was now obliged to purchase for thousands of patients. Until 1996, these

¹²⁸ Fieldwork interview with Gabriela Chaves (Rio de Janeiro, 2014) (transcript on file with author).

¹²⁹ Galvão, 'Access to Antiretroviral Drugs in Brazil' (n 114) 1863; Galvão, 'Brazil and Access to HIV/AIDS Drugs' (n 1) 1112; Nunn (n 57) 134.

¹³⁰ Serra (n 118).

¹³¹ Nuria Homedes and Antonio Ugalde, 'Improving Access to Pharmaceuticals in Brazil and Argentina' (2006) 21 Health Policy and Planning 125.

¹³² Serra (n 118); Galvão, 'Access to Antiretroviral Drugs in Brazil' (n 114) 1862.

¹³³ Galvão, 'Access to Antiretroviral Drugs in Brazil' (n 114) 1863.

¹³⁴ Fieldwork interview with Mesquita (n 2).

¹³⁵ Carlos Andre F Passarelli and Veriano Terto Jr, *Non-Governmental Organizations and Access to Anti-Retroviral Treatments in Brazil* (1st edn, 2003) 252 <http://www.columbia.edu/itc/hs/pubhealth/p8725/all_week_8_articles.pdf> accessed 25 May 2015.

¹³⁶ Fieldwork interview with Mesquita (n 2). Interestingly, this figure (USD600 million) is the total annual budget for the WHO.

medicines were in the Brazilian public domain and could be reproduced by indigenous pharmaceutical companies without licences. The cumulative impact of these two laws profoundly changed the AIDS treatment programme. In addition, it brought the issue of availability of drugs to the HIV and medicine access discourse in Brazil.¹³⁷

Many informants interviewed for this study contend that the ratification of two different and conflicting laws is emblematic of trying to implement international law in local spaces, thereby leading to insurmountable social fractions.¹³⁸ This is not surprising as attempts at institutional transfer of legal rules from one production regime to another often produce a legal irritation in the new context.¹³⁹ Thus, within the context of this study, the combined effect of implementing a law that allows for free medicines for all and another law allowing for the legal protection of previously unprotected pharmaceutical products and inventions was an increase of government expenditure in the AIDS programme. For example, federal spending on AIDS increased from USD330 million to USD600 million from 1997 to 2002.¹⁴⁰ This increase in cost threatened the sustainability of the government's HIV/AIDS programme. The rise in cost, as suggested by some scholars, is due to three factors. First, the number of people on ARV treatment increased due to new infections. Second, because ARVs do not cure the HIV virus and due to the improved efficacy of ARVs, many HIV patients are living longer which means the treatment will be administered indefinitely. Third, patients need to change treatment to newer lines of ARV as immunities develop. These newer costs are expensive and under patent, meaning the patent owner has the sole right to sell and dictate the price of the drugs. These combined factors meant that the government was spending more on ARV provision and for longer periods – a threat to the sustainability and universality of the health programme.

In response to the rising costs and to mitigate the effect on the AIDS programme, the Brazilian government passed Law 9787/99, known as the Law of Generic Medicines, in 1999. This law defines a generic medicine to mean a product similar to the

¹³⁷ Nunn (n 57) 93.

¹³⁸ Fieldwork interview with Paranagua (n 43); fieldwork interview with Parker (n 50); fieldwork interview with Reis (n 112); fieldwork interview with Chaves (n 128).

¹³⁹ Gunther Teubner, 'Legal Irritants: How Unifying Law Ends up in New Divergences' (2001) *Varieties of Capitalism* 417-41.

¹⁴⁰ Serra (n 118).

reference or innovator drug and is expected to be interchangeable with the latter.¹⁴¹ With this definition, the law classified the Brazilian pharmaceutical markets into ‘reference medicines’ (brand or innovator medicines), ‘generics’ and ‘similar medicines.’¹⁴² It also dealt with various facets of licencing and inspection of pharmaceutical products and services as well as technical standards and norms for reference, innovative, generic, and similar drugs.¹⁴³ Significantly, the law required that under the government system, all purchasing contracts are to be generic while all prescriptions are to be written using the generic name, essentially introducing generics into the Brazilian market.¹⁴⁴ This means that whereas private medical practices can prescribe any suitable drug, regardless of whether it is patented or generic, this law mandates all government prescriptions to exclusively refer to generic versions of drugs.

The Law of Generic Medicines also made the use of CLs more flexible and simpler, while regulatory reforms were introduced to accelerate the market entry of generics after the expiration of its on-patent version. In so doing, this law fundamentally helped promote competition between medicines and reduced the cost of medicines for chronic diseases such as HIV. For instance, ARV treatment expenditure for consumers was reduced from a yearly cost of USD4,860 per person in 1997 to USD1,000 per person in 2001.¹⁴⁵ This is because generics are 40-45 per cent cheaper than their on-patent counterpart.¹⁴⁶ Thanks to these price reductions, the government managed to save approximately USD1.2 billion on AIDS treatment costs.¹⁴⁷

In addition, the law helped spur growth in the local pharmaceutical sector. A study by Cohen and Lybecker demonstrates that this law benefitted local producers and increased the market for generics by 40 per cent.¹⁴⁸ Other scholars such as Homedes and Ugalde point out that this law facilitated healthy competition among local

¹⁴¹ Bermudez and others (n 13) 136.

¹⁴² Gabriela Chavez and Renata Reis, ‘Health, Intellectual Property and Innovation: A Case Study of Brazil’ (2011) South Centre 73.

¹⁴³ Bermudez and others (n 13) 136.

¹⁴⁴ Matthew Brian Flynn, ‘Pharmaceutical Governance in Brazil: Globalization, Institutions and AIDS’ (PhD thesis, University of Texas at Austin 2010) 58; Chavez and Reis (n 142) 74; Bermudez and others (n 13) 136.

¹⁴⁵ Homedes and Ugalde (n 131) 125.

¹⁴⁶ Gabriela Chaves, Marcela Vieira, and Renata Reis, *Access to Medicines and Intellectual Property in Brazil: Reflections and Strategies of Civil Society* (1st edn, 2008) <http://www.scielo.br/pdf/sur/v5n8/en_v5n8a09.pdf> accessed 21 May 2015.

¹⁴⁷ Serra (n 118).

¹⁴⁸ Jillian Clare Cohen and Kristina M Lybecker, ‘AIDS Policy and Pharmaceutical Patents: Brazil’s Strategy to Safeguard Public Health’ (2005) 28 *The World Economy* 220.

manufacturers, spurring innovation and consolidation of the local pharmaceutical industry.¹⁴⁹ Former Brazilian Minister of Health Jose Serra contends that the incentive created by the Law of Generic Medicines helped build Brazil's capacity to internally produce eight of the 13 components of first line anti-AIDS drugs, thereby boosting local manufacturing capacity.¹⁵⁰ Brazil currently has the largest pharmaceutical sector and market in Latin America and has one of the top 10 globally. At the time of this research, the sector locally produces 80 per cent of medicine units marketed in the country, which totals to 74.6 per cent of market value sales.¹⁵¹ Of course, foreign firms based in Brazil lobbied heavily against this law, as they feared for loss of market access. The Brazilian transnational pharmaceutical companies association (ABIFERMA) launched campaigns aimed at consumers and physicians questioning the quality and safety of generic medicines.¹⁵²

However, in spite of the efforts by the government to mitigate the growing cost of ARV because of the NAP and its constitutional obligations, the federal expenditure on health still remained high. Though the Brazilian state's ability to locally produce majority of its pharmaceutical needs contributed significantly to the improvement of access to highly active antiretroviral therapy (HAART) treatments, it was still not enough to stem the rising costs of new-line HAART treatments that are more efficient but expensive and patent-protected. This inevitably called for expedient political and legal action. In response, the federal government threatened to issue CLs to coax foreign pharmaceutical companies that have patents in Brazil to reduce the cost of ARVs sold. In 2001, the Brazilian government started price negotiations with foreign companies to reduce the local cost of certain ARVs. In most cases, these negotiations were successful due to the threat of CLs. For instance, according to Cohen and Lybecker, Roche reduced the price of *nelfinavir* in Brazil by 40 per cent after the Ministry of Health threatened to issue a CL.¹⁵³ Merck – another foreign pharmaceutical company – offered a 60 per cent discount on its ARV drug *Efavirenz*, which was still under patent in Brazil despite being in the public domain due to the pipeline mechanism.¹⁵⁴ Abbott was also able to offer considerable discounts after the Brazilian government threatened to break its patent.

¹⁴⁹ Homedes and Ugalde (n 131) 125.

¹⁵⁰ Cohen and Lybecker (n 148).

¹⁵¹ See Bermudez and others (n 13) 138.

¹⁵² *ibid* 136.

¹⁵³ Cohen and Lybecker (n 148).

¹⁵⁴ Galvão, 'Access to Antiretroviral Drugs in Brazil' (n 114) 1864; Reis, Terto Jr, and Pimenta (n 92) 26.

However, it has been argued that the threat of CLs without their actual use has grown futile. Chaves et al. assert that the threat of CLs has become ineffective as the prices agreed in later rounds of negotiations in 2004 and 2005 were unsatisfactory. They posit a need for the Brazilian state to invoke compulsory licencing as it is within its sovereign right and its TRIPS obligation to do so. For instance, the government was only able to secure one per cent cut for the ARV drugs *lopinavir/ritonavir*.¹⁵⁵ The discounts secured for other new-line ARV drugs *tenofovir* and *atazanavir* were 5.2 per cent and 7.7 per cent respectively.¹⁵⁶ Yet, even with the reductions, the price of the NAP remained high, threatening its sustainability. In fact, a study by Chaves and Reis showed that the generic versions of the ARV supplied by Indian manufacturers such as Cipla, Ranbaxy, and Aurobindo were much cheaper, with an annual cost of USD164 per patient compared to Merck's version that costs USD580 per patient per year.¹⁵⁷ Moreover, even though the government was able to secure a 60 per cent discount for the price of Merck's *Efavirenz*, Merck was still selling the drugs at cheaper prices in countries at the same development level as Brazil and with still fewer HIV patients.¹⁵⁸

In May 2007, Brazil granted a CL for *Efavirenz* which is patented by Merck under the pipeline mechanism.¹⁵⁹ It is important to note at this point that the Brazilian government attempted for the second time to negotiate with Merck for its ARV *Efavirenz*. Specifically, Carlos Correa notes that prior to the issuance of the CL, Merck offered USD1.59 to USD1.10 per dose, which the Brazilian government deemed unsatisfactory.¹⁶⁰ Merck, however, did not provide a counteroffer to the Brazilian government, ignoring the size of the Brazilian market as it was predominantly used by 77,000 patients (or 45 per cent) under the HIV programme as one of the medications for first line treatment.¹⁶¹ This explains why the government issued the CL. In fact, the study by Staffen et al. showed that the government reported

¹⁵⁵ Chaves, Vieira, and Reis (n 146) 170.

¹⁵⁶ *ibid.*

¹⁵⁷ Price estimate is for 2005-2006. Reis, Terto Jr, and Pimenta (n 92) 27.

¹⁵⁸ Carlos Correa, 'The Use of Compulsory Licenses in Latin America', *Compulsory Licensing: Practical Experiences and Ways Forward* (1st edn, Springer 2015) 52 ('The Use of Compulsory Licenses in Latin America').

¹⁵⁹ Chaves, Vieira, and Reis (n 146) 170.

¹⁶⁰ Correa, 'The Use of Compulsory Licenses in Latin America' (n 158).

¹⁶¹ *ibid*; Reis, Terto Jr, and Pimenta (n 92).

a reduction of 72.2 per cent in the cost of supplying this drug.¹⁶² Reis, Terto, and Pimenta, on the other hand, found that for 2007 alone, the acquisition of a cheaper version of *Efavirenz* from India saved the Brazilian government USD30 million.¹⁶³ Nevertheless, one cannot discount the impact of the threat and use of CLs to the sustainability of the government policy of free HIV/AIDS treatment. This is especially so in the context that these drugs are sold at exorbitant prices in other parts of the developing world. Indeed, the Brazilian approach, which consists of local production of majority of its pharmaceutical needs as well as its ability to utilise the flexibilities embedded in its IPLB, increased its bargaining position with foreign multinational pharmaceutical companies. This has contributed significantly in improving domestic access to essential life-saving ARV treatments and has so far ensured that the government's ARV programme remains sustainable.

3.4 Local Actors, Engagement with Patent Law, and Impact of HIV/AIDS in Brazil

As stated earlier, Brazil is one of the few countries in the world that offers free universal ARV drugs to its HIV-positive citizens. The Brazilian response to the HIV/AIDS epidemic challenges the perception that it is economically impossible to intervene and reverse the tragic HIV trends in low-income countries.¹⁶⁴ Additionally, it calls attention to the way law and public policy can be integrated towards legal, political, and human advancement.¹⁶⁵ Importantly, the successful development and implementation of Brazil's HIV/AIDS programme underscores the importance of a cordial relationship between the State, private sector, and civil society. Thus, any analysis of the 'Brazilian Model' should be discussed in light of the roles played by these various actors, particularly the activism of CSOs, and within the context of the 'social mobilisation of Brazilians confronting the military dictatorship and demanding democracy and a return to civilian rule.'¹⁶⁶

¹⁶² Rosina, Wang, and De Campos (n 62) 191. Based on UNAIDS Programme estimates, 38 per cent of the 200,000 patients benefited from the CL on *Efavirenz* in 2007. See *Thematic Segment: HIV And Enabling Legal Environments* (1st edn, 2011) <http://www.unaids.org/sites/default/files/en/media/unaids/contentassets/documents/pcb/2011/thematic%20segment_final_correction2Dec.pdf> accessed 30 May 2015.

¹⁶³ Reis, Terto Jr, and Pimenta (n 92).

¹⁶⁴ João Guilherme Biehl, 'The Activist State: Global Pharmaceuticals, AIDS, and Citizenship in Brazil' (2004) 22 *Social Text* 106.

¹⁶⁵ *ibid.*

¹⁶⁶ Berkman and others (n 105).

CSOs first rose to prominence in Brazil in the early 1980s – a period characterised by slow transition from 20 years of authoritarian military rule to a gradual return to democratic rule. This transition to democracy spurred the re-emergence of political parties and trade unions as well as the formation of NGOs, which eventually gave rise to strong waves of social activism that changed the course of events in Brazil. These new non-state actors challenged the old military ways such as corruption, cronyism, and dilapidated public systems. They called for better infrastructure,¹⁶⁷ a new constitution, election, and free congress, among other things.¹⁶⁸ One of the prominent groups in this national mobilisation for democratic transition was the Sanitary Reform Movement (*Sanitarista*).

Formed in the early 1980s, the *Sanitarista* – a coalition of health care professionals, academics, and student groups – was part of the resistance to the dictatorship and its privatisation of social security health services. In its activist heydays, the *Sanitarista* demanded a health system responsive to not only the needs of the people but also controlled by the public.¹⁶⁹ Additionally, the group argued for and defended the right to health as a fundamental human right to be guaranteed by the Constitution.¹⁷⁰ The concomitant effect of this demand was the inclusion of right to health in the Brazilian Constitution and the creation of the Unified Health System, which spurred the development of the Brazilian public health system.¹⁷¹

At the local level, the *Sanitarista* was most active in São Paulo, which subsequently was also the epicentre of the AIDS epidemic.¹⁷² The group led the first response to the initial AIDS cases reported in the city in 1983 partly due to its active involvement at the São Paulo State Health Department.¹⁷³ The same year, the first HIV/AIDS organisation HIV Prevention Action Group (*Grupo de Apoio à Prevenção à AIDS* or GAPA) was founded in São Paulo. It helped develop a strong human rights-oriented perspective in the municipal government's conception of its health-related

¹⁶⁷ Joanildo A Burity, 'Reform of the State and the New Discourse on Social Policy in Brazil' (2006) 33 *Latin American Perspectives* 67.

¹⁶⁸ Berkman and others (n 105) 1166.

¹⁶⁹ *ibid* 1163; see also Sonia Fleury, 'Brazilian Sanitary Reform: Dilemmas Between the Instituting and the Institutionalized' (2009) 14 *Cien Saude Colet* 744.

¹⁷⁰ Berkman and others (n 105) 1164; Nunn and others (n 127).

¹⁷¹ Sabine Kleinert and Richard Horton, 'Brazil: Towards Sustainability and Equity in Health' (2011) 377 *The Lancet* 1721.

¹⁷² Berkman and others (n 105) 1164.

¹⁷³ *ibid*.

responsibilities.¹⁷⁴ They also helped develop São Paulo's first AIDS programme that included the free distribution of ART – *Zidovudine* (AZT) – to patients in the state. This jumpstarted public policy dialogue on the epidemic and prompted the federal government to expand the programme nationally in the form of the NAP.

According to Kelly Safreed-Harmon, the limited AIDS response programme in place in São Paulo, with the active involvement of the *Sanitarista*, embodied a sophisticated understanding of the relationship between health and human rights.¹⁷⁵ This relationship had significant bearing on other issues such as stigma and discrimination, and on access to medicines. The theoretical basis that motivates the *Sanitaristas* as well as other HIV NGOs can be found in the revision of the Marxist conception of the state and a critical reading of the collective health. That is, a belief that the contemporary role of the state lies beyond the social contract of guardianship and includes the pedagogical function of construction, consolidation, and reproduction of the cultural direction of the hegemonic class.¹⁷⁶ Sonia Fleury notes that the *Sanitarista*'s agitation for the collective health was framed by a critical interpretation of commercialised medicines, the crisis of its inefficiency, and a hope of organising a health system which is capable of responding to prevailing demands and is democratically organised and managed based on rational planning.¹⁷⁷ The result of this theoretical-political construction was the creation of the SUS as well as the National Health Assembly. The latter encouraged and spurred the direct participation of citizens and patients in the management, control, and monitoring of health actions and service delivery.

Acting on the *Sanitarista*'s preference for more local governance, the federal government embarked on a series of decentralising programmes, first, by the transfer of resources to the state and municipal government.¹⁷⁸ Thus, though the Ministry of Health, on behalf of the federal government, is the lead public organisation for health services delivery, the state and municipal governments as well as citizen councils play crucial roles in the sub-national and grassroots delivery of health programmes.¹⁷⁹ The

¹⁷⁴ Kelly Safreed-Harmon, 'Human Rights and HIV/AIDS in Brazil' (*TheBody.com*, 2008) <<http://www.thebody.com/content/art52667.html>> accessed 21 May 2015.

¹⁷⁵ *ibid.*

¹⁷⁶ Fleury (n 169) 746.

¹⁷⁷ *ibid.*

¹⁷⁸ Cohen and Lybecker (n 148) 214. According to Cohen and Lybecker, the federal government transfers 71 per cent, state governments contribute 15 per cent, while municipal governments contribute the remaining 14 per cent.

¹⁷⁹ *ibid.* See also Organisation for Economic Co-operation and Development (OECD), 'Public Sector Integrity In Brazil' (OECD Secretariat 2011) <<http://www.oecd.org/gov/ethics/49019867.pdf>> accessed 7 September 2016.

concomitant effect of this is that it allowed state and municipal governments to tailor health programmes to the particular needs of the local population. Further, it gave state and municipal governments the power on specific tax and expenditure functions, and the flexibility to ‘opt-out’ of managing health services and let the federal government take the responsibility of providing them. This is usually applied to poorer municipalities and/or states, especially in the supply of basic medicines.¹⁸⁰ This flexibility allowed the state and municipal governments to take on roles they are capable of seeing through, thereby increasing efficiency and ensuring that tangible goals are met.

The renaissance of the civil society movement in the democratisation process spurred the formation of numerous health-related NGOs throughout the country focusing on the issues of AIDS, access, and anti-discrimination on all fronts. Health professionals and activists such as Dr. Alan Berkman and Richard Parker contend:

The explosion of health-related civil society groups sprang out of social solidarity built up out of common suffering and struggle for democracy and citizenship became a countervailing force to the stigma surrounding the emergence of HIV.¹⁸¹

Indeed, this vibrant rebirth of civil society groups – especially in the late 1980s to early 1990s when the reported cases of HIV/AIDS were at an all-time high – saw a rapid growth in the formation of CSOs to include LGBT groups, human rights organisations, policy activists, medical professionals, and academics. Encouraged by the prior successful activities of the *Sanitarista*, the newly formed civil society groups made right to health a central demand by co-opting ‘galvanized actions aimed at securing civil and human rights mandated by the new progressive constitution of 1988.’¹⁸² They pressured the national government to create a national AIDS programme and demanded that the government and fellow citizens respect the rights of people living with HIV/AIDS (PLWHA). Within this context, these civil movements framed the public discourse regarding health services, access to medical care, medicines, and medical innovation from a re-democratisation agitation to a legal process backed by the Constitution.

¹⁸⁰ Cohen and Lybecker (n 148) 214.

¹⁸¹ Berkman and others (n 105) 1165.

¹⁸² Biehl (n 164) 108.

It is important to note that this period was also characterised by protest against the Structural Adjustment Program (SAP) of the IMF and the World Bank, which prioritised currency devaluation and reduced governmental expenditure on social services, such as a reduction in public health financing and privatisation of health services. Thus, though relatively independent of each other, these two issues – the effect of SAP on public services including health care and the emergence of HIV/AIDS with fatal consequences – came together to produce a new discourse in the field of social policy. This new field of social policy, according to Joanildo Burity, was fleshed out against the backdrop of programmes of state reforms that ‘ranged from redefining the State’s role in the economy to reconsidering how it should function in relation to society in the field of public policy and advocating the adoption of new management models.’¹⁸³ This new social policy, therefore, reconsiders the role and duties of the state from other functions that, though still public in nature, do not explicitly require the direct engagement of the state such as the formulation of social programmes. It was within the formulation of social programmes that the civil society groups established a collective agenda to tackle the problem produced by the AIDS epidemic. To do this, these civil society movements focused on issues of health rights and access to medicine, which blossomed to take on new life within the Brazilian public sphere.

Methods Employed by Civil Society

As mentioned earlier, civil society groups played a key role in producing knowledge, expertise, and awareness regarding HIV. To effect the required change and response, these groups adopted several tactics such as policy advocacy, HIV/AIDS de-stigmatization campaigns, and legal suits against government policies that negate the health care responsibilities of the government.

Legal Suits

Couching their activism on the principle of freedom from discrimination as provided for under the Brazilian Constitution, these civil society groups brought class action suits against the state and municipal governments. In these struggles, the judiciary became an insurgent actor ruling against the state (both federal and municipal) and proved to be a supportive important ally by ruling favourably for citizens and social

¹⁸³ Burity (n 167) 74.

activists. The courts argued that in most instances, the Brazilian Constitution creates a legal obligation on the part of the government to take steps to actualise the rights therein. For instance, activist groups filed lawsuits seeking to defend the rights of PLWHA from discrimination in housing, education, the workplace, and elsewhere.

When AIDS was newly emerged in Brazil, it was associated with heavy stigma and discrimination. Several people living with HIV were turned away from care services, lost their jobs, and were abandoned by their families. Observing how HIV-positive status is historically represented as a deviation in sexual and social behaviours, and HIV-positive individuals perceived as the ‘other’, these AIDS advocacy groups – in petitioning the courts – argued that these ‘descriptions restrict the adoption of public health policies in relation to HIV as well as establishing punitive measures for HIV-positive individuals.’¹⁸⁴ According to Roger Raupp Rios, these lawsuits – in addition to improving the lot of the PLWHA – also helped in strengthening a less discriminatory understanding of the legal person concept¹⁸⁵ and a better definition of collective right. Therefore, these lawsuits aimed at simultaneously improving tangible rights (such as health care) and intangible rights (such as social inclusion and representation). In a similar vein, Miriam Ventura (lawyer, founder, and executive director of Advocaci-Citizen for Human Rights) believes that the lawsuits against all forms of unjustifiable and unconstitutional attitudes against HIV-positive individuals was decisive because ‘it led to the social inclusion of PLWHA, the introduction of the language of human rights in [Brazilian] daily practices, and to stimulate the fight for social efficacy of legal standards for all.’¹⁸⁶ As a result, these lawsuits not only influenced how the AIDS epidemic is understood and addressed but also influenced AIDS-related policies and the broader conceptualization of public health.

Similarly, AIDS activist organisations used lawsuits to challenge insurance policies that did not cover HIV patients as well discriminatory policies that required people to undergo HIV tests in order to qualify for jobs and be admitted to public exams.¹⁸⁷ For instance, in 2000, CSOs in São Paulo filed a suit requesting that genotype laboratory tests be performed by a public health network. Previously, the Ministry of Health

¹⁸⁴ Rios (n 107) 235.

¹⁸⁵ *ibid* 236. According to Roger Rauup Rios, the definition of legal person was a previously exclusionary category limited to mean only the heterosexual, middle class, or male person.

¹⁸⁶ Miriam Ventura, *Strategies to Promote and Guarantee the Rights of People Living with HIV/AIDS* (1st edn, 2003) <http://www.columbia.edu/itc/hs/pubhealth/p8725/all_week_8_articles.pdf> accessed 21 May 2015.

¹⁸⁷ Safreed-Harmon (n 174).

limited genotype testing to patients with primary therapeutic failure and are already on ARV treatment, whereas AIDS CSOs petitioned for this examination to be made available to all patients with repeated therapeutic failure and regardless if they are on ARV treatment.¹⁸⁸ In this case, the court ruled in favour of the petitioners and determined that the three levels of SUS ‘should implement genotype test of the HIV virus with the scope of the SUS, for all bearers of virus.’¹⁸⁹ AIDS advocacy groups were successful in this because they focused ‘on specific programmatic issues that have operationalized the constitutional right to health.’¹⁹⁰ One can therefore argue that though the awareness of human rights is already in the public discourse in Brazil, the lawsuits and legal activism of AIDS NGOs fine-tuned it to represent changing times. For this reason, the legal conflicts helped overcome the exclusionist mentalities and broke down legal categories and the mechanism of inequality which has spread throughout law and society.

In the same vein, civil society groups played a key role in knowledge and expertise production regarding the adverse effect of patents on medicine access. In this role, the activism of the GTPI/REBRIP was most prominent. Created in 2001, REBRIP is a network of NGOs, patient groups, unions, and professional groups engaged in ‘the process of regional integration and trade, and committed to the construction of a democratic society grounded in economic, social, cultural, ethical and sustainable development.’¹⁹¹ GTPI specifically deals with IP-related issues and its repercussions on Brazilian society. In 2005, the Brazilian government declared ARV drugs *lopinavir* and *ritonavir* (marketed under the brand name *Kaletra*) as public interest, which would have enabled the government to issue a CL, allowed for the local manufacture of the drug at a lower price, and enabled the transfer of technology to local firms. Instead, the government signed a contract with the pharmaceutical company Abbott – the makers of *Kaletra*. Though the contract lowered the price of the drug, it contained clauses that were in conflict with public interest. Specifically, the government guaranteed to Abbott that it will not issue a CL for *Kaletra*, agreed that Abbott will not have any responsibility for technology transfer or FDI to manufacture the drug locally, and accepted a fixed price of USD1,380 per patient per

¹⁸⁸ Passarelli and Terto (n 135) 259.

¹⁸⁹ *ibid.*

¹⁹⁰ Berkman and others (n 105) 1167.

¹⁹¹ Reis, Terto Jr, and Pimenta (n 92) 31. GTPI also work closely with other international NGOs such as Doctors Without Borders and Oxfam. It actively mobilises other NGOs within and outside Brazil and champions South-South collaborations among HIV organizations in the Global South.

year until 2011 when the patent expires, regardless of the increase in demand or variations in international prices.¹⁹² In reaction, GTPI filed a public civil action suit against the Brazilian government and Abbott – the first of its kind – demanding that a CL be issued.¹⁹³ The suit received negative preliminary hearing on the grounds that not only would a CL possibly trigger trade retaliation, which would lead to drug stock-outs, but also that Brazilian pharmaceutical companies do not have the technological capacity to locally produce the drug.¹⁹⁴ The GTPI appealed the preliminary decision and the appeal is still pending.

In addition, the GTPI/REBRIP and the MSF conducted an independent study on the feasibility of local Brazilian laboratories to locally manufacture the *lopinavir/ritonavir* combination. The study found that four Brazilian pharmaceutical firms (two public and two private) could produce antiretroviral medicines at an even cheaper price offered by Abbott, i.e. USD0.41.¹⁹⁵ The report was simultaneously corroborated by another independent report conducted by the Clinton Foundation and the UNDP in the same year.

Policy Advocacy and Patent Opposition

Many HIV/AIDS scholars in Brazil have argued that the mobilisation by civil society groups can singlehandedly be credited in shaping and framing Brazil's HIV/AIDS discourse.¹⁹⁶ This is because the activism of CSOs framed the discourse as a human rights issue rather than a solely medical or social awareness issue. The mobilisation for improved actualisation of health rights, such as access to essential medicines, medical innovation, and technology, brought to the fore the issue of IP – specifically patents – on medicine access. This was the case especially after the 1996 International AIDS Conference in Vancouver made public the news that ARV ‘when used in combination, could effectively control HIV progression in the human body.’¹⁹⁷ This completely transformed the context of the response to control HIV and changed the notion of AIDS from being a fatal disease to one that could be treatable and considered chronic.¹⁹⁸ In fact, according to Veriano Terto Jr., the Vancouver

¹⁹² Reis, Terto Jr, and Pimenta (n 92) 29.

¹⁹³ *ibid* 34.

¹⁹⁴ *ibid*.

¹⁹⁵ Fieldwork interview with Viera (n 111); fieldwork interview with Felipe Carvalho (Rio de Janeiro, 2014).

¹⁹⁶ Fieldwork interview with Viera (n 111).

¹⁹⁷ Reis, Terto Jr, and Pimenta (n 92) 27.

¹⁹⁸ Fieldwork interview with Terto Jr (n 119).

Conference positively affected HIV and treatment activism in Brazil. He described the AIDS movement and treatment campaign in Brazil post-Vancouver Conference thus:

Vancouver [conference] changed our conception of people living with AIDS. From it being a death sentence, it became a person would live and be treated. This helped to finally break that stigma that linked AIDS to death. And then so treatment became something very, very important for Brazilian activism to engage in the AIDS. It changed us completely. So, because of that, and because we knew about the difficulties, but also we had the experiences of the right to life and the right to health, we immediately linked the treatment as a human right and the ARV as a human right. And so our strategy became to file lawsuits against the government, and second, to reinforce our legal claims with the Constitution that had been approved in 1988.

It was the intense civil society campaigns after the 1996 AIDS conference that prompted the government to approve the Sarney Law, guaranteeing the free distribution of HIV/AIDS medicine.¹⁹⁹

Civil society activism was notable once more in 1999 when the Ministry of Health revealed the need to supplement the budget to ‘correct the lag of resources caused by the devaluation of Brazilian Real vis-à-vis the United States Dollars in purchasing these medicines.’²⁰⁰ That is, the cost of purchasing the new combination ARV as well as the economic effect of devaluating the Brazilian real meant that the government was spending more on drug purchasing than was financially practical. This issue brought to the fore questions of sustainability of the AIDS programme, specifically the free dispensation of ARV. This watershed moment changed the dynamic of the health right discourse in Brazil, and it was within this new context that the CSOs in Brazil (and elsewhere) adopted a patent-based definition of the HIV crisis. This social construction of patent-based interpretation of the HIV crisis contends that the broad protection provided by the new global IP regime, particularly patent protection on pharmaceutical product and process, has an adverse effect on access to essential HIV/AIDS medicines. It also illuminates patent-based methods of deepened protection (e.g. ever-greening), among others. The AIDS civil society argued that by placing a high price tag on medicine, pharmaceutical companies are making important drugs unavailable to the millions of people desperately in need of the drugs. The

¹⁹⁹ Passarelli and Terto (n 135) 254.

²⁰⁰ *ibid.*

effect is that these pharmaceutical companies therefore ‘determine[...] those who can benefit from new, improved ARVs and those that will die due to lack of the same medications, most likely the millions of patients from poorer countries.’²⁰¹

In response to this, many AIDS advocacy groups forged partnerships amongst themselves as well as with international organisations such as Oxfam and MSF to publicise the negative impacts of the TRIPS Agreement and bilateral trade treaties on medicine. The aim of these alliances is to lend visibility to the social impact of IP trade agreements, monitor international forums that discuss IP issues and access to medicines, and influence government decision on patent applications while developing alternatives that can widen access to medicines. The success of these initiatives lies in the fact that the problem of IP was made accessible and understandable to everyone.²⁰² For instance, Parasselli and Terto note that it was the advocacy operations of AIDS civil groups that brought awareness to ‘the need for budget supplement in the Ministry of Health so that drugs and other health materials can be purchased and distributed without interruption.’²⁰³ By raising awareness of the cost of purchasing these drugs thanks to patent monopolies, these activist groups brought public knowledge regarding the influence of IP and patents on drug access. In this way, IP was no longer seen as an arcane subject for the highly educated selected few. Further, this awareness enabled ordinary Brazilians to petition his/her municipal and state – and to a larger extent, national government – to implement or consider pro-public health policies when processing patent applications and in trade or investment agreements.

In another notable instance of civil society mobilisation, ABIA²⁰⁴ and GTPI filed a pre-grant opposition in 2006 in an attempt to stop the INPI from granting patents for essential medicines. The pre-grant opposition was filed against Gilead’s ARV medication *Viread (tenofovir disoproxil fumarate)*. ABIA and GTPI presented technical grounds against the grant of patent by calling into question the

²⁰¹ Reis, Terto Jr, and Pimenta (n 92) 30.

²⁰² ‘The Case of TDF in Brazil’ (*Patentoppositions.org*, 2012) <http://patentoppositions.org/case_studies/4f106d0504a7f92f5b000003> accessed 20 February 2014.

²⁰³ Passarelli and Terto Jr (n 135) 260.

²⁰⁴ ABIA was founded in 1987 by Walter Almeida and Hebert De Souza, popularly known as Betinho. Betinho was most active in developing ABIA’s strategy of addressing governmental omission or violation of civil and political rights of those living with the virus. For details on the functions of the organisation, visit <http://abiids.org.br>, ‘ABIA | Associação Brasileira Interdisciplinar De AIDS’ <<http://abiids.org.br>> accessed 1 June 2015.

‘inventiveness’ of the drug and argued that the synthesis of the key substance *tenofovir* as described in the patent application is known in the state of art before the filing date.²⁰⁵ It is also cited in the US Patent and Trademark Office’s rejection of Gilead’s patent application for the drug. In 2008, the INPI rejected Gilead’s application. The appeal by Gilead is still pending.

Similarly, civil society groups are involved in writing position papers and in presenting research studies to Congress on IP-related issues and their impact on public health. Commenting on this, GTPI Coordinator Marcela Viera concludes that various forces within Brazil have been trying to narrow the discourse and understanding of the right to health and GTPI has been pushing for a broader concept of the right to health.²⁰⁶ In this vein, GTPI continues to participate in public hearings at the request of Congress, acts as *amicus curiae* on cases involving IP rights for medicines in Brazil, and generally pushes the counter-narrative of broadening the right to health and access to medicines discourse within Brazil.²⁰⁷

De-stigmatization Campaigns

In addition to legal suits and policy advocacy, AIDS NGOs also used de-stigmatization campaigns to raise awareness on health rights and the dignity of seropositive patients. These campaigns included but were not limited to rallies, demonstrations, and distribution of condoms, as well as vigils in some cities to remember those lost to the disease. Significantly, ABIA played an active role in addressing governmental omission and disseminating information on the virus, which at that time was lacking. These actions translated to ABIA adding a political focus to civil society activism whilst playing significant social roles in setting priorities for the SUS. As a result, according to Berkman et al., AIDS CSOs were elected into Public Health Councils to participate in the discussion and implementation of public health programmes.²⁰⁸ The Public Health Councils meet every four years to deliberate on issues about national health planning at the local and state levels. The SUS then uses input from these deliberations to plan the national health conference. This allows the proactive involvement of PLWHA in HIV/AIDS response within the SUS. It is clear

²⁰⁵ Reis, Terto Jr, and Pimenta (n 92) 36.

²⁰⁶ Fieldwork interview with Viera (n 111).

²⁰⁷ *ibid.* GTPI has presented position papers on some bills in Congress such as the Bill of Law 22/2003 on non-patentability of ARV medicines, Bills of Laws 2511/07 and 3995/08 on use claims and polymorph, and Bill of Law 3709/08 on prior consent from the public health sector.

²⁰⁸ Berkman and others (n 105) 1167.

that these CSOs are influential in not only shaping policy and generating a common discourse on right to health, medicine access, and the HIV epidemic, but have also been successful in establishing lines between seemingly distinct realms of ‘science’, ‘politics’, and ‘law’ by entering in the process policy debates and contesting interpretations that are particularly restrictive of policy space.

3.5 Brazil in the International Arena

As stated earlier, Brazil quickly implemented the full trade agreement package without using the transition period when it joined the WTO. Since the transition into the TRIPS regime, the constitutional obligations of the government has led to the implementation of innovative regulatory policies, and the consequent export of these policies to international forums such as the WTO and the WIPO, especially given Brazil’s growing willingness to challenge WTO-based restrictions. Thus, David Trubek et al. observe that as the Brazilian state began to play a more robust role in the promotion of economic growth and social protection, successive administrations protected domestic policy space by challenging restrictive interpretations of global trade rules.²⁰⁹ In this new environment, trade policymaking became more closely included in the overall development strategy, and Brazil invested in the legal and related skills needed for success in trade disputes.

Brazil was one of the most active countries in the Uruguay Round negotiations, but this did not mean much as it subsequently capitulated to pressures from developed countries.²¹⁰ Many scholars have explained the reasons for this, which include but are not limited to the following: (a) the acceptance of the GATT trade package was the *sine qua non* for receiving aid from the US and Europe; (b) several countries in the Global South lacked the technical expertise and human resources to fully engage in

²⁰⁹ David Trubek and others, *Law and the New Developmental State: The Brazilian Experience in Latin American Context* (Cambridge University Press 2013) 331. David Trubek used the Brazilian experience to describe the emergence of a new developmental state (NDS), its implications for law, new approaches to development, and new legal tools.

²¹⁰ To map the weakening of the Brazilian stance at the Uruguay Round, see (a) statement by Ambassador George Marciel, Representative of Brazil, ‘General Agreement on Trade and Tariffs: Multilateral Trade Negotiations Group Frameworks’ (1977) MTN/FR/W/1; (b) statement by HE Mr Marcos Castrioto de Azambua, Special Representative of the President of the Republic, General Secretary for Foreign Policy, ‘General Agreement on Trade and Tariffs: Multilateral Trade Negotiations Group Frameworks’ (1990) MTN.TNC/MIN(90)/ST/38; and (c) statement by HE Mr Celso Amorim, Minister of External Relations, ‘General Agreement on Trade and Tariffs: Multilateral Trade Negotiations Group Frameworks’ (1995) MTN.TNC/MIN(94)/ST/101.

trade negotiations; and (c) many of the countries in the Global South were either going through economic turmoil in the late 1980s and 1990s or were undergoing the structural adjustment programmes enforced by the IMF and World Bank, which required these countries to sign on the global trade regime.²¹¹ However, as have been shown, Brazil has been able to roll back some of the adverse effects of TRIPS internalization through concerted effort in law, politics, and various administrative frameworks. In doing so, the country has been able to recapture the discourse by balancing public interest and social responsibility with private rights.

At the international level, Brazil faced aggressive responses because of its policies at home. The first was the WTO dispute between Brazil and the US, i.e. *Brazil – Measures Affecting Patent Protection*.²¹² In this case, the US complained that the Brazilian industrial property law (Law Number 9.279/96) and the ‘local working’ requirement for the grant of patent is discriminatory and therefore violates Articles 27.1 and 28.1 of the TRIPS Agreement. The US also questioned Article 68(4) of the IPLB regarding parallel importation. Analogous to this event was the growing collaboration and sympathetic alliance among countries of the Global South regarding public health flexibilities due to the growing ravages of HIV/AIDS in these countries.²¹³ The US later withdrew the case before the Dispute Settlement Body panel after Brazil threatened to file a counter-dispute. However, Brazil agreed to inform the US whenever it wished to apply this legal provision against a US company. Nevertheless, the symbolism of this case cannot be ignored. On one hand, the Brazilian condition for CLs creates a legal ambiguity and pushes, in a sense, what is generally understood as the liberal reading of TRIPS flexibilities. Conversely, the US action appeared to be an attempt to send a signal to developing countries not to adopt measures that are not in line with the US pharmaceutical industry’s strategy and

²¹¹ Brazil was not the only country that played an unsuccessful role at the Uruguay Round. Indeed, one could argue that the Global South in general failed at the Uruguay Rounds negotiations. See Raghavan (n 60), which describes the divide-and-conquer tactics used by the Quad at the negotiations; Peter Drahos, ‘Global Intellectual Property Rights in Information: The Story of TRIPS at the GATT’ (1995) 13 Prometheus (‘The Story of TRIPS at the GATT’), on the use of Section 301 by the US to pressure developing countries into signing the agreements. See also Peter Drahos, ‘Trade-Offs and Trade Linkages: TRIPS in a Negotiating Context’ (*Quaker United Nations*, 2000) (‘Trade-Offs and Trade Linkages’). <<https://www.anu.edu.au/fellows/pdrahos/reports/pdfs/2001tradeoffstradelinkages.pdf>> accessed 1 June 2015. For a *twailian* view, see BS Chimni, ‘Political Economy of the Uruguay Round of Negotiations: A Perspective’ (1992) 29 International Studies (‘Political Economy of the Uruguay Round of Negotiations’).

²¹² *Brazil – Measures Affecting Patent Protection* (2001) WTO Dispute Settlement Body, WT/DS199.

²¹³ Two years prior to the *Brazil – Measures Affecting Patent Protection* case, the South African Pharmaceutical Manufacturers Association and 39 mostly multinational pharmaceutical companies took the Government of South Africa to court after the government approved a legislative proposal which contained the explicit authorisation of parallel imports of patented pharmaceuticals. See Tshimanga Kongolo, ‘Public Interest versus the Pharmaceutical Industry’s Monopoly in South Africa’ (2001) 4 The Journal of World Intellectual Property.

interests.²¹⁴ Specifically, Shanker observes that the US did not have a strong case against Brazil; rather, its action is part of the American strategy to test the provisions of the TRIPS Agreement through case law and the dispute settlement mechanism.²¹⁵

Outside the WTO, Brazil continues to be to an active advocate of a human rights-based approach to trade, development, and IP rules in other forums such as the Mercosur, WHO, and WIPO. Together with Argentina, it launched the WIPO Development Agenda (WIPO/DA) in 2004.²¹⁶ The proposal argued for the incorporation of UN Millennium Development Goals to promote a development-centred approach to the global IP regime. Specifically, the WIPO/DA aimed at blocking new advancement in the protection of IPR while integrating substantive proposals on how to combine public policy interest with the private sector's role on innovation and protection of rights.²¹⁷ Indeed, the introduction of this agenda by Brazil and Argentina was a reaction to the growing discourse on certain TRIPS-plus narratives, especially the Substantive Patent Law Treaty (SPLT). The SPLT raises patent protection standards substantially including initiatives that only consider the rights of patent holders. Michelle Badin notes that for Brazil, the WIPO/DA was influenced by shifting dynamics at home, especially the interventionist actions of the Brazilian state in fostering national development, particularly in the health sector, as well as institutional changes such as the creation of an IP division within the *Itamaraty*.²¹⁸ In the case of the latter, the IP unit benefitted from an uncommon capacity-building to meet the highly technical approach required by WTO issues. This unit is also actively involved in the Inter-Ministerial Group on Intellectual Property (GIPI), which consists of 11 ministries such as the Ministries of Health, Science and Technology, Foreign Affairs, Trade and Development, and others. Additionally, the emergent anxiety among Brazilian policy circles of another Uruguay Round with the growing acceptance of SPLT and its TRIPS-plus clauses, as well as the ever-increasing knowledge gap still separating rich and poor countries, are some of the Brazilian motives behind the WIPO/DA.

²¹⁴ Daya Shanker, 'Brazil, the Pharmaceutical Industry and the WTO' (2002) 5 *The Journal of World Intellectual Property* 57.

²¹⁵ *ibid* 99.

²¹⁶ WIPO, 'Proposal by Argentina and Brazil for the Establishment of a Development Agenda for WIPO' (2004) <http://www.wipo.int/edocs/mdocs/govbody/en/wo_ga_31/wo_ga_31_11.pdf> accessed 1 June 2015.

²¹⁷ Sanchez Badin (n 59) 275.

²¹⁸ *ibid*.

The proposal by Brazil and Argentina were supported by other developing countries and at the 2007 General Assembly of WIPO, member states adopted 45 recommendations that constitute the ‘WIPO Development Agenda’. Scholars such as Laurence Helfer champion this regime-shifting strategy as an opportunity for states dissatisfied with several provisions of particular international agreements to recalibrate them in a different forum to satisfy their need.²¹⁹ Others posit that discussing the same issue in various forums weakens a state’s position and could lead to concessions, which may be reflected in future WTO negotiations.²²⁰ Nonetheless, the Brazilian contribution to the operation of new policies and procedures in international circles cannot be ignored or downplayed. In defending its domestic policies while actively engaging at the international level, Brazil has established a norm of constructive engagement with the TRIPS framework and demonstrated that it is comfortable with ‘asserting claims that preserve its discretion over the appropriate balance between access and protection of knowledge assets.’²²¹

3.6 Summarising the Brazilian Context

Globally, there is growing recognition of the need for a more balanced IP regime, especially as high prices – an attendant result of market monopoly due to patent protection – affect the availability of life-saving medicines. However, the pharmaceutical industry has been pushing for an ever stronger and more imbalanced IP regime in trying to consolidate its gains.

Analysis of the Brazilian context has shown ways to balance IP rights with socioeconomic development goals and the public interest. Though the country quickly implemented the TRIPS Agreement due to external pressures and as part of its trade liberalization policies without using the transition period, internal circumstances such as the HIV/AIDS crisis, budgetary constraints, and the government’s constitutional obligation to provide health care for all Brazilians has influenced the evolving role of patent law in Brazilian society.

²¹⁹ Laurence R Helfer, ‘Regime Shifting: The TRIPS Agreement and New Dynamics of International Intellectual Property Lawmaking’ (2004) 9 *Yale Journal of International Law* 54.

²²⁰ Gontijo (n 8) 20.

²²¹ Okediji (n 89) 245.

Furthermore, the confluence of local non-state actors' cultural disposition towards litigation and the technical expertise regarding important patent law issues has helped Brazil substantially adopt innovative regulatory policies. Exploring history as well as local politics shows that the country is not interested in a patent system that does not support health policies. In this sense, health policies underpin and frame Brazil's engagement with patent law.

In fact, at the time of the fieldwork in Brazil, there are bills currently at the Brazilian House of Representatives proposing changes to the patent law. If implemented, the bills would include the participation of health professionals in the analysis of pharmaceutical patents,²²² allow third parties to challenge patent application before or after grant,²²³ allow the exploitation of patented products for the purpose of public non-commercial use without the consent of patent holder,²²⁴ and further increase access to medicines.²²⁵

By linking its patent regime to the health sector, Brazil has developed a health-oriented patent examination system. Even though opinion remains divided on the ANVISA prior consent system, the fact remains that public health and the right to health perspective are taken into account in patent discourse – an area in which private rights that are contrary to the majority's interest usually prevail. In fact, in recent years, Brazil has adopted the notion of health within the context of national development and industrial policy. Known as health-industrial complex,²²⁶ the government has sought to improve access to medicines and advanced medical technology through partnerships with private companies. It is hoped that public-private partnership (PPP) agreements would increase transfer of technology and the production of higher value-added drugs.

The next chapter will demonstrate how India, in contrast, linked its patent regime to the development of its pharmaceutical sector. In this regard, India employed a strategy to protect its robust generic pharmaceutical sector and achieve pharmaceutical autonomy. As will be seen, the Indian government's extensive

²²² Bill 3.943/2012 and Bill 5.402/2013.

²²³ Bill 5.402/2013.

²²⁴ Bill 5.402/2013.

²²⁵ Bill 139/1999.

²²⁶ Carlos Augusto Graboys Gadelha, 'Development, Health-Industrial Complex and Industrial Policy' (2006) 40 *Revista de Saúde Pública* <<http://dx.doi.org/10.1590/S0034-89102006000400003>> accessed 16 March 2015.

interventions in the drug production sector, in turn, catalysed actions to promote a patent regime that protects the pharmaceutical sector. For India, industrial development (especially for its ‘sunshine’ sector, i.e. pharmaceuticals) underpins and contours its participation in the IP system.

4. India

Introduction

India's economic journey from being an impoverished country to an emerging global economy is an inspiring example for many developing nations. After almost two centuries of British rule, India gained independence in 1947. In gaining its independence, the new government inherited an impoverished economy that was largely agrarian, a population with minimal literacy and high poverty rate, as well as abysmal infrastructures. As part of the nation-building effort, India adopted a Five-Year Development Plan in the first few years after its independence, which has continued to this day. The Plan took stock of the state of the nation at that time and sought to 'initiate a process of development [to] raise living standards and open out to the people new opportunities for a richer and more varied life.'¹ Due importance was given to the establishment of modern industries, modern scientific and technological institutes, and the development of the space and industrial sectors. However, this did not result in significant improvement except in the pharmaceutical sector.

This chapter focuses on India – a country characterised as the 'pharmacy of the developing world'² – due to the important role of Indian generic manufacturers in supplying affordable medicines throughout the developing world. According to MSF, approximately 50 per cent of drugs distributed by the UN Children's Fund (UNICEF) and 70 per cent of ARV drugs dispensed by the International Dispensary Association (IDA), The Global Fund to Fight AIDS, Tuberculosis and Malaria (GFATM), and the Clinton Foundation since July 2005 are from Indian suppliers.³ Further, due to the shrinking markets of developed countries, many Western pharmaceutical companies are looking to the developing country markets of China, Brazil, and India, among others, to compensate for lacklustre drug sales in the US and Europe. As a result, the country has become a key battleground on contentious patent issues relating to the

¹ Planning Commission, 'First Plan (1951–1956)' (Government of India 1951), ch 1, para 1

² Médecins Sans Frontières (MSF), *Examples of the Importance of India as the 'Pharmacy for the Developing World'* (1st edn, MSF 2007) <http://www.msfast.org/sites/default/files/MSF_assets/Access/Docs/ACCESS_briefing_PharmacyForDevelopingWorld_India_ENG_2007.pdf> accessed 5 March 2015.

³ *ibid.* See also Timothy Bazzle, 'Pharmacy of the Developing World: Reconciling Intellectual Property Rights In India with the Right to Health' (2010) 42 *Georgetown Journal of International Law*, which explores how India has reconciled the emergence of global IPRs with its role as the pharmacy of the developing world, all the while interpreting these competing obligations in terms of the right to health.

limits of flexibilities in the TRIPS Agreement. By focusing on the Indian pharmaceutical sector, this chapter critically explores the understanding of patents by the Indian state based on how the notion of patent is conceptualised in policy and in law. Second, this chapter looks into the policy options and priorities embraced by Indian policymakers in the wake of the Patent (Amendment) Act of 2005 (IPAA) and how current policy landscape in the post-TRIPS world affects, if at all, the ability of the state to accomplish the development goals of a world-class pharmaceutical sector. Finally, this chapter unpacks the alliances, patterns, and schisms among key actors to understand how they challenge and/or influence the state's understanding and application of patents.

Patent laws do not operate in a social, cultural, political, and policy vacuum, and the mere implementation of IPRs under the TRIPS Agreement will not necessarily spur local development nor lead to transfer of technology. Rather, patent policies that are twinned with a specific goal within the larger context of the national economic development plan can be instrumental in achieving the objectives of the TRIPS Agreement. In observing these prosaic mechanics of law, institutional interactions, and globalisation, the central argument of this chapter is that patent laws work better in furthering the developmental agenda when implemented to reflect local realities and tied to larger policies, be it industrial, health, or otherwise. As this chapter shows, India leveraged on this to achieve its economic and technological goals.

It is this linking of patents with industrial development that enabled local pharmaceutical industrialists to play a key role in the patent discourse. Unlike in Brazil where civil society groups spearheaded and framed patent regime change and discourse, generic pharmaceutical companies took the lead in knowledge and expertise production in India's patent regime. It is this interaction of industrialists and the changing narratives or circulation of ideas over time that produces interesting legal regimes for patents and medicines that fulfil the needs of the local population. In fact, it is said that Mahatma Gandhi asked or encouraged Khwaja Abdul Hamied, founder of the Chemical, Industrial and Chemical Laboratories in Mumbai (now Cipla) to manufacture essential medicines for India in 1939. It is this drive for pharmaceutical autonomy and self-sufficiency that underpinned the initial indigenous industrialists' engagement with the patent regime.

To be sure, it is not to say that civil society actors did not play any role in the development of India's patents. They did and continue to do so. But they only came to the scene due to a series of separate but interconnected actions such as the HIV/AIDS epidemic in sub-Saharan Africa and other parts of the developing world, the challenge of South Africa's Medicines and Related Substances Control Amendment Act of 1997 (which was launched in 1998 by 38 pharmaceutical companies and the corollary publicity campaign launched by transnational civil society), and the aborted US-Brazil WTO dispute. All these came to a head at the Doha Development Round. One of the takeaways from this chapter, therefore, is the significant role of the pharmaceutical sector in patent compliance and governance in India – something that was absent in Brazil. Importantly, the Brazil and India case studies underscore three key factors that need to be in place in terms of narrative, actors, and politics for a successful patent regime to evolve out of the interaction of all those forces – active law, strong private sector engagement, and informed and active civil society movement.

Finally, as this chapter will show, the battle is not over as the dialectical relationship between the state and key actors, and among actors, continues. If anything, the Indian experience could be understood as a local reproduction of the international. That is, a symptomatic reflection of the ongoing battle over 'new' capital knowledge – its access and control – between the developed economies of the North and the new geopolitical constellation called BRICS – Brazil, Russia, India, China, and South Africa. The battle is also currently symbolised in many forms, from the proliferation of bilateral and plurilateral agreements, the creation of the BRICS Development Bank as a possible competitor to the World Bank, to the recent wave of hacks of sensitive information online.

The remainder of the chapter is divided as follows: the first section maps the historical development of patent law in India from its colonial, post-colonial, and global phases. The objective of this exercise is to provide a broad context for understanding how the development of the Indian generic pharmaceutical sector is tied to the ideas circulating at that time – that domestic interests are best served by a certain kind of IP law. It is these ideas, buttressed by existing socio-economic factors, which shaped the Indian Patent Act of 1970 (IPA). The second section looks at India's interaction with the TRIPS Agreement at the local level, focusing on how

ideas circulate, the manner in which particular policy options get constructed, and – as an extension – how others get extinguished, with regard to patent law jurisprudence among various state and non-state actors in India. Focusing largely on domestic compulsions, it examines how India’s national development gets conceptualised and counted within the national IP policy establishment. It also highlights the roles played by industrial alliances created in previous years and by transnational civil society groups which helped in knowledge and expertise production regarding the possible impact of the TRIPS Agreement on India’s pharmaceutical sectors and overall development framework. The third section provides an analysis and critique of the IPAA by looking at key aspects of the law, specifically novelty, inventive step, CL, and the opposition system. Attendant to this, key jurisprudential cases, decisions, and the role of the courts will also be examined to extrapolate an emerging Indian patent jurisprudence that recognises the need to balance patent obligations with the constitutional right to life and health (framed in this context as access to medicines). In the fourth section, the focus is on how key actors are coping and adapting since India phased fully into the TRIPS regime. Specifically, the strategies used by civil society groups to further the specific access to medicines agenda as well as those adopted by the pharmaceutical industry in patent law making are highlighted. The fifth section concludes this chapter.

4.1 Historical Evolution of Patent Law in India

Colonial Encounters

The first piece of legislation in India relating to patents was Act VI of 1856, which granted ‘certain exclusive privileges to inventors of new manufacture for a period of 14 years.’⁴ The law was intended to replicate the successes of the British industrial revolution in India by giving impetus to local industries. It remains to be an important improvement on patent law at that time because it ‘embodied the most progressive and innovative idea of inventor being given exclusive privilege through the operation of the Act rather than by the Act of the Crown.’⁵ That is, instead of an inventor obtaining exclusive privilege or monopoly for his invention from the Crown, he was

⁴ P Narayanan, *Patent Law* (4th edn, Eastern Law House 2013) 6.

⁵ Rajesh Sagar, ‘Introduction of Exclusive Privileges/Patents in Colonial India: Why and for Whose Benefit?’ (2007) *Intellectual Property Quarterly* 324.

made entitled to it by operation of law, subject to certain restrictions and upon the fulfilment of certain conditions.

Another interesting aspect of Act VI of 1856 is its definition of the term ‘inventor’, which included not only the actual and genuine creator of an original product, but also a person who brings or imports an invention into India.⁶ The idea behind this, according to legal historian Rajesh Sagar, is to provide an incentive for the importation of inventions by ‘[encouraging] capitalists of India and abroad to import and commercialise the technologies in India, thereby increasing India's technological capacity.’⁷ The ‘inventor’ could, under this Act, also authorise others to make, sell, or use the invention for a term of 14 years from the time of filing of such specification.⁸ This ties into the historical reasoning of granting exclusive privilege to encourage the introduction of knowledge and inventions within the importing country and for increasing diffusion and aggregation of technology.

A major drawback of Act VI of 1856 was the high cost for obtaining exclusive privileges in India, which was set at INR100. According to Sagar, the amount then was equivalent to almost 16 months’ wages of an average Indian. This, he asserts, made the system ‘not conducive to encourage local inventors to take advantage of the system due to a very high cost-prohibitive factor.’⁹ However, it was repealed after one year because it was enacted without the sanction of Her Majesty.¹⁰ According to V. K. Unni as well as Rajesh Sagar, the Legislative Council of India consequently did not have the authority to pass Act VI of 1856.¹¹ This is because India, as a subject of the British Crown, should have the prior permission of the Crown or Representative before any law is passed by the Indian legislature.¹² As a result, Act VI of 1856 was replaced by Act V of 1859, which was founded on the provisions of the English Patent Act of 1852. The new Act of 1859 retained the original scheme for the grant, refusal, and enforcement of exclusive privileges, but significantly departed from the concepts of ‘inventor’ and ‘novelty’ in Act VI of 1856. Among the significant aspects

⁶ *ibid* 6.

⁷ *ibid*.

⁸ Narayanan (n 4).

⁹ Sagar (n 5) 9.

¹⁰ *ibid* 7.

¹¹ Sagar (n 5) 7; see also VK Unni, *Indian Patent Law and TRIPS: Redrawing the Flexibility Framework in the Context of Public Policy and Health* (2011) 324 <http://www.mcgeorge.edu/documents/conferences/globejune2012_indianpatentlaw.pdf> accessed 3 March 2015.

¹² Unni (n 11).

of this new Act is its extension of the right of the British patent holder to 12 months in India instead of the open six months stipulated by Act VI of 1856.

Section XVII of Act V of 1859 also provided that an importer of an invention within India 'shall not be deemed to be an inventor' within the meaning of the Act.¹³ This is a significant departure from Act VI of 1856, which included an importer of an invention within the meaning of the term 'inventor'. This provision discouraged the diffusion of technology by making the importation of technology less attractive. This is because under Act V of 1859, an imported invention is not protected, which made the imported product an easy target for free riders. Thus, the only route for an importer of an invention to obtain exclusive privilege is through an application for and the approval of letters of patent in Britain, and subsequently applying for an exclusive privilege in India under Section XX of Act V of 1859 as a British patentee claiming priority rights.

Act V of 1859 also considerably expanded the 'priority rights' of British patentees, much to the detriment of Indian interests, by broadening the 'assessment of novelty of an invention for granting exclusive privilege to include both India and the United Kingdom, which Act of 1856 was limited only to India.'¹⁴ Even though granting exclusive privileges to importers of inventions and having limited novelty assessment in Act VI of 1856 were in the best interests of India, Act V of 1859 completely reversed the legislative policy based on a 'model already used at that time by the United Kingdom and other countries and was found to be extremely useful in gaining technological advantage, while India, being a colony was deprived of this benefit.'¹⁵ In fact, P. Narayanan argues that the purpose of this legislation was 'to enable the English Patent holders to acquire control over Indian markets.'¹⁶ This is not surprising as Act VI of 1856, Act V of 1859, and subsequent laws enacted by the British during the colonial period produced a considerable impediment for the direct transfer or importation of technology by creating a time-consuming and costly process to the detriment of India. Later amendments and refinements of the patent laws in India did not ameliorate the situation. Instead, these laws further burdened the colony and benefited the imperial power.

¹³ Sagar (n 5) 9.

¹⁴ *ibid.*

¹⁵ *ibid.*

¹⁶ Narayanan (n 4).

The Patents and Designs Protection Act, which introduced legislation for the protection of industrial designs, was enacted in 1872, while the Protection of Inventions Act was enacted in 1883. Both laws were consolidated in the Inventions and Designs Act in 1888. In 1911, the British government enacted the Indian Patent and Designs Act, which created ‘a system of patent administration in India under the administration of Controller of Patents.’¹⁷ It allowed for a patent term of 16 years, which can be extended for an additional seven to 10 years if the working of the patent has not been sufficiently remunerative to the patentee.¹⁸

The Indian Patent and Designs Act of 1911 continued with the imperial legacy of exploitation by establishing a ‘form of intra-British Empire priority system such that an applicant for an Indian patent who had within the previous twelve months filed an application for the same invention in the United Kingdom was entitled to the benefit of the earlier United Kingdom filing date.’¹⁹ In addition, it did not categorically state what was patentable, and widely worded claims were permitted. As such, new and old products and processes were described in a patent. This was specifically used by foreign MNCs to prevent indigenous research laboratories and pharmaceutical companies from concentrating on developing the manufacturing process. According to Sudip Chaudhuri, the MNCs did this by describing all the known, possible, and even old processes in patent applications, and because the Indian Patent and Designs Act of 1911 did not categorically state what was patentable, indigenous companies were forbidden by the patent office to use it.²⁰

This severely affected indigenous pharmaceutical companies that were already locally manufacturing modern drugs. In fact, several eminent chemists such as Prafulla Chandra Ray, T. K. Gajjar, and A. S. Kottibhasker were already producing drugs as early as 1905.²¹ Consequently, under the Indian Patent and Designs Act of 1911, indigenous companies were forbidden from processing a patented drug into

¹⁷ Unni (n 11) 325; Narayanan (n 4) 6.

¹⁸ Sudip Chaudhuri, citing ss 14 and 15 of the Patent and Designs Act of 1911. See Sudip Chaudhuri, *The WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries* (2006) 129.

¹⁹ Janice Mueller, ‘The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation’ (2007) 68 *University of Pittsburgh Law Review* 507.

²⁰ *ibid.*

²¹ Chaudhuri (n 18) 21-22. According to Chaudhuri, the evolution of the indigenous drug companies can be traced back to a series of public research laboratories set up by provincial governments. These public sector laboratories set up as early as 1899 produced vaccines for local plagues, cholera, typhoid, and rabies. By the early 1940s, these laboratories started synthesising new drugs and finding new uses for existing drugs. See Chaudhuri (n 18) 29-36.

formulations or from importing it, and MNCs asserted their patent right to proceed legally against firms that tried to manufacture or import the patented drug.²² For example, an MNC importing a drug for INR2 would sue an indigenous company importing a similar drug for INR2.²³ The effect of the colonial patent system was a stunted industrial sector, especially as regards pharmaceuticals, and led to sky-high prices for basic drugs in India. This was confirmed by the Kefauver Committee²⁴ Report, which found that India was one of the nations with the highest priced drugs in the world at that time (cited in the Ayyangar Committee Report, discussed in the next section). Critical essential medicines such as penicillin and antibiotics were wholly imported.²⁵ Estimates suggest that foreign firms controlled 68 to 70 per cent of the Indian market,²⁶ and essential drugs such as insulin and penicillin were not manufactured locally.²⁷

In a similar vein, Dhavan et al. assert that though MNCs were present in the pharmaceutical sector, they mainly engaged in processing imported bulk drugs into formulations.²⁸ This is because the patent system, they argue, provided foreign patent holders with too little responsibility and too much power such that ‘multinational[s] could make onerous technical collaborative deals.’²⁹ Drug formulation does not involve any technical knowledge or skill. In this regard, importation was widely practised by many foreign MNCs as a way of controlling competition from generic drug makers and preventing the transfer of technological knowledge to India. As a result, foreign companies did not establish any production units in India, but engaged in assembling bulk drugs into formulation.³⁰ Colonial laws in force at that time helped these foreign firms calcify their position within the Indian market even though they were not keen on manufacturing.

In fact, Sagar contends that, contrary to the popularly accepted opinion that the TRIPS Agreement is the first harmonisation effort for establishing uniform patent systems across different nations, it was in fact ‘British imperialistic aspirations that had

²² Chaudhuri (n 18) 21-22.

²³ *ibid* 130.

²⁴ The US Senate Committee headed by Senator Estes Kefauver.

²⁵ Planning Commission (n 1), ch 32.

²⁶ Amy Kapczynski, ‘Harmonization and its Discontent’ (2009) 97 California Law Review 1577 (‘Harmonization and its Discontent’).

²⁷ Planning Commission (n 1), ch 32.

²⁸ Rajeev Dhavan, Lindsay Harris and Gopal Jain, ‘Whose Interest? Independent India’s Patent Law and Policy’ (1990) 32 Journal of the Indian Law Institute 473.

²⁹ *ibid*.

³⁰ Chaudhuri (n 18) 28.

achieved such harmonization'³¹ prior to the TRIPS Agreement. In his review of patent law modelled after the British system, Sagar observes that by 1935, about one-half (63/140) of the world's total number of patent territories had their patent law either as an extension or a close modification of British patent law.³² Similarly, Ragavan asserts that the various IP statutes in colonial India lacked 'a clear policy direction to pave way for industrial development through patents'³³ for the colony. Instead, it prioritised wealth extraction and exploitation of Indian conditions to the benefit of the metropolis. In this view, the introduction and transplantation of the alien concept of exclusive privileges, which was hardly of any utility to a larger cross-section of the Indian populace due to systemic bias in the form of high fees and an exclusionary legislative policy, made colonial patent law disadvantageous to colonial India.

The colonial patent regime structure, in limiting competition from indigenous manufacturers, also led to the underdevelopment of the pharmaceutical sector. MNCs were more interested in process importing instead of undertaking basic drug manufacturing. This strategy is not surprising as the same tactics were also employed by foreign drug makers in Nigeria, as will be seen in the next chapter. However, the Indian government rectified this imbalance by not only changing its patent law, but also by developing public sector laboratories to encourage the improvement of indigenous technological capacity in partnership with private companies. The following section will focus on these post-colonial interventions and their impact on the pharmaceutical sector.

Post-Colonial Interventions

When India gained its independence from Great Britain in 1947, the newly independent Indian government wasted no time in crafting an indigenous patent law. Cognizant of its dire socio-economic realities, especially the tragedy of the partition war, and in the spirit of nationalism and economic development circulating among the political and capitalist class,³⁴ the new government set up committees to look into ways to make the patent system work for the newly democratic India. In this regard, the government set up two key committees: the Patents Enquiry Committee I (1950)

³¹ Sagar (n 5) 12.

³² *ibid.* See also J Vojacek, *A Survey of the Principal National Patent Systems* (Prentice-Hall Inc. 1936) 42.

³³ Srividhya Ragavan, *Patent and Trade Disparities in Developing Countries* (Oxford University Press 2012) 31 (*Patent and Trade Disparities in Developing Countries*).

³⁴ In 1944, a small group of influential business leaders in Bombay drew up and published a plan for the economic development of India. The Bombay Plan will be discussed further in coming sections.

under the chairmanship of Dr. Bakshi Tek Chand³⁵ and the Patent Enquiry Report II headed by Rajagopala Ayyangar (1959).³⁶ The Committees were tasked to review the patent law in India with a view to 'ensure that the patent system is more conducive to the national interest and welfare.'³⁷

The Tek Chand Report criticised the failure of India's patent system to stimulate invention and encourage exploitation of new inventions for industrial purposes. Consequently, it recommended the use of CLs to prevent abuse of the patent process and curb patent abuse and working of inventions (licences of right).³⁸ The recommendation of the Tek Chand Report led to the amendment of Sections 22, 23, and 23A to 23G of the Indian Patents and Designs Act of 1911 (*vide* Act 32 of 1950).³⁹ The Tek Chand Report is primarily viewed as more of a plea for improvement rather than a radical overhaul of the colonial patent system. According to Dhavan et al., it was concerned more with the 'management of already existing patent regime rather than a reassessment of the then current law and its impact on the political economy as a whole.'⁴⁰ This is not to say that the task of the Tek Chand enquiry was futile, but rather it did no more than emulate, even copy, the provisions pending in the legislation before the UK parliament at that time. In spite of this cosmopolitan imitation, the Tek Chand Report, if anything, did instigate national discourse on the importance of developing a national patent regime that prioritises national issues and paves the way for national industrialisation.

The Ayyangar Report, on the other hand, suggested a new patent regime for India cognizant of the following: the level of industrial development of the country at that time, with special reference to its economic conditions, and the level of its scientific and technological advancement and its future needs so as to minimise, if not to eliminate, the abuses to which a system of patent monopoly is capable of being subjected to.⁴¹ More aware of economic issues than its predecessor, the Ayyangar Report is significant in many respects. First, it forms the backbone of the current

³⁵ Report of the Patent Enquiry I (1950) (Tek Chand Report).

³⁶ Shri Justice N Rajagopala Ayyangar, 'Report on the Revision of the Patent Laws' (Government of India 1959) <http://spicyip.com/wp-content/uploads/2013/10/ayyangar_committee_report.pdf> accessed 10 March 2015 (Ayyangar Report).

³⁷ Narayanan (n 4) 6.

³⁸ Dhavan, Harris, and Jain (n 28) 511.

³⁹ *ibid* 432-42.

⁴⁰ *ibid* 431.

⁴¹ Ayyangar Report (n 36), para 44.

Indian patent regime.⁴² Second, the Ayyangar Report is significant in its inquiry into the adaptability of foreign patent laws to meet the needs of the Indian state.⁴³ Specifically, it examined ‘whether and how IP regime can be used effectively to achieve national ambitions, and investigates the history of several foreign patent regimes.’⁴⁴ In fact, the Ayyangar Report observed that 90 per cent of patents were owned by MNCs, and that they worked only 10 per cent of these.

Based on the comparative analysis of foreign patent regimes, the Ayyangar Report proposed the amendment of sections of the patent law antithetical to the present needs and development aspirations of India.⁴⁵ In order to make patent law work for India, the Ayyangar Report suggested a classification of inventions to which patent protection should be made available. It did this by precisely defining patentable and non-patentable inventions and by removing process patents for food, medicines, and chemicals.⁴⁶ The Ayyangar Report also suggested the inclusion of a local working requirement so as to establish in India a ‘new industry or an improvement of an existing industry, which would profitably employ the labo[u]r and capital of the country and thus increase the national wealth[.]’⁴⁷ The Ayyangar Report likewise proposed for the inclusion of a disclosure clause that allows the inventor to make public the invention and the manner of its working so that ‘on the expiry of the life of the patent the public are enabled to work the invention themselves and in competition with each other[.]’⁴⁸ Finally, the Ayyangar Report suggested the inclusion of a provision preventing India from joining other international patent regimes such as the Paris Convention.⁴⁹

Opinions vary regarding the legacy of the Ayyangar Report. The debate seems to be divided between those who herald the report as radically changing the patent discourse in India. Narayanan, for example, calls the Ayyangar Report ‘the backbone of Indian patent law’⁵⁰ while Chaudhuri and Kapczynski laud it as a breakthrough in

⁴² Srividhya Ragavan, ‘Of the Inequality of Uruguay Rounds’ (2006) 10 Marquette Intellectual Property Law Review 301 (‘Of the Inequality of Uruguay Rounds’).

⁴³ *ibid* 281.

⁴⁴ Ayyangar Report (n 36), para 2.

⁴⁵ *ibid*, para 29; see also Ragavan, *Patent and Trade Disparities in Developing Countries* (n 33) 34.

⁴⁶ Ayyangar Report (n 36), para 45(1).

⁴⁷ *ibid*, para 38.

⁴⁸ *ibid*.

⁴⁹ Ayyangar Report (n 36), para 57; see also Unni (n 11) 327.

⁵⁰ Narayanan (n 4); see also Unni (n 11) 327 and Ragavan, *Patent and Trade Disparities in Developing Countries* (n 33) 33.

indigenous post-colonial law making.⁵¹ However, certain scholars think otherwise. Dhavan et al. point out that the Ayyangar Report ‘did not seriously consider whether the patent system was actually suited for India.’⁵² Consequently, the report curtailed the opportunity for a nationwide discourse on alternatives to the patent system.⁵³ Not only that, it inadvertently provided unmitigated assurances to foreign patent holders that India’s patent system was not going to be fundamentally changed.⁵⁴

Nevertheless, the suggestions from both the Tek Chand and Ayyangar Committees show the importance of studying the economic situation of a country and tailoring a patent system that works for the newly democratic India, thereby spurring domestic inventions and industries. In deliberately seeking to understand the economic realities of recent independence while planning for the future, India understood that patents are not just private rights but also tools that – when used appropriately and at the right time – foster development. The Ayyangar Report, in particular, remains noteworthy in its analysis of patent regimes and the importance of creating a patent regime cognizant of a nation’s socio-economic realities. It highlighted the developmental and nationalistic aspirations and ideas circulating among the domestic capitalist class at that time. It is this understanding that underpins the discourse on the patent regime in India as will be seen 35 years later, and should serve as a lesson for other countries which are similarly placed.

Though the Ayyangar Report was submitted in 1959, it would take a decade before legislative changes were undertaken. This is not surprising, as it is well known that laws are shaped by a multiplicity of influences. In the case of the Ayyangar Report, multinational lobbyists, analyses by Joint Committees set up by the government, as well as parliamentary debates influenced consequent legislative changes.⁵⁵ In the end, the IPA incorporated most of the recommendations of the Ayyangar Report even though some believe that the new law deviated significantly from the ethos of the report.⁵⁶

⁵¹ Chaudhuri (n 18); Kapczynski, ‘Harmonization and its Discontent’ (n 26) 1576.

⁵² Dhavan, Harris, and Jain (n 28) 445-74.

⁵³ *ibid.*

⁵⁴ Dhavan, Harris, and Jain (n 28) 474.

⁵⁵ *ibid*; Mueller (n 19) 512.

⁵⁶ Dhavan, Harris, and Jain (n 28) 474.

The IPA⁵⁷ introduced salient features to Indian patent jurisprudence. First, it abolished product patents for pharmaceuticals and agrochemicals and only allowed process patents. That is, it allowed an inventor to only claim protection for the best processes known to him/her for the manufacture of pharmaceutical products. Secondly, it reduced the term of drug and food patents from ‘at least sixteen years to five years from the date of sealing or seven years from the date of filing complete specifications’,⁵⁸ whichever is shorter. For other patents, the duration was 14 years. The philosophy behind this change was to encourage the access of Indian society to foreign technologies, especially in pharmaceuticals, that otherwise might be unavailable due to cost and pricing structures under a strong proprietary IP protection system.⁵⁹ In addition, Indian policymakers believed it was a matter of ‘national security that India provides medicines and treatment at prices its people could afford for diseases and illnesses that were specific to the Indian subcontinent.’⁶⁰ In this regard, the patent law was used as a vehicle to foster pharmaceutical autonomy.

The IPA resuscitated an almost dying Indian pharmaceutical sector, including public and private research laboratories. The prohibition of product patents for pharmaceuticals, it has been argued, led indigenous pharmaceutical firms to focus on generic manufacturing of drugs by copying patented drugs through reverse engineering. It was under the umbrella of the IPA that the Indian pharmaceutical industry grew at the fastest possible rate. Within a decade after its introduction, indigenous pharmaceutical firms were able to domestically reverse-engineer known drugs patented elsewhere. Reverse engineering helped lower the cost of drugs sold to both domestic and international consumers. The sector also exported to many countries that could not afford the original product made in the developed countries.

From a TWAIL perspective, the abolition of product patent protection in pharmaceuticals speaks directly as a response to the colonial ethos of international law to bring about greater material equality. The non-patenting of pharmaceutical processes allowed for technology acquisition, transfer, development, diffusion, and

⁵⁷ Patent Act (1970) (which came into force in 1972) and subsequent amendments, Ipindia.nic.in, ‘History of Indian Patent System’ (2015) <<http://ipindia.nic.in/ipr/PatentHistory.htm>> accessed 2 September 2015.

⁵⁸ Chaudhuri (n 18) 37.

⁵⁹ Amiya Kumar Bagchi, Parthasarathi Banerjee, and Uttam Kumar Bhattacharya, ‘Indian Patents Act and its Relation to Technological Development in India – A Preliminary Investigation’ (1984) 19 *Economic and Political Weekly* 294.

⁶⁰ Luigi Palombi, ‘The Role of Patent Law in Regulating and Restricting Access to Medicines’ (2009) 6 *SCRIPTed* 401.

incremental innovation in the shortest of time.⁶¹ This is because reverse engineering, subsequent development, and production of patented drugs required only a fraction of time and money compared to the original drug discovery process, thus allowing Indian pharmaceutical firms to produce drugs cheaper and faster than their foreign counterparts.⁶² Further, the IPA eliminated the monopoly status enjoyed by many foreign MNCs as it only allowed new process patents.⁶³ This is a drastic shift from previous colonial laws that allowed the patenting of *all* known processes, whether new or otherwise, including importation. Under the IPA, only one method or process – the best known to the applicant – could be patented for a particular drug. The effect of this new law was a drop in foreign patent applications in India, as foreign MNCs could no longer engage in frivolous patenting, and consequently increased the share of patents granted to indigenous Indian firms by the US patents office from 0.02 per cent from 1977 to 1987 to 0.06 per cent from 1996 to 2000.⁶⁴ That is, the drop in frivolous patenting in India started allowing the development of the Indian pharmaceutical industry, which was then able to increase its own patent filings in the US.

The IPA resulted in making the Indian pharmaceutical sector more diverse and technically competitive. Since the end of the 1980s, India has been exporting more and importing less pharmaceuticals. The sector has grown to be one of the biggest GDP generators for the country. For example, while only two indigenous companies were amongst the top 10 firms in terms of retail sales in 1970, by 1996 this rose to six, and by 2001 it was up to eight.⁶⁵ By 1991, domestic firms accounted for 70 per cent of the bulk drugs production while 80 per cent of formulations were produced in the country.⁶⁶ Between 1998 to 2008, the export surplus widened from EUR370 million to EUR2 billion.⁶⁷ Basic manufacturing by MNCs also accelerated after the abolition of product patents because of the removal of the industrial policy restriction on the expansion into formulation unless bulk drugs are produced in specified

⁶¹ Kalpana Chaturvedi, 'Policy and Technology Co-Evolution in the Indian Pharmaceutical Industry' (Open University 2005) <<https://www.open.ac.uk/ikd/documents/working-papers/ikd-working-paper-8.pdf>> accessed 10 March 2015.

⁶² *ibid.*

⁶³ Chaudhuri (n 18) 37.

⁶⁴ Dwijen Rangnekar, 'No Pills for Poor People: Understanding Disembowelment of India's Patent Regime' (2006) *Economics and Political Weekly* 411 ('No Pills for Poor People').

⁶⁵ *ibid.*

⁶⁶ Jean Lanjouw, 'The Introduction of Pharmaceutical Product Patents in India: "Heartless Exploitation of the Poor and Suffering"?' (1998) National Bureau of Economic Research Working Paper 6366.

⁶⁷ Deutsche Bank Report, 'Indian Pharmaceutical Industry on Course for Globalization' (Deutsche Bank 2008) 1 <https://www.dbresearch.com/PROD/DBR_INTERNET_EN-PROD/PROD0000000000224095.pdf> accessed 2 April 2015.

amounts. Thus, it is also not surprising that the post-independence period saw a shift in drug therapy from treating symptoms to treating the disease itself. Within the next three decades, India emerged as the leading manufacturer and exporter of generic drugs to developing countries in Asia, Latin America, and Africa.

In addition to the amendment of its patent law, the government of India also introduced other policies that worked in tandem with patent laws. Specifically, the government introduced some form of control on drug prices to ensure access to medicines. The Drugs (Display of Prices) Order of 1962 and the Drugs Control of Prices Order (DPCO) had the effect of freezing the price of drugs. The DPCO set the price of drugs sold within India and put a ceiling on overall prices set by pharmaceutical companies, thus providing affordable medicines for the masses. In essence, the DPCO divided bulk drugs, which are usually basic raw materials or APIs, into essential and ‘other’ bulk drugs. Prices of essential drugs would be allowed to rise with the prior approval of the government (or the relevant agency in charge). The prices of ‘other’ bulk drugs were then frozen ‘at the level prevailing immediately before the announcement of the DPCO.’⁶⁸ It is important to note at this juncture that the DPCO is strictly an executive decision with no mandate in the statute. Over the years, the DPCO has been reviewed and amended by the government to reflect the socio-economic needs of the Indian population.

Moreover, to enhance local production of drugs, the government initiated investment in local manufacturing firms and education especially in the area of chemistry, pharmaceutical research and biotechnology, and building sophisticated research institutions. Scholars such as Gehl Padmashree writes that to encourage local technological knowledge, the government developed extensive skill in chemistry-based reverse engineering which formed the core of their processes and product development skills.⁶⁹ Specifically, government created an ‘extensive scientific infrastructure and skilled human capital that would be absorbed into the

⁶⁸ The findings from the 1975 Hathi Committee Report on essential drugs played a crucial role in the development of the Indian pharmaceutical industry. The findings from the Committee led the government to exempt nearly 200 essential drugs from the sway of patenting. See N Lalitha, ‘Access to Indian Generic Drugs: Emerging Issues’, *Intellectual Property, Pharmaceuticals and Public Health: Access to Drugs in Developing Countries* (1st edn, Edward Elgar 2011) 228.

⁶⁹ Gehl Sampath Padmashree, ‘Economic Aspects of Access to Medicine After 2005: Product Patent Protection and Emerging Firm Strategies in the Indian Pharmaceutical Industry’ (Commission on Intellectual Property Rights, Innovation and Public Health (CIPRH) 2005).

pharmaceutical sector.⁷⁰ This encouraged innovation and meant that Indian firms thrived and invested into several kinds of generic activities. An example of Indian drug innovation was the release in 2001 of the HIV drug *Triomune* – the world’s first fixed-dose antiretroviral drug. It was produced by Cipla, and sold at USD600 per year, but reduced to USD1 per day for MSF. Luigi Palombi asserts that the low price of *Triomune* encouraged Merck – a US pharmaceutical company – to reduce the price of *Crixivan*, a highly active ARV therapy to roughly the same price, which in turn caused Bristol Myers Squibb and Glaxo SmithKline to follow suit.⁷¹

The importance of the IPA became obvious during the HIV/AIDS crisis of the 1990s and early 2000s when Cipla, an Indian generic company, offered to sell the triple therapy ARV drugs of *stavudine+lamivudine+nevirapine* for USD350 per year – a stark reduction from the USD10,000 which the originator company charged.⁷² The introduction of cheaper versions of the expensive ARV treatment not only crashed the market price but also helped in scaling up treatment worldwide. Since then, other generic companies from India have entered the ARV market, which further reduced the price.⁷³ Currently, India is 3rd in global volume terms and 14th in global value terms. It also meets 70 per cent of in-country needs for bulk drugs, formulations, dry intermediaries, and others.⁷⁴ India is the top drug exporter into the US.⁷⁵ In fact, some estimates suggest that India’s pharmaceutical industry supplies 40 per cent of over-the-counter and generic prescription drugs consumed in the US.⁷⁶ However, even though the drug industry is one of the country’s most important economic engines, exporting USD10-15 billion in products annually,⁷⁷ the sector is hugely dependent on imports of APIs from China, with cumulative imports going up from USD2.5 billion in 1996 to USD15 billion in 2010.⁷⁸

Global Struggle

⁷⁰ *ibid* 13; see also Palombi (n 60) 402 and Chaturvedi (n 61) 15-17.

⁷¹ Palombi (n 60) 402.

⁷² Chaudhuri (n 18) 8. See also Deutsche Bank Report (n 67) 3.

⁷³ *ibid*.

⁷⁴ Sakthivel Selvaraj, Dinesh Abrol, and K Gopakumar, *Access to Medicines in India* (2014) 22.

⁷⁵ Heather Timmons, ‘India Expands Role as Drug Producer’ *New York Times* (2010) <http://www.nytimes.com/2010/07/07/business/global/07indiadrug.html?_r=0> accessed 14 March 2015.

⁷⁶ Gardiner Harris, ‘Medicines Made in India Set Off Safety Worries’ *New York Times* (2014) <<http://www.nytimes.com/2014/02/15/world/asia/medicines-made-in-india-set-off-safety-worries.html>> accessed 15 March 2015.

⁷⁷ *ibid*. See also Gardiner Harris and Katie Thomas, ‘Low-Cost Drugs in Poor Nations Get a Lift in Indian Court’ *New York Times* (2013) <<http://www.nytimes.com/2013/04/02/business/global/top-court-in-india-rejects-novartis-drug-patent.html>> accessed 15 February 2015.

⁷⁸ Fieldwork interview with Dinesh Abrol (Delhi, August 2014) (transcript on file with author).

Prior to phasing fully into the TRIPS regime in 2005, India used the TRIPS Agreement's transitional provisions under Article 65 thereof, which gave developing countries a 10-year window from 1995 to 2005 to make necessary changes to their IP regimes. It shows how a large developing country has played the TRIPS Agreement implementation game and underscores the importance for less developed countries to utilise the flexibilities available in the TRIPS Agreement.⁷⁹ According to Peter Yu, by experimenting with different policy options and delaying the introduction of TRIPS standards, India successfully maintained an IP system that was tailored to its local needs, interests, conditions, and priorities.⁸⁰ Although Article 65 of the TRIPS Agreement allowed for a transition period, only 13 countries used this provision. Of these 13, only six used up the complete period.⁸¹

Despite using the transition clause, the period leading up to the 2005 deadline was not easy or smooth. This is not surprising as even though India accepted the TRIPS Agreement as part of the single undertaking, it was one of the countries from the Global South (along with Argentina, Brazil, Nigeria, and Thailand) that opposed the inclusion of IP rules in the wider body of global trade rules. India has always taken the position that substantive matters relating to IP are outside the purview of global trade rules. It viewed the inclusion of an IP regime in the international trade framework as a tool by which wealthy nations could impose strong IPRs as the cost of much-needed access to Western markets.⁸² Specifically, the inclusion of both process and product patents in all areas of technology, including pharmaceuticals, was heavily criticised as it meant the country should now provide for patent protection in areas where it previously did not do so.⁸³ Thus for India, any IP regime should strike a balance between the rights of patentees and the public interest, and between the promotion of industrialisation and securing the transfer of technology. It is this understanding of IP (and patents in particular) that formed the lynchpin of amendment-related politics and discourse during the transition period, and the subsequent revisions to India's patent law.

⁷⁹ *ibid.*

⁸⁰ Peter K Yu, 'Are Developing Countries Playing a Better TRIPS Game?' (Social Science Research Network 2013) <<http://ssrn.com/abstract=1915117>> accessed 2 March 2015.

⁸¹ Swaraj Paul Barooah, 'India's Pharmaceutical Innovation Policy: Developing Strategies for Developing Country Needs' (2013) 5 Trade, Law and Development.

⁸² Mueller (n 19) 517.

⁸³ Fieldwork interview with Amit Sengupta (Delhi, August 2014) (transcript on file with author). See also the report by Economic and Political Weekly, 'Intellectual Property Rights: The Geneva Surrender' (Economic and Political Weekly 1989) 1201-04, on the Indian stance and specific objections throughout the Uruguay Round negotiations.

The contentious politics of India's compliance with its obligations under the TRIPS Agreement led to three implementation stages. The *first amendment* added Chapter IVA, titled 'exclusive marketing rights', to the IPA and provided for mechanisms for receiving pharmaceutical product patent applications – the so-called 'mailbox' filing – as stipulated by Articles 70(8) and 70(9) of the TRIPS Agreement, which required countries to have adequate infrastructure for receiving and filing patent applications from the date of enforcement of the TRIPS Agreement. The *second amendment*, the Patent Amendment Bill of 1999, introduced over 70 changes such as CLs, working requirements, and non-patentable inventions. This second amendment was in accordance with Article 65(2) of the TRIPS Agreement, which entitles a developing country member 'to delay for a further period of four years the date of application, as defined in paragraph 1, of the provisions of this Agreement other than Articles 3, 4 and 5.'⁸⁴ The *third amendment* included new criteria for patentability. The intricacies of this amendment will be discussed in the ensuing sections.

4.2 Everyday Resistance: International Law in Local Spaces

Analysing the interaction of the TRIPS Agreement at the local levels in India – i.e. how the TRIPS Agreement interfaced with local institutions, non-state actors, and laws – requires a historical and economic backstory on how India conceptualised the idea of development, and thus patents, post-independence. This backstory maps the circulation of ideas among the key actors – from the influence of the capitalist class in the methods and strategies of aggregate planning in India, the rise of reformist agitation among Third World states that informed India's negotiations and dialogues in international forums, to the informed resistance of civil society groups in shaping public discourse. The multiplicity of these influences provide a lens through which to understand India's engagement at the negotiations in the run-up to the creation of the WTO, the heated public debates in the lead-up to the 2005 patent law amendment, as well as the on-going national engagement on patent jurisprudence within India today. Understanding these varied influences may clarify the impact of the divergent pulls and pressures, both global and local in nature, on IP law making in a vocally democratic country like India.

⁸⁴ TRIPS Agreement, art 65(2).

As stated earlier, the newly independent Indian state inherited an impoverished economy from the British government. Life expectancy and literacy levels were low, poverty levels were high, communicable diseases were rife, and the country was capital-deficient due to its proxy involvement in the Second World War. Except for a few pockets of items within the manufacturing sector, the sector itself was underperforming. Based on these conditions, the Indian government set out to promote a rapid rise in the standard of living of the people and to improve the country's overall economic performance. One of the targeted sectors was health and drug technology due to the magnitude and significance of health issues, which included non-existent to limited access to and availability of medicines as local prices of drugs were one of the highest in the world.⁸⁵ This price anomaly could be attributed to numerous factors, but the most glaring was that drug availability was significantly controlled by foreign companies operating a 'small number of plants that formulated a limited range of medicines while importing the balance.'⁸⁶ This caused, in addition to high prices, market manipulation of drugs by MNCs. Citing the case of Parke Davis' promotion of *choloramphenicol* – an antibiotic usually prescribed for typhoid but marketed as a common cure for infections such as cough and common cold, thus leading to the build-up of resistance and which proved to be fatal during the typhoid outbreak – Rangnekar contends that it was this scenario that augmented the need for reform of the patent law, the local drug system, and the development of local technological and research capacity to enable India to become self-sufficient.⁸⁷ In fact, this need for self-sufficiency underscored the Ayyangar Report, which sought to make patents work for the Indian nation, thereby reversing the negative impact of colonial law.

The planned economic development in India in the form of the Five-Year Plans (FYPs) and the review of relevant laws to complement the development process had already begun prior to independence. The Bombay Plan, for example, provided for a 15-year economic plan for India in January 1944.⁸⁸ It was authored by leading Indian industrialists and technocrats at that time, including J. R. D. Tata (son of a cousin of Jamsedji Tata, one of India's pioneer industrialists), G. D. Birla (founder of the Birla

⁸⁵ The Kefauver Committee mentioned this in its report. See Michael Kidron, *Foreign Investments in India* (Oxford University Press 1965) 251.

⁸⁶ Rangnekar, 'No Pills for Poor People' (n 64) 410.

⁸⁷ *ibid.*

⁸⁸ The official title is 'A Brief Memorandum Outlining a Plan of Economic Development for India' and was named after the city where the authors convened. See PS Lokanathan, *The Bombay Plan*, Foreign Affairs (1945); see also Amal Sanyal, 'The Curious Case of the Bombay Plan' (2010) 6 Contemporary Issues and Ideas in Social Sciences.

group of industries), Sir Ardeshir Dalal (administrator and technocrat), Lala Shriram (industrialist, Delhi Cloth Mills), Kasturbhai Lalbhai (textile and shipping magnate), D. Shroff, and Purushottamdas Thakurdas (businessmen). It specified clear objectives to be kept in mind in the economic planning of India as well as the general lines on which development should proceed. Significantly, the Bombay Plan foreshadowed the first FYP launched in 1951, just three years after independence. According to Amal Sanyal, one of the purposes of the Bombay Plan was to initiate some form of planned domestic industrialisation after independence and attain in 15 years' time 'a general standard of living which would leave a reasonable margin over the minimum requirements of human life.'⁸⁹ Other commentators such as P. S. Lokanathan consider the Bombay Plan to be a concrete statement of 'the objectives to be kept in mind in economic planning in India, the general lines on which development should proceed and the demands which planning is likely to make on the country's resources.'⁹⁰ The Bombay Plan was therefore, in a sense, a compass in the way development and economic growth should proceed.

The Bombay Plan emphasised the importance of developing basic industries for the exploitation of India's large industrial potentials. It is no wonder that key sectors such as power, mining and metallurgy, engineering, agriculture, chemicals, armaments, transport, and cement were among the industries listed to be developed within the 15-year period of the Bombay Plan.⁹¹ What is interesting about the Bombay Plan, apart from its admirable objectives, was the group of gentlemen who authored it. It highlights the role of industrialists in pushing forward a particular agenda, which included but was not limited to an indigenous technology sector with a strong research development base. As a result, the Bombay Plan came to be very much seen as a nationalistic aspiration of the domestic capitalist class.⁹²

Although the Bombay Plan was not officially adopted, it has been considered a reflection of the interests and ideas circulating among the capitalist class and, by extension, the policymakers of the time as some of the initial authors of the Bombay Plan went on to become practitioners in government. For example, Purushottamdas Thakurdas and G. D. Birla were involved in building business associations such as the

⁸⁹ Sanyal (n 88) 6-10.

⁹⁰ Lokanathan (n 88), s II.

⁹¹ *ibid.*

⁹² Vivek Chibber, *Locked in Place: State-Building and Late Industrialization in India* (Princeton University Press 2003) 88.

India Chamber of Commerce and the Federation of Indian Chamber of Commerce and Industry. D. Shroff became the founder-director of the Investment Corporation of India as well as chairman of the Bank of India. In a 2004 speech, the then prime minister of India Dr. Manmohan Singh extolled the significance of the Bombay Plan in the making of modern India. Commenting on the Bombay Plan, he remarked:

The Bombay Plan laid great emphasis on public investment in the social and economic infrastructure, in both rural and urban areas, it emphasized the importance of agrarian reform and agricultural research, in setting up educational institutions and a modern financial system. Above all, it defined the framework for India's transition from agrarian feudalism to industrial capitalism, but capitalism that is humane, that invests in the welfare and skills of the working people. In many ways, it encapsulated what all subsequent Plans have tried to achieve.⁹³

The Bombay Plan was also important in shaping many government policies afterwards, especially the FYPs. In his analysis of the history of Indian businesses, Dwijendra Tripathi noted that the Bombay Plan helped shift government attention that previously exclusively focused on commercial trade to manufacturing.⁹⁴ Specifically, he states:

The authors of [the Plan] recognised the need for planned development, emphasised state ownership and control of key industries, and concurred with the idea of a centrally directed authority to ensure successful implementation of the economic plans. Although they assigned a legitimate role for the private sector in the future economic set-up, they candidly conceded that it would have to function under tight state direction.⁹⁵

Of course, opinions differ regarding the reasons for state failure in spite of the development efforts of the business class in India. On one hand, it has been argued that such failure is due to the inability of the state to take advantage of the enthusiasm of the business class. Instead, the state instituted a system that stifled business initiative, overextended administrative capacity, and lost coherence in a dense web of bureaucratic tape.⁹⁶ On the other hand, the argument is that the Indian capitalist class did not support the developmental state in any relevant sense and opposed

⁹³ Paranjoy Guha Thakurta, 'Bombay Plan and Mixed-Up Economy' *The Hindu Businessline* (2004) <<http://www.thehindubusinessline.com/2004/09/07/stories/2004090700010800.htm>> accessed 16 April 2015.

⁹⁴ Dwijendra Tripathi and Jyoti Juman, *The Concise Oxford History of Indian Business* (2007) 333.

⁹⁵ *ibid.*

⁹⁶ Sanyal (n 88) 13.

disciplinary planning that would allow the government to regulate the flow of investment and punish non-compliance.⁹⁷

Irrespective of this, the striking similarities between the Bombay Plan and the government's FYPs cannot be denied. Noting the resemblance between the Bombay Plan and the first three FYPs, M. Naidu argues that it is an example of the muddled relationship between law makers and the Indian bourgeoisie and how easy it is for one to influence the other and vice versa.⁹⁸ Others observe that the similarity between the Bombay Plan and the FYPs is an example of the impact of capitalist preferences on state-building.⁹⁹ If anything, the resemblance between both documents shows how ideas circulate, the manner in which particular policy options get constructed, and, as an extension, how others get extinguished vis-à-vis the capitalist and political class.

India has come a long way since the time of the Bombay Plan, but the ethos of the Plan – the need for planned development and economic independence, building indigenous technological and scientific competency, and improving standard of living – still echoes in government policy and public discourse. These same sentiments permeated the contours of India's involvement in the negotiations leading up to the creation of the WTO as well as in local discussion regarding joining a new world organisation.

As mentioned earlier, India has always maintained a position at the Uruguay Round negotiations based on the principle that any IP matter was outside the purview of the GATT. Focusing on patents, the Indian representative at the Uruguay Round specifically stated that 'India is not in favour of raising the levels of patent protection unduly, particularly in the area of pharmaceuticals, because of its adverse implications for the growth of indigenous industry as well as research and development efforts.'¹⁰⁰ This is not surprising because India has made it increasingly clear through its IPA that it will pursue laws that will work for the nation. It believed that 'IPRs are not trade-

⁹⁷ Chibber (n 94) 30.

⁹⁸ M Naidu, 'The Bombay Plan' (*Workers' International News*, 1944) <<https://www.marxists.org/history/etol/newspape/win/vol05a/no07a/naidu.htm>> accessed 16 June 2015.

⁹⁹ Chibber (n 94) 85.

¹⁰⁰ 'Statement by Dr Subramanian Swamy, Union Minister of Commerce, Law and Justice' (1990) Multilateral Trade Negotiation: Uruguay Round (MTN/TNC/MIN(90)/ST/46). See also *Economic and Political Weekly*, 'The Geneva Surrender' 1201.

related and instead, the WIPO is the appropriate forum to deal with IP issues.’¹⁰¹ For India, bringing IP issues to the WTO through the TRIPS Agreement was a mistake, as the WIPO exists to deal with global IP-related mandates. According to A.V. Ganesan, chief negotiator of India at the Uruguay Round, India was firmly opposed to the inclusion of substantive norms and standards for the protection of IPRs within the negotiating mandate.¹⁰² This is because it believed that the inclusion of IP rules in GATT is inimical to its national interest as it ‘intrudes into domestic policy space and would constrain their freedom to pursue economic and social policies best suited to their individual needs.’¹⁰³ These attitudes framed not only the perception of the legitimacy of, but also interaction with and consequent resistance to, the TRIPS Agreement in the local spaces in India.

About the time when the Uruguay Round negotiation activities began, there was an ongoing paradigm shift among the developing countries at the international level – an NIEO. This shift in thinking based on the belief of a just and equitable international economic order influenced India’s stance at the Ministerial negotiations and diffused into the debates at the home front. The NIEO thinking adopted a ‘reformist approach’ in transnational governance and international law making. Promulgated by the UN Declaration in 1974, it sought to restructure and reform the asymmetry in international economic relations and systems, and transfer economic benefits from developed to developing states.¹⁰⁴

The NIEO, it has been argued, was the ‘most important international law initiative taken by the developing world in attempting to remedy colonial inequities.’¹⁰⁵ It was not a single entity but rather a political brand holding together a set of loosely compatible agendas with interrelated agendas.¹⁰⁶ In particular, the NIEO sought for control of the extraction and marketing of domestic natural resources by Third World

¹⁰¹ Peter Drahos, ‘Global Intellectual Property Rights in Information: The Story of TRIPS at the GATT’ (1995) 13 *Prometheus*; see also TN Srinivasan and Suresh D Tendulkar, *Reintegrating India with the World Economy* (Institute for International Economics 2003).

¹⁰² AV Ganesan, ‘Negotiating for India’, *The Making of the TRIPS Agreement: Personal Insights from the Uruguay Round Negotiations* (1st edn, World Trade Organization 2015) 3.

¹⁰³ *ibid.*

¹⁰⁴ United Nations General Assembly, ‘Declaration on the Establishment of a New International Economic Order (3201 (S-VI)’ (United Nations 1974) <<http://www.un-documents.net/s6r3201.htm>> accessed 19 April 2015 (NIEO Declaration). See also Nils Gilman, ‘The New International Economic Order: A Reintroduction’ (2015) 6 *Humanity*.

¹⁰⁵ Antony Anghie, *Imperialism, Sovereignty and the Making of International Law* (Cambridge University Press 2005) 313.

¹⁰⁶ Gilman (n 104) 3.

states,¹⁰⁷ the regulation of transnational corporations,¹⁰⁸ a no-strings-attached transfer of technology from the rich to the poor countries of the Global South,¹⁰⁹ the cancellation of debts,¹¹⁰ and the right of every country to adopt the economic and social system that it deems the most appropriate for its own development and not to be subjected to discrimination of any kind as a result.¹¹¹ If anything, the NIEO discourse represents an attempt by many formerly colonised nations to enter global debate – once the purview of an old boys’ European network – as equal members, if not partners.

Although the NIEO failed¹¹² to achieve many of its stated objectives, it underscored India’s participation at the Uruguay Round as well as that of many post-colonial countries, including Brazil. Viewed from this conjuncture, the NIEO explains the political and economic thought in India – international cooperation based on improving the economic position of the Global South in relation to the Global North. For the country, any international agreement that did not further this agenda did not warrant signing up to.

Furthermore, India’s domestic economic policy at that time also influenced its resistance to the TRIPS Agreement. On the home front, it pursued statist economic policies which saw excessive government control over the economy and the ‘Licence Permit Raj’ – a vast system of national and state-level quotas and licences¹¹³ – were in force. This led to a balance of payment crisis. Although liberalization had already begun, there existed among policymakers and the general public a protectionist stance which saw the opening up of the economy to FDI as well as to international trade as either unnecessary or anti-self-reliance. These left-leaning policies and philosophies

¹⁰⁷ NIEO Declaration (n 104), para 4(e).

¹⁰⁸ *ibid.*, para 4(g).

¹⁰⁹ *ibid.*, para 4(p).

¹¹⁰ *ibid.*, para 4(o).

¹¹¹ *ibid.*, para 4(d).

¹¹² See D Otto, ‘Subalternity and International Law: The Problems of Global Community and the Incommensurability of Difference’ (1996) 5 *Social and Legal Studies*, on why the NIEO failed. According to her, the NIEO failed due to many reasons, which included but are not limited to: the consensus adoption of a new blueprint for global economic cooperation by the General Assembly in 1990 which made no reference to the NIEO; the seeming futility of reshaping the international economic environment and transferring economic benefits from developed to developing states; and the fact that two central disputes of the Charter of Economic Rights and Duties of States (CERDS) were never resolved – first, the issue of expropriation or nationalization of property owned by foreigners in decolonised states and the associated questions of compensation and, second, the justification of commodity cartels. Gilman also notes that the various factors that contributed to the failure of NIEO, which includes the unravelling of political solidarity of the Third World states, fragmentation and forum shopping that weakened the attempt to use international law to rein in the sovereign prerogatives of powerful countries, as well as the economic might of the developed countries of the North. See Gilman (n 104) 9.

¹¹³ Mueller (n 19) 516.

created considerable opposition to globalisation and India's integration into the global economy. Significantly this anti-globalisation stance allowed for the fusion of expertise and allegiance between indigenous pharmaceutical companies and civil society groups. At home, various civil society groups spearheaded the campaign against the TRIPS Agreement and played an important role in knowledge formation and expertise production on its possible impact on the country's robust generic sector because they understood the likely negative effects on health rights, knowledge access, and food security.¹¹⁴

The IDMA, the largest and best-known association that represents the domestic Indian pharmaceutical industry, was one of the most outspoken industry bodies on this issue. Working towards this end, the IDMA heavily lobbied the government and prepared draft letters to various members of the Parliament, urging them to protect the health rights of citizens and the pharmaceutical sector. Together with CSOs, professional bodies, and student groups, the IDMA pushed for public resistance thereby generating a negative image of the TRIPS Agreement, the Dunkel Draft, and the GATT in public media.

Among the CSOs, the National Working Group on Patent Laws (NWGPL), which was headed by B. K. Keayla, specifically played an active role in providing studies for informed debate in the Parliament and in the public regarding the Uruguay Round agenda and the effect of the new international body on the availability and affordability of medicines. A former bureaucrat in the Finance Ministry, Keayla joined Ranbaxy between the late 1980s and early 1990s where he was influential in the counter-hegemonic resistance by organising national and international seminars or conferences and facilitating research on the constitutional issue of the implementation of the TRIPS Agreement. Keayla's dual role as head of NWGPL and executive at Ranbaxy underscores the ability of big corporations to mobilise leading sources of expertise to elaborate, interpret, and defend their agendas and influence standard-setting. Ranbaxy also financed the work of NWGPL to develop research and build public opinion, and even provided office space in a prime location for the NWGPL.¹¹⁵

¹¹⁴ Fieldwork interview with Professor BS Chimni (Delhi, 2014) (transcript on file with author).

¹¹⁵ Fieldwork interview with Dr N Raghuram (Delhi, September 2014) (transcript on file with author).

Ranbaxy was not the only Indian generic company working in collaboration with civil society groups. Other companies such as Cipla and Dr. Reddy's funded research activities on the potential impact of the proposed IP regime on the country's pharmaceutical sector and public health.¹¹⁶ Since the amendments were bringing in monopoly protection for pharmaceutical inventions for the very first time, they were obviously a concern for the IDMA. The association was most interested in ensuring the protection of the interests of its members and was the most vocal in opposing the TRIPS Agreement at home and abroad.

The pharmaceutical sector continued to play a vocal role in the lead-up to the 2005 amendments to the IPA. The IDMA was also active during the Doha Round as some of its members were present during the negotiations. In the lead-up to the 2005 IPA amendments, it was the IDMA which provided the language of the important Section 3(d) (discussed *infra*). According to Amit Sengupta, the Left parties had asked for a more stringent definition of patentability, and the IDMA provided the text, which limited patents for pharmaceutical substances to 'new chemical entities' or to 'new medical entities involving one or more inventive steps.'¹¹⁷ This particular clause protects not only public health interests in ensuring that only genuine patent applications are approved, but also protects the generic sector by preventing patent 'ever-greening'. Ever-greening refers to the patenting strategy of seeking and securing multiple patents around a single invention and is not exclusive to pharmaceuticals. In an interview, Biswajit Dhar commented that Section 3(d) was 'included for innovation purposes as [India] cannot allow minor innovations to be treated at par with something, which we consider a breakthrough.'¹¹⁸ Thus, by successfully including the limiting and clearer language of only new chemical entities (NCEs) in patent application, the IDMA was able to achieve a more tempered patent regime for India, thereby reducing the space for frivolous patenting.

In opposition to the IDMA is the Organisation of Pharmaceutical Producers in India (OPPI), which is primarily an association of foreign pharmaceutical MNCs operating

¹¹⁶ *ibid.*

¹¹⁷ Fieldwork interview with Sengupta (n 83). It is worth mentioning that besides IDMA, the other major player was the farmer's movement. During the Uruguay Round Negotiations, nearly 200,000 farmers were mobilised by Karnataka Rajya Raitha Sangha – a farmer's movement in Bangalore – to protest against the Dunkel Draft. This protest was picked up by other farmers in different parts of India. See Shefali Bhimal and Saritha Rai, 'Attack on Cargill by Karnataka Rajya Raitha Sangha Brings Dunkel Draft Issue in Focus' (*India Today*, 1993) <<http://indiatoday.intoday.in/story/attack-on-cargill-by-karnataka-rajya-raitha-sangha-brings-dunkel-draft-issue-in-focus/1/302677.html>> accessed 10 October 2015.

¹¹⁸ Fieldwork interview with Biswajit Dhar (Delhi, 2014) (transcript on file with author).

in India. The OPPI pushed a pro-Dunkel Draft agenda in a very quiet manner at the top government level¹¹⁹ and lobbied for the adoption of the TRIPS Agreement, which it argued ‘would encourage genuine scientific and technological research, reverse years of brain drain in the science and technology sector and spur foreign direct investment.’¹²⁰ The OPPI also opposed the pre-grant patent opposition clause in the IPA, believing that it unduly prolonged the patent application process. In so doing, the OPPI opposed several of the policy provisions pushed for by both the NWGPL and the IDMA by hedging its argument on the potential economic and innovation benefit to India by joining the global economy.

If anything, the dichotomy between the IDMA and the OPPI shows how fragmented the Indian pharmaceutical sector is. The interaction between the IDMA and the OPPI indicates how a reform preferred by one sectorial player might be seen as damaging by another as well as the predictable bipolarity among actors with divergent interests. In fact, the formation of a third group, the Indian Pharmaceutical Alliance,¹²¹ heightens this fragmentation. Founded in 1999, the Indian Pharmaceutical Alliance consists of the biggest generic companies, namely Cipla, Dr. Reddy’s, Ranbaxy, Lupin Laboratories, Alembic Limited, Primal India, Sun Pharmaceutical, and Wockhardt Limited. Together, these companies account for 30 per cent of domestic production and 33 per cent of domestic export. In the lead-up to the 2005 IPA amendments, the Indian Pharmaceutical Alliance lobbied for the inclusion of a specific limitation on patentability preventing the patenting of new uses of known substances, as well as the patenting of many new forms of known substances.¹²²

Paradoxically, the OPPI found support from the Indian Pharmaceutical Alliance in the lead-up to the 2005 IPA amendments in areas including but not limited to licences of rights and CLs. This is not surprising as most members of the Indian Pharmaceutical Alliance engage in significant independent R&D, a move away from reverse engineering of branded drugs which is still employed by a majority of the members of the IDMA.¹²³ In a 2002 letter from the Indian Pharmaceutical Alliance to the Minister of Commerce and Industry, Shri Murasali Maran notes that the Indian Pharmaceutical

¹¹⁹ Fieldwork interview with Raghuram (n 115).

¹²⁰ Homi R Khusrokhhan, ‘Letter to the Ministry of Science and Technology from the Organization of Pharmaceutical Producers in India (OPPI), dated 28 April 1999’ (document on file with the author).

¹²¹ See Rangnekar, ‘No Pills for Poor People’ (n 64) 414.

¹²² Fieldwork interview with Sengupta (n 83).

¹²³ Mueller (n 19) 537.

Alliance supports patent protection for pharmaceutical products provided such protection is balanced by public health requirements.¹²⁴ Working towards this end, the Indian Pharmaceutical Alliance made a strong pitch for strengthening CLs, licences of rights, and the Bolar provisions¹²⁵ – the latter being a form of legal exemption from the right conferred by patent for the purposes of obtaining regulatory approval or other commercial purposes. The fragmentation within domestic manufacturers provides significant complexity when explaining the multiplicity of factors in the way the TRIPS regime interacts in local spaces. The sector's diversity, according to Janice Mueller, also illustrates the fallacy of viewing the patent debate in India as a purely two-sided argument between foreign and domestic drug companies.¹²⁶ As will be seen below, the lack of homogeneity is significantly changing the landscape many years post-TRIPS Agreement.

Indian civil society groups played an integral role in the Uruguay Round negotiations by keeping up the public discourse on GATT in mass media. This is vastly different from the Brazilian example as discussed in the previous chapter. In India, these actors that included academics, patient groups, as well as professional groups such as journalists and health workers played crucial roles in knowledge, expertise production, and framing policy discourse on IP-related issues vis-à-vis India's economic needs and development aspirations. They successfully influenced the agenda of government by ensuring that adequate flexibilities and public interest protections were included in the TRIPS Agreement. Indeed, India is credited for the inclusion of the TRIPS Agreement flexibilities.¹²⁷

The interregnum period from 1995 to 2005, especially the lead-up to the final amendment to the IPA in 2005, saw active local civil society demonstrations. Significantly, the second wave of activism saw increased participation of and partnership between transnational civil society groups and local NGOs. The MSF, the South African Treatment Action Congress, and the ABIA organised protests in their home countries in solidarity with their counterparts in India. Locally, NGOs and health groups such as the Delhi Network of Positive People (DNP+), the People's Health Movement, the Lawyers Collective, and the Human Rights Network, among

¹²⁴ Letter from DG Shah (Secretary General of the Indian Pharmaceutical Alliance) to Shri Murasali Muran (Honourable Minister of Commerce and Industry) dated 23 March 2000 (document on file with the author).

¹²⁵ *ibid.*

¹²⁶ *ibid.*

¹²⁷ Kapczynski, 'Harmonization and its Discontent' (n 26) 1573.

others, organised protests against the implementation of a sweeping interpretation of the TRIPS Agreement into local law that does not consider the nuances of Indian realities and without including the broadest flexibilities in place.¹²⁸ In 2001, for example, the Lawyers Collective HIV/AIDS Unit launched the Affordable Medicines and Treatment Campaign (AMTC) – a coalition of networks of PLWHA, NGOs, and individuals – to campaign for the inclusion of public health safeguards in the IPAA and the exclusion of TRIPS-plus provisions.¹²⁹ The objective of the AMTC was to demand and create an environment that will ensure sustained accessibility and affordability of all medicines and treatment for every individual in India, including access to affordable medicines for PLWHA.¹³⁰ The Lawyers Collective, together with national and international civil society actors, engaged in extensive advocacy in the form of dialogues, seminars, and white papers. According to Julia George, the advocacy campaigns of CSOs in India successfully led to the retention and inclusion of key public health safeguards in the IPA when Parliament finally amended the law in 2005. These safeguards include the retention of the pre-grant opposition provided in the IPA, the inclusion of post-grant opposition proceedings, and the amendment of provisions relating to compulsory licencing.¹³¹ The latter, according to Gopakumar and Tahir Amin, underscores India's role as a generic drug supplier to developing countries.¹³²

Civil society groups have continued their activism post-TRIPS implementation through the submission of amicus curiae briefs in legal cases and through civil protests. The Lawyers Collective, NWGPL, Drug Action Forum, and MSF all provided submissions to the Technical Expert Group on Patent Law Issues (Mashelkar Committee Report).¹³³ The Mashelkar Committee was set up following

¹²⁸ Fieldwork interview with Vikas Sharma (Delhi, August 2014) (transcript on file with author); see also Ethan B Kapstein and Joshua W Busby, *AIDS Drugs for All: Social Movement and Market Transformations* (Cambridge University Press 2013) 117-18.

¹²⁹ Julia George, 'India, Intellectual Property and Access to Medicines: Developments and Civil Society Initiatives in India', *Intellectual Property Rights and Access to ARV Medicines* (1st edn, ABIA 2009) 130.

¹³⁰ Affordable Medicines and Treatment Campaign (Lawyerscollective.org, 2001) <<http://www.lawyerscollective.org/access-to-medicine/atm-background.html>> accessed 6 May 2015.

¹³¹ George (n 129) 130.

¹³² See also KM Gopakumar and Tahir Amin, 'Patents (Amendment) Bill 2005: A Critique' (2005) 40 *Economic and Political Weekly* 1.

¹³³ According to the popular Indian IP website, Spicy IP, the Patents (Amendment) Act of 2005 that introduced pharmaceutical product patents in India suffered fairly long innings prior to coming into force. It first began as the Patents (Amendment) Bill of 2003 under the BJP government but soon lapsed due to a change in government and the consequent dissolution of the Lok Sabha. The new Congress-led coalition government endorsed the Patents (Amendment) Bill of 2003, however, since they were unsure of whether it would go through Parliament well in time to meet the TRIPS Agreement deadline of 1 January 2005, they had it passed as a Presidential Ordinance. Due to pressure from the Left parties, changes were immediately made to the Ordinance and cleared by the Parliament in the third week of March as the Patents (Amendment) Bill of 2005. This is not to say that the Left

the introduction in Parliament of the Patents (Amendment) Bill of 2005. It was specifically tasked to examine two important questions, i.e. whether it would be TRIPS-compatible to limit the grant of patents for pharmaceutical substances to NCEs or to new medical entities (NMEs) involving one or more inventive steps,¹³⁴ and whether it would be TRIPS-compatible to exclude microorganisms from patenting.¹³⁵

In this respect, the mandate of the Mashelkar Committee was restricted to TRIPS analysis and not the broader policy consideration of how best to balance public health goals with pharmaceutical innovation goals. In its submission, the NWGPL argued that patents should be made available ‘for basic novel inventions including pharmaceutical substances as defined in Section 2 and 3 whether products or processes in all fields of technologies excluding invention of the Indian Patent Act provided they are new, involve an inventive step and are capable of industrial application.’¹³⁶ The Lawyers Collective, for its part, argued that it would be TRIPS-compatible to limit the grant of patent to NCEs.¹³⁷ The Mashelkar Committee Report concluded that it would not be TRIPS-compliant to limit the granting of patents for pharmaceutical substances to NCEs only and excluding microorganisms from patents.¹³⁸ However, it reiterated the importance of providing drugs to the people of India at affordable prices. It also reaffirmed the importance of preventing the grant of frivolous patents. In doing so, the Mashelkar Committee Report reaffirmed the government’s understanding that patent rights should be balanced and calibrated with public health, national security, and public interest concerns.

Nevertheless, these acts of counter-hegemonic resistance, especially among local actors within India, are important in spearheading instances of dialogue, scrutiny, and education. Civil society groups, through their activism, have been able to shape the contours of national dialogue and international law norms and exemplify the *twillian*

was completely satisfied. Some issues remained outstanding and rather than risk any further delays, the government strategically did what it does best when caught in a spot – it appointed a committee. If anything, the Mashelkar Committee was nothing more than a deft move by the government to prevent any further stalling of the passage by the Left parties of the IPA by raising the issue of the TRIPS Agreement, particularly after being summoned twice earlier to the WTO over allegations of violating it. See <http://spicyip.com/2007/01/mashelkar-committee-report-on-patents_28.html> accessed on 17 October 2015.

¹³⁴ RA Mashelkar et al, *Report of the Technical Expert Group on Patent Law Issues* (2006) 6 <http://ipindia.nic.in/ipr/patent/mashelkar_committee_report.doc> accessed 27 August 2014 (Mashelkar Committee Report).

¹³⁵ *ibid* 8.

¹³⁶ *ibid* 27.

¹³⁷ *ibid* 30.

¹³⁸ *ibid* 8-12.

tenet of resistance. If anything, their persistent opposition to the TRIPS Agreement shows that they never ceded to its domination.

4.3 Indian Patents (Amendment) Act of 2005: Unpacking Key Issues

As mentioned above, in order to come into full compliance with its obligations under the TRIPS Agreement, India amended the IPA three times, with the third and final amendment coming into force on the 4 April 2005.¹³⁹ This section examines and critiques the IPAA, focusing on significant provisions that touch on public health and innovation – the latter being imperative for continued development of the pharmaceutical sector. The thesis specifically focuses on the following areas – patentable subject matters (i.e. what can and cannot be patented), criterion for patentability, CL provisions, opposition systems, and the limitation on exclusive right, along with analyses of their interpretation by judicial authorities. The analysis in this section shows that while India was able to exploit the residual flexibility and legal ambiguity in the TRIPS Agreement, it did not go far enough to deepen the space for law making and regulatory diversity. That is, while it determined what works best from a national policy perspective and included certain clauses to that effect, it did not tighten up the patent provisions, as will be seen. Yet, it provides a learning tool for Nigeria and many other developing countries to emulate. The thesis concludes the section by arguing that the mantle falls on the courts to close the legal loopholes that still exist in the IPAA through progressive judgments.

a) Patentable Subject Matters

Section 2 defines key terms used throughout the IPAA. Importantly, it explains the definition of terms such as invention, inventive step, new inventions,¹⁴⁰ and pharmaceutical substance. Specifically, Section 2(j) defines an invention to mean ‘a *new product or process involving an inventive step*’¹⁴¹ while an inventive step is explained to mean ‘a feature of an invention that involves *technical advance as*

¹³⁹ There was an executive ordinance before this, which was passed in order to have it ready for the January 1 deadline, but the bill was passed only in April 2005.

¹⁴⁰ New invention is explained to mean ‘any invention or technology, which has not been anticipated by publication in any document or used in the country or elsewhere in the world before the filing of patent application with complete specification.’ IPAA, s 2(l).

¹⁴¹ IPAA, s 2(j).

*compared to the existing knowledge or having economic significance or both that makes the invention not obvious to the person skilled in the art.*¹⁴² It broadens the definition of pharmaceutical substance to mean ‘*any new entity involving one or more inventive steps.*’¹⁴³ Thus a patent is granted only to a new product or process involving an inventive step and capable of industrial application. The inclusion of the patentability of pharmaceutical products and processes is the cornerstone of bringing Indian patent law into full compliance with the TRIPS Agreement and the major point of advocacy of the generic industry and civil society.

In their review of the IPAA, Gopakumar and Amin point out that the provision is too broad and allows for the patenting of all types of pharmaceutical substances.¹⁴⁴ To rectify this lacuna, they suggest the addition of the term ‘chemical’, i.e. new *chemical* entity, to limit pharmaceutical patents to just chemical entities and not any pharmaceutical entity. Gopakumar and Amin also believe that economic significance should not be the sole criterion for evaluating the inventive step of an invention. In their estimation, ‘it is not the purpose of patents to recognise economic significance of an invention as economic significance of an invention depends on many other factors.’¹⁴⁵

b) Exceptions to Patentability

Like the Brazilian Patent Act, the IPAA includes an extensive list of exclusions from patentability. Found in Sections 3 and 4, some of these include frivolous inventions, traditional knowledge, methods of agriculture or horticulture, inventions against public order or morality, and others. However, the most significant exclusion from patentability is the derivatives of known substances enshrined in Section 3(d), which reads:

The mere discovery of a new form of a known substance which does not result in the enhancement of the known efficacy of that substance or the mere discovery of any new property or new use for a known substance or of the mere use of a known process, machine or apparatus unless such known process results in a new product or employs at least a new reactant.¹⁴⁶

¹⁴² *ibid*, s 2(ja) (emphasis added).

¹⁴³ *ibid*, s 2(ta).

¹⁴⁴ Gopakumar and Amin (n 132) 2.

¹⁴⁵ KM Gopakumar, ‘Product Patents and Access to Medicines in India: A Critical Review of the Implementation of TRIPS Patent Regime’ (2010) 3 *The Law and Development Review* 333.

¹⁴⁶ IPAA, s 3(d). An explanation was appended to the clause, which notes that salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combination, and other derivatives

What is significant about Section 3(d) is the scope and extensive list of non-patentable items, with the aim of preventing ever-greening,¹⁴⁷ thereby limiting the negative impact of such frivolous patenting on medicine access. It is well known that obtaining patents on new uses of known substances as well as use of a compound in a particular way is a regular practice in the US and is employed by pharmaceutical companies to extend the life of their patent rights. According to the National Institute for Health Care Management, of the 1,035 new drug applications approved by the US Food and Drug Administration from 1989 to 2000, majority (65 per cent) were for incrementally modified drugs.¹⁴⁸ Also, a recent study by Kapczynski et al. on secondary patents in the pharmaceutical industry found that secondary claims are common, thereby technically providing substantial additional patent life.¹⁴⁹ This negates the time limit of patent terms as new patents continue to keep the subject matter under protection.¹⁵⁰ Thus, when placed within the wider context of national IP laws and pharmaceutical patent practice, the importance of Section 3(d) becomes significant.

By stipulating that only new and more efficacious forms are patentable, Section 3(d) – in contrast to the rhetoric often peddled by the US – encourages innovation, thereby creating substantial scope for competition in the pharmaceutical sector. Section 3(d) was recently tested in the Novartis case.¹⁵¹ Basel-headquartered Novartis contested the rejection of its patent application for anti-cancer drug Glivec by the Indian Patent Office and subsequently by the Intellectual Property Appellate Board (IPAB) and had challenged the IPAB's interpretation of Section 3(d). Novartis argued that its *betacrystal* form of *Imatinib Mesylate* is more 'efficacious' than the base compound

of known substance will be considered to be the same substance, unless they differ significantly in properties with regard to efficacy.

¹⁴⁷ Ever-greening is defined as pursuing patent thickets by seeking and securing multiple patents around a single invention. See Dwijen Rangnekar, 'Context and Ambiguity in the Making of Law: A Comment on Amending India's Patent Act' (2007) 10 *The Journal of World Intellectual Property* 31 ('Context and Ambiguity in the Making of Law'); see also Amy Kapczynski, 'Engineered In India — Patent Law 2.0' (2013) 369 *New England Journal of Medicine* 2 ('Engineered In India').

¹⁴⁸ The National Institute for Health Care Management Research and Educational Foundation, 'Changing Patterns of Pharmaceutical Innovation' (NIHCM Foundation 2002) <<http://www.nihcm.org/pdf/innovations.pdf>> accessed 5 March 2015.

¹⁴⁹ See Amy Kapczynski, Chan Park, and Bhaven Sampat, 'Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents' (2012) 7 *PLoS ONE*.

¹⁵⁰ Rangnekar, 'Context and Ambiguity in the Making of Law' (n 147) 376.

¹⁵¹ *Novartis AG v Union of India* (2013) Supreme Court of India, Civil Appeal Nos 2706-2716 OF 2013 (Supreme Court of India) (Novartis case).

imatinib (which was discovered prior to 1995 and is therefore not patentable) as it is easier to store and process, and is also 30 per cent more bioavailable than *imatinib*.¹⁵²

The Indian Supreme Court ruled that the ‘new form of a drug must demonstrate an improvement in its therapeutic effect or curative property as compared to the old form to secure a patent and the beta crystalline form of *Imatinib Mesylate*, fails the test of section 3(d).’¹⁵³ The Court also discussed at length the meaning of therapeutic efficacy with respect to pharmaceutical products, and observed that there are different possible meanings. The definition may be limited only to action resulting in a curative effect, or it might be more broadly extended to cover improved safety or reduced toxicity. In the end, the Court decided to leave open what is the appropriate definition of enhanced (therapeutic) efficacy – the narrower or broader interpretation – because it did not need to reach that conclusion in this particular case.¹⁵⁴

Furthermore, noting the claim made by Novartis regarding increased ‘bioavailability’, the Supreme Court observed that ‘bioavailability’ measures the level at which the drug is made available in the human body and may or may not have an influence on the therapeutic or curative effect of the drug.¹⁵⁵ As a result, the Court held that such effect was not demonstrated.

While the Novartis judgment is seen as a vindication of not just India’s legislative process but also a triumph of human rights over profit,¹⁵⁶ some scholars contend that the ruling was not far-reaching enough, as it did not explain the meaning of ‘therapeutic efficacy.’ Dinesh Abrol, Convener of the NWGPL, commented on the definition of therapeutic efficacy in the Novartis case:

The Court could have even strengthened the therapeutic efficacy concept by clarifying and defining so that some more things would happen. It could have actually gone to the level of saying, okay, therapeutic efficacy will now be defined in this manner and it would include concrete terms we can work with. It could have actually said, okay, fine, polymorphs, salt, crystals, derivatives unless shown to be doing this, this, this, will not be granted patents and so on, etc. And it could have actually dealt with the issue of how to deal with if a drug

¹⁵² *ibid*, paras 14 and 23.

¹⁵³ *ibid*, para 190.

¹⁵⁴ *ibid*, para 192.

¹⁵⁵ *ibid*, para 184.

¹⁵⁶ Leena Menghaney, ‘Drop the Case’ (2013) 48 *Economic and Political Weekly*; Amit Sengupta, ‘Two Decades of Struggle’ (2013) 48 *Economic and Political Weekly*.

improves contraindications, second toxicity is reduced...how would it be treated? It could have even directed the government to actually, let's say, evolve patent guidelines in a better manner, how the patent authorities should actually be enforcing them, how the patent office manual can be changed, how the examiners should be examining etc. we would have created jurisprudence on that.¹⁵⁷

This view is supported by K. M. Gopakumar of the Third World Network (TWN), who agrees that because the court did not clarify the meaning of 'therapeutic efficacy', i.e. whether it meant 'technological efficacy' or 'economic efficacy', India opened itself up to future contestation.¹⁵⁸ Commenting on the case, he notes:

By insisting on therapeutic efficacy, the courts opened door for the patenting of known substances when they are efficacious. This means anybody can claim patents on a drug that is known but it has more bioavailability. And does bioavailability mean efficacious? So does it satisfy therapeutic efficacy? We don't know because the courts did not clarify. Does that mean fixable combinations are patentable? Again we don't know. The court missed a very useful opportunity to stop the patenting of known substances and do away with this discretionary element. And because [courts] didn't spell it out, this issue will come back again.¹⁵⁹

From his perspective, this leaves the country and millions of people that depend on generic drugs vulnerable, as there is a threat of diluting policy concerns regarding the patenting of known substances through subsequent judicial interpretation or the practices of patent offices.¹⁶⁰

In contrast, Justice Prabha Sridevan, the judge who ruled on the Novartis case at the Chennai High Court, believes that the fact that the court left out the definition of 'therapeutic efficacy' is a good thing. Addressing the reasoning behind the non-definition of 'therapeutic efficacy', she states:

There is a reason for the open-ended quality to [not defining therapeutic efficacy]. And that's because that as far as pharma patents for sure and other patents too maybe, you really don't know...there is really no horizon. It keeps extending. And so it would be foolhardy for us to limit it today because we really don't know. It is better to leave it to the wisdom of a future court to decide whether what we said was

¹⁵⁷ Fieldwork interview with Abrol (n 80).

¹⁵⁸ Fieldwork interview with KM Gopakumar (Delhi, September 2014) (transcript on file with author).

¹⁵⁹ *ibid.*

¹⁶⁰ KM Gopakumar, 'The Need to Curb Patents on Known Substances' (2013) 48 *Economic and Political Weekly* 55 ('The Need to Curb Patents on Known Substances').

therapeutic efficacy would include this new quality that is now being argued.¹⁶¹

It can be argued therefore that by leaving open the definition, the court is protecting the interest of not only the public but of the manufacturers as well. In not capping what is termed ‘therapeutic efficacy’, the court leaves the room open for future innovations and circumstances. If anything, the Novartis case has shown the importance of Section 3(d) in limiting practices that might result in the grant of patents for insubstantial technological contributions. It also provides an intelligent balance for India’s obligations under the international treaty and its commitment to protect and promote public health considerations, not only of its own people but also in many other parts of the world.¹⁶²

In spite of considerable focus on the jurisdictional decision on ‘therapeutic efficacy’, other scholars have pointed out that the discourse on Section 3(d) needs to focus on the interpretation by patent offices. According to Sakhtivel Selvaraj, the issue should be on the number of patent officers with skills and expertise to examine patents using the 3(d) provision.¹⁶³ Patent officers are the first point of contact on any patent issue and therefore should be thoroughly informed about what this provision means and how to interpret it, what is and is not a frivolous patent, and what is a real objective blockbuster drug.¹⁶⁴ In a similar vein, IP lawyer and academic Shamnad Basheer asserts that the ‘Indian Patent Office suffers from a chronic shortage of adequately trained and specialised personnel. As a result, they lack access to leading prior art databases to undertake a thorough and comprehensive examination of complex patent applications.’¹⁶⁵

Section 3(d) is currently seen as an example of judicial innovation tool¹⁶⁶ – a form of counter-hegemonic resistance from a developing country in recalibrating a seemingly inequitable global IP rule.¹⁶⁷ But none of this matters if the first point of call of a patent application is not well-trained in the technical and complex text of patent

¹⁶¹ Fieldwork interview with Justice Prabha Sridevan (Chennai, September 2014) (transcript on file with author).

¹⁶² Novartis case, para 66.

¹⁶³ Fieldwork interview with Sakhtivel Selvaraj (Delhi, September 2014) (transcript on file with author).

¹⁶⁴ *ibid.*

¹⁶⁵ Fieldwork interview with Shamnad Basheer (Kolkata, August 2014) (transcript on file with author).

¹⁶⁶ Ruth L Okediji, ‘Legal Innovation in International Intellectual Property Relations: Revisiting Twenty-One Years of the TRIPS Agreement’ (2014) 36 University of Pennsylvania Journal of International Law 233.

¹⁶⁷ Dwijen Rangnekar, ‘Drugs in 3(d) and What Matters in the Novartis Case at Supreme Court’ (Kafila 2012) <<http://kafila.org/2012/08/21/drugs-in-3d-and-what-matters-in-the-novartis-case-at-supreme-court-dwijen-rangnekar/>> accessed 6 April 2012) (‘Drugs in 3(d)’).

examinations. Thus, having a well-trained patent officer is tantamount to strengthened and effective patent jurisprudence. It is therefore not surprising that many patent examiners are now being sponsored by foreign pharmaceutical associations to train in the US. While this training has the potential of improving the technical skills of India's patent examiners, it would also likely compromise the policy under Section 3(d) as the examiners imbibe standards of evaluation not relevant to India. In so doing, orienting them to the narrative of (foreign) pharmaceutical companies appears to be detrimental to the public interest.

c) Opposition Systems

Another important aspect of the IPAA is the inclusion of pre-grant and post-grant patent opposition. Section 25 on pre-grant opposition allows any person to file an opposition at any time before the grant of a patent on certain specified grounds.¹⁶⁸ The section delineates 11 specified grounds in which interested parties can oppose a patent application. These include 'prior publication of a patent application but a patent has not been granted',¹⁶⁹ 'lack of inventive step, non-invention under Section 3 of the Patents Act',¹⁷⁰ insufficient or unclear description of the invention in the specification,¹⁷¹ and failure to disclose the source of biological material used for the invention.¹⁷² The pre-grant opposition is noteworthy as it signifies the first instance when a challenge can be made before the grant of a patent. In addition, it conserves administrative time otherwise spent on examining a patent application that could later be invalidated.¹⁷³ It is important to note that pre-grant opposition is not a new inclusion via the IPA amendment. It was carried from the Patent Act of 1911 and was retained in the IPA and its subsequent amendments.

The IPAA also requires the Patent Office to grant the person a hearing.¹⁷⁴ Ragavan points out that the pre-grant opposition provision was retained because it was felt that the approximately 6,000 applications pending in the mailbox protection system would escape scrutiny. Retaining the pre-grant opposition was intended to weed out frivolous patent applications.¹⁷⁵ In this instance, the pre-grant opposition works as a

¹⁶⁸ IPAA, s 25.

¹⁶⁹ *ibid*, s 25(b).

¹⁷⁰ *ibid*, s 25(e).

¹⁷¹ *ibid*, s 25(g).

¹⁷² *ibid*, s 25(j).

¹⁷³ Ragavan, *Patent and Trade Disparities in Developing Countries* (n 33) 8

¹⁷⁴ IPAA, s 25(1).

¹⁷⁵ Ragavan, *Patent and Trade Disparities in Developing Countries* (n 33) 48.

mechanism to check the genuineness of the patent application and allows any third party to contest the application before it is granted.¹⁷⁶

Furthermore, the IPAA added a post-grant opposition system to the patent law. Post-grant opposition allows an interested person to oppose a patent within one year after the application has been granted.¹⁷⁷ Many Indian generic pharmaceutical companies, CSOs, as well as patient groups keenly knowledgeable of the esoteric IPAA have often invoked this law. Indeed, both the pre- and post-grant opposition clauses are seen by many as a key victory for health activists and civil society groups alike, and these groups have often invoked these provisions in recent times. It shows how non-state actors actively participating in the judicial setting are shaping emerging patent jurisprudence in India. Importantly, it represents a mechanism uniquely used to get around one of India's debilitating constraints, particularly backlog, and reduces the time taken to resolve disputes in India.¹⁷⁸ Key cases are discussed in the subsequent section.

d) Compulsory Licence

The IPAA provides for four grounds for the issuance of a CL, which many contend is 'the broadest and most comprehensive of all the world's patent systems.'¹⁷⁹ These grounds are broadly divided into (a) abuse of patent, (b) government use for public interest, (c) national health emergency, and (d) dealing with the licencing of related patents. These will be elaborated below. Chapter XVI of the IPAA comprising of Sections 82 to 94 and titled 'Working of Patents, Compulsory Licences and Revocation' deals with the broad principles and context for the issuance of CLs.

Abuse of Patent

Section 84 specifically refers to abuse of patent as a basis for the granting of a CL. In this instance, the patentee is culpable for the issuance of a CL on the ground that reasonable requirements of the public with respect to the patented invention have not been satisfied¹⁸⁰ because of the non-availability of the patented invention to the public at a reasonable affordable price,¹⁸¹ and due to the non-working of the patented

¹⁷⁶ *ibid.*

¹⁷⁷ IPAA, s 25(2).

¹⁷⁸ Fieldwork interview with Sridevan (n 161).

¹⁷⁹ Mueller (n 19) 580.

¹⁸⁰ IPAA, ss 84(1)(a) and (7)(a-e).

¹⁸¹ *ibid.*, s 84(1)(b).

invention within India.¹⁸² Section 84(7)(a-e) provides the definition for ‘reasonable requirement of the public’, which includes the following: refusal of the patentee to grant licence on reasonable terms;¹⁸³ prejudiced conditions imposed by the patentee for the grant of licence;¹⁸⁴ if the patent is not worked in India on a commercial scale to an adequate extent or not worked to the fullest extent that is reasonably practicable;¹⁸⁵ and if the working of the patented invention in India on a commercial scale is being prevented or hindered by the importation from abroad of the patented article.¹⁸⁶ It thus appears that Section 84(7) seeks to cover possible impediments such as anti-competitive practices.

On reasonable price, the IPAA did not define or explain what it deems to be such, but commentators including Basheer and Kochupillai suggest that the context for reasonable price of a patented article will depend upon the circumstances of each case.¹⁸⁷ Using a case of HIV medicines, they contend that if the price being charged in the US and EU is the same as that charged in India, this could raise a *prima facie* case.¹⁸⁸

It is important to note at this junction that Section 84 allows for a lapse of three years from the date of grant of a patent and allows any person, despite being already a holder of a licence under the patent,¹⁸⁹ to apply for a CL. However, the applicant should make out a *prima facie* case in order to be granted a CL. This means that the onus to prove the conditions for the grant of a CL is on the applicant and not on the patent holder.

Under Section 84, the Controller – with a view to securing certain purposes – should review a CL application by making sure that the patented invention is worked on a ‘commercial scale within India without undue delay and to the fullest extent that is reasonably practicable’¹⁹⁰ and to safeguard that the ‘interests of any person working or developing an invention in India under the protection of patent are not prejudiced.’¹⁹¹

¹⁸² *ibid*; as mentioned above, non-working is also a ground for issuing a compulsory licence in Brazil.

¹⁸³ IPAA, s 84(7)(a).

¹⁸⁴ *ibid*, s 84(7)(b).

¹⁸⁵ *ibid*, s 84 (7) (c).

¹⁸⁶ *ibid*, s 84 (7) (d).

¹⁸⁷ Shamnad Basheer and Mrinalini Kochupillai, ‘The “Compulsory License” Regime in India: Past, Present and Future’ (Social Science Research Network 2005) 9 <<http://ssrn.com/abstract=1685129>> accessed 21 March 2015.

¹⁸⁸ *ibid*.

¹⁸⁹ IPAA, s 84(2).

¹⁹⁰ *ibid*, s 89(a).

¹⁹¹ *ibid*, s 89(b).

The licensee also has the right to enforce the patent against infringers if the patentee refuses or neglects to do so within two months after being called upon. In such instances, the licensee ‘may institute proceedings for the infringement in his own name as though he were the patentee, making the patentee a defendant.’¹⁹²

So far, there has been only one successful case of CL application in India. In 2011, Natco, an indigenous generic pharmaceutical company, applied for a CL under Section 84(1) to manufacture and sell a generic version of *Nexavar* (the generic name is *sorafenib tosylate*) used in the treatment of primary kidney cancer and advanced primary liver cancer. Bayer Pharmaceutical Corporation (Bayer) currently holds the patent for *Nexavar*.¹⁹³ Couching its application on the ‘reasonable price’ requirement, Natco argued that *Nexavar* has a limited availability in India, as it is only available in pharmacies attached to large hospitals in select cities of Delhi, Mumbai, Kolkata, and Chennai.¹⁹⁴ The company pointed out that the price of *Nexavar* (sold at INR280,428 per month or INR33,65,136 per year) makes the drug out of reach for over a million Indians diagnosed with the disease.¹⁹⁵ Specifically, when Bayer sells the product, it reaches less than one per cent of patients while almost 99 per cent of patients who are unable to afford the drug are left to die every year.¹⁹⁶

Furthermore, Natco underscored the ‘non-working’ requirement provision, stating that the patentee Bayer imports and sells the drug *sorafenib* instead of locally manufacturing in India.¹⁹⁷ The applicant also mentioned the inherent difficulty in obtaining a licence to manufacture and sell the product *sorafenib* in India and the subsequent refusal of the patentee to grant a licence (refusal to grant licence on reasonable term clause). Finally, Natco argued that it will not only manufacture the drug in India but that it will be sold at a fraction of the current price at INR8,880 per month.¹⁹⁸ It will also donate the tablets to patients who cannot afford even the proposed price. Noting the aforementioned points, the Controller found that Natco

¹⁹² *ibid*, s 110 titled ‘Right of the Licensee under Section 84 to Take Proceedings against Infringement’. In the event that the patentee is called as a defendant, he is not liable for any cost unless he enters an appearance and takes part in the proceedings.

¹⁹³ PH Kurian, ‘The Compulsory License Application from M/S Natco Pharma Ltd’ (Official Journal of the Indian Patent Office 2011).

¹⁹⁴ *ibid*, paras 2 and 7(b).

¹⁹⁵ *ibid*, para 7(a).

¹⁹⁶ *ibid*, para 7(c).

¹⁹⁷ *ibid*, para 7(a).

¹⁹⁸ *ibid*, para 9(e).

met all the requirements for a CL application and thus granted the applicant the licence to produce *Nexavar* in India. However, he ruled that Natco should pay Bayer 6 per cent royalty.

One area in the *Natco v Bayer* case which has garnered the attention of experts is the ‘non-working’ requirement. The requirement of ‘non-working’, usually used as a tool for domestic economic enhancement, raises an important question of compatibility with the TRIPS Agreement. While Section 83(b) of the IPA explicitly states that importation does not mean ‘work’ (it reads patents are not ‘granted merely to enable patentees to enjoy monopolies for the importation of the patented article’),¹⁹⁹ the TRIPS Agreement, on the other hand, mandates the grant and enjoyment of patent rights regardless if the products are manufactured locally or imported.²⁰⁰ Taken on face value, provisions of ‘non-working’ which are also present in the Indian patent law is not compatible with the TRIPS Agreement. Janice Mueller, in her extensive analysis of Indian patent law, believes that India and many other developing countries with the ‘non-working’ requirement will undoubtedly be challenged by MNCs that ‘strongly prefer to consolidate production facilities in order to achieve economies of scale and related efficiencies.’²⁰¹ Rangnekar, on the other hand, argues that in maintaining the non-working requirement, India demonstrates its intent to explore space left open by legal ambiguity.²⁰² In a similar vein, Basheer and Kochupillai firmly believe that ‘non-working’ does not contravene the TRIPS Agreement. Specifically, they note:

The Paris Convention clearly stated that ‘importation’ would not amount to working of a patent, and that if a patent wasn’t worked, this could be treated as an ‘abuse’. Secondly, TRIPS is premised on the promise of technology transfer to developing countries. And a local working provision is geared towards encouraging such technology transfer. By forcing patentees to ‘work’ their patents in India, the regime encourages local use/transfer of the said technology.²⁰³

¹⁹⁹ IPAA, s 83(b).

²⁰⁰ Article 27(1) reads ‘[s]ubject to the provisions of paragraphs 2 and 3, patents shall be 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.’⁵ Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights *enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced*’ (emphasis added).

²⁰¹ Mueller (n 19) 596.

²⁰² Rangnekar, ‘Context and Ambiguity in the Making of Law’ (n 147) 375.

²⁰³ Basheer and Kochupillai (n 187) 9-11.

In the *Natco v Bayer* case, the Controller found that the mere importation of Bayer's drug into India did not amount to 'working' and is convinced that 'worked in the territory of India' means manufactured to a reasonable extent in India.²⁰⁴ It held that Bayer could not give reasons as to why working (i.e. manufacture) of the patented drug was not possible in India. This decision therefore makes it distinctly clear that 'working' as used in the IPA cannot include 'importation'. Bayer challenged the decision at both the IPAB and the Bombay High Court. Both petitions were dismissed.

Apart from the *Natco* case, there have only been two other instances of CL application in India. BDR Pharmaceutical filed a CL application for an anti-cancer drug *Dasatinib*, which is sold under the trade name *Sprycel* and patented by Bristol-Myers Squibb. The application was rejected.²⁰⁵ Lee Pharmaceutical Company also filed a CL application for AstraZeneca's diabetes management drug *Saxagliptin*. The decision was rejected in January 2016.²⁰⁶ Opinions vary on why there has been a low number of CL applications in India. Gopakumar Nair, former president of IDMA, attributes the lack of data to support CL applications as one of the reasons.²⁰⁷ India, according to him, suffers from a dearth of accurate or even up-to-date data on diseases, patient usage, production of generics, or drug consumption. In instances where data is available, their authenticity is questioned.²⁰⁸ This hampers CL application and is the reason for the high incidence of *prima facie* rejection. However, D. G. Shah, the secretary general of the Indian Pharmaceutical Alliance, posits that the pressure exerted by the USTR and the US International Trade Commission on the government of India is the reason why the government is reluctant to grant another CL.²⁰⁹ In fact, at a recent conference, D. G. Shah stated that the industry does not see CLs as a viable business model, as there are bigger profits to be made outside India.²¹⁰

Government Use for Public Interest

²⁰⁴ Kurian (n 193), para 9(e).

²⁰⁵ See Dilasha Seth and Soma Das, 'DIPP Defers Decision on Issuance of Compulsory License for Cancer Drug Dasatinib' (*Times of India-Economic Times*, 2014) <http://articles.economictimes.indiatimes.com/2014-10-16/news/55106950_1_cancer-drug-dasatinib-health-ministry-compulsory-licence> accessed 5 November 2015.

²⁰⁶ See Balaji Subramanian, 'Compulsory License Application Filed over Astrazeneca's Saxagliptin' (*Spicy IP*, 2015) <<http://spicyip.com/2015/07/compulsory-licence-application-filed-over-astrazenecas-saxagliptin.html>> accessed 15 September 2015.

²⁰⁷ Fieldwork interview with Gopakumar Nair (Mumbai, September 2014) (transcript on file with author).

²⁰⁸ *ibid.*

²⁰⁹ Fieldwork interview with DG Shah (Mumbai, September 2014) (transcript on file with author).

²¹⁰ See <<http://spicyip.com/wp-content/uploads/2016/08/Consilience-2016-Report.pdf>> accessed on 12 August 2016.

Section 92(1) deals with the instances for which a CL may be issued for public interest purposes by notification in the Patent Office journal, regardless of the time that has elapsed since the grant of the patent. These instances include national emergency, extreme urgency, or public non-commercial use. It further mandates the Controller to grant a licence to ‘any private entity’ that applies on such terms and conditions he thinks fit²¹¹ while ensuring that the articles manufactured under the patent will be available to the public at the lowest prices consistent with the patentees deriving a reasonable advantage from their patent rights.²¹²

The difference between Sections 84 and 92 is that the patent holder is culpable for the grant of a CL in the former while the CL is granted irrespective of the patent holder in the latter. Further, Section 84 allows for a time lapse of three years while the applicant need not wait for such period to apply for a CL under Section 92. Also, the Controller has discretionary powers regarding the terms and procedure of a CL application within the context of Section 92, which many believe makes the procedure long and cumbersome, as ‘both the Act and Rules do not prescribe any time limit for the conclusion of the proceeding.’²¹³ The possible effect is an indefinite delay on the grant of a CL. Further, according to IP and health economist Shaktivel Selvaraj, Section 92 allows the government to make medicines available for public health facilities.²¹⁴ However, due to political pressure from foreign pharmaceutical companies, the Indian government is yet to avail itself of this provision despite the constant stock-out of drugs in public health facilities.

National Health Emergency

Added in the IPAA, Section 92(A) allows for the grant of a CL for the export of patented pharmaceutical products in certain exceptional circumstances, such as to countries with insufficient or no manufacturing capacity for the concerned product to address public health, and provided that a CL has been granted by such a country.²¹⁵ These exceptional circumstances include situations relating to HIV/AIDS,

²¹¹ IPAA, s 92(1)(i).

²¹² *ibid*, s 92(1)(ii).

²¹³ Fieldwork interview with Nair (n 207).

²¹⁴ Interview with Selvaraj (n 163).

²¹⁵ IPAA, s 92A(1). The explanation for pharmaceutical products reads: ‘For the purposes of this section, “pharmaceutical products” means any patented product, or product manufactured through a patented process, of the pharmaceutical sector needed to address public health problems and shall be inclusive of ingredients necessary for their manufacture and diagnostic kits required for their use.’

tuberculosis, malaria, or other epidemics.²¹⁶ Section 92(A) fits into the Doha Declaration, which emphasised that flexibilities were available in the TRIPS Agreement to address public health needs.²¹⁷ Many commentators contend that it was the position of India and other developing countries at the beginning of the negotiations that the Doha Declaration should cover their current and future health needs, which led to the inclusion of pharmaceutical manufacturing capability in the Doha Declaration and in the subsequent August 2003 Decision on the Implementation of Paragraph 6 of the Doha Declaration.²¹⁸ Where a CL is applied for export, the Controller ‘shall grant a compulsory licence solely for manufacture and export of the concerned pharmaceutical product to such country under such terms and conditions as may be specified and published by him.’²¹⁹ This will be without prejudice to the extent to which pharmaceutical products are produced under CLs.

Licencing of Related Patents

Section 91 deals with the licencing of related rights. In this instance, a CL is granted to alleviate the situation where a patentee or licensee is hindered or prevented from his right to work any other patented invention without infringing on another’s pre-existing ‘basic’ or ‘dominant’ patent.²²⁰ The provision also specifies two conditions for the grant of a Section 91 CL. First, the CL applicant should show that it is in a position to grant to the first patentee a cross-licence under the second patent on ‘reasonable terms’²²¹ and second, that the other invention has ‘made substantial contribution to the establishment and development of commercial or industrial activities in India.’²²²

Part of the reason that a patent regime has flourished in India is because it has been able to carve out a regime that reflects its socio-economic realities and development needs. Like Brazil, India has shown that harmonising with the TRIPS Agreement

²¹⁶ IPAA, s 92A(3).

²¹⁷ ‘WTO | Ministerial Conferences - Doha 4th Ministerial - Ministerial Declaration’ (2001) WT/MIN(01)/DEC/1 <https://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_implementation_e.htm> accessed 4 March 2015.

²¹⁸ ‘WTO | Ministerial Conferences - Doha 4th Ministerial - Ministerial Declarations and Decisions’ (2001) WT/MIN(01)/17 <http://www.wto.org/english/thewto_e/minist_e/min01_e/mindecl_implementation_e.htm> accessed 27 April 2015. See also Duncan Mathews, ‘From the August 30, 2003 WTO Decision to the December 6, 2005 Agreement on an Amendment to TRIPS: Improving Access to Medicines in Developing Countries?’ (2006) 10 Intellectual Property Quarterly, which discusses the 2005 amendment to article 31 of the TRIPS Agreement, which intended to improve access to medicines in developing countries by waiving pharmaceutical licencing requirements.

²¹⁹ IPAA, s 92A(2).

²²⁰ *ibid*, s 91; Mueller (n 19) 605.

²²¹ *ibid*, s 91(2)(i); Mueller (n 19) 605.

²²² *ibid*, s 91(2)(ii).

works when ample flexibilities are embedded and embraced. The next section explores how actors are adapting and utilising the new TRIPS-compliant patent regime.

4.4 Medicine Access and the Nation-State as Site of Global Struggles

How are key stakeholders adjusting to post-TRIPS India? How are policies, jurisprudence, norms, and counter-norms relating to patent rights and access to medicines shaped (and continues to be shaped) post-TRIPS? This section focuses on these issues by looking into the performative strategies adopted by key actors in the dense configurations and reconfigurations of patent jurisprudence, justice, and medicine access discourse in post-TRIPS India. While India has fully phased into the TRIPS Agreement, it is demonstrated herein that the battle is by no means over as various actors have developed strategies to expand their autonomy within the Indian legal space. Focusing on the use of pre-emptive injunctions by foreign pharmaceutical companies, pre- and post-patent opposition by CSOs and indigenous pharmaceutical firms alike, as well as legal tie-ups via voluntary licences (VLs), the thesis demonstrates emerging alliances, patterns, and schisms among key actors to highlight how they challenge and/or influence the state's understanding and application of patents.

Pre-emptive Injunctions

According to the Oxford Law Dictionary, an injunction is a court order by 'which an individual is required to perform, or is restrained from performing, a particular act.'²²³ There are two types of injunction. A temporary injunction is a temporary stay pending a trial and is 'predicated on the assumption that if the patentee were to ultimately win at trial, the non-grant of a temporary injunction would detrimentally impact the patentee and her rights in the interim.'²²⁴ A permanent injunction, on the other hand, is awarded only after the conclusion of a trial and the patent is found to be valid and infringed.

²²³ Jonathan Law and EA Martin, *A Dictionary of Law* (Oxford University Press 2009).

²²⁴ Shamnad Basheer, Jay Sanklecha, and Prakruthi Gowda, 'Pharmaceutical Patent Enforcement', *Patent Law in Global Perspective* (1st edn, Oxford University Press 2014) 607.

In India, the law governing the grant of injunctions is set down in the Civil Procedure Code, and is conditioned upon the following pre-requisites: (a) there is a *prima facie* case in favour of the plaintiff; (b) irreparable injury would be suffered by the plaintiff if the injunction is not granted; (c) the balance of convenience is in favour of the plaintiff; and (d) the public would not be harmed by the grant of injunction. The reason for these conditions, according to Basheer, is the protection of an IP owner against the ‘vicissitudes of a long trial, where the alleged infringer could flood the market with competing products and destroy the value of a time-sensitive IP rights.’²²⁵ Thus, the court should scrutinise the plaintiff’s application to ensure that the pre-requisites are present before an injunction is granted.

There is growing evidence to show that foreign MNCs are pre-emptively using injunctions against local generic players to protect the market of patented drugs and delay the entry of low-cost generic medicines.²²⁶ Courts are also granting these *ex parte* injunctions *prima facie*. That is, the courts are granting restraining orders without hearing from the defendants (usually generic firms) or making sure that the pre-requisites apply. The Economic Times, for example, reported that the number of *ex parte* injunctions has grown from six in 2012, to 10 in 2013, and over 15 in 2014.²²⁷ Table 2 below provides a snapshot of recent cases:

²²⁵ Shamnad Basheer, ‘Jugaad Justice?’ (<http://www.livemint.com/>, 2015) <<http://www.livemint.com/Opinion/HUvXJ9hMCRnNpPg9GDMmZJ/Jugaad-justice.html>> accessed 7 June 2015.

²²⁶ Aparajita Lath, ‘Analysing the Pitfalls of Indian Patent Injunctions based on Fear of Infringement’ (2014) 19 Journal of Intellectual Property Rights 255. See also Times of India-Economic Times, ‘Pharma MNCs Use RTI Law to Protect Market for Patented Drugs & Delay Entry of Generics’ (2013) <http://articles.economictimes.indiatimes.com/2013-01-24/news/36526946_1_generic-firms-generic-version-bayer-spokesperson> accessed 7 March 2015.

²²⁷ Lath (n 226).

Year	Plaintiff	Defendants	Products	Decision
2009	Bristol-Myers Squibb (BMS)	Dr. BPS Reddy, HeteroDrugs, BDR Pharmaceuticals, Shilpa Medicare and Natco	<i>Dasatinib</i>	Interim injunctions against all of them except Shilpa Medicare
2011	Vifor (International) AG	Symed Laboratories	Indian patent number 221536 ²²⁸	<i>Ex parte</i> interim injunction
2012	Pfizer and Sugan Pharmaceuticals	Cipla, Natco	<i>Sunitinib</i>	<i>Ex parte</i> interim injunction
2014	Novartis	Ranbaxy Laboratories, Wockhardt Ltd, Biocon, Alembic Pharmaceuticals, Glenmark Generics, Cadila Healthcare and Bajaj Healthcare	<i>Vildagliptin</i>	Permanent injunction against Bajaj Healthcare and interim injunction to the rest
2015	Novartis	Cipla	<i>Indacaterol</i>	<i>Ex parte</i> injunction

Table 2: Snapshot of Recent Pharmaceutical Patent Injunction Cases

Several scholars and health activists have expressed concerns regarding the negative impact of such interim restraining orders to the public and patent law in India. In their extensive analysis of *ex parte* injunctions in Indian courts, Basheer et al. note that these injunctions have a ‘draconian’ effect on competitors, who are forced to desist from manufacturing and selling the allegedly infringing good, as well as on consumers, who are denied access to cheaper goods.²²⁹ In an interview about the use of injunctions as strategy, Leena Meenghaney, Regional Head (South Asia) at the Access Campaign at MSF, commented on the effect:

It is not surprising injunctions are new tactics employed by foreign MNCs in post-TRIPS India to not only limit market access of competitor but also to control the access of cheaper generic versions. This impacts everyday lives of people as generic firms are forced to withdraw these products from the market while the fears of financial damage discourages investment of new product development and launch.²³⁰

Similarly, Justice Sridevan Prabha points out that granting *ex parte* injunction causes irreparable hardship to the public who are denied access to important medicines. As

²²⁸ Process for preparation of water soluble iron carbohydrate complex of a particular weight.

²²⁹ Basheer, Sanklecha, and Gowda (n 224) 605.

²³⁰ Fieldwork interview with Leena Menghaney (Delhi, August 2014) (transcript on file with author).

damage to health cannot be compensated, the court therefore should not only think of the two adversaries before it but also the effect on the public.²³¹

The rise of injunctions points to a deeper and potentially more troubling trend among pharmaceutical MNCs and a departure from their earlier strategy of launching patent infringement suits only after a generic firm has rolled out a competing drug in the market. The use of *ex parte* injunctions not only has an adverse impact on access to medicines, as it affects the rights of patients to access cheaper generic versions of drugs, but also helps foreign pharmaceuticals maximise their monopoly and increase their profits.

Pre- or Post-Patent Opposition

As mentioned earlier, Section 25 of IPA allows for both pre- and post-grant oppositions. Patent opposition allows interested parties to file an opposition at any time before or after grant of a patent. Indian civil society groups have always been cognizant of the dangers posed by IP to access to medicines. As a result, these groups have been able to employ opposition clauses against what they see as frivolous patent applications or applications deemed injurious to public health.

Recent years have seen a spike in patent opposition. For example, in 2013, Natco and a group of civil society and patient groups comprising of I-Mak, Sankalp Rehabilitation Trust, and DNP+ successfully filed a pre-grant patent opposition against Gilead's *Sovaldi* (generic name *sofosbuvir*).²³² The application sought to prevent Gilead or Pharmasset from gaining a patent in India on *sofosbuvir* – a drug for Hepatitis C. In the opposition filings, I-MAK argued that the technologies comprising these patent applications are known (old science), while the patent document describing the invention is not sufficient, and therefore does not fully comply with patent law requirements.²³³ Natco's opposition was also based on the grounds that the patent for *sofosbuvir* is not inventive, and thus does not meet the standards for patent protection in India. Sankalp Rehabilitation Trust and DNP+ presented their argument on grounds of access, citing the high cost of the drug, which retails at USD80,000 (or USD1,000 per pill).²³⁴ This, they argued, makes the drug out of reach for the

²³¹ Fieldwork interview with Sridevan (n 161).

²³² I-MAK.org, 'I-MAK and DNP+ Pre-Grant Opposition to Opposition to Sofosbuvir (India)' (2014) <<http://www.i-mak.org/sofosbuvir/>> accessed 15 March 2015.

²³³ *ibid.*

²³⁴ Sankalp Rehabilitation Trust Petition (documents on file with author).

estimated 12 million Indians who are chronically infected with Hepatitis C.²³⁵ In 2015, the patent was rejected, which Gilead appealed. In 2016, the Deputy Controller handed down a clear victory to Gilead, dismissing the contentions raised in the various oppositions that had been filed against the patent application.

In the same vein, the Indian Network of Positive People and the Positive Women Network successfully filed a pre-grant patent opposition in 2008 against Boehringer Ingelheim's patent application for *nevirapine* (a pediatric ARV). Indeed, the practice of patent opposition has seen civil society groups and generic pharmaceutical companies being on the same side against foreign pharmaceuticals.

According to D. G. Shah, there is an increase in the number of patent oppositions filed by Indian generic companies, and the Indian Pharmaceutical Alliance files 20 to 25 patent oppositions per month.²³⁶ For instance, in 2012, Cipla successfully filed a post-grant opposition against Pfizer/Sugen's patent on the drug *Sutent* (generic name *sunitinib malate*), a liver and kidney cancer drug.²³⁷ Pfizer and Sugem were granted the patent for the cancer drug in 2007. The following year, Cipla opposed the patent grant on the following grounds: (a) the claimed invention was publicly used in India before the priority date of claim;²³⁸ (b) the invention as claimed is obvious and did not include an inventive step;²³⁹ and (c) the patentee failed to disclose information as required under Section 8 of the IPA.²⁴⁰

In analysing the Sugent patent case, Rajiv Choudhry notes that the lack of inventiveness was the main thrust of the opposition as the claimed compound is *prima facie* obvious, which is based on the concept of 'structural obviousness'.²⁴¹ Thus, in a case of *prima facie* obviousness, the patentee should demonstrate that 'there are actual differences between the claimed compound and the prior art such that the invention as

²³⁵ *ibid.*

²³⁶ Fieldwork interview with Shah (n 209).

²³⁷ CH Unnikrishnan, 'India Revokes Patent for Pfizer's Sutent' (*LiveMint*, 2012) <<http://www.livemint.com/Companies/nAHUvoEXEzEXXIC66jG6ZI/India-revokes-patent-for-Pfizers-Sutent.html>> accessed 12 March 2015. Natco has previously filed a CL application on public health grounds to supply Sutent to neighbouring Nepal. The application was rejected. See Shamnad Basheer, 'Natco's Doha CL Application: Patent Office Rules in Favour of Pfizer' (*Spicy IP*, 2008) <<http://spicyip.com/2008/07/natcos-doha-cl-application-patent.html>> accessed 9 April 2015.

²³⁸ Rajiv Choudhry, 'Cipla Succeeds in Revoking Pfizer / Sugem's Patent on Sunitinib' (*Spicy IP*, 2012) <<http://spicyip.com/2012/10/breaking-news-CIPLA-succeeds-in.html>> accessed 12 April 2015.

²³⁹ *ibid.*

²⁴⁰ *ibid.*

²⁴¹ *ibid.*

a whole is non-obvious.’²⁴² Though Pfizer/Sugen sought to distinguish the claims from the cited prior art document, they could not prove actual difference between the claimed compound and the cited prior art document. As a result, the Controller annulled the patent. In deciding the case, the Controller held that ‘the invention that is claimed in the patent does not involve any inventive step...and hence not patentable under section 2 (1) j of the Indian Patents Act.’²⁴³

The opposition system provides a unique opportunity for Indian civil society groups to build their capacity on matters relating to patents. It also brought networks of patient groups together with other CSOs and generic drug manufacturers to rally for the cause of access to medicines. Of course, the partnership of CSOs and generic pharmaceutical companies does not mean that both groups are always in agreement. It shows how networks can successfully promote the idea that patents equates to denial of access to people desperately in need. It is a good example of Peter Drahos’ general point on how socially mediated acts of nodal interpretation and mobilisation have influenced collective action in the IP regime.

It is important to mention at this point that in these patent opposition cases, civil society groups often invoke the human right to life argument. This is unlike in Brazil where treatment activism is based on the human right to health. This is because the Indian Constitution does not formally recognise the right to health as a fundamental right. As a result, in most pharmaceutical patent opposition cases, CSOs invoke the right to life, which is recognised by the Indian Constitution. With the use of right to life in patent litigations, Leena Meenghaney notes:

Not too many people go to court based on right to health. So the whole idea that we should provide universal access to medicines is not very well established in the government, and if you look at the recent press reports, it is very interesting when they say free medicines. And it is almost as if they’re offering charity to the citizens. It is not like, [the State] recognises your right to health and within that, provides you access to medicines. In India, access is always about charity. It is the government saying we’re doing it as a favour to you, and in that sense, I think the government and the Ministry of Health doesn’t recognise it as strongly. Their main contention in sort of moving away from the rights-based approach is simply that that we don’t want to be responsible before providing all these expensive drugs and treatments

²⁴² *ibid.*

²⁴³ *ibid.*

to patients. Which is very different from Brazil, but then the courts sort of say, you just have to provide it. It is the courts that have been interpreting right to life to also mean right to health.²⁴⁴

Therefore, in mooring the treatment access activism on the right to life, CSOs in India have been able to reinterpret and even strike down IP laws that impede access to medications. In fact, in the *F Hoffmann-LA Roche AG v Cipla Ltd* case,²⁴⁵ the court based its decision on the right to life, which it interpreted as the right to health. In this case, the plaintiff Roche sought an interim injunction to restrain Cipla from manufacturing and selling the generic version of the cancer drug *Erlotinib* (sold under the brand name *Tarceva*), for which the plaintiff holds a patent. In his decision, the judge ruled that the right to life will be denied if the general public is denied access to life-saving drugs and the effect of such denial is un-compensable. In this regard, in granting the injunction, the ‘Court would in effect be stifling Article 21 [which protects the right to life] so far as those [who] would have or could have access to Erlotinib are concerned.’²⁴⁶ Based on this, the court dismissed the injunction.

Voluntary Licence

A VL is where an ‘innovator pharmaceutical company of a patented product offers, on his own accord, a licence to a third party (usually a generic producer) to produce, vend and distribute the patented product.’²⁴⁷ In exchange, the generic producer(s) ‘pays royalty to the innovator company on the net sales made by the licensee.’²⁴⁸

Since India harmonised its law with TRIPS standards, there has been a gradual increase in the number of VLs between Indian generic companies and foreign MNCs. Indian companies such as Dr. Reddy’s, Aurobindo, Cadila Healthcare, and Torrent have entered into supply agreements with MNCs such as GSK, Astrazeneca, and Abbott. For example, when Gilead’s patent for HIV drug *Viread* was rejected in 2006, it signed voluntary non-exclusive licences with 11 Indian generic companies for the manufacturing and sale of the drug while awaiting the decision on its appeal.²⁴⁹ It also

²⁴⁴ Fieldwork interview with Menghaney (n 230).

²⁴⁵ *F Hoffmann-LA Roche AG v Cipla Ltd* (2008) IA 642/2008 IN CS (OS) 89/2008, IA 642/2008 IN CS (OS) 89 (IA 642/2008 IN CS (OS) 89/2008) (*Roche v Cipla*).

²⁴⁶ *Roche v Cipla*, para 85.

²⁴⁷ Tahir Amin, *Voluntary Licensing Practices in the Pharmaceutical Sector: An Acceptable Solution to Improving Access to Affordable Medicines?* (1st edn, Oxfam 2007) <<http://www.i-mak.org/storage/Oxfam%20-%20Voluntary%20Licensing%20Research%20IMAK%20Website.pdf>> accessed 12 March 2015.

²⁴⁸ *ibid.*

²⁴⁹ See *KEI Request for Investigation into Anticompetitive Aspects of Gilead Voluntary Licenses for Patents on Tenofovir and Emtricitabine* (1st edn, Knowledge Ecology International 2007) <<http://www.keionline.org/misc-docs/ftcgilead12feb07.pdf>> accessed 9 March 2015. According to KEI.org, Gilead’s licence further prohibits the

signed further licences that included patents on the product *Emtricitabine* (FTC), sold under the trade name *Emtriva*, and combinations of *Tenofivir disoproxil fumarate* (TDF) and FTC, sold under the trade name *Truvada*, or the once-a-day triple combination product *TDF+FTC+Efavirenz* (EFV), sold under the trade name *Atripla*.²⁵⁰ The licensees in India include Emcure Pharmaceuticals, Hetero Drugs, Strides Arcolab, Alkem Laboratories, Aurobindo Pharma, FDC Ltd., J.B. Chemicals & Pharmaceuticals, Matrix Laboratories, Medchem International, Ranbaxy Laboratories, and Shasun Chemicals & Drugs, and the licence covers 99 countries. In addition, Gilead reportedly required companies seeking VLs to withdraw patent oppositions.²⁵¹

Many scholars and health activists view the latest wave of VLs as unconscionable and objectionable. As Gilead does not have patents for two of the FTC or combinations involving FTC in India while the patent decision for TDF is still pending, Gilead is able to control the Indian competition by signing an agreement with potential competitors whilst undermining India's progressive patent laws. According to MSF, this leads to 'restricted competition.'²⁵² The significance of the agreement is that it neutralises competition from generic companies, which would have otherwise filed patent oppositions and/or CLs to manufacture the drugs.

In 2014, Gilead also issued another set of VLs to 11 Indian companies to manufacture and sell *Sovaldi*, a patented Hepatitis C drug in several low- and middle-income countries.²⁵³ The deals entitle the licensees to full technology transfer of the Gilead manufacturing process to enable them to boost production, and the licensees are free to fix their own prices for their versions against a seven per cent royalty payment on low generic sales to Gilead.²⁵⁴ In addition, the geographical scope of the agreements excludes certain middle-income countries with high rates of Hepatitis C, such as Brazil and Ukraine. The deals have generated a lot of division among health activists

supply of APIs to firms and markets not approved by Gilead. Licenced sellers are also required to purchase APIs from Gilead affiliated and licenced suppliers.

²⁵⁰ *ibid.*

²⁵¹ *ibid.*

²⁵² *MSF Review of the July 2011 Gilead Licences to the Medicines Patent Pool* (1st edn, MSF 2011) <http://www.msfast.org/sites/default/files/MSF_assets/HIV_AIDS/Docs/AIDS_Briefing_GileadLicenceReview_ENG_2011.pdf> accessed 9 March 2015.

²⁵³ Gilead.com, 'Gilead Announces Generic Licensing Agreements to Increase Access to Hepatitis C Treatments in Developing Countries | Gilead' (2014) <<http://www.gilead.com/news/press-releases/2014/9/gilead-announces-generic-licensing-agreements-to-increase-access-to-hepatitis-c-treatments-in-developing-countries>> accessed 20 September 2015.

²⁵⁴ *ibid.*

within and outside India as many see it as a move by Gilead to tightly control competition. This type of tie-ups, activists assert, will mean fewer patent challenges.²⁵⁵ Tahir Amir contends that ‘Gilead’s action is a strategic move to leverage its relevant drugs’ potential and save its patent protection.’²⁵⁶ According to James Love, the highly restrictive licencing ‘falls short of ensuring widespread affordable access to these new drugs in middle-income countries, where over 70 [per cent] of people with hepatitis C live today.’²⁵⁷ However, other actors do not see this as an issue. D. G. Shah believes that this will promote competition and further drive down prices.²⁵⁸

Regardless, it is clear that a VL, in the manner being pursued by Gilead and others, limits the option of full use of flexibilities such as CLs and patent oppositions. This is not surprising as big Indian generics, in collaboration with foreign MNCs, will be reluctant to file CL applications because it would be seen as a direct affront to the MNCs. Besides, collaboration with foreign MNCs via VL tie-ups means that the Indian counterparts have better chances of tapping those markets. Further, the growing number of VLs between foreign MNCs and foreign generic companies has led to schism between parts of the generic industry and parts of civil society, according to Shamnad Basheer.²⁵⁹ This is because the collaboration between foreign MNCs and local generic companies diminishes the propensity of local generics to team up with civil society groups on patent challenges.

Mergers and Acquisitions

Mergers and acquisitions (M&As) within the Indian pharmaceutical industry is not a new phenomenon. What is new in the post-TRIPS situation is the drive with which MNCs are trying to expand not only in the patented markets, but also in the generic markets.²⁶⁰ In recent years, the share of MNCs in the domestic formulations market has dramatically increased from less than 20 per cent in March 2008 to 28 per cent in

²⁵⁵ Fieldwork interview with Gopakumar (n 158).

²⁵⁶ Tahir Amin, ‘OPINION: The Dirty Motivation Behind Gilead’s Hepatitis C Agreement’ (*America.aljazeera.com*, 2014) <<http://america.aljazeera.com/opinions/2014/11/pharmaceuticals-gileadhepc.html>> accessed 12 March 2015.

²⁵⁷ James Love, ‘The Gilead HCV License: Glass Half Empty, or Half Full?’ (*Keionline.org*, 2014) <<http://keionline.org/node/2083>> accessed 9 October 2015.

²⁵⁸ Fieldwork interview with Shah (n 209).

²⁵⁹ Fieldwork interview with Basheer (n 165).

²⁶⁰ Sudip Chaudhuri, ‘The Pharmaceutical Industry in India After TRIPS’, *The New Political Economy of Pharmaceuticals: Production, Innovation and TRIPS in the Global South* (1st edn, Palgrave 2013) 113.

December 2010.²⁶¹ Notable takeovers include the takeover of Ranbaxy by Daiichi Sankyo in June 2008, Orchid by Hospira USA, Piramal by Abbott (US), Shantha by Sanofi Aventis, Matrix by Mylan (US), and Para by Reckitt Benkiser, to mention a few.

Also, most of these acquisitions are brown field in nature, which is when a company purchases or leases existing production facilities to launch a new production activity. While various factors point to the reason for these M&As, what should be worrying is the position and independence of indigenous firms to push forward counter-hegemonic norms on patent law. It also raises the question of India's self-sufficiency and health security as key indigenous firms are now in foreign hands. It also affects manufacturing as most of the foreign firms are interested in importation instead of local manufacturing. According to Gopakumar of the TWN, M&As are akin to India 'giving away its prime companies, and raises question on of Indian ability to independently use the flexibilities in [its] patent law.'²⁶² MSF Coordinator Leena Menghaney further adds: 'Today Indian [pharma] industries no longer an Indian industry. What we have are big pharma's little mini-GSKs. It would be stupid to say that [we] have Indian generic industry, which is independent, and takes on challenges.'²⁶³ Other key actors do not see this as a problem. According to Gopakumar Nair, president of IDMA, M&As are a good opportunity for medium-sized Indian companies to take over the mantle of leadership and fill the vacuum left by big generics.²⁶⁴

4.5 Summarising the Indian Context

This chapter has shown the sophisticated space in which law, in this case patent law, interacts with actors in the local spaces. It has also been shown that there is a hegemonic order and counter-hegemonic contestation co-existing in the Indian IP sphere.

²⁶¹ *ibid* 115.

²⁶² Fieldwork interview with Gopakumar (n 158).

²⁶³ Fieldwork interview with Menghaney (n 230).

²⁶⁴ Fieldwork interview with Nair (n 207).

Adopting a *twailian* lens in the form of a historiographical mapping of the patent regime in India provides complementary insights into the specific ‘rationalities’ setting the parameters of colonial patent law. Specifically, it revealed how MNCs exercised their patent rights and prevented Indian companies from undertaking basic drug manufacturing. This not only stunted the growth of the sector but made essential medicines in India one of the most expensive at that time. By introducing the IPA, which abolished product patent protection in pharmaceuticals, the post-colonial Indian state developed a regime to suit its own distinctive set of concerns. This led to the growth of a globally competitive domestic industry. This signifies, from a *twailian* lens, a pertinent example of a dynamic subaltern resistance and reform – a capacity to revolt effectively against misappropriations of the formal norms and institutions of international law.²⁶⁵ Adoption of Section 3(d) marked a turning point for health and development policy in India. Instituting a stricter standard of non-obviousness and novelty for obtaining a patent reaffirmed India’s primary commitment to protecting its citizens’ lives and health.

Using nodal governance theory, it can be seen how the expansion of IP law among non-state actors responded not just to material interests, but also to acts of framing that allowed these actors to interpret their interests, build alliances, and persuade the court and the state to support their cause. The IPAA and subsequent use of flexibility clauses enshrined within the law exemplifies how civil society groups and generic manufacturers have both used the language of human right to life and the need for pharmaceutical autonomy in political action to promote public policy change. In fact, the activism of CSOs in invoking the opposition clauses provides a rich account of the new politics of IP and the way nodal mobilisation has co-evolved in the shadow of law.

Thus far, Indian scholars, health activists, and pharmaceutical companies (both foreign and generic) continue to disagree on the overall best patent policy fit for India. Some argue in favour of higher and tighter thresholds to prevent ever-greening and ensure access. Others are against this, suggesting that patents would limit the innovation and R&D required for developing new drugs. Admittedly, India’s patent law contains provisions targeting industry development and enabling transfer of

²⁶⁵ Luis Eslava and Sundhya Pahuja, ‘Between Resistance and Reform: TWAIL and the Universality of International Law’ (2011) 3 Trade, Law and Development 128.

technology by ensuring local manufacturing and preventing frivolous patents that could jeopardise access. This contestation has also spilled out into other areas; key actors are working within both the legal and market spaces to carve out counter-norms, thereby expanding the aperture on discourse on medicine access and patent law. This will undoubtedly shape how Indian patent law will be construed in the future. Nonetheless, the prosaic events happening within India has shown the move to local jurisdictions as the foci of legal development.

Lastly, the Indian government's position with IP policy in recent years has been a confusing one, with the government seemingly trying to placate the US, while also trying to placate civil society, thus having contrary positions. With respect to the latter, the government recently set up an IP think tank to develop a national IPR policy that will lay the future roadmap for IP in India. Recommendations from the think tank include the setting up of a National Institute of Excellence on IPRs to enhance awareness of IPRs among all stakeholders, expedited patent examination, an IP exchange, and the encouragement of Corporate Social Responsibility funds into open innovation. It remains to be seen if these will be implemented by the government.

The next chapter will demonstrate how the post-colonial patent regime in Nigeria, in contrast to Brazil and India, was introduced without regard to economic realities or as a matter of deliberate industrial policy. As a result, there is a sense in which lack of patent policy should be underscored as a critical part of the Nigerian patent law history. As will be seen, the failure of law reform is a corollary to the discourse of (failed) economic reforms as it affects patenting and the patent regime in Nigeria.

5. Nigeria

Introduction

As observed in the last chapter, India insisted on adapting its patent regime to suit its local need for affordable high-quality drugs and to foster the development of a robust pharmaceutical sector. Accordingly, the country implemented a patent regime that spurred the development of its drugs sector. This push for a custom patent regime was also reflected in India's efforts towards the inclusion of flexibilities in the TRIPS Agreement during the Uruguay Round negotiations and the subsequent legislative implementation of innovative flexibilities. In so doing, the country was not only able to carve out a policy space within the seemingly restrictive TRIPS space but also protected its subsector from ever-greening practices. In post-TRIPS India, however, private sector and civil society groups involved in the intersection of pharmaceuticals and health continue to expand the aperture on norms governing patent laws, and highlighting in the process the tension a developing country faces between policy requirements and political pressures on one hand, and between incentivising the creation of new medicines and ensuring maximum possible access to medicines on the other.

In this chapter, the focus is on Nigeria – the second largest economy in Africa, with a growing population and expanding industrial sector. Apart from being the researcher's country, the choice of Nigeria as a case study on the intersection between patent law, development, and access to medicine discourse is informed by two factors. First, Nigeria currently has the second largest economy and is the most populous country in Africa. This prominent position affords the country the power to influence and set policy agenda on norms governing patent law and public policy discourse in sub-Saharan Africa. Second, the country has always been a significant interlocutor for Africa and the Global South at various international forums. At the onset and in the course of the Uruguay Round negotiations that established the WTO, especially during the TRIPS Agreement negotiations, Nigeria was outspoken in its objection to the inclusion of an IP regime within the multilateral trade framework. Nevertheless, there is a sharp disconnect between government rhetoric at international forums and government actions at the local level. This is in stark contrast to the prevailing situation in traditional 'TRIPS opponent' countries such as Brazil and India, whose stance at international forums is usually reflective of their IP policies at home.

Three main issues are discussed in this chapter. First, the conceptualisation of patent by the state, i.e. in law and by policymakers. Second, the interpretation of this understanding of patent into law and policy vis-à-vis the TRIPS Agreement; that is, how ideas circulate, the particular way in which policy options are constructed – and, as an extension, how others are extinguished. Third, how non-state actors – private sector and civil society groups – challenge and/or influence this understanding and conceptualisation of patent into law and policy.

In investigating these three issues, the thesis has found a deficit in the engagement and conceptualisation of the patent regime by both the state and non-state actors because patent is not seen as a useful tool in policy or a problem to be solved in the first place. Further, patent stakeholders such as the private sector and civil society groups, which have played (and continues to play) a foundational role in the cognitive shaping and production of knowledge on patents in Brazil and India, are absent in Nigeria. This is because the country lacks the presence of these key influencers who would have been traditionally involved in the problematizing of patent discourse. As a result, patent regime has never been significant in the Nigerian context and does not work the way it does in Brazil and India.

The rest of the chapter is divided as follows: Part I provides a detailed evolution of patent law in Nigeria in order to contextualise and unpack the Nigerian encounter with patent law. While this exercise shows a legal and historical disconnect caused by the absence of interaction between foreign patent law and local actors or institutions, resulting in little direct benefit to the country, the hasty implementation of a post-colonial patent law by the military government also laid a shaky ground for rewriting patent law that is reflective of the country's socio-economic reality and of benefit to the Nigerian people. With focus on key aspects of the law, Part II situates the current Nigerian Patent Act vis-à-vis the TRIPS Agreement to show how the latter interacts with laws, institutions, and actors at the domestic level. In this section, the role of courts in deciding the substantive issue of patent law is also discussed. Part III captures the attitude of the Nigerian state towards patents by reflecting on the 'official' use of patents provided in the Patents and Designs Act of 1990 (PDA) as an effective mechanism for achieving the cardinal goals of public health care and economic development. In essence, the thesis looks at how the language of patent is employed and deployed by the National Office for Technology Acquisition and Promotion (NOTAP) and among policymakers. In so doing, the thesis maps how ideas circulate – the particular way in which policy options are selected and others rejected. Part IV examines the dynamics of patent discourse by probing into how the private sector and civil society groups engage, if at all, with patent discourse. This chapter

also shows how the implementation of select Nigerian government policies such as the Nigerian Enterprises Promotion Decree, the ISI policy, and the IMF/World Bank SAP eviscerated pharmaceutical manufacturing companies while years of military regime corrupted civil society psyche, thus blunting activism. In juxtaposing these actors and conceptual sites, the thesis shows how these policies advertently disembowelled the pharmaceutical sector, weakened civil society groups, and incapacitated regulatory institutions from active engagement with patent regime. Part V concludes this chapter by summarising the Nigerian context.

The findings in this chapter show how seemingly unrelated factors affect the way patent is conceptualised in law and policy vis-à-vis public health and development. In contextualising the law, policies, and local socio-economic events, this chapter shows that any developmental and legal inquiry that favours a mechanical harmonisation with the TRIPS Agreement to the whims of foreign interests or institutions, or transplanting the experiences of other subaltern countries, is unsuitable for Nigeria. Instead, any future discourse, legal reform, and policy recommendation on patent law should be cognizant of not only the country's past failures and its unique environment, but also the structural and governance gaps that have hindered the development of a progressive patent regime in Nigeria.

5.1 Historical Evolution of the Patent Regime in Nigeria

Colonial Encounters

As a former British colony, patent law was first introduced to the Lagos colony and the Southern Protectorate¹ in 1900 through the Patent Ordinance² and the Patent Proclamation.³ Two years later, the Patent Proclamation of 1902 introduced patent law and protection to the Northern Protectorate.⁴ Each of these enactments contained full-scale provisions for the recognition, grant, and control of patents in Nigeria and were comparable to the English law on the subject at that time. Applications for patents were made to the patent office, appeals from the decisions of the Registrar were brought before the Attorney General who had the power to consider such appeals, and patents were granted to a successful applicant by the

¹ The Southern Protectorate consisted mainly of Lagos and the Southwest region of Nigeria. The British annexed Lagos in 1861.

² Patent Ordinance No 27 (1900). See Bankole AA Sodipo, 'Piracy and Counterfeiting: The Freedom to Copy vs Intellectual Property Rights' (PhD thesis, Queen Mary, University of London 1995) 41.

³ Patent Ordinance No 17 (1900).

⁴ The Northern Protectorate consisted of the North Central, Northeast, and Northwest of modern Nigeria.

High Commissioner in the name of the Crown.⁵

In 1914, the Southern and Northern protectorates were amalgamated to create modern-day Nigeria. In 1916, a new patent law – the Patent Ordinance of 1916 – repealed previous patent ordinances and made the new ordinance applicable throughout the newly formed country. The UK Patent Ordinance of 1925 was subsequently introduced in Nigeria, replacing the Patent Ordinance of 1916. Titled the Registration of UK Patent Ordinance,⁶ it disallowed patent application in Nigeria and instead provided for the registration in Nigeria of patents already granted in the UK as long as the application for registration was made within three years from the date of issue of the patent.⁷ This law established a dependent patent regime⁸ in which patent application could no longer be made in Nigeria while only patents granted in the UK can be registered in Nigeria. It also conferred rights and privileges in Nigeria to the extent that these were granted by the UK law. In other words, the Patent Ordinance of 1925 only allowed for and recognised British patents.

Furthermore, the Patent Ordinance of 1925 also excluded patents granted in other countries from registration in Nigeria – a ploy employed to maintain a British monopoly of the Nigerian market.⁹ For example, a seminal study by Owen Adekibi on the Nigerian patent system between 1949 to 1970 found that out of the 2,250 patents registered between 1949 to 1970, about 64 per cent were owned by UK citizens or enterprises and the rest by citizens of other countries.¹⁰ This shows bias for patents based in the UK. Furthermore, about 90 per cent of this figure was registered during the decade following Nigeria's independence from Britain in 1960. This scramble for patent protection, according to Adekibi, suggests the 'apprehension of foreigners, mainly British, about the change in government and the possibility of increased competition in the industrial capabilities in the Nigerian market.'¹¹ Importantly, it shows that the colonial patent regime, which lasted over five decades, was not only created from the perspective and for the benefit of colonial powers but also for the protection of colonial territorial rights and privileges acquired under a patent granted in the metropolitan country.¹²

An analysis of the Patent Ordinance of 1925 in Nigeria and Act VI of 1856, Act V of 1859, and subsequent laws enacted by the British during the colonial rule in India – which were

⁵ Gaius Ezejiyor, 'The Law of Patents in Nigeria: A Review' (1973) 39 *African Legal Studies* 40.

⁶ Patent Ordinance No 6 (1925).

⁷ Ezejiyor (n 5).

⁸ Edith Penrose, 'International Patenting and the Less-Developed Countries' (1973) 83 *The Economic Journal* 770.

⁹ Owen T Adikibi, 'The Multinational Corporation and Monopoly of Patents in Nigeria' (1988) 16 *World Development* 512.

¹⁰ *ibid* 512.

¹¹ *ibid* 517.

¹² Ezejiyor (n 5).

discussed in the previous chapter – shows their marked similarity. These laws were introduced by Britain and instituted dependent patent regimes in the respective colonies. This is not surprising; neither is it a strictly British endeavour. Colonial metropolis such as France, Belgium, and Portugal often applied legal rule from the centre to the colonies. Indeed, the Paris Convention allowed patent laws of the colonial metropolis to regulate issues of patent in the various colonies.¹³ The consequence of this is Nigeria's adoption of both the strength and weakness of the English system without regard for prevailing local circumstances such as economic and infrastructural underdevelopment, high poverty and illiteracy rates, and other compelling factors bothering on security and otherwise.

The institutionalisation of English patent laws in Nigeria have been critiqued as unnecessary and irrelevant to the local population by many scholars because it did not take into account already existing indigenous laws and customs for recognising and rewarding creative inventions. Specifically, critics contend that the introduction of a patent regime when industrialisation was still at a nascent stage in Nigeria was not only regressive, but also reflects the reality that the introduction of a patent regime in Nigeria by colonial powers was for the exploitation of local resources and market instead of the encouragement of local innovation.¹⁴ This is because patents registered in foreign countries are not taken for the interests of the economy granting the patents or with a view to manufacture there, but with the main objective of protecting an export market from rival manufacturers, particularly those in other parts of the world. According to Adebambo Adewopo, the patent regime in existence at that time was not based on one of the justifications for patents, which is to reward the inventor for his/her invention, thereby encouraging creativity. Rather, it was put in place for the interest of the imperial powers.¹⁵ Echoing the same sentiment, George Sipa-Adjah Yankey opines:

[The colonial patent regime] was never meant to encourage either indigenous inventive activity, local research and development, innovation or to accomplish an effective transfer of technology. It was geared rather towards the protection of property rights in machinery technology relevant for the exploitation of gold and other mineral and human resources in the colonies.¹⁶

¹³ See GHC Bodenhausen, *Guide to the Application of the Paris Convention for the Protection of Industrial Property (as Revised at Stockholm in 1967)* ((Colombettes 32) United International Bureaux for the Protection of Intellectual Property 1968) 18.

¹⁴ See Okechukwu Timothy Umahi, 'Access to Medicines: The Colonial Impacts on Patent Law of Nigeria' <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1975928> accessed 15 March 2015.

¹⁵ Adebambo Adewopo, 'Public Health, Access to Medicines and Role of Patent System in Nigeria' (2011) *Nigerian Journal of Intellectual Property Law* 169 ('Public Health, Access to Medicines and Role of Patent System in Nigeria').

¹⁶ George Sipa-Adjah Yankey, 'The Role of International Patent System in the Transfer of Technology to West Africa: Case Studies of Ghana and Nigeria' (PhD, University of Warwick 1987) 106.

This is certainly true in the case of colonial patent law in Nigeria. According to Adikibi, of the 2,250 patents granted between 1949 to 1970, 67 per cent of patented processes were standardised and widely available, 22 per cent were obsolete, while 11 per cent were considered worthy for the grant of a patent.¹⁷ In this vein, the system was calculated to benefit British patent owners and exploit the local population. Much of the funds accumulated went into reserve in Britain to serve the metropole's post-war needs.¹⁸

Further, most of the patents granted were not locally worked or utilised in Nigeria. That is, the patented items were not produced in the patent-granting developing country but were imported. This distorted market forces and enabled foreign patent holders to charge prices higher than they could expect under more competitive conditions in the absence of patents. This underscored the points put forward by Vaitos and Penrose that the introduction of a patent regime in a least developed country – which Nigeria and India were at that time – negates the industrialisation objectives of those countries because the system encourages foreign monopolies.¹⁹ These patents, Penrose specifically notes, did not assist in industrialisation, benefit local industry, encourage foreign investment, nor stimulate local manufacturing by local businessmen. This is because these patents were sought primarily to enhance the monopoly position of the foreign patentees in the local market.²⁰ As a result, the patent system stifled the growth of indigenous technological capacities and innovation which could have developed through imitation and adaptation.

Looking back, Nigeria adopted a patent system at a nascent industrialisation stage. Even when a patent system was put in place, none of the patents granted were exploited by patent owners or even licenced to local producers. Since it had very few inventions worth patenting in developed countries, the country did not receive the 'expected reciprocal advantages from granting patents to foreigners on inventions worked in those countries.'²¹ Consequently, instead of achieving its stated objectives such as contributing to research, development, and transfer for technology, the colonial patent regime achieved the contrary. The system instead allowed patent owners, mostly foreigners, monopoly control of local market, stifling local development and restricting the transfer of technology as a result.

¹⁷ Adikibi (n 9) 517.

¹⁸ Bill Freund, 'Oil Boom and Crisis in Contemporary Nigeria' (1978) 5 *Review of African Political Economy* 91, 92.

¹⁹ See Constantine Vaitos, 'Patents Revisited: Their Function in Developing Countries' (1972) 9 *The Journal of Development Studies*; Penrose (n 8) 785.

²⁰ Penrose (n 8) 785.

²¹ *ibid.*

Post-Colonial Spectacle

On 1 October 1960, Nigeria obtained its independence from Great Britain. However, it was not until *Rhone - SA Poulenc and May & Baker v Lodeka Pharmacy (Rhone-Poulenc case)*²² – which tested the applicability of colonial patent laws – that the first patent case was heard.

In the *Rhone-Poulenc* case, the parties were importers of chemical products and other pharmaceutical preparations. The claimants, Rhone - SA Poulenc and May & Baker, took out a UK patent for *chlorpromazine* in 1951, which they subsequently registered in Nigeria in 1957 under the Patent Ordinance of 1925 as Patent Number 367. In 1964, the Federal Ministry of Health placed a supply order for the patented product *chlorpromazine* under the market name *Largactil*. The defendant, an indigenous pharmaceutical company called Lodeka Pharmacy, supplied large quantities of the patented product to the Federal Ministry of Health. Additionally, the defendant displayed the drug at a National Trade Fair that same year.

The claimants sued Lodeka Pharmacy, alleging that the latter infringed on their patent by selling, storing, and offering for sale the patented product. During trial, the defendant acknowledged the patent right of the claimants, but argued that the importation of the patented product was no infringement as the product was imported under the request of the Federal Ministry of Health on behalf of the Nigerian government for public use. The defendant relied on Section 46(1) of the UK Patents Act of 1949, which stated that ‘notwithstanding anything in this Act, any Government department, and any person authorized in writing by a Government department, may make, use and exercise any patented invention for the service of the Crown in accordance with the provisions of this section.’²³

The judge issued an interim injunction against Lodeka Pharmacy to prevent further infringement pending the determination of the case. In deciding the case, the judge ruled that the patent law did not apply to the Nigerian government in its totality as the Patent Ordinance of 1925 as well as Section 46 of the UK Patents Act of 1949 do not permit the Nigerian government to exercise the prerogative of the British Crown.²⁴ In his ruling, Justice Ikepeazu specifically held that:

[The] only significant effect the 1949 Act had in Nigeria was in respect of the

²² (1965) LLR 9.

²³ Umahi (n 14) 10-11.

²⁴ Ezejiofor (n 5).

rights and privileges that ensued from the issuance of a certificate of registration after the registration of a United Kingdom patent in Nigeria as provided by s. 6 of 1925 ordinance. Therefore, the re-registration law does not permit the Nigerian government to exercise the Crown prerogative under the Act to supply patented drug.²⁵

Consequently, His Lordship gave judgment in favour of the applicant and issued a permanent injunction against the defendant.

The negative ruling of the *Rhone-Poulenc* case prompted the then Federal Military Government to repeal the Patent Act of 1925 in 1968 and introduce the Patents (Limitation) Decree of 1968.²⁶ This new decree allowed the government to purchase patented pharmaceutical products (under the Government Use clause). Specifically, Section 15 of the Patents (Limitation) Decree empowered the Health Commissioner to authorise any person, including government departments, to purchase, make, use, and vend any patented articles for the services of a government agency in the Federation if he was satisfied it is in the public interest to do so.²⁷ The Decree also exempted the government from infringement of a patent granted with respect to the articles concerned or the liability to pay royalties or compensation to the patentee.²⁸ Further, the Decree authorised the Permanent Secretary of the concerned Ministry to give the patentee such information as he pleased concerning the extent of use.²⁹ Finally, special provision was made for the use of these powers in times of national emergency such as war, for the service of the war and the maintenance of the economy. According to Yankey, the Decree was modelled after the BIRPI³⁰ Model Law for developing countries³¹ because of Nigeria's active participation as the Acting Registrar of Patents in the various proceedings that eventually resulted in the birth of the BIRPI Model Law.³² The BIRPI Model has often been criticised as unreflective of the specificities of different socio-economic realities and aspirations of developing countries.³³ Thus, it is not surprising that the essence of the policy behind the patent system still remains elusive in the face of a public health and development crisis in Nigeria.³⁴

The Patents (Limitation) Decree was a reaction to the *Rhone-Poulenc* case, and was created to

²⁵ Ezejiofor (n 5). See also Umahi (n 14) 10 -11; Sodipo (n 2) 46-47.

²⁶ Patents (Limitation) Decree No 8 (1968).

²⁷ *ibid*, s 15.

²⁸ *ibid*, s 1(3).

²⁹ *ibid*, s 1.

³⁰ BIRPI stands for *Bureaux Internationaux Reunis pour la Protection de la Propriete Intellectuelle* (United International Bureaux for the Protection of Intellectual Property). It was the predecessor of the WIPO, the global governing body for IP-related issues.

³¹ Yankey (n 16) 213.

³² *ibid*.

³³ Ulf Anderfelt, *International Patent-Legislation and Developing Countries* (Martinus Nijhoff 1971) 210.

³⁴ Umahi (n 14) 6.

essentially limit the powers of the patentee and protect the government from infringement. It was introduced at a time when Nigeria had no robust national technological or industrial base. In this respect, the law was not enacted to positively encourage domestic inventiveness, support the local industrial base to harness economic development objectives, or address a particular policy need. This was unlike the situation in Brazil³⁵ and India³⁶ where extensive studies were carried out to understand the utility of a patent regime for development. Those studies found that patents not only encouraged monopoly practices but also stunted technological development. It was based on the findings on the impact of patents that the Indian Patent Act of 1972 and Brazil's Law Number 5.772/71 of 1971 – which respectively prohibited the patentability of processes for food, chemical, and medicines – were enacted. In both countries, the new patent laws were developed to ensure that patents were more conducive to and worked for national development interests.

This was not the case in Nigeria as the post-independent patent law was a knee-jerk reaction to the decision of the *Rhone-Poulenc* case. It was a serious counter-movement against the strengthening and modernisation of the patent regime to make it favourable to economic development. If anything, it shows an acute lack of understanding of the linkages between law and development and at worst, made a spectacle of the whole legislative process. This law was not crafted to encourage indigenous inventive activity and continues to be a handicap to various sectors and national development. It is important to note that this was the time of the first military junta following the 1966 counter-coup that overthrew a civilian government. The military era was known by arbitrary decrees and the flagrant disregard of established legal rules and system, to mention a few. Historical studies of Nigeria's military regime have observed that several socio-economic, political, and legal policies implemented during that period had little or no positive impact on the socio-economic development of the country.³⁷ As will be seen, the lack of evidence-based patent law making (and development policy in general) was insidiously felt a couple of years later when Nigeria could not effectively marshal the windfall of high oil prices to develop an indigenous manufacturing base.

³⁵ Ch 3, s 3.1.

³⁶ Ch 4, s 4.1.

³⁷ Ajibola A Abdulrahman, 'The Impact of Military Rule on Nigeria's Nation Building, 1966-1979' (2014) 15 Historical Research Letter; Patrick Oluseun Bamgboye, 'The Military and Socio-Economic Development in Nigeria (1983-1999) A Critical Appraisal' (2014) 5 Mediterranean Journal of Social Sciences; Max Siollun, *Nigeria's Military Coup Culture: From Major Nzeogwu to LT-Colonel Dimka (1966-1976)* (2009).

Global Struggle

Nigeria was among the Group of Ten countries,³⁸ led by Brazil and India, that initially opposed the inclusion of IP rules within the global trade framework. The Nigerian delegate at the Brussels Ministerial Meeting, for example, argued that:

GATT should confine itself to only trade-related issues and not the regime of protection and enforcement of intellectual property rights as the latter would impose an unbearable burden on us [Nigeria] and stifle [the country's] aspirations towards access to technology.³⁹

Thus, Nigeria saw the whole process of TRIPS as an imposition by the developed countries from its inception. However, it is interesting to note that while Nigeria contested the inclusion of IP rules at the GATT negotiations, arguing that the inclusion of such a regime will force the country to make legal adjustments inconsistent with its level of development, the country had already locally implemented what could be seen as a maximalist IP regime detrimental to its development. This showed a sharp disconnect between the government's rhetoric at international forums and its policies at home. Thus for Nigeria, there is a significant divergence between its stance at the Uruguay Round and the reality in its domestic turf.

As part of the Single Undertaking package, Nigeria signed up to and accepted the TRIPS Agreement when it acceded to the WTO. Being a developing country, Nigeria was given a 10-year transition period to phase into the TRIPS Agreement. However, even though the country was supposed to change its IP laws to be TRIPS-compliant in 2005, it has yet to do so. In fact, efforts by several foreign organisations such as the USTR, the WIPO, and the WHO to help the country bring its patent law into compliance with the TRIPS Agreement by 2005 were futile. A WHO official who worked closely on the issue shared that:

It was really difficult to get the law passed. Between 2002 and 2004, we conducted extensive seminars and sensitization classes with both law makers and civil society groups but nothing happened. The lawmakers were not interested and the civil society groups were simply interested in basic service delivery and access to donor funds. Also at the end of the electoral term, the old lawmakers were replaced with new ones, which meant we had to start the training all over again. It was really tiring and disheartening. The IP Bill has been on the floor of the [House of Assembly] for years and nothing has happened. After a while I stopped following up.⁴⁰

³⁸ Known as the Group of Ten, these countries were Argentina, Brazil, Cuba, Egypt, India, Nicaragua, Nigeria, Peru, Tanzania, and Yugoslavia.

³⁹ Senas J Ukpanah, 'Statement at the Ministerial Level Meeting in Brussels (MTN.TNC/MIN (90)/ST/34, Multilateral Trade Negotiations, Uruguay Rounds)' (1990).

⁴⁰ Fieldwork interview with WHO official (Abuja, October 2014) (transcript on file with author).

In a similar vein, an official at the Federal Ministry of Health concedes that the ‘bill has not been passed but when it does come into law, it will be progressive because the West African Health Organization (WAHO)⁴¹ provided the guideline for the drafting of the bill.’⁴² According to him, the guidelines provide for a harmonised TRIPS implementation across ECOWAS member states and strengthen the maximum utilisation of the TRIPS flexibilities and safeguards.

Despite not amending its patent law in light of its TRIPS commitments, Nigeria has not yet been subject to full WTO dispute settlement procedures (DSP) or US Section 301 sanctions. The last WTO Trade Policy Review of Nigeria published in 2011 notes not only that the national law on IP remains unchanged, but also that the country has a weak enforcement and management system.⁴³ Similarly, the 2016 USTR Special 301 Report found the country to have ineffective or inadequate IPR protection systems and is an ‘entry point [...] into Africa for counterfeit and pirated goods—often threatening health and safety.’⁴⁴ This raises the important question of why the country has not undergone DSP. As will be seen, the answer lies in the absence of countervailing forces in the form of a strong pharmaceutical sector to move the country towards compliance. At the time of writing, Nigeria has not yet updated its laws to comply with the TRIPS Agreement even though aspects of its legal regime conforms to relevant provisions of the TRIPS Agreement.⁴⁵

5.2 Unpacking the Patents and Designs Act of 1990

The patent regime currently in force in Nigeria stems from the Patent Ordinance Decree promulgated by the military after the decision in the *Rhone-Poulenc* case. In 1970, the Patent Ordinance Decree was changed into the PDA of 1970.⁴⁶ The PDA was updated in 1990 and is still in force to date.

⁴¹ The WAHO is the regional Agency of the Economic Community of West African States (ECOWAS) and is charged with the responsibility of safeguarding the health of the peoples in the sub-region. ECOWAS members include Benin, Burkina Faso, Cape Verde, Côte d’Ivoire, The Gambia, Ghana, Guinea, Guinea Bissau, Liberia, Liberia, Mali, Niger, Nigeria, Senegal, Sierra Leone, and Togo.

⁴² Fieldwork interview with Tile Tano, Deputy Director, Food and Drugs Services, Ministry of Health (Abuja, November 2014) (transcript on file with author).

⁴³ World Trade Organization, ‘Trade Policy Review: Nigeria’ (WTO 2011) 39.

⁴⁴ Office of the US Trade Representative, ‘The 2016 Special 301 Report’ (USTR 2016) 16 <<https://ustr.gov/sites/default/files/USTR-2016-Special-301-Report.pdf>> accessed 3 May 2016.

⁴⁵ Nigeria has been a member of the Paris Convention since 1963, a member of the WTO since 1995, and a member of the Patent Cooperation Treaty (PCT) since 2005.

⁴⁶ Patents and Designs Act (1990), Laws of the Federation of Nigeria, ch 344 <<http://www.nigeria-law.org/Patents%20and%20Designs%20Act.htm>> accessed 2 April 2014 (PDA).

This section specifically focuses on five areas – patentable subject matters (i.e. what can and cannot be patented as well as the criterion for patentability), rights granted by the PDA, and flexibilities within the PDA (such as compulsory licence provisions and government use). Focusing on these sections allows for a critique and analysis of the PDA to show how it interacts with laws, institutions, and actors in Nigeria. The analysis from this section shows that although flexibilities and safeguards exist in Nigerian patent law, such law can still be exploited for health purposes. The section concludes by arguing that the mantle falls not only on the courts but also on the legislative arm of the government (House of Assembly) to marshal and approve progressive patent legislation, the civil society to educate the legislators on existing progressive alternatives elsewhere, and the regulatory agencies to enforce the modus operandi of IPRs. At this juncture, it is important to note there exists a new, yet to be approved IP Bill⁴⁷ pending before the Nigerian House of Assembly, however, the analysis in this section will focus on the current PDA.

a) Patentable Subject Matters

According to the PDA, an invention is patentable if it falls under two categories: (a) if it is new, results from inventive activity, and is capable of industrial application;⁴⁸ and (b) if it constitutes an improvement upon a patented invention.⁴⁹ The PDA defines a ‘new’ invention to be that which does not form part of the state of the art,⁵⁰ while an invention is deemed to result from ‘inventive activity’ when it does not obviously follow from the state of the art, either as to the method, application, combination of methods, or product which it concerns, or as to the industrial result it produces.⁵¹ Finally, an invention is capable of industrial application if it ‘can be manufactured or used in any kind of industry, including agriculture.’⁵² The PDA defines ‘state of the art’ as everything concerning that art or field of knowledge which has been made available to the public anywhere and at any time through any means (i.e. a written or oral description, by use, or in any other way).⁵³

⁴⁷ This Bill – known as *An Act to Provide for the Protection and Administration of Intellectual Property Rights and for Other Related Matters* – provides for the establishment of an Intellectual Property Commission of Nigeria responsible for all matters relating to IPR administration and enforcement, as well as the creation of the Intellectual Property Appeal Board responsible for hearing and determining all IP matters. The Bill also codifies existing diverse legislation regarding the different categories of IP in Nigeria (such as the Copyright Act (2011), Trademarks Act (1990), and the PDA) into a single document and provides for new legislation regarding utility models, layout designs, and the protection of traditional knowledge and expressions of folklore.

⁴⁸ PDA, s 1(1)(a).

⁴⁹ *ibid*, s 1(1)(b).

⁵⁰ *ibid*, s 2(a).

⁵¹ *ibid*, s 2(b).

⁵² *ibid*, s 2(c).

⁵³ *ibid*, s 3.

A close reading of Section 1(1)(b) reveals one of the many lacunae present in the PDA. Section 1(1)(b) could be deemed to refer to utility models or petty patents although there is no specific references to such in the PDA. According to the WIPO, a petty patent or utility innovation is an ‘exclusive right granted for an invention, which allows the right holder to prevent others from commercially using the protected invention, without his authorization, for a limited period of time.’⁵⁴ Unlike patents, utility models are much cheaper to obtain, with less stringent requirements and for a shorter term – usually between seven to 10 years. Further, protection for utility models is often sought for innovations of a rather incremental character which may not meet the patentability criteria.⁵⁵ In fact, while the requirement of ‘novelty’ should be met for utility models, the requirement for ‘inventive step’ or ‘non-obviousness’ may be much lower or altogether absent. This may lead to ever-greening or patent thickets – the latter described as a dense network of overlapping patents that slows down the commercialisation of new inventions.

For an emerging economy like Nigeria with excruciating health burdens, patent application (and IP registration of any kind) should require a stringent examination procedure to prevent abuse of the system and protect public interest. When juxtaposed against the larger goal of harnessing the IP regime for innovation and economic development and considering the fact there is no examination of either novelty or inventive activity, the PDA creates a loophole that could be exploited at the expense of the country and public interest. As such, any specific or vague reference to utility models in the PDA needs to be excluded.

b) Exceptions to Patentability

Under the PDA, non-patentable inventions include those that contravene public order or morality, plant or animal varieties or biological processes for the production of plants or animals,⁵⁶ as well as principles and discoveries of a scientific nature. Unlike the Brazilian⁵⁷ and Indian Patent Acts, which include a broad list of non-patentable subject matters, the limited list in the PDA leaves the option open to all sorts of inventions and indeed, interpretations.

Moreover, the inclusion of ‘principles and discoveries of scientific nature’ raises the pertinent question of whether pharmaceutical products and processes are patentable as there is no

⁵⁴ World Intellectual Property Organization, ‘Protecting Innovations by Utility Models’ <http://www.wipo.int/sme/en/ip_business/utility_models/utility_models.htm> accessed 3 March 2015.

⁵⁵ *ibid.*

⁵⁶ PDA, ss 1(4)(a), 1(4)(b), and 1(5).

⁵⁷ While the list of non-patentable matters is not explicitly codified in the Brazilian Patent Act, the Brazilian INPI Guidelines for the Examination of Patent Filings in the areas of Biotechnology and Pharmaceuticals as well as the ANVISA subject matter guideline on what is held patentable in Brazil provide the parameter for patentable objects. See chapter 3.

guideline on what can be classified as discoveries of scientific nature. This lacuna creates a particular conundrum as pharmaceuticals and petrochemicals are the most patented inventions in Nigeria.⁵⁸ According to the Patent Registrar, seven out of 10 patent applications received by the Patent Office are for pharmaceutical products and are mostly filed by foreign applicants.

In fact, this issue of non-patentability of principles and discoveries of nature was raised in the case of *Beijing Cotec New Technology Corp. & Churchbell Pharmaceutical v Greenlife Pharmaceuticals Co. Ltd. & Ors.*⁵⁹ Here, the plaintiffs Beijing Cotec New Technology Corp. (a foreign company) and Churchbell Pharmaceuticals (its Nigerian affiliate) filed an *ex parte* injunction and Anton Pillar order against the defendant Nigerian company Greenlife Pharmaceuticals. According to the plaintiffs, their patent for *dihydroartemisinin* – an antimalarial drug registered in Nigeria as Patent Number 13566 and sold under the brand name *Cotecxin* – was infringed upon when Greenlife Pharmaceuticals imported and marketed the patented article without their permission.⁶⁰ In this light, the plaintiffs contended that they had the sole right to import, sell, and market anti-malaria drugs containing *dihydroartemisinin* in Nigeria. Subsequent to the suit, an action was also brought against the national drug regulatory body, the National Agency for Food and Drug Administration and Control (NAFDAC), whose role is akin to the US Food and Drug Administration in approving the sale of *Alaxin*, the generic version marketed by Greenlife Pharmaceuticals.

Based on *prima facie* evidence and the fact that the defendant did not file a counter-affidavit, Justice C. P. N. Senlong ruled that the plaintiffs/applicants were indeed the owners of registered Patent Number 13566 and issued an *ex parte* order restraining Greenlife Pharmaceuticals and its agents from making, importing, or selling the anti-malaria drug *Alaxin* pending the determination of the Motion of Notice for Interlocutory Injunction.⁶¹

However, in a later countersuit, Greenlife Pharmaceuticals and its agents applied for a motion to discharge the *ex parte* order on the ground that Beijing Cotec New Technology Corp. and Churchbell Pharmaceuticals concealed, suppressed, and misrepresented facts when they applied for the *ex parte* injunction. They further averred that the alleged patent is not patentable as ‘*Artemisinin* is a generic compound from which *Dihydroartemisinin* was derived

⁵⁸ Interview with Aisha Salim, Patent Examiner, Commercial Law Department, Ministry of Trade, Commerce and Investment (Abuja, February 2015) (transcript on file with author).

⁵⁹ (2003) FHC/L/CS/718/03 (Federal High Court Lagos Division).

⁶⁰ *Beijing Cotec New Technology Corp & Anor v Greenlife Pharmaceuticals Co Ltd & Ors* (n 59) 499.

⁶¹ *ibid.*

and that even though *Dihydroartemisinin* constitutes an improvement, *Artemisinin* itself is not an invention or a patented invention but *mere principles and discoveries of scientific nature*.⁶²

Furthermore, Greenlife Pharmaceuticals also argued that because *Dihydroartemisinin* is a derivative of *Artemisinin*, it follows that it cannot be patented as the latter forms part of state of the art, having been known and used in China for over 2,000 years.⁶³ Greenlife Pharmaceuticals also claimed that the specification for *Dihydroartemisinin*, did not ‘give the description of relevant invention with any appropriate plans and drawings but simply a process of producing a drug called *Cotecxin*, which according to section 9(1)(b) is not registrable.’⁶⁴ As such, the invention did not comply with the appropriate registration procedure under the PDA and therefore should not be granted patent protection.

In deciding the countersuit, Justice Mohammed Shuaibu ruled that even though the patent right does not confer to the plaintiff absolute right, it does confer to the plaintiff some recognizable right that should be protected by the court. However, based on the evidence before the court, which included (a) NAFDAC’s prior letter to the plaintiff requesting for letter of patent (b) an 18-month delay by the plaintiffs in providing the said letter, which shifted the balance of convenience to the defendants; and (c) the inability of the plaintiffs to prove that they will suffer irreparable damage, with an order of injunction being the only adequate remedy, Justice Shuaibu vacated the *ex parte* injunction against Greenlife Pharmaceuticals. The issue of patentability of ‘principles and discoveries of scientific nature’ was left undecided. In failing to tackle this, the court missed an opportunity to not only clarify the law but also to advance patent jurisprudence in Nigeria.

c) *Rights Conferred*

The PDA does not allow for substantive examination of a patent application. Unlike in Brazil where ANVISA thoroughly examines a pharmaceutical patent application,⁶⁵ and in India where Section 3(d) of the IPA provides the lens through which patents are examined,⁶⁶ the

⁶² *ibid*, paras 7(a)-(o) (emphasis added).

⁶³ *ibid*.

⁶⁴ *ibid*, para 37; Section 9(1)(b) stipulates that ‘[s]ubject to this section, on the application of any person (including a public officer acting in the exercise of his functions) the court shall declare a patent null and void - (b) if the description of the invention or the claim does not conform with section 3(2) of this Act and section 3(2) states every patent application shall disclose the relevant invention in a manner sufficiently clear and complete for the invention to be put into effect by a person skilled in the art or field of knowledge to which the invention relates; and the claim or claims referred to in subsection (1)(a)(iii) of this section shall define the protection sought and shall not go beyond the limits of the said description.’

⁶⁵ Ch 3, s 3.2.

⁶⁶ Ch 4, s 4.3.

PDA allows only for a simple formal examination of applications, i.e. checking whether required documents are in order.

Specifically, Section 4(1) of the PDA requires the Registrar to examine every patent application as to its conformity with Sections 3(1), (3), and (4), which deal with written declarations showing the name of the application, its specifications, and its claims. If the Registrar is satisfied, the patent is then granted ‘without further examination.’⁶⁷ In fact Section 4(2) explicitly forbids asking the following questions: (1) ‘whether the subject of the application is patentable under section 1’,⁶⁸ i.e. if it is new, results from inventive activity, and is capable of industrial application; and (2) whether the ‘description and claims satisfy the requirements of section 3(2) on claims’, i.e. if the relevant invention is disclosed in a clear and complete way for the invention to be put into effect by a person skilled in the art or field of knowledge⁶⁹ and on prior application.⁷⁰ Thus, while the PDA stipulates that only new inventions that result from an inventive step and are capable of industrial application, or are improvements from an earlier patented invention are to be granted patent rights, it does not scrutinise such patent applications to see if they conform to the stated criteria. In an interview, patent examiner Aisha Salim explains:

We don’t substantially examine patents. The law does not even allow it. What is we do here is just to check if the application is in order. So we check if the application form is properly filled out, all the attachments such as the specification claims and PCT documents are clearly and eligibly written out. Once all the required documents are place, the Registry usually issues patent certificates. In fact, we hardly ever reject an application. In cases where an application is incomplete, we keep them in view pending when the applicant brings the complete document.⁷¹

When probed further on the capacity of the Patent Office to examine patents, she clarifies:

[Nigerian] patent laws do not provide for the substantive examination, so it starts from the laws. Since our laws don’t even provide for substantive examination, the manpower is not even something that has been considered yet.⁷²

Of course, there are many problems, especially from a public interest perspective, that could arise due to the lack of substantive examination, such as granting patents to unqualified inventions, i.e. inventions that are not new, do not result from inventive activity, and are

⁶⁷ PDA, s 4(2).

⁶⁸ *ibid*, s 4(2)(a).

⁶⁹ *ibid*, s 4(2)(b).

⁷⁰ *ibid*, s 4(2)(c).

⁷¹ Fieldwork interview with Salim (n 58).

⁷² *ibid*.

incapable of industrial application. This is especially pertinent considering the various health crises in the country such as malaria, HIV/AIDS, and tuberculosis, to mention a few.

Some legal practitioners⁷³ contend that the registration system for patents is suitable for Nigeria where there is a dearth of expert patent examiners and limited resources for the due diligence required in conducting substantive examinations. Therefore, the registration system not only saves government funds but also reduces long delays usually prevalent in jurisdictions that allow for substantive examination. While it may be argued in some cases that substantive examination leads to delays, Nigeria does not have a high volume of patent application when compared to those in other emerging economies like Brazil, China, or India. In fact, data collected from the Nigerian Patent Registry shows that the country receives less than 1,000 patent applications in a year (see Table 3). This voids the argument regarding undue delays and volumes in relation to Nigeria.

Year	Indigenous Applicants	Foreign Applicants	Total
2000	40	403	443
2001	31	472	503
2002	35	461	496
2003	60	454	514
2004	74	448	522
2005	81	297	378
2006	98	248	346
2007	93	562	655
2008	92	711	803
2009	83	631	714
2010	75	855	930
2011	64	747	811
2012	42	676	718
2013	50	869	919

Table 3: Patent Application in Nigeria from 2000 – 2013. According to the patent office, 60 per cent of the registered patents are for pharmaceuticals.

Where a patent is granted, the PDA accords patent rights solely to a statutory inventor,⁷⁴ defined as ‘the person who, whether or not he is the true inventor, is the first to file, or validly to claim a foreign priority for, a patent application in respect of the invention.’⁷⁵ However, in situations where the statutory inventor is not the true inventor, i.e. when the primary inventor licences the right to a third party for furtherance of research, Section 2(2) allows for the primary inventor to be named in the application.

⁷³ Allen and Ogunkeye cited in Onyeka Uche Ofili, *Intellectual Property Rights Protection and Economic Development: The Case of Nigeria* (1st edn, European Scientific Institute 2014) <<http://eujournal.org/files/journals/1/books/OnyekaUcheOfili.pdf>> accessed 11 March 2015.

⁷⁴ PDA, s 2(1).

⁷⁵ *ibid.*

The PDA allows for protection for 20 years from date of filing, provided that annual fees are duly paid,⁷⁶ although a six-month grace period is given in situations of late payment. Once a patent is granted, Section 6 of the PDA accords the patentee the right to preclude any other person from making, importing, selling, or using the product, or stocking it for the purpose of sale or use.⁷⁷ The same applies where the patent has been granted in respect of a process.⁷⁸

The High Court exercises jurisdiction to the exclusion of any other court on matters of infringement.⁷⁹ While there is no explicit clause allowing for post-grant opposition, patent rights can still be challenged once granted. Section 4(4) of the PDA specifically stipulates that ‘patents are granted at the risk of the patentee and without guarantee of their validity.’⁸⁰ In this view, the courts do not recognise a presumption of validity for issued patents. This means that an ownership of a patent in Nigeria does not mean that the patent is valid, and when the validity of the patent is challenged, the onus is on the patentee to prove such validity.

While a patent application can be filed only for one invention, it may include, in connection with that invention, claims ‘for any number of products or for any number of manufacturing processes for those products, and for any number of applications of those products.’⁸¹ In addition, an application may include claims for ‘any number of processes, and for the means of working those processes, for the resulting product or products and for the application of those products.’⁸² While claims infringement lawsuits (or even patent cases, for that matter) are neither prominent nor popular in Nigeria, two cases in recent past are worth noting. The first case, *Pfizer Incorporated v Polyking Pharmaceutical Limited and Anor*,⁸³ highlights the question of claims where the defendants question the validity of a plaintiff’s patent right since it registered for patent on the product and not the process. In this case, plaintiff/applicant Pfizer sued the defendants for infringing on its Patent Number RP 9708, which covers the chemical compound with the generic name *Piroxicam*. *Piroxicam* is used in treating fever, pain, and inflammation in the body. According to Pfizer, the defendants were importing, selling, and stocking for sale the patented article under the generic name *Rossiden* without its

⁷⁶ PDA, ss 7(1) and (2).

⁷⁷ *ibid*, s 6(1)(a).

⁷⁸ *ibid*, s 6(1)(b).

⁷⁹ *ibid*, s 26(1); also according to s 251(1)(f) of the 1999 Constitution of the Federal Republic of Nigeria, the High Court have and exercise jurisdiction to the exclusion of any other courts in civil causes and matters, which include any federal enactment relating to copyrights, patents, designs, trademarks and passing-off, industrial designs and merchandise marks, business names, commercial and industrial monopolies, combines and trusts, standards of goods and commodities, and industrial standards.

⁸⁰ PDA, s 4(4).

⁸¹ *ibid*, s 3(a).

⁸² *ibid*, s 3(b).

⁸³ (1992) FHC/L/CS/178/1992 (Federal High Court, Lagos Division).

permission. Consequently, Pfizer sought for an *ex parte* injunction and Anton Piller order against the class sued⁸⁴ until further court orders.

In its defence, Polyking Pharmaceuticals asserted that the patent in question is null and void as the specification claim used by Pfizer in its Nigerian patent application is derived from its UK patent application, and thus does not represent specification claim under Nigerian law. Further, the defendant averred that Patent Number RP 9708 held by Pfizer has not been infringed upon because, according to Nigerian law, one can either claim for a *product* patent or a *process* patent. Explicating on this, the defendant argued that the process used in the manufacturing of *Proxicam* is not the same as the process used in manufacturing the *Rossiden* capsules. Therefore, since Pfizer registered a claim for the product Patent Number RP 9708 and not the process patent, its patent has not been infringed upon in the importation and sale of the *Rossiden* capsules as the manufacture of the latter, even though it contains the said patented article, was arrived at using a different process.

Pfizer countered that the assertion that one can only claim for either a *product* patent or a *process* patent but not for both is erroneous. As the PDA allows for an application to be made for only one invention, a patentee can – in connection with that invention – include claims for any number of products or manufacturing processes for those products, and for any number of applications of those products.⁸⁵ Moreover, with the onus of proving the validity of the patent, the plaintiff called an expert witness who disagreed with the view of the defendant and averred that ‘regardless of the possibility of producing any chemical product by different processes, so long as the products of different processes were the same compound, they cannot differ in potency.’⁸⁶

Finding for the plaintiff, the judge ruled that the *Rossiden* capsules stocked and sold by the defendants is the same organic compound contained in the plaintiff’s patent and as such, the defendants have infringed the plaintiff’s Patent Number RP 9708.

Another case of patent infringement in which the court found the patent to be valid and infringed upon is that of *Pfizer Limited v Tyonex Nigeria Limited and Ebamic Pharmacy Limited*.⁸⁷ In this case, Pfizer filed an injunction against two pharmaceutical companies Tyonex Nigeria Limited and Ebamic Pharmacy Limited for importing, stocking, and selling

⁸⁴ *ibid*, paras 6-12.

⁸⁵ *ibid*, s 3(a).

⁸⁶ *ibid*.

⁸⁷ (2010) CA/L/25/08 (Court of Appeal (Lagos Division)).

in Nigeria a generic version of *Norvasc* (the generic name is *Amlovas*), which contained the patented article *amlodipine besylate* and used in treating hypertension. According to Pfizer, the active ingredient contained in *Amlovas* was *amlodipine besylate*, which was invented by Pfizer and patented in Nigeria under Patent Number RP 9970. In deciding the case, the judge ruled that the defendants infringed on Pfizer's patent by importing, stocking, and selling an item containing a patented product without the permission of the right holder. The court subsequently granted an injunction and awarded damages in favour of Pfizer.

d) Compulsory Licence

Section I of the First Schedule to the PDA allows for the grant of a CL and defines the conditions for its use in Nigeria. The PDA allows for the grant of two classes of CLs – (a) court-sanctioned CL (i.e. a judicial order) and (b) Minister-sanctioned CL.

Court-Sanctioned Order

A court can issue an order for CL at any time after the expiration of a period of four years after the filing of a patent application or three years after the grant of a patent. An application for a CL through the courts is allowed in four instances: (a) when 'the patented invention, being capable of being worked in Nigeria, has not been so worked';⁸⁸ (b) when the working of the patented invention does not reasonably meet the demand for the product;⁸⁹ (c) the refusal of the patentee to grant licences on reasonable terms or the grant of a licence that unfairly and substantially prejudices the establishment or development of industrial or commercial activities in Nigeria;⁹⁰ and (d) if an invention protected by a patent in Nigeria cannot be worked without infringing rights derived from a patent granted on an earlier application or benefiting from an earlier foreign priority. In the case of the latter, a CL may be granted to the patentee of the later patent to the extent necessary for the working of his invention.⁹¹

In applying for a CL, the applicant should prove to the court that he has attempted to obtain a contractual licence from the patentee within a reasonable time and under reasonable terms but has been unable to do so.⁹² In addition, he should guarantee to the court to work the relevant invention sufficiently to remedy the deficiencies that gave rise to his application.⁹³ However, a CL will not be granted if the patentee satisfies the court that his actions in relation to the patented invention are justifiable in the circumstances and not merely shows that the patented

⁸⁸ PDA, First Schedule, s 1(a).

⁸⁹ *ibid*, s 1(b).

⁹⁰ *ibid*, s 1(c).

⁹¹ *ibid*, s 2.

⁹² *ibid*, s 5.

⁹³ *ibid*.

article is freely available for importation.⁹⁴ A CL is transferable with the consent of the court⁹⁵ and the court can cancel a CL if the licensee fails to comply with the terms or conditions of the licence.⁹⁶ The court may also vary the terms of the CL if new facts justify such variation or if the patentee has granted contractual licences on more favourable terms.⁹⁷

The court-sanctioned CL raises various points of possible contention. First, the local working requirement of the PDA highlights germane questions of compatibility with the TRIPS Agreement. Section 14 of the First Schedule of the PDA explains ‘working of patented invention’ to mean either ‘the manufacture of a patented article,’⁹⁸ ‘the application of a patented process,’⁹⁹ or ‘the use in manufacture of a patented machine by an effective and serious establishment existing in Nigeria on a scale which is adequate and reasonable in the circumstances.’¹⁰⁰ Importantly, Section 6 explicitly forbids the importation of a patented article in the utilisation of a CL.

On the other hand, Article 27(1) of the TRIPS Agreement requires patents to be ‘available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced’.¹⁰¹ Of course, it could be argued that local working that requires manufacturing in the locality of the patent protection fulfils the ethos of Article 7, which ensures IP protection contribute to the promotion of technological innovation, 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.¹⁰² In this vein, all three requirements of Article 7 – technological innovation, transfer and dissemination of technology, and use of technological knowledge – fit into the justification of local working. However, since the PDA does not allow importation while TRIPS recognises importation leads to legal uncertainty. Also, the fact that the position of the WTO Dispute Settlement Body on the issue of local working remains unclear further creates undue friction.

Another possible point of contention is the fact the PDA does not define what would amount to ‘reasonable terms’ or ‘reasonable time’ in the context of which a CL should be granted by

⁹⁴ PDA, First Schedule, s 4.

⁹⁵ *ibid*, s 7.

⁹⁶ *ibid*, s 9.

⁹⁷ *ibid*, s 10.

⁹⁸ *ibid*, s 14(a).

⁹⁹ *ibid*, s 14(b).

¹⁰⁰ *ibid*, s 14(c).

¹⁰¹ TRIPS Agreement, art 27.

¹⁰² TRIPS Agreement, art 7.

the patentee to a third party. However, it has been argued that the incidence of reasonability in all cases would have to be determined by the courts in all circumstances, and each case has to be determined on its own merits.¹⁰³ Nevertheless, the fact that the courts need to approve CL applications can itself be confusing, time-consuming, and prone to undue delays. With Nigerian courts known to be slower than molasses in January, this judicial provision clearly favours transnational corporations who are majority patent holders over local producers or the public interest. Moreover, the prerogative of the patentee to approach the court to establish his actions in relation to the patent are justifiable could give rise to the withholding of a CL if the patent holder presents legitimate reasons.

Minister-Sanctioned Order

Section 13 of the First Schedule allows a Minister, by order in the Federal Gazette, to approve a CL for certain patented products and processes declared by the order to be of vital importance for defence, economic, or public health purposes.¹⁰⁴ Within this context, a CL can be sanctioned before the expiration of the period mentioned in Section 1 of the First Schedule, i.e. before the expiration of the four-year period after the filing of a patent application or the three-year period after the grant of a patent while importation is also permitted. A CL under this instance falls within the ambit of public health purposes of the Doha Declaration. According to Adewopo, a Minister-sanctioned CL is a practical justification for the supply of drugs by way of production, importation, or necessary measures to procure supplies of drugs and other treatment during dire times without weakening or undermining the patents on those medicines.¹⁰⁵ The government of Nigeria, through the Minister, is yet to issue a CL for health purposes despite the various health epidemics experienced in Nigeria in recent times, such as the polio and meningitis outbreaks and the current HIV/AIDS crisis. As will be discussed below, factors such as the absence of a patent regime framework, and the strong influence of donor presence in the delivery of medicines explains why this this clause has not been invoked by the state.

e) Government Use

Section 20 of the PDA allows a Minister, who is satisfied that it is in the public interest to do so, to authorise any person to purchase, make, exercise, or vend any patented article or invention for the service of a government agency in the Federal Republic.¹⁰⁶ This ministerial

¹⁰³ Templars Law Firm, 'Patentability under the Nigerian Patents and Designs Act (PDA): An Introductory Analysis' (2012) <<http://www.templars-law.com/wp-content/uploads/2015/05/Patentability-Under-the-Nigerian-Patent-Act.pdf>> accessed 4 March 2015.

¹⁰⁴ PDA, First Schedule, s 13.

¹⁰⁵ Adewopo, 'Public Health, Access to Medicines and Role of Patent System in Nigeria' (n 15) 177.

¹⁰⁶ PDA, First Schedule, s 16.

authorisation may be exercised before or after the relevant patent has been granted and to any person, whether or not he is authorised directly or indirectly by the patentee to make, use, exercise, or vend the relevant article or invention.¹⁰⁷ The PDA defines a ‘Minister’ to mean a Minister of the Federation, including a State Commissioner, and exempts him as well as any person authorised by the government from liability for the infringement of any patent relating to the relevant article or invention, and from liability to make any payment to the patentee by way of royalty or otherwise.¹⁰⁸ Although the TRIPS Agreement does not specifically refer to government use of patents, it recognises such use in its references to the concept of public non-commercial use and of patents ‘used by or for the government.’¹⁰⁹ The government use clause has only been invoked once when the Federal Ministry of Health placed a supply order for the patented product *chlorpromazine* in 1964. This led to the first patent case in Nigeria – the *Rhone-Poulenc* case.

Government use as specified in the PDA is prone to misuse in many ways. It does not, for example, define nor provide a guideline on what would amount to an exercise ‘in the public interest.’ Moreover, the definition for ‘Minister’ is too broad and poses a problem of consistency. Although the PDA technically allows a State Commissioner to invoke government use of patented article, in reality, a State Commissioner does not have the power to do so as patents and designs are under the Exclusive Legislative List. The Exclusive Legislative List deals with specific items which only the National Assembly has the sole prerogative to legislate on, to the exclusion of the state and local governments. Thus, it is only the Minister of Health, with explicit approval from the National Assembly, who can invoke the government use clause. Also, the PDA gives the Minister the choice of whether or not to inform the patent holder of the government use of the patented object ‘if it is clear to the Minister such information is not contrary to the public interest to do so.’¹¹⁰ This is in fact incompatible with the TRIPS Agreement, which mandates the government or contractor to inform the right holder.¹¹¹

Finally, even if the PDA allows for the grant of a CL in Nigeria, it may not work because the country currently does not have the manufacturing capability to engage in such, as will be discussed *infra*. Nevertheless, it should be included under safeguards for future use.

¹⁰⁷ *ibid.*

¹⁰⁸ PDA, First Schedule, s 17.

¹⁰⁹ TRIPS Agreement, art 31(b).

¹¹⁰ PDA, First Schedule, s 18.

¹¹¹ TRIPS Agreement, art 31(b).

In sum, although the PDA incorporates certain aspects of the TRIPS Agreement, it is still lacking in key respects, particularly on patentable subject matters as well as relevant TRIPS flexibilities to ensure maximum health safeguards. For example, both the Bolar exceptions and parallel importing are not included in the PDA. Bolar exceptions allow a company (usually generic) to conduct research on a patented drug in order to have it ready for the market as soon as the patented drug version goes off patent. Due to the long-term nature of pharmaceutical research, Bolar exceptions ensure that the patented drug is available immediately after the expiration of patent. Parallel importing, on the other hand, allows a country to ‘shop around’ for the lowest price of the same product wherever it may be distributed. This is based on the principle that one’s patent right is exhausted once the patented invention is released into the market. The TRIPS Agreement allows for national, regional, and global parallel importation. Inclusion of these flexibilities is also in line with the Doha Declaration, which recognises the gravity of the public health problems afflicting many developing and least developed countries and therefore recommends the implementation of 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.’¹¹² However, the high incidence of counterfeit drugs in Nigeria could prevent the use of this clause. According to the NAFDAC, 48 per cent of drugs available in Nigeria are fake or below standard.¹¹³ Nevertheless, it could be argued that the language of the PDA shows that the Nigerian state has an understanding of the patent regime. The next section will examine how this is employed in policy frameworks and for what purposes.

5.3 State Regulatory Agencies and Patent Regime

This section attempts to capture the attitude of the Nigerian state towards patents by reflecting on the ‘official’ use of patents provided in the PDA as an effective mechanism for achieving the cardinal goals of public health care and economic development. By ‘official’, the research refers to state actors created to deal with patents or those whose oversight duties interfaces with the patent regime. Thus, the focus here is how the language of patent is employed and deployed by governmental bodies in the monitoring, approval, and audit of pharmaceutical-related and industrial development in Nigeria. Thus, the notion of how ideas circulate among these actors and the manner in which particular policy options are crafted – and, as an extension, how others are extinguished – is explored.

¹¹² World Trade Organization, ‘The Doha Declaration on TRIPS and Public Health (2001)’ WT/MIN(01)/DEC/2 <https://www.wto.org/english/tratop_e/trips_e/implement_para6_e.htm> (Doha Declaration), para 4.

¹¹³ Dora Akunyili, ‘Counterfeit and Substandard Drugs, Nigeria’s Experience: Implications, Challenges, Actions and Recommendations’ (World Bank, Washington DC, 2005).

Over the years, Nigerian policymakers at the federal and state levels have created various regulatory and monitoring agencies concerning all activities in relation to pharmaceutical manufacturing and technology transfer. The agencies whose work intersect on the issue of patents for development and public health purposes are NOTAP and NAFDAC. These agencies ensure the establishment of coordination mechanisms among various agencies to improve detection, investigation, and prosecution of cases of counterfeit medical products and the commercialisation of technology transfer, respectively. In looking into the circulation of ideas, the thesis has found that there is little understanding of the patent regime within these agencies in terms of its relationship to their mandate. Thus, despite the content of the PDA, patents are of limited impact in development and public health frameworks as it pertains to these organisations.

NOTAP was initially created as the National Office of Industrial Promotion by Decree 70 of 1979. Its current acronym was introduced in 1992 by virtue of Decree 82 of 1992.¹¹⁴ NOTAP is tasked with the acquisition, promotion, and development of technology, as well as the commercialisation of foreign technology brought into the country.¹¹⁵ Within this remit, NOTAP assists in the patenting of all inventions and innovations carried out by government-funded research institutes and others in the private sector. According to NOTAP's Director of Technology Transfer and Research Lucky Nwosa, the agency is supposed to commercialise all R&D results and inventions brought into the country by liaising with local research institutes for the adaptation of such imported technology, promoting locally generated technologies in the process.¹¹⁶ Furthermore, NOTAP helps inventors by linking them with patent offices worldwide and by assisting the inventor in drafting patent applications.

However, in reality, the commercialisation of such processes is non-existent. As stated by Mr. Nwosa:

We do not get notified of most of the technology that come into this country. Most government ministries work in silos and the lack of communications among departments affect our ability to do any tangible, meaningful work. There have been situations where patents have been registered here but the Ministry of Trade responsible for that did not inform us. How can we commercialise technology when we don't even know what comes in? The telecoms sector, held Nigeria for ransom for many years because people with

¹¹⁴ Kristin Peterson and Olatubosun Obileye, 'Access to Drugs for HIV/AIDS and Related Opportunistic Infections in Nigeria' (US Agency for International Development 2002) 45.

¹¹⁵ Fieldwork interview with Lucky Nwosa, Director, Technology Transfer and Research (TAR) at NOTAP (Abuja, 2015) (transcript on file with author).

¹¹⁶ *ibid.*

network license refused to commercialise it. Remember, we had less 500,000 telephone lines in the for the whole nation of or something million people. So it was only until during the Obasanjo administration that they were now able to licence these networks. How can we commercialise technology when we don't even know what comes in? We know what patent is and we can help Nigeria utilise but the systems is disorganised that no one knows exactly what is happening.¹¹⁷

This suggests that although NOTAP is aware of its regulatory role and has the capacity to fulfil its functions, institutional bottlenecks prevent it from doing so. However, Mr. Nwosa notes that in many occasions, foreigners seeking to commercialise their technology in Nigeria are put off by the contract terms, which requires the sharing of technological information with NOTAP.¹¹⁸ In other instances, contractual agreements between the Nigerian government and foreign entities are usually unfavourable to the country, which further hinders the transfer of technology.

Besides the issue of non-notification of foreign technology, the communication between government ministries responsible for patent issuance is generally almost non-existent. For example, the patent registry is located in the Ministry of Trade and Investment, which deals with foreign trade, investment, and all other commercial activities. On the other hand, NOTAP, which deals with patent registration and technology transfer, is located in the Ministry of Science and Technology. Also, the WTO Department is under the Trade Department at the Ministry of Trade and Investment while the patent registry is under the Commercial Law Department, which is under the Legal Department. According to the principal trade officer at the WTO Department, Onyejekwu Simeon, there is a tug of power between the Commercial Law Department and the Trade Department, where each department feels threatened by the other and any interaction is seen as an intrusion into the other's turf.¹¹⁹ This sentiment is echoed by other interviewees at the Ministry of Trade.¹²⁰ This has led to the lack of synergy and fragmentation of IPR administration under different agencies, departments, and ministries, which has not worked effectively for the development of IP.¹²¹

Another important player to take into consideration is NAFDAC, which was created to tackle the issue of fake and pirated drugs. Pirated products began to emerge in the Nigerian market

¹¹⁷ *ibid.*

¹¹⁸ *ibid.*

¹¹⁹ Fieldwork interview with Onyejekwu Simeon (Abuja, 2014) (transcript on file with author).

¹²⁰ Fieldwork interview with Salman Mann (Abuja, 2014) (transcript on file with author); Fieldwork interview with Ruth Okoye (Abuja, 2014) (transcript on file with author).

¹²¹ Adebambo Adewopo, 'According to Intellectual Property: A Pro-Development Vision of the Law and the Nigerian Intellectual Property Law and Policy Reform in the Knowledge Era' (Nigerian Institute of Advanced Legal Studies (Lagos) 5th Inaugural Lecture, 2012) 66.

in the early 1980s due to the oil bust, affecting government expenditure and causing the scarcity of essential goods. In response, the government decided to award import licences, although these licences were awarded on the basis of political patronage. Many people who were unqualified to import drugs started importing drugs and flooding the market with substandard and counterfeit drugs.

The situation was further exacerbated by the implementation of the SAPs (discussed *infra*), which mandated an end to government-subsidised health programmes. Because the state was massively downsized, regulatory bodies were incapacitated to do the work of the law.¹²² Thus, Nigeria had become a dumping ground for fake and counterfeit medicines by the early 1990s. For instance, 109 children died in 1990 after ingesting paracetamol syrup that contained toxic diethylene glycol solvent instead of propylene glycol.¹²³ In 1995, Nigeria donated 88,000 doses of meningitis vaccine to its neighbour Niger, but before the authorities realized that these vaccines were fake, about 60,000 people had already been ‘inoculated.’¹²⁴ These incidents prompted the government to create a regulatory agency tasked with ensuring the safety of food and drugs in Nigeria.

Created in 1993, NAFDAC is responsible for the regulation and control of the importation, exportation, manufacture, advertisement, distribution, sale, and use of food and drugs.¹²⁵ In addition to this, the agency also conducts appropriate tests to ensure that the quality of these items is up to the standard specified and approved by the Governing Council. It also investigates production premises, investigates imported drugs, and compiles standard specification guidelines for the production, importation, exportation, sale, and distribution of drugs.

The duties of NAFDAC place it in the role of ensuring effective and efficacious medicines in Nigeria. Specifically, the fact that it should also approve the importation and distribution of medicines means that it engages with patents one way or the other. In fact, the *Beijing Cotec New Technology Corp. & Churchbell Pharmaceutical v Greenlife Pharmaceuticals* case discussed above is a pertinent example of how this was applied. However, there is no mention

¹²² Kristin Peterson, ‘Intellectual Property Designs: Drugs, Governance, and Nigerian (Non-) Compliance with the World Trade Organization’, *Rethinking Biomedicine and Governance in Africa: Contributions from Anthropology* (1st edn, Transcript Verlag 2012) 143 (‘Intellectual Property Designs’).

¹²³ Akunyili (n 113).

¹²⁴ Abiodun Raufu, ‘Nigeria Leads Fight Against “Killer” Counterfeit Drugs’ (*WHO Bulletin*, 2006) <<http://www.who.int/bulletin/volumes/84/9/06-020906/en/>> accessed 7 February 2016.

¹²⁵ *National Agency for Food and Drug Administration and Control Act* (1st edn, Federal Government of Nigeria 1993) <http://www.nafdac.gov.ng/images/PUBLICATIONS/NAFDAC_ACT/Nafdac_Act_Real_Copy.pdf> accessed 19 August 2016 (NAFDAC Act).

of patents in the NAFDAC Act. An interview with a NAFDAC official is even more revealing:

We understand patent. It is something is required by protect an intellectual work. But we don't really use in our line of work. Our focus is on counterfeit and fake drugs, not patents. We are here to protect Nigerians from the fake, substandard and counterfeit drugs.¹²⁶

This legal indeterminacy creates a system where contradiction and incoherence thrives. Instead of a single cohesive strategy and an effective enforcement mechanism, an arbitrary system is created where even authoritative regulatory agencies permit conflicting outcomes with devastating consequences.

5.4 Engagement of Non-State Actors with Patent Law

This section looks into how non-state actors participate in and engage with patent discourse, if at all. Specifically, the thesis examines how these actors – private sector and civil society groups – challenge and/or influence the understanding and conceptualisation of patent into law and policy. For the purpose of this analysis, pharmaceutical manufacturers comprise of both indigenous and foreign companies, while civil society refers to a combination of local patient groups, social movements and health society groups, professional associations, and others.

Pharmaceutical Sector

Analyses from previous chapters underscored the role of pharmaceutical firms in patent law making. From successfully including the IP regime in global trade rules in international forums such as the WTO to embedding significant procedural protections and substantive limits in the new Indian Patent Act, these actors have exploited law's gravitational pull in framing processes to formulate demand and persuade the state to strengthen patent law in order to protect their investments in pharmaceutical research and development. With this in mind, the thesis turned to the Nigerian pharmaceutical sector to explore how this particular actor engages with patent law.

In spite of the size of the sector, currently estimated at USD1.28¹²⁷ billion and anticipated to

¹²⁶ Fieldwork interview with Ali Ibrahim, Deputy Director, i/c Pharmacovigilance/Post Marketing Surveillance, National Agency for Food and Drug Administration and Control (NAFDAC) (Abuja, 2015) (transcript on file with author).

¹²⁷ Frank Gumel, 'Investment Opportunities in the Pharmaceutical Sector - Nigeria/Pakistan' (PwC 2014) 16.

more than double to USD1.3 trillion by 2020,¹²⁸ there appears to be an ongoing deficiency in its engagement with patent law. This is because there is very few original research being carried out by companies in Nigeria to warrant monopoly protection provided by patents. Of the five pharmaceutical company executives interviewed for this thesis (coming from three local firms and two foreign affiliates), none of their companies conduct original pharmaceutical research and development of drugs. The industry, according to these executives, does not need patents to operate because these are not important in what they do. For example, Yetunde Ali, who works for a foreign affiliated company, reflected on the drug companies and their engagement with the patent regime in Nigeria:

[Our company] in Nigeria has not produced any new chemical entity that requires us to apply for patent. I don't think any company in Nigeria engages in such research. However, our parent company abroad has registered patents in Nigeria but the molecule that was patented was discovered and produced outside Nigeria even though we had to undertake clinical trials when the chemical entity was introduced to the Nigerian market. So we just register those produced abroad here. We were not involved in the research. Even when our parent company patents a product, the products still gets copied under 2-3 years. Patent are not respected here.¹²⁹

Commenting on this, Abraham Okeke explains the situation:

[The company] does not engage in any original research and development of drugs here in Nigeria. These countries you mentioned [India and Brazil] have the structural facilities like electricity, the infrastructure and even educated population that can undertake such intensive research. We don't have such in Nigeria. We only do basic packaging and formulation of elementary items like vitamins, analgesics and paracetamol. Just basic items, nothing innovative. Nothing is manufactured locally here. That is why patent is not our focus. We have nothing to protect, really.¹³⁰

Similarly, Mike Ajufo comments further:

The situation is different in Nigeria in that every single pharmaceutical company currently operating in the country, both foreign and local, are not doing any substantive research. We are not developing new drugs; we are not even in the process of developing new drugs. It is very expensive to engage in such here. The pharmaceutical companies here are involved in tertiary manufacturing – the manufacturing of finished goods without any research

¹²⁸ Pharmaceutical Manufacturers Group of Manufacturers Association of Nigeria (PMG-MAN) Nigeria Pharma Expo 2015, 'West Africa Pharma Market Biggest Show Nigeria Pharma Manufacturers Expo 2015 is set to display above 200 Exhibitors from 11 countries & more than 4,000 Products / Services on pharma manufacturing technologies for Central & West African pharma markets' <http://www.nigeriapharmaexpo.com/press_release.html> accessed 4 January 2016.

¹²⁹ Fieldwork interview with Yetunde Ali, Regulatory Head, Biofem Pharmaceuticals (Lagos, July 2016) (transcript on file with author).

¹³⁰ Fieldwork interview with Abraham Okeke, Company Secretary, Swiss Pharmaceutical Company (Lagos, July 2016) (transcript on file with author).

input. We make basic items that do not require patents. We are not into original research and development yet.¹³¹

Similarly, an interviewee from the PMG-MAN, an umbrella organisation for manufacturers of pharmaceuticals and allied products in Nigeria, concurs. According to him, the organisation does not engage with Nigerian policymakers on patent issues as the group is more concerned with ensuring government assistance. He clarifies:

Patents are not our focus right now. Maybe they will be in the future but not currently. We are instead engaging with the government on other issues. We are engaging the Executive who gives out the contract for drug procurement. We are also engaging with the Legislature who will put it in the law that [drug] companies need to be encouraged if they are making efforts to produce locally and the quality is top notch. So we are pushing hard in both directions and we asking both the Executive and the Legislature to patronise local drug manufacturers. So we are working hard to make sure jobs stay in Nigeria; we are also working hard to make sure that Nigerian medicines are of the highest international quality. This is why we are not focusing on patents.¹³²

In this context, the sector does not need to engage with in the patent discourse either to theorise its interests, build alliances, or mobilise government support for a particular type of patent regime. Consequently, the ongoing legal innovations and contestations found in local spaces in Brazil and India is non-existent in Nigeria because the patent regime – as a legal phenomenon, a constructed knowledge, and a policy tool – is largely seen as irrelevant and inapplicable.

The Nigerian situation echoes the principles of nodal governance, which emphasises the role of nodes in governance especially in the way nodal networks link up to create concentrations of power for purposes of exercising governance. For nodes to be able to influence governance, they should have four essential characteristics: first, a node should have a way of thinking (mentalities) that cognitively shapes how individuals and organisations see the world and act accordingly, technologies for applying and exercising influence over the course of events at issue, resources to support and mobilise the operation of the node and fuel its influence, and the existence of institutions that enable the directed mobilisation of resources, mentalities, and technologies over time.¹³³ How then does the nodal governance theory apply to Nigerian pharmaceutical actors? Going by the interview excerpts, the pharmaceutical actors

¹³¹ Fieldwork interview with Mike Ajufo, Technical Director Evans Pharmaceutical Plc (Ogun State, July 2016) (transcript on file with author).

¹³² Fieldwork interview with interviewee from PMG-MAN (Lagos, July 2016) (transcript on file with author).

¹³³ Jennifer Wood and Clifford D Shearing, *Imagining Security* (Willan 2007) 26; Scott Burris, Peter Drahos, and Clifford Shearing, 'Nodal Governance' (2005) 30 *Australian Journal of Legal Philosophy* 12.

in Nigeria do not have the mentality, i.e. the attitude towards and engagement with patent law. They do not see patents as valuable because they are not engaging in original research that deserves monopoly protection. Due to this lack of engagement, there is no need to seek state compliance on patent issues. While they do have technologies for applying and exercising influence as well as resources to fuel mobilisation because of the size of the sector, the institution (effective patent regime) does not exist. This ties back to the law in place as well as the ability of state institutions to enforce protection, i.e. prevent copying. Since the patent regime is predicated on the development of innovative products, it means that the patent regime will also be absent in contexts where development of innovative drugs is absent. Conversely, since the country lacks widespread patent infrastructure, industry actors cannot challenge and/or influence the conceptualisation of patent into law and policy.

This is in stark contrast to Brazil and India which have large generic manufacturing sectors with the technological capabilities to not only reproduce patented drugs, but to also undertake original research and development of new drugs. In those jurisdictions, both the brand name and generic companies have a vested interest in an effective and enforceable patent regime. In other words, because the drug companies in those countries have the ability to undertake the development of new pharmaceutical entities, they are able to activate their nodal networks to mobilise government compliance on patent regimes because the existence and enforcement of such a regime ensures market-segmented monopoly that allows them to recoup the financial expenses associated with pharmaceutical research. It also explains why foreign MNCs adopt various tactics to restrict competition from Indian generics either through legal tie-ins of VLs or outright purchase of generic competitors. This is because for brand-name companies, indigenous drug manufactures pose a considerable threat due to their capacity to formulate and manufacture more advanced patented drugs, thereby reducing their market profit. It is the existence of a fair market structure in Brazil¹³⁴ and India¹³⁵ in the form of a strong generic industry as well as the ability of patent law to affect monopoly and market access which explain the strong use of patent language in policy and legal decisions and in public debates in those countries.

Investigating the extent of the engagement of Nigerian drug manufacturers with patent law raises the question of why is there no original research being undertaken in the sector. What are the issues that prevent the sector from developing the technical and technological capacity required for pharmaceuticals, and consequently improve sectoral participation in patent

¹³⁴ Ch 3, s 3.3.

¹³⁵ Ch 4, s 4.1.

discourse? In order to arrive at a position that allows for a more integrated insight, this section will also examine a tangle of historical, political, and economic events that influenced and reshaped Nigeria's drug sector. Specifically, it explains how government policies such as the Indigenisation Decree, ISI policy, and the SAP – the latter triggered by the oil boom and bust of the 1970s and the 1980s – eviscerated the pharmaceutical manufacturing companies, in turn weakening the ability of the pharmaceutical manufacturing sector to engage in domestic inventiveness.

Since Nigeria became independent in 1960, achieving economic development through rapid industrialisation has remained a major challenge. Nigeria started exporting oil in 1957, however, it was the oil boom of the 1970s due to the two price hikes orchestrated by the Organization of Petroleum Exporting Countries (OPEC) in 1973–74 and 1979–80 that triggered a substantial windfall for the country and resulted in a large transfer of wealth to the state's coffers.¹³⁶ In the wake of the oil boom, the country suddenly became wealthy, completely restructuring the economy from agrarian-based to oil-exporting. This sudden large increase in income subsequently led to a general decline of national production in other sectors – or what is known as Dutch Disease – which had serious repercussions on important segments of the country's economy. For example, the oil sector accounted for less than three per cent of GDP and a modest USD370 million in exports in 1969 but by 1980, the oil sector had come to account for nearly 30 per cent of GDP and oil exports totalled USD25 billion.¹³⁷ It also accounted for 90 per cent of foreign exchange earnings and 70 per cent of budgetary revenues.¹³⁸ The country also saw a decline in agricultural exports (cash crops such as groundnut, cotton, and palm oil), which formed the main non-oil tradable sector and source of GDP prior to the export of oil. Moreover, the oil boom also led a significant shift in emphasis from planning for industry to primary product export and possibly deindustrialisation. According to Bill Freund, the oil boom increased the importation of luxury consumer goods which poured into the country on an unprecedented scale to the detriment of Nigerian exports. In 1974, Nigerian imports were worth NGN1.737 million; by 1976, they reached NGN5.140 million and in 1977, NGN7.297million. By mid-1978, they were running at an annual rate of NGN8.76 million.¹³⁹ Importation of items such as cars, electronics, and other finished goods

¹³⁶ Ngozi Okonjo-Iweala, 'Point of View: Nigeria's Shot at Redemption' (International Monetary Fund 2008) <<http://www.imf.org/external/Pubs/FT/fandd/2008/12/okonjo.htm>> accessed 3 July 2015.

¹³⁷ National Centre for Economic Management and Administration (NCEMA), 'Understanding Structural Adjustment Programme in Nigeria' (Global Development Network (GDN) 2004) 11 <http://www.gdn.int/html/GDN_funded_papers.php?mode=download&file=Nigeria-first-draft_176.pdf> accessed 9 March 2015.

¹³⁸ BJ Ndulu and others, *The Political Economy of Economic Growth in Africa, 1960-2000* (Cambridge University Press 2007) 148-49.

¹³⁹ Freund (n 18) 94.

increased exponentially. According to Freund, car importation surpassed the 10,000 mark such that Nigerian roads were increasingly clogged by fleets of motorised two-wheeled vehicles.¹⁴⁰

In the drugs sector, the attendant increase in oil export earnings led to three structural changes. First, it led to an increase in the number of brand-name pharmaceutical companies setting up manufacturing plants in Nigeria, which expanded pharmaceutical manufacturing in the country at that time.¹⁴¹ Previously, companies such as Beecham, May and Baker, Pfizer, and Glaxo had distribution and trading outlets in the 1940s and 1950s while others such as Bayer, Wellcome, Roche, Hoerst, and Boots arrived later in the 1960s. In fact, although the first production plant was registered in Nigeria in 1942, actual production activities did not start until the late 1960s.¹⁴² By 1970, these companies had already scaled up their presence by building manufacturing plants or expanding distribution plants to be able to distribute to other parts of West Africa. In so doing, these companies took advantage of the lucrative oil market and the emergent middle class. With the success of these pharmaceutical companies, Nigeria metamorphosed into a regional hub for the export of pharmaceuticals into other parts of West Africa.¹⁴³

Second – and as a corollary – the oil boom increased the presence and relative wealth of the Nigerian middle class at that time. This resulted in an expanded income, thereby touching off new waves of consumerism and creating a growing demand for finished and imported goods. According to Kristin Peterson, the members of the emergent middle class were able to ‘afford luxury goods and with sensibilities oriented toward the high symbolic value associated with brand name drugs.’¹⁴⁴ This emergent middle class, flush with new wealth, became not only the marketing focus of these companies but also spent heavily in purchases. In addition, increased rent from oil export led to the introduction of subsidised health programmes such as free drugs in government hospitals, which also added to the sales output for pharmaceutical companies. In fact, data from industry earnings were estimated at around USD48 million in 1973, and by 1980 earnings increased to about USD200 million and the employment of nearly 10,000 Nigerians.¹⁴⁵ Between 1977 and 1981, the pharmaceutical subsector grew by 110 per

¹⁴⁰ *ibid.*

¹⁴¹ Kristin Peterson, *Speculative Markets: Drug Circuits and Derivative Life in Nigeria* (Duke University 2014) 41 (*Speculative Markets*).

¹⁴² SI Ebohon, ‘Nigerian Policy Towards Foreign Companies: Case Study of the Multinational Pharmaceutical Formulation Plants, 1972-1983’ (PhD, University of Manchester 1985) 146 (‘Nigerian Policy Towards Foreign Companies’)

¹⁴³ Peterson, *Speculative Markets* (n 141) 41.

¹⁴⁴ *ibid.* 42.

¹⁴⁵ *ibid.*

Third, the increased presence of pharmaceutical manufacturers triggered by the profitable oil boom led to an increase in the number of pharmacists, especially those who worked as marketers for brand-name pharmaceutical companies.¹⁴⁷ The new crop of pharmacists did not only receive marketing training by attending conferences and seminars abroad – all sponsored by pharmaceutical companies – but were also given credit lines and bulk discounts on drug purchases. These pharmacists, not traders, dominated the drug supply and marketing chain. At the same time, new pharmacy schools at major universities were opening up to meet demands for local pharmacists, which at the time of independence were only three.

With the above in mind, certain questions arise – did the substantial presence of foreign drug producers result in increased participation of the sector in patent law and jurisprudence? Was any local value added in terms of organising and reshaping the politics of patent law and governance in Nigeria, either through transfer of technology to local producers or pushing forward reformist patent law similar to the engagement of Indian generics at during same period? The answers lie in the structure and organisational frame of the foreign pharmaceutical companies operating in Nigeria in that period as well as the policy instruments introduced to reconfigure the economy following the oil crisis of the 1980s.

In the period leading up to the 1970s, indigenous pharmaceutical manufacturing companies were almost non-existent while foreign drug companies were not engaged in original research and development. It has been argued that the research intensity of the global pharmaceutical industry was not replicated in Nigerian pharmaceutical affiliates due to the high cost of maintaining facilities and the slim chance of major discoveries due to lack of local facilities and technical know-how.¹⁴⁸ Most of the raw materials and heavy duty machines required to produce the drugs were imported. Simple items such as spare parts for machines were also imported; in the event of breakdown, machines were shipped outside the country for repair. This made the cost of local manufacturing exorbitant. In addition to this, the country also lacked the skilled labour force able to engage in intensive pharmaceutical research. Therefore, even though these companies opened manufacturing plants, they all engaged in basic formulation of drugs. Even the Nigerians working in these plants were not placed in

¹⁴⁶ Ebohon, 'Nigerian Policy Towards Foreign Companies' (n 142) 147.

¹⁴⁷ Peterson, *Speculative Markets* (n 141) 42.

¹⁴⁸ SI Ebohon, 'Globalization, Technology Transfer and the Knowledge Gap: Case Study of the Global Pharmaceutical Industry in Nigeria' (2012) 11 *Global Journal of Social Sciences* 27 ('Globalization, Technology Transfer and the Knowledge Gap').

managerial and research positions due to the lack of professional and technical experience in pharmaceutical and allied research. The few Nigerians engaged in the production value chain were mostly limited to quality control positions. However, Terisa Turner contends that the lack of local expertise were excuses given by foreign companies to retain control and dominance of their companies.¹⁴⁹

Nonetheless, the boomerang effect of this was the failure to locally capture know-how and know-why of pharmaceutical manufacture. That is, imported technology was not adapted to the local situation and therefore did not lead to any significant transfer of technology, which would have led to local industrialisation. Thus, because the subsector lacked any meaningful integration and linkage with the Nigerian economy, it created a knowledge gap that made technological transfer impossible, perpetuating a regime of technological dependency as a result. Unfortunately, evidence from the fieldwork in Nigeria, as discussed earlier, shows this knowledge gap still plagues the subsector till this day. The implication of this structure of production is that the country is perennially trapped in knowledge dependence mode and restricted innovation growth. If no new research is being undertaken, then there is no need to apply for patents to protect newly developed pharmaceutical entities as patent monopoly acts as a mechanism for generating high earnings needed to cope with the extreme financial endeavour of pharmaceutical research. In fact, looking at this from a TWAIL perspective, the reluctance to adapt technology to local context so as to encourage domestic inventiveness can be seen as a vestige of colonial exchanges. That is, it perpetuates a structure wherein the Global North continues to be the privileged centre of knowledge and technological advancement to the exclusion and detriment of the subaltern. This continues the ownership and concentration of technology in the Global North, forestalling the development of and continuing the technology dependency of developing countries. However, it can also be argued that responsibility lie with the Nigerian government that did not take deliberate steps to ensure the development of local technological knowledge. This is unlike India where the government, in addition to changing its patent law, also invested in education especially in the area of chemistry, pharmaceutical research, and biotechnology, and built sophisticated research institutions.¹⁵⁰ In a similar vein, the Brazilian government also created the Central Medicines Agency (CEME) in order to develop the country's pharmaceutical technology base.¹⁵¹

¹⁴⁹ Terisa Turner, 'Multinational Corporations and the Instability of the Nigerian State' (1976) 3 *Review of African Political Economy* 63, 65.

¹⁵⁰ Ch 4, s 4.1.

¹⁵¹ Ch 3, s 3.1.

Furthermore, even though foreign drug companies were engaged in pharmaceutical manufacturing, they were not financially equipped nor ideologically engaged to participate in cognitive shaping and expertise production in relation to patent governance. That is, many of the local affiliates of foreign companies were concerned with repatriating profits to the parent company, usually located in Europe or North America.¹⁵² For example, 50 per cent of Nigeria's foreign exchange outlay on imported drugs at that time, Ebohon states, went to Britain where most of the companies producing drugs in Nigeria have their headquarters.¹⁵³ This is still being practiced by the subsector. Commenting on this, Abraham Okeke notes that 'once his company [Swiss Pharmaceuticals] achieves its financial target, the money is immediately wired abroad.'¹⁵⁴ It can be suggested, therefore, that foreign subsidiaries in operation at the time were not involved in active participation or engagement with domestic patent regime introduced five years prior.

Thus, even though the Nigerian economy was growing during that period thanks to the oil boom, this growth was largely ephemeral, i.e. characterised largely by foreign-owned and foreign-managed industries, often dependent on imported raw materials and engaged in aggressive transfer pricing and money laundering schemes where profits are shifted from the country where they are in business into locations where they are often not in business. This structural contradiction in the pharmaceutical industry became obvious when the oil boom began to decline. To reconfigure the dominance of foreigners in the economy, which was also apparent in other sectors, the government introduced the Nigerian Enterprises Promotion Decree of 1972 – often referred to as the Indigenisation Decree.¹⁵⁵

The Indigenisation Decree was a series of private sector-focused policy instruments introduced by the federal military government to prevent continued foreign monopoly of the vital productive sectors of the country's economy.¹⁵⁶ Through this Decree, the government sought to reserve certain categories of industrial activity for Nigerian citizens by compelling foreign businesses in a large number of specified activities to transfer their ownership wholly

¹⁵² Raymond Baker, 'Plundering a Continent' (*Global Financial Integrity*, 2012) <<http://www.gfintegrity.org/press-release/plundering-a-continent/>> accessed 29 March 2016 ('Plundering a Continent'); Peterson, *Speculative Markets* (n 141) 42.

¹⁵³ Ebohon, 'Nigerian Policy Towards Foreign Companies' (n 142) 154.

¹⁵⁴ Fieldwork interview with Okeke (n 130).

¹⁵⁵ Prior to the Nigerian Enterprises Promotion Decree of 1972, the Nigerian government implemented various laws to increase the participation of Nigerians in the economy. These included the Immigration Law of 1962, which sought to control the entry of foreign business into Nigeria; the Companies Decree of 1968, which aimed to bring under the control of the Nigerian government 'local' subsidiaries of foreign firms, and later to secure the participation of Nigerians in such businesses; and the Industrial Training Fund Decree of 1971, which sought to encourage the acquisition of relevant industry skills in order to create a ready source of indigenous manpower capable of playing a more meaningful role in the fast-growing Nigerian economy.

¹⁵⁶ Chibuzo SA Ogbuagu, 'The Nigerian Indigenization Policy: Nationalism or Pragmatism' (1983) 82 *African Affairs* 241.

or partly to private Nigerian investors and businessmen.

The aim of the policy was three-pronged. First, to encourage more involvement of Nigerian citizens in the ownership, management, and control of productive enterprises in the country.¹⁵⁷ Second, to reduce profit repatriations and ensure greater retention of profits accruing from the economic sector.¹⁵⁸ Third, to enhance industrial development by substantially encouraging transfer of technology from foreign investment in intermediate and capital goods production.¹⁵⁹

The Decree was introduced in two phases. The first phase of the Decree in 1972 promulgated that Nigerians had to hold at least 40 per cent equity shares in certain industries, while the second phase in 1977 mandated that 60 per cent of transnational corporate assets be sold to Nigerian indigenes.¹⁶⁰ It was the 1977 Decree which targeted industries with local manufacturing and production presence that affected the pharmaceutical subsector.

The Indigenisation Decree was predicated on a strong feeling of political and economic nationalism and not based on the actual existing capability or readiness of Nigerian indigenes to perform higher functions in the productive sector of the economy. Of course, this new nationalistic thinking did not happen in a vacuum. It grew out of two factors. First, the experience of the Nigerian civil war, which changed the country's attitude towards foreign capital. According to Ebohon, the refusal of Britain and America – Nigeria's traditional allies – to come to the aid of the federal government in nipping the secessionist agenda reversed the country's official thinking against the open-door policy towards Western capital.¹⁶¹ Second, the emergence of ideas regarding the development of a New Economic Order further propelled the enactment of the Decree. Like Brazil and India, there was growing discontent – circulation of ideas of some sort – within the Nigerian government regarding the unequal exchange and exploitation between developed and developing nations. For Nigeria, this deepening shift and perspective on global economic systems manifested in its readiness to canvass for a new international economic system where developing countries would attain economic parity. Thus, it is not surprising that the emerging intellectual discourse and politics reflected – at the time – the suspicion of Nigerian policymakers of private foreign investors

¹⁵⁷ *ibid.*

¹⁵⁸ *ibid* 251.

¹⁵⁹ Andrew H Apter, *The Pan-African Nation: Oil and the Spectacle of Culture in Nigeria* (University of Chicago Press 2005) 38.

¹⁶⁰ *ibid.*

¹⁶¹ SI Ebohon, 'Conflict and Accommodation in a Post-Imperial Order: Reflections on Nigerian Policy towards Foreign Capital, 1972-2010' (2012) 1 *International Journal of Developing Societies* 62 ('Conflict and Accommodation in a Post-Imperial Order').

and the emergent concern against colonial and neo-colonial structures anywhere in Africa. By promulgating the Indigenisation Decree, the government hoped to achieve an exclusion or complete elimination of foreign personnel from commercial and industrial activities.

The Indigenisation Decree succeeded in transferring a significant percentage of transnational assets into local hands. For example, in the pharmaceutical sector and prior to the Indigenisation Decree, foreign pharmaceutical companies were private with 100 per cent foreign equity capital.¹⁶² By 1974, two years after the implementation of the first phase, the stake of indigenous stakeholders in the subsector increased. According to Ebohon, by this period, seven of the 13 foreign plants operating in the country divested at least 40 per cent of their equity holdings for purchase by Nigerian investors, while the remaining 60 per cent were still retained by the parent companies.¹⁶³ By 1979, two years after the second phase was enacted, 12 out of the 13 foreign drug plants were completely indigenised.¹⁶⁴ This, in turn, led to an unprecedented growth of local entrepreneurs and succeeded in including Nigerians in this key sector.

However, some commentators take the view that the Decree also fostered the growth of a comprador class – members of a national business class of senior corporate managers who derive their position and status from connection to foreign corporations of developed nations.¹⁶⁵ In his analysis of the Indigenisation Decree, Ogbuagu argues that the comprador class lacked the ‘capital, skilled managerial and technical knowledge in manufacturing to effectively and meaningfully replace the foreigners in the industries reserved for them by law.’¹⁶⁶ In fact, Ebohon mentions that most of the new equity holders in the pharmaceutical companies were retired army officers, traditional rulers, and local businessmen who had little or no knowledge on how to run technology- and research-intensive pharmaceutical companies. Not only that, most of these indigenous investors were able to buy their pharmaceutical equity due to their connection to the government or foreign executives.¹⁶⁷ This view is supported by Andrew Apter, who notes that the equity shares from the indigenisation policy ‘were privately distributed to connected partners who would tow management line with their dividends and as a result, led to less active involvement of Nigerians in the management and more the rise of a newly connected elite who formed a tight circle of

¹⁶² Ebohon, ‘Nigerian Policy Towards Foreign Companies’ (n 142) 189.

¹⁶³ *ibid* 190.

¹⁶⁴ *ibid*.

¹⁶⁵ Kenneth Roberts, *Key Concepts in Sociology* (Palgrave Macmillan 2008) 41.

¹⁶⁶ Ogbuagu ‘The Nigerian Indigenization Policy’ (n 156) 264.

¹⁶⁷ Ebohon, ‘Nigerian Policy Towards Foreign Companies’ (n 142) 199.

comprador cronies around foreign capital.’¹⁶⁸ Other scholars such as Iwuagwu further reports that the Decree hardly changed company control or relationships with parent companies, but instead changed the leadership (e.g. chairman of the Board).¹⁶⁹ As a result, the Nigerians were mostly figureheads without any serious executive or administrative responsibilities bequeathed to them, while foreign owners continued to occupy almost all strategic positions. This often led to cases of indigenous managers colluding with foreign companies.¹⁷⁰ The negative effect of this cronyism, Thomas Biersteker goes on to report, was that dividends of shares were not productively invested back into the business but favoured patterns of conspicuous consumption.¹⁷¹ Subsequently, the indigenous managerial class which the Decree sought to construct became effectively ‘denationalized since it acted as a peripheral managerial class to foster the growth of global accumulation.’¹⁷²

In essence, although the Indigenisation Decree reduced the presence of foreign participation, it did not really lead to positive structural change in the subsector. The fact that foreign pharmaceutical companies were engaged in elementary formulation and packaging activities in the first place meant that new Nigerian managers were not privy to advanced technological information that could have been adapted locally. In fact, Ebohon states that despite the rudimentary production activities in these plants, expatriates still controlled their daily management.¹⁷³ These expatriates were in collaboration with their headquarters abroad which made critical corporate decisions while Nigerian managers only rubber-stamped decisions already taken outside the country. Thus, though the Decree indigenised equity, it did not indigenise technology nor facilitate technology acquisition that would have enabled original drug production.

The Indigenisation Decree was not the only policy implemented by the Nigerian government in its attempt to facilitate technology transfer and subsequently attain industrialisation. Like most other post-colonial states at that time, Nigeria also introduced and implemented the ISI policy.¹⁷⁴ As previously discussed (see Chapter 3 on Brazil), the ISI strategy sought to

¹⁶⁸ Apter, ‘The Pan-African Nation’ (n 159) 37.

¹⁶⁹ Obi Iwuagwu, ‘Nigeria and the Challenge of Industrial Development’ (2009) 37 *African Economic History* 161.

¹⁷⁰ Ebohon, ‘Nigerian Policy Towards Foreign Companies’ (n 142) 124.

¹⁷¹ Thomas Biersteker, ‘Indigenization and the Nigerian Bourgeoisie: Dependent Development in an African Context’, *The African Bourgeoisie: The Development of Capitalism in Nigeria, Kenya and the Ivory Coast* (1st edn, Lynne Rienner Publishers 1987) 148.

¹⁷² Ebohon, ‘Nigerian Policy Towards Foreign Companies’ (n 142) 125.

¹⁷³ *ibid* 221.

¹⁷⁴ For an assessment of the ISI implementation in Nigeria, see Tom Forrest, *The Advance of African Capital: The Growth of Nigerian Private Enterprise* (University Press of Virginia 1994); Charles Chukwuma Soludo, Michael Osita Ogbu, and Ha-Joon Chang, *The Politics of Trade and Industrial Policy in Africa* (Africa World Press 2004); Adebayo Olukoshi, *The Politics of Structural Adjustment in Nigeria* (James Currey 1993); Festus O Egwaikhide, ‘Import Substitution Industrialisation in Nigeria: A Selective Review’ (1997) 39 *The Nigerian Journal of Economic and Social Studies*; Ana Paula F Mendes, Mário A Bertella and Rudolph FAP Teixeira, ‘Industrialization in Sub-Saharan Africa and Import Substitution

mobilise national economic resources in order to establish domestic production facilities for manufacturing goods which were formerly imported. The same ethos underpinned the ISI policy instruments introduced in Nigeria in the early '60s and continued till the '80s. Precisely, the government hoped that in eliminating importation, it would kick-start domestic production and initiate local industrialisation. Industrialisation would subsequently produce much needed dynamic change in the economic structure of the country, with attendant substantial benefits trickling down to the people.

It has been argued that economic performance in the decades after the implementation of the ISI strategy was unimpressive. Instead of reducing the country's over-dependence on imported goods, it intensified Nigeria's external dependence since the country relied on imported raw materials, foreign technology, and even skilled manpower.¹⁷⁵ In the pharmaceutical sector, the ISI policy proved to be antithetical to growth and was a highly ineffective strategy for development. This is due to the sector's heavy reliance on imported raw materials, foreign technology, and skilled manpower. For example, estimates show that 80 to 90 per cent of raw materials required by foreign companies with manufacturing bases in Nigeria in the 1970s and early 1980s were imported.¹⁷⁶ The situation has not changed to any great extent in recent decades, with a 2011 report by the UN Industrial Development Organization stating that Nigerian drug manufacturers still imported all their active pharmaceutical ingredients and virtually all their inactive pharmaceutical ingredients such as adhesives, syrups, etc.¹⁷⁷ Evidence from the fieldwork interviews for this thesis further corroborates this. All pharmaceutical executives that were interviewed mentioned that they wholly import the items used in their factories.¹⁷⁸ One executive explained the situation:

We import all our products even packaging. Everything is imported in this country including our packing such as cartons and outer packing including paper. The only thing we do not import is water, however, the ingredient we use in purifying the water are all imported. No pharmaceutical raw material is manufactured in Nigeria. None.¹⁷⁹

Like the Indigenisation Decree, the government ignored many of the factors needed for

Policy' (2014) 34 Rev Econ Polit; LN Chete and others, 'Industrial Development and Growth in Nigeria: Lessons and Challenges' (The Brookings Institute 2012) <http://www.brookings.edu/~media/Research/Files/Papers/2014/11/learning-to-compete/L2C_WP8_Chete-et-al.pdf?la=en> accessed 11 May 2014.

¹⁷⁵ Mendes, Bertella, and Teixeira 'Industrialization in Sub-Saharan Africa and Import Substitution Policy' (n 174) 121; Chete and others, 'Industrial Development and Growth in Nigeria' (n 174) 2.

¹⁷⁶ Ebohon, 'Conflict and Accommodation in a Post-Imperial Order' (n 161) 27.

¹⁷⁷ Charles Wambebe and Nelson Ochekepe, 'Pharmaceutical Sector Profile: Nigeria' (United Nations Industrial Development Organization (UNIDO) 2011) 35 <https://www.unido.org/fileadmin/user_media/Services/PSD/BEP/Nigeria_Pharma%20Sector%20Profile_032011_Ebook.pdf> accessed 2 August 2015.

¹⁷⁸ Fieldwork interviews with senior pharmaceutical company executives (Lagos, July 2016) (transcript on file with author).

¹⁷⁹ Fieldwork interview with Ajufo (n 131).

overseeing the emergent industrial sector such as the management of technologies transferred or acquired. Chete et al., in their analysis of the ISI programmes, note that it was the need to rectify the shallow nature of Nigeria's technological capacity, among other factors, which fuelled the implementation of the Indigenisation Decree.¹⁸⁰ However, as the analysis above has shown, the unsuccessful indigenisation of technical and technological capabilities required for initiating, executing, and managing pharmaceutical projects subsequently limited implementation. Consequently, there is a near complete absence of indigenous R&D in Nigeria's drug sector. Balance of payments problems also affected imports and other resources required for industrial production, thereby imposing additional obstacles to industrial development.¹⁸¹ The end of the oil boom in the 1980s and the SAP further exacerbated the obstacles.

The oil bust of the early 1980s left the country fiscally and structurally exposed. This led to a deterioration of public finances, a balance of payments crisis, foreign exchange shortage, and a debt crisis. To rectify this, the World Bank and IMF recommended a series of fiscal and economic policy reforms which the Nigerian government accepted and implemented in 1986. These included the devaluation of the Nigerian naira, removal of subsidies and grants on food, agricultural, and petroleum products, the curtailment of loans to state government, and the privatisation of public enterprises.¹⁸² The SAP policies aimed at realigning domestic expenditure and production patterns so as to reduce dependence on imports, enhance the non-oil export base, and put the economy on the path of steady and balanced growth.¹⁸³

The effects of the SAP policies have been diverse in Nigeria. While the microeconomic reforms have yielded little result, the negative social ramifications were immense. The devaluation of the currency led to price inflation and massive job loss, plummeting many into below the poverty line. The privatisation of health care also led to the introduction of user fees and increased domestic expenses, while the removal of the subsidy on fuel and agricultural goods increased hardship and household poverty incidence, especially for Nigeria's middle class and poor who depend on government-subsidised programmes.

Of all the policies introduced, the devaluation of the Nigerian currency had the most negative impact on the pharmaceutical sector. Devaluation decreased earnings and increased the prices

¹⁸⁰ Chete and others (n 174) 2.

¹⁸¹ *ibid.*

¹⁸² Yusuf Bagura, 'IMF and World Bank Conditionality and Nigeria's Structural Adjustment Programme', *The IMF and the World Bank in Africa: Conditionality, Impact and Alternatives* (1st edn, Scandinavian Institute of African Studies 1987) 100.

¹⁸³ NCEMA (n 128).

of food and other basic necessities, which in turn caused a sharp deterioration in the living standards of the majority of the people. Per capita income declined from USD949.4 in 1985 to USD280.7 in 1987 and fluctuated between USD240 and USD361 between 1988 and 2000.¹⁸⁴ Consequently, the population living below the poverty line rose from 34.7 per cent (75.0 million) in 1985 to 67.1 per cent (102.3 million) in 1996.¹⁸⁵ A general decline in per capita income meant that the previously relatively affluent middle class could no longer indulge in luxury goods and expensive brand-name drugs, which affected the sales output and turnover of drug companies. Peterson asserts that drug companies which had previously occupied a major chunk of the Nigerian market could no longer operate in the country because the naira was rapidly losing value, leading to a general decline in sales.¹⁸⁶ As a result, 'the brand-name companies in operation at that time either completely ended their product lines and manufacturing or attempted to move their activities to other existing markets.'¹⁸⁷

Furthermore, devaluation also increased the cost of imports as these companies mostly imported the APIs needed in drug manufacturing. The market effect was increased price of drug manufacturing but poor sales, as consumers could no longer afford the now expensive products. The situation further worsened as the government scaled back on financing and providing essential health services. Consequently, the brand-name parent companies ended credit extensions to local marketers cum pharmacists and when the pharmacists could not pay off their debts, their businesses folded. With high financial and market loss, the brand-name companies divested from their Nigerian businesses – or what Peterson termed as market abandonment¹⁸⁸ – which generated a massive shortage of drugs. Within 10 years of the implementation of the SAP in 1986, the majority of pharmaceutical companies ceased production.¹⁸⁹

The above analysis of select Nigerian industrial policies shows how these policies incapacitated the ability of the pharmaceutical sector from developing. Also, in not engaging in adaptive research on patented drugs, foreign drug companies blocked the transfer of technology to the host country, Nigeria. Since the research intensity of the foreign pharmaceutical industry was not replicated in the Nigerian affiliates beyond basic formulation and minor quality control activities, this severely limited the prospect for local technological

¹⁸⁴ *ibid* 35.

¹⁸⁵ *ibid*.

¹⁸⁶ Peterson, *Speculative Markets* (n 141) 55.

¹⁸⁷ Kristin Peterson, 'On the Monopoly: Speculation, Pharmaceutical Markets, and Intellectual Property Law in Nigeria' (2014) 41 *American Ethnologist* 131 ('On the Monopoly').

¹⁸⁸ *ibid* (emphasis added).

¹⁸⁹ Peterson, *Speculative Markets* (141) 54.

development. Consequently, due to the absence of indigenous R&D in the subsector, the attendant regime of patents necessary to protect and reward the development of innovative products will be lacking. In this scenario, there will be no need for local pharmaceutical companies to engage and mobilise the government on patent issues. This explains the absence of the pharmaceutical private sector in the patent regime and discourse in Nigeria.

Civil Society Organisations

As shown in previous chapters, the mobilisation of civil society groups in Brazil and India is rapidly changing the prosaic materialisation and architecture of domestic legal regimes governing patents. Couching their activism on the constitutional right to health (as in Brazil) and access to medicines (as in India), civil society groups have – in the last decade or so – enhanced their scope to include in their advocacy issues relating to IP law, specifically the impact of patent protection on public health. That is, they have managed to problematize the patent regime as a barrier to access to life-saving drugs because of the monopolistic power of patents to push up prices of drugs beyond the reach of those who desperately need it. By problematizing patent laws as espoused in TRIPS Agreement as antithetical to access, Brazilian and Indian civil society groups did not only establish causation but connected facts in ways that helped determine responsible parties (brand-name pharmaceutical companies and unfavourable local laws) as well as ways to remedy the situation.

The consequential effect of this framing is the rise in civic activism on patent-related litigation, notably public action to issue CLs, the filing of amicus curiae briefs in patent-related cases, and in using domestic legal processes such as pre- or post-grant oppositions and the constitutional right to health to challenge patent grants. This has led to dramatic policy resolutions, radical legal decisions, and the transformation of rights-based activism and relief work. Importantly, civil society groups have helped in the mainstreaming and cognitive shaping of public discourse on IP and patents – a subject area that has previously been an exclusive preserve of jurists, academics, and scientists. This is in direct contrast to civil society workings in Nigeria.

Nigeria's CSOs are complex and have a highly varied socio-economic history and taxonomy. Their activism is marked by their proliferation and fragmentation, which has subsequently impacted the ideation of civil society participation. Up until the early 1980s, civil society activism was neither popular nor mainstream and civil disobedience in the form of trade union strikes was mainly organised in reference to issues of marginalisation and dissatisfaction with

government policies.¹⁹⁰ During this period, most CSOs appeared to be ‘immersed solely with exalting and defending the distinctive interests of their members, especially in the area of private practice in various professional occupations or along ethnic/tribal lines.’¹⁹¹ It was not until the oil boom and the attendant rise in educational standards that the language of human rights gained currency in Nigeria and was co-opted by these groups in the framing and contestation of advocacy issues. Since then, groups such as trade unions, religious institutions, student unions, and professional associations such as the Nigerian Bar Association and Nigeria Labour Congress – the latter being an umbrella organisation for trade unions in Nigeria – dominate the civic engagement space.

Using the language of human rights, these groups campaigned for specific economic and social demands such as improved conditions for the masses, environmental rights, and resistance against state corruption. For example, when the SAP was implemented, student-led riots and trade union strikes, which ground the country to a halt, were framed on social and economic rights to education, health, and social safety nets which the programme destroyed. Likewise, when the military regime annulled the 1993 election that was widely seen by many as free and fair, civil society activity was further galvanised to assume a pointed organisational focus on the civil and political right to vote. These groups were able to organise massive protests that pushed General Babangida – the then military dictator – from office in 1993 when his long transition programme finally proved fraudulent. In fact, according to Kew and Oshikoya, CSO activism ‘spearheaded by human rights organizations, joined forces with trade unions, the Bar, student unions, and most importantly, the leading political opposition party to force Babangida to hand power to a transitional government offering to hold new elections.’¹⁹²

The return to democratic rule in 1999 increased the number and variety of civil society activism in the public space to include patient groups, foreign donor-funded organisations, and even foreign NGOs working on various issues such as election monitoring, lesbian and gay issues, religious rights, and public health implementation programmes. In a study conducted by Ogbogu and Idogho, it was shown that CSOs comprising of community

¹⁹⁰ Abdul Raufu Mustafa, ‘Civil Rights and Pro-democracy Groups in and Outside Nigeria’, *Nigeria during the Abacha Years (1993-1998): The Domestic and International Politics of Democratization* (1st edn, Institut Français de Recherche en Afrique 2001) 145. See also Chidi A Odinkalu, ‘The Management of Transition to Civil Rule by the Military in Nigeria (1966-1996)’, *Nigeria during the Abacha Years (1993-1998): The Domestic and International Politics of Democratization* (1st edn, Institut Français de Recherche en Afrique 2001).

¹⁹¹ Matthew Todd Bradley, ‘Civil Society and Democratic Progression in Postcolonial Nigeria: The Role of Non-Governmental Organizations’ (2005) 1 *Journal of Civil Society* 61, 66.

¹⁹² Darren Kew and Modupe Oshikoya, ‘Escape from Tyranny: Civil Society and Democratic Struggles in Africa’, *The Handbook of Civil Society in Africa* (1st edn, Springer 2013) 15.

development associations, support groups for PLWHA, and other health groups played important roles in the earlier phase of Nigeria's response to the HIV/AIDS epidemic.¹⁹³ Today, these CSOs are significant actors in the implementation of the public health programme on malaria, HIV/AIDS, tuberculosis, and infant or maternal care, to mention a few, with these programmes ranging from prevention to care and support. This new generation of public health CSOs is more cosmopolitan and has ties with international organisations such as the UN, the WHO, and the GFATM. They attend international conferences, receive funds from foreign governments and donor organisations, and are party to a global discourse on public health management, especially regarding diseases that plague Nigeria.

In spite of this, there is paucity in Nigerian CSO engagement and activism around IP-related issues and their impact on public health. This raises the question of why have these organisations not gone beyond basic implementation programmes and service delivery roles to a substantial role bordering on the problematizing of institutional frameworks that create barriers to access and treatment. That is, why is civil society activism in Nigeria not targeting structural issues such as fixing patent laws in Nigeria to ensure medicine access and sustainable public health management? The answers to this question is three-pronged.

First, the psychological effect of military dictatorship adversely affected civil society psyche and blunted the once dynamic civil society activism. Since independence from Britain in 1960, Nigeria has experienced civilian rule (1960-66, 1979-83, and 1999 onwards) and military rule (1966-79 and 1983-99). The period of military regime stands out clearly as the architect of collective disenchantment in civil society engagement.

Due to the austerity measures introduced by the military government at the onset of the oil bust, many civil society groups participated in acts of civil disobedience such as public demonstrations and strikes as a way to inform the government of their displeasure with the austerity measures. In response, the military government proscribed several CSOs, mostly labour unions and professional associations, that dared to criticise its policies or which embarked on public demonstrations and strikes. Key figures were arrested, detained, and sometimes tortured without recourse to legal processes. As Remi Aiyede has pointed out, the military regime introduced decrees that not only allowed for persons to be detained for a period of three months without trial for any act prejudicial to state security but also placed the

¹⁹³ Irene Ogbogu and Omokhudo Idogho, 'The Role of Civil Society Organizations in HIV/AIDS Control', *AIDS in Nigeria: A Nation on the Threshold* (1st edn, Harvard University Press 2006) 297.

government above the law by protecting the military government against court proceedings by public sector workers.¹⁹⁴

In addition to overt repression, which created an extremely oppressive climate, the military government bought out political and civil actors through bribery and material inducement, thereby co-opting the civil society movement and corrupting its moral foundations. Kew and Oshikoya, for example, observed the devastating effect of the SAP, which gutted public infrastructure and social safety nets and increased government largesse which proved increasingly irresistible to political leaders and some civil society actors.¹⁹⁵ This worsened economic situation made it easy for some activists to be easily influenced. Likewise, Peter Lewis states that the government 'diversified its strategies of control to include political manipulation, populist side-payments, elite dispensations, expansion of the parallel economy and political patronage.'¹⁹⁶ The regime bankrolled many several groups to openly canvass for the prolonging of military rule and countering of democratisation pressures, subsuming the rest under various government ministries, undermining their effectiveness and affecting their focus.¹⁹⁷ By co-opting CSO activism, the government was able to quell their influence.

Even the coming of General Sani Abacha into power in 1993, who continued the military dictatorship in Nigeria, did not abate the repression of civilian and democratic activism. If anything, the Abacha regime intensified the climate of fear and authoritarian control. Particularly, the hanging of the environmental rights activist Ken Saro-Wiwa along with eight others in 1995 created a collective feeling of despair, despondency, and powerlessness among key activist groups. Even though the return to civilian rule in 1999 added a new lease on life to CSO advocacy in Nigeria as the various groups recovered their strength and bargained major reforms with the democratic government, the state continues to use, in certain occasions, intimidation techniques. The overall impact of this on the national psyche is the pacification of even the most ardent of groups and a reduced influence of civil society sway. Therefore, it is not surprising that CSOs working on public health continue to demonstrate this weakened position, especially with their inability to foment policy-deepening coalitions.

Second, the overwhelming presence of donor funding in the provision of health services also explains why Nigerian public health-focused CSOs have not directed their gaze towards

¹⁹⁴ E Remi Aiyede, 'The Dynamics of Civil Society and the Democratization Process in Nigeria' (2003) 37 *Canadian Journal of African Studies / Revue Canadienne des Études Africaines* 1, 8-9.

¹⁹⁵ Kew and Oshikoya (n 192) 15.

¹⁹⁶ Peter Lewis, 'From Prebendalism to Predation: The Political Economy of Decline in Nigeria' (1996) 34 *The Journal of Modern African Studies* 79, 88.

¹⁹⁷ Aiyede (n 194) 10.

patents. This is largely due to the fact that most of the essential medicines for diseases such as HIV/AIDS, malaria, and tuberculosis dispensed in hospitals are provided by donor organisations. In an interview, the Assistant Director for Policy and Strategy of the National Agency for the Control of AIDS (NACA) mentioned that majority of drugs used in the treatment of HIV/AIDS, malaria, and tuberculosis are donated to the Nigerian government. She explains further:

Majority of the drugs we dispense are given to us by international organizations such as Global Funds, the US President's Emergency Plan for AIDS Relief (PEPFAR), United Nations AIDS Program (UNAIDS). Domestic HIV funding has been very low and unstable, and that is why we largely depend on international funding sources.¹⁹⁸

Similarly, the Director of the Saving One Million Lives Initiative, Dr. Kelechi Ohiri, states:

Majority of the NGOs here receive donor funding which they use to procure the drugs. In this environment, there will be no need to look at patent issue as patent is not seen a problem or hindrance to medicines access.¹⁹⁹

In fact, the President's Comprehensive Response Plan for HIV/AIDS in Nigeria states that 74.65 per cent of the HIV/AIDS fund is donor-sourced while the remaining 25 per cent is from the Nigerian government.²⁰⁰ In contrast, 100 per cent of Brazil's HIV/AIDS programmes are funded by the Brazilian state (federal, state, and municipal governments)²⁰¹ while the Indian government provides 90 per cent of the funds for its AIDS programmes.²⁰² In another report, the 2014 National HIV/AIDS Epidemiological and Impact Analysis, which provides scientific insight into the nature of Nigeria's HIV/AIDS epidemic and the impact of government efforts, provides that international funding steadily increased to USD445.2 million in 2012 from USD317.2 million in 2009 (35 per cent of this was spent on treatment and care).²⁰³ It follows, therefore, that the overwhelming presence of donor funds has a noticeably disempowering effect on CSO engagement on patent issues in Nigeria. Since majority of funds for medicine purchase are internationally sourced, then patents – which are

¹⁹⁸ Fieldwork interview with Ope Abegunde Assistant Director, Policy and Strategy, NACA (Abuja, February 2015) (transcript on file with author).

¹⁹⁹ Fieldwork interview with Kelechi Ohiri, Director, Saving One Million Lives Initiative (Abuja, January 2015) (transcript on file with author).

²⁰⁰ Federal Ministry of Health, 'President's Comprehensive Response Plan for HIV/AIDS in Nigeria' (Federal Ministry of Health 2013) 19 (PCRPP Report).

²⁰¹ Interview with Fabio Mesquita, Director National HIV/AIDS Program, Ministry of Health (Brasilia, June 2014) (transcript on file with author).

²⁰² 'HIV and AIDS in India' (*Avert.org*, 2015) <<http://www.avert.org/professionals/hiv-around-world/asia-pacific/india>> accessed 26 March 2016.

²⁰³ National Agency for the Control of AIDS (NACA), 'National HIV/AIDS Epidemiology and Impact Analysis (NHEIA) Report' (NACA 2014) 47. Nigeria has the second highest HIV burden in Africa after South Africa, with 3.4 million people living with HIV and only 491,021 receiving ARV drugs. The country's tuberculosis burden is equally high at 100,401. For assessment of HIV/AIDS burden in Nigeria, see National AIDS/STI Control Programme, 'Integrated National Guidelines for HIV Prevention, Treatment and Care' (Federal Ministry of Health 2014).

problematized in Brazil and India as the reason for high drug prices and encumbrance to medicine access – are eliminated. In other words, patents are not seen as a problem. This means that there is less tendency for CSO groups to engage the state on patent law reform or to insist on the use of TRIPS flexibilities to ensure availability of and access to medicines.

Third, there is a general lack of patent knowledge or awareness on patent issues. While Nigeria is active at the international level, often championing the cause of the African Group,²⁰⁴ local awareness of the IP regime is deficient. For example, a health activist who was interviewed stated:

I don't know intellectual property because it is not an issue for us in Nigeria. Our problem is corruption and the mismanagement of donor funds. Patent is not the issue here, corruption is. There is the GAVI problem that is heating up the Ministry of Health right now. It is issues like these that we focus on. There is also the bureaucracy problem that causes drugs stock-outs. We have instances where ARVs worth thousands of dollars have been destroyed because they were unused and some even expired, yet if you go to Garki [Government hospital] they tell you they don't have drugs. But the money is there, the drug is there so what happened to them?²⁰⁵

Correspondingly, Kelechi Ohiri elucidates:

Patent is a non-issue here and there are many reasons for that. There is no strong policy space to trigger the kind of discussions and activism you have in Brazil and India. Donors provide the funds for procurement and for many of these CSOs, procurement is opportunity for graft. Also, donor organisations are not really interested in setting up frameworks on IP and access related issues mainly because result and monitoring is ambiguous. Add to the fact that these organisations are looking for value for their money.²⁰⁶

In fact, a report by a local newspaper showed how significant government and donor funding in the HIV/AIDS campaign failed to translate to good numbers due to corruption. According to the report, Nigeria spent more than USD4.4 billion between 2008 and 2012 on HIV/AIDS treatment, yet the number of people living with HIV/AIDS in Nigeria rose from 2.98 million to 3.5 million; AIDS-linked deaths climbed from 192,000 to 217,000; and new infections increased from 336,000 to 388,000 during that same period.²⁰⁷ These statistics provide glaring

²⁰⁴ Ukpanah (n 39).

²⁰⁵ Fieldwork interview with a health activist (Abuja, January 2015) (transcript on file with author). The GAVI issue the interviewee referred to was the cash programme audit report on funds disbursed to Nigeria to support immunisation activities from 2011 to 2013. The audit was undertaken by GAVI's Programme Fiduciary Oversight team. The report describes systemic weaknesses regarding the operation of controls and procedures in national systems used to manage GAVI cash-based support. As a result of specific findings, the government of Nigeria has agreed to repay funds deemed to have been misused, which are quantified as USD2.2 million (copy of report on file with author).

²⁰⁶ Fieldwork interview with Ohiri (n 199).

²⁰⁷ Bunno Esdiaké, 'Nigeria's HIV/AIDS Fight Gulps Billions of Dollars, Yields Little' (*Telegraph Newspaper*, 2013) <<http://telegraphng.com/2013/10/nigerias-hiv-aids-fight-gulps-billions-dollars-yields-little/>> accessed 29 October 2013.

evidence to support the argument that huge amounts of money donated to fight HIV/AIDS are being siphoned away. Therefore, when faced with issues of corruption, it is perhaps unsurprising that the legal consciousness about the possibilities of patents is absent among CSO circles in Nigeria. For these actors, treatment activism is about ensuring availability of drugs and vaccines donated by foreign organisations as well as ensuring that there are effective systems to deliver these to all who need them. In this context, priority is given to the development of stronger, sustainable, and efficient health systems and not on the reform of patent law as the latter is not seen as problematic.

Furthermore, in Nigeria, patent law is not part of life. That is, it is not living law. It also does not help that that law as it stands is old. As discussed in the previous section, the current patent law was passed 45 years ago in 1970 and though it was modified in 1990, the modifications are minor and not up to date. This, coupled with the problem of insufficient legal knowledge on patent issues, explains why many CSOs do not engage with it. As a result, there is also little or no understanding in NGO circles of how international regimes such as the TRIPS Agreement affect access to drugs. This points to the need for the law to adapt to changing social needs. In the analyses of the Brazil and Indian patent regimes, the ‘living law’ of patents was observed. In those jurisdictions, law in action²⁰⁸ was evident – in policy tools, in commerce, and engaged with by many associations, not only by those that the law has recognised (inventors) but also by those that it has overlooked or passed by (patient groups, the sick, and health activists). In these jurisdictions, patent law is seen as an instrument which could be used to solve social problems, i.e. to protect and incentivise invention, while also used to resolve social issues, e.g. access to medicines. In engaging in claims and counter-claims put forward and bargained over by these competing groups, patent norms are expanded and amplified.

If anything, the analysis in this section has underscored an omission prevalent in the literature on access to medicines – the importance of local actors patent discourses. Particularly, it advances existing knowledge on how the use of legal and regulatory tools of patents is linked to the practices of different actors, such as inventors (in this case, brand-name or generic pharmaceutical manufacturers) and civil society groups, that underpin the regime.

²⁰⁸ Thanks to Professor David Nelken of Kings College for this point.

5.5 Summarising the Nigerian Context

This chapter has critically discussed the patent regime in Nigeria. Specifically, its origins, the main sections governing patent rights, and how it interacts with the TRIPS Agreement. It also highlighted the ways in which regulatory agencies and non-state actors engage with patent law.

As mentioned in previous chapters, pharmaceutical patents operate under the notion that an inventor should disclose the invention to facilitate development and for public consumption of the patented invention. In turn, the inventor is given the exclusive right to price and sell the invention for a limited time in a competition-free environment in order to recoup the investment for developing said invention. Thus, the patent system is a social institution created to facilitate this exchange.

Underlying this notion of exchange between inventors versus the state or consumer is the assumption of fair market; that is, an equitable just structure that allows buyers (in this case, the state or consumers) and sellers (in this case, inventors) to exchange any type of good (patented invention). However, how the market should work to facilitate this fair exchange is not defined in patent law even though actions such as CLs exist as corrective measures against market failures. This structure of patents raises the crucial question of what happens when the market *does not exist*, as was the case in Nigeria when brand-name companies pulled out of the country and indigenous manufacturers were unable to fill the vacuum.

Importantly, this structure also raises the question of what is the actual purpose of patent law when key actors (inventors or in this case, pharmaceutical companies) that underpin the fair exchange are absent? In the case of Nigeria where widespread pharmaceutical manufacturing infrastructure is absent, patent regime is inconsequential. The concomitant effect is that actors (pharmaceutical industry stakeholders) that normally push for a robust patent regime in policymaking circles and in influencing government decisions cannot do so. This is unlike in India where the patent regime was hugely influenced by the existence of a strong pharmaceutical sector. It would not be unreasonable to presume that the level of interest in the various epochs of Indian patent regime development – from the 1970s when the country changed its colonial law to the 2000s when it transitioned into the TRIPS regime – is proportionate to the size of the Indian market and of the entities interested in accessing it. Further, the existence of a fair market structure in India in the form of a strong generic industry as well as the ability of patent law to affect monopoly and market access explain the

strong patent language in policy and legal decisions and in public debates. The Nigerian pharmaceutical market discontinuity and ensuing lacuna in the patent regime evokes the question of the impact of patent policy and regime on prospects of development.

Moreover, the inability of local civil society actors to engage with patent law also explains the absence of an organised pressure group, determined to make the government reformulate a richer patent policy in such a way that it can enhance the indigenous pharmaceutical sector while simultaneously protecting public interest. This relates back to the concerted effort of civil society activism in Brazil and India, especially the active role which civil society played in reshaping patent laws in these countries' laws. The civil society groups in these countries were able to instigate, promote, and legitimise ideas regarding patent law and its effect on sectoral development and health. It is their engagement with law that changed the national architecture, discourse, and strategies on patent regime. This underscores the nodal governance literature which emphasises that strong nodes have strong purposes, can formulate demands, and can create concentrations of power for purposes of influencing governance.²⁰⁹ Conversely, weak nodes are unable to formulate these demands or work together, thus are incapable of influencing governance. Nigeria, having a weak pharmaceutical sector and CSO without the capacity to mobilise the government, has proven this.

The lesson from this chapter is that laws and policies alone are not enough in the multi-scalar and longitudinal understanding of the issues arising from patent governance as regards socio-economic development. Rather, the strong presence of relevant interest groups is also required to not only elevate discourse but also to produce expertise and govern knowledge in related issue areas. It is hoped that analyses from this thesis contribute to the understanding of the importance of local actors and strong institutions in the creation of national patent law and its relationship with economic development and the protection of public interests.

²⁰⁹ Peter Drahos, 'Intellectual Property and Pharmaceutical Markets: A Nodal Governance Approach' (2004) 77 Temple Law Review 404.

6. Conclusion

This empirical thesis explored Third World attempts to use the patent regime as set out in the TRIPS Agreement to effect certain development and public health goals. It also discovered the ways these countries are challenging global norms in pharmaceutical patent protection. To explicate Third World attempts, the thesis used the different examples of Brazil, India, and Nigeria and told the story of patent law making within each of them. It also investigated how non-state actors in these countries influence the conceptualisation and implementation of patent law making, thereby creating narratives and counter-narratives in patent law making as it relates to access to medicines.

Theoretically, the thesis adopted a TWAIL perspective, a critical legal approach generating a vibrant on-going debate around questions of colonial history, power, identity, and difference, and what these mean for international law.¹ As mentioned in Part 1 of Chapter 2, TWAIL seeks to promote and include the voices and experiences of the countries and peoples of the developing world in opposition to an unjust global order.² As applied to this thesis, TWAIL played three important roles. First, it provided the historical perspective for mapping the origins of patent regime in the countries under study. Specifically, the thesis showed that patent law was introduced in the countries under study through colonial acts when IP standards were transplanted directly from the imperial metropolis to the colonial territories.³ More so in India and Nigeria than in Brazil, the colonial patent laws revealed the forces of empire at work in the sense that the patent law enforced at the time favoured the colonial countries at the expense of the colonies.

Second, TWAIL helped in unpacking the TRIPS regime and provided the context for understanding Third World engagement within it. Specifically, the harmonising nature of the TRIPS Agreement is reminiscent of the European colonial expansion and foregrounds a

¹ Antony Anghie, 'Time Present and Time Past: Globalization, International Financial Institutions, and the Third World' (2000) 32 *New York University Journal International Law and Politics*. James Thuo Gathii, 'TWAIL: A Brief History of its Origins, its Decentralized Network, and a Tentative Bibliography' (2011) 26 *Trade, Law and Development* 27.

² Makau Muthua, 'What is TWAIL?' (2000) *The American Society of International Law Proceedings* 36.

³ Peter Drahos, 'Developing Countries and International Intellectual Property Standard-Setting' (2002) 5 *The Journal of World Intellectual Property* ('Developing Countries and International IP Standard-Setting'); Ruth L Okediji, 'The International Relations of Intellectual Property: Narratives of Developing Country Participation in the Global Intellectual Property System' (2003) 7 *Singapore Journal of International and Comparative Law*; Peter K Yu, 'A Tale of Two Development Agendas' (2009) 35 *Ohio Northern University Law Review*; Peris Jones, 'When "Development" Devastates: Donor Discourses, Access to HIV/AIDS Treatment in Africa and Rethinking the Landscape of Development' (2004) 25 *Third World Quarterly* 387.

fundamental issue: the imposition on different contexts and realities of Eurocentric ‘ideals.’⁴ The exclusive proprietary interests enshrined within the TRIPS Agreement, according to TWAIL, perpetuate development asymmetries between the Global North and South. This is because insisting on a global harmonised patent regime, no matter how minimal, robs many Third World countries of the opportunity to grow and develop technological capabilities through copying and mimicry. As analyses in Chapters 1 and 2 showed, many developed countries did not allow patents on chemical and pharmaceutical substances, which afforded them the opportunity to develop their technological and industrial sectors.⁵ The transplanting of Western legal regimes into countries in the Global South not only robbed them of opportunities which Western countries had, but also hampers access to the information, knowledge, and technology needed for competitiveness, internal growth, and development.⁶

Third, as TWAIL preaches the reform of international law to make it more equitable and inclusive,⁷ TWAIL scholars such as Sundhya Pahuja and Luis Eslava have suggested a re-direction of gaze from the international to the local to capture the various forms of resistance and reform of international law occurring daily in local forms of the Third World.⁸ These actions, they argued, may appear unrelated to the international but in actuality is.⁹ It is in taking up this call to focus on the resistance and reforms occurring in Third World forums that underscored the analyses and understanding of pharmaceutical patent regime law making in the local forums of Brazil and India – and by extension, its absence in Nigeria. In this regard, TWAIL imbued meaning in these acts of Third World patent law making as not only reformist, because these law making projects are expanding the aperture on various international rules and norms governing pharmaceutical patents and medicines access discourse, but are also counter-hegemonic because they are providing an alternative – a counter-narrative of sorts – to current understanding of the international patent regime.

However, the thesis criticised TWAIL as insufficient because it ignores the asymmetries within Third World states. These asymmetries, the thesis argued, demarcates which Third World state engages in reform and resistance vis-à-vis international law and scholarship, and who is excluded. As a result, the thesis adopted, in Part II of Chapter 2, the nodal governance

⁴ Martti Koskeniemi, ‘Histories of International Law: Dealing with Eurocentrism’ (Inaugural lecture delivered on 16 November 2011 on the occasion of accepting the Treaty of Utrecht Chair at Utrecht University, Utrecht University 2011).

⁵ Surendra J Patel, ‘Intellectual Property Rights in the Uruguay Round: A Disaster for the South?’ (1989) 24 *Economic and Political Weekly* 980.

⁶ Okediji (n 3).

⁷ Muthua (n 2).

⁸ Luis Eslava and Sundhya Pahuja, ‘Between Resistance and Reform: TWAIL and the Universality of International Law’ (2011) 3 *Trade, Law and Development* (‘Between Resistance and Reform’); Luis Eslava and Sundhya Pahuja, ‘Beyond the (Post)Colonial: TWAIL and the Everyday Life of International Law’ (2012) 45(2), *Journal of Law and Politics in Africa, Asia and Latin America - Verfassung und Recht in Übersee (VRÜ)* (‘Beyond the (Post)Colonial’).

⁹ Pahuja and Eslava, ‘Between Resistance and Reform’ (n 8) 103.

theory as a supplementary theoretical framework.¹⁰

The thesis drew from Peter Drahos' theory of nodal governance to understand how complex systems construct order, produce knowledge, and influence governance systems that mimic or complement the ordering work of systems themselves.¹¹ Nodal governance proved useful for this thesis in two ways. First, it illuminated the asymmetries within Third World states by highlighting the presence and capacity of actors (nodes). In so doing, it showed how actors in the Third World forums employed and deployed knowledge in ways that promoted their respective agendas while strengthening their collective capital. As a result, nodal governance theory illuminated actors' mentalities, methods used for exerting and mobilising influence, modes of governance employed, their structure, as well as the dialectic relationships between and among actors.¹²

Second, nodal governance showed the way non-state actors (nodes) organise themselves around key issues in a particular way. In doing so, it facilitated the understanding of the nuts and bolts of patent ecosystems in local forums that produce general outcomes by identifying actors involved in processes such as knowledge creation, capacity building, and resource mobilisation to manage a course of events.¹³ By illuminating the intricacies of patent law making, it explained why pharmaceutical patents are relevant and used in legal and policy discourse in the local forums of Brazil and India but are absent in Nigeria. Thus, in combining TWAIL and nodal governance theory, the thesis identified the complexities, workings, and actors engaged – and by extension, absent – in the use of the patent regime set out in the TRIPS Agreement to effect certain development and public health goals.

¹⁰ Scott Burris, Peter Drahos, and Clifford Shearing, 'Nodal Governance' (2005) 30 *Australian Journal of Legal Philosophy* 31.

¹¹ Peter Drahos, 'Intellectual Property and Pharmaceutical Markets: A Nodal Governance Approach' (2004) 77 *Temple Law Review* ('IP Nodal Governance Approach'); Peter Drahos and John Braithwaite, *Information Feudalism: Who Owns the Knowledge Economy?* (2002); John Braithwaite and Peter Drahos, *Global Business Regulation* (1st edn, 2000).

¹² Burris, Drahos, and Shearing (n 10) 34.

¹³ *ibid* 37.

6.1 Major Findings

At the onset, this thesis asked three research questions:

1) How are patents conceptualised into law and policy vis-à-vis the TRIPS Agreement in Brazil, India, and Nigeria?

In broad terms, the thesis found that patent law is conceptualised and implemented differently within Brazil, India, and Nigeria due to the confluence of various actors involved in patent law making as well as several domestic and international socio-political processes that unfolded over time.

Prior to the TRIPS Agreement, a patent was understood and conceptualised in Brazil as a deliberate industrial policy to encourage transfer of technology and industrial development. With these goals in mind, Brazil implemented a patent regime in 1971 that did not grant protection to pharmaceutical products and processes to allow for transfer of technology. Due to external pressure from the US and panels at the WTO, the country quickly implemented the TRIPS Agreement. This led to the Brazilian Congress' introduction and approval of Industrial Property Law 9.279/96 in 1996 – much earlier than the WTO deadline of 2005 for middle income countries.¹⁴ However, as analyses in Chapter 3 has shown, Brazil also passed Law 9313 (also known as the Sarney Law) to provide free access to ARVs due to internal circumstances such as the HIV/AIDS crisis and widespread social mobilisation and activism waged by health CSOs.

Because Brazil had already phased into the TRIPS Agreement, thereby making it difficult to locally produce ARV drugs patented elsewhere, the cost of free ARV drugs ballooned, threatening the AIDS programme. The combination of budgetary constraints, inflating health costs, and the government's constitutional obligation to provide health care for all Brazilians spurred the government to introduce Law 9787/99, known as the Law of Generic Medicines, in 1999. The law required all purchasing contracts under the government system to be generic, while all prescriptions are to be written using the generic name, essentially introducing generics into the Brazilian market.¹⁵ The Law of Generic Medicines also made the use of CLs more flexible and simpler, while regulatory reforms were introduced to accelerate

¹⁴ Amy Nunn, *The Politics and History of AIDS Treatment in Brazil* (Springer 2008) 3.

¹⁵ Matthew Brian Flynn, 'Pharmaceutical Governance in Brazil: Globalization, Institutions and AIDS' (PhD thesis, University of Texas at Austin 2010) 58; Gabriela Chavez and Renata Reis, 'Health, Intellectual Property and Innovation: A Case Study of Brazil' (2011) *South Centre* 74; Jorge A Bermudez and others, *The WTO TRIPS Agreement and Patent Protection in Brazil: Recent Changes and Implications for Local Production and Access to Medicines* (Oswaldo Cruz Foundation, Rio de Janeiro 2002) 136.

the market entry of generics after the expiration of its on-patent version. Brazil also amended its patent policy to adopt a human rights approach wherein a patent application is examined vis-à-vis its impact on public health. Thus, Law 10196/2001 was added as Article 299c to Brazil's IP legislation, which instituted the 'prior consent' (*Anuência Prévia*) mechanism.¹⁶ This empowered ANVISA to grant patents for pharmaceutical products and processes on public health grounds. In other words, ANVISA examines pharmaceutical patent applications to make sure the grant of patents will not negatively affect public health. It is therefore fair to say that the threat to the country's policy of universal access to AIDS medicines due to the high cost of patented medicines and the social mobilisation of health activism shifted Brazil's understanding and conceptualisation of patents from a strictly industrial policy to pro-human rights in its articulation.

India, from the onset, conceptualised and implemented patent law based on its socio-economic realities and development goals of pharmaceutical autonomy or self-sufficiency. As such, patents are seen as an instrument of industrial policy and patent laws were implemented in ways to preserve and enhance the competitiveness of the local pharmaceutical industry.¹⁷ The quest for pharmaceutical autonomy continued in the post-TRIPS era as the government availed itself of the transitional period and interpreted the TRIPS Agreement in ways that ensured the use of flexibilities. Specifically, Section 3(d) considers derivative forms of known substances, i.e. salts, esters, ethers, and polymorphs, to be the same substance, unless it is shown that the new derivative improved efficacy of the known substance.¹⁸ Thus, as Chapter 4 argued, the Indian Patent Act appears to be a successful attempt at striking a balance between protecting IPRs and promoting local innovation.

Nigeria, however, does not seem to have a concise conceptualisation of patent law. Unlike Brazil and India where the post-colonial patent regime was a deliberate act of the government bearing in mind the needs and realities of the country, the reverse was the case in Nigeria. In Nigeria, post-colonial patent law – Patent Rights Limitation Decree (1968)¹⁹ – was implemented as a response to the court ruling of the first patent case in Nigeria, which the military government found offensive to its powers to issue orders in pursuance of the government use clause under the patent law. This showed that patents were not conceptualised in the first place by the Nigerian state either as a matter of deliberate industrial

¹⁶ Monica Steffen Guise Rosina, Daniel Wang, and Thana Cristina De Campos, 'Access to Medicines: Pharmaceutical Patents and the Right to Health', *Access to Knowledge in Brazil: New Research on Intellectual Property, Innovation and Development* (1st edn, Yale Law School 2008) 191.

¹⁷ Amy Kapczynski, 'Harmonization and its Discontent' (2009) 97 California Law Review.

¹⁸ Section 3(d), Patent (Amendment) Bill (2005). See ch 4, s 4.3.

¹⁹ Patents (Limitation) Decree No 8 (1968).

policy or as part of its development pursuits. As Nigeria has not fully phased into the TRIPS Agreement, the 1968 patent law – though renamed and slightly updated in 1990 – has continued to this day. This shows, if anything, a lack of deliberate patent conceptualisation in law and policy, which has underscored the government's general movement towards a patent regime even in the post-TRIPS era.

2) How do ideas regarding patents circulate? That is, what influences the way in which particular policy options get constructed – and, as an extension, how others get extinguished with regard to patent law and policy in the aforementioned countries?

In general terms, the thesis found that various key factors that unfolded overtime influenced the circulation of ideas regarding patents, thereby leading to the emergence of narratives and counter-narratives on patent regime discourse. These factors include colonial experience, development aspirations, and the confluence of local politics (which could be either political or socio-economic in nature).

Colonialism was one of the factors that influenced ideas on patents. The colonial patent regime in India, for instance, encouraged abuse of patent monopoly which led to high drug prices, non-working patented articles that stifled transfer of technology, and often delayed the introduction and production of essential drugs and stifled industrial development.²⁰ This led to the emergence of a general movement towards reforming the colonial patent regime seen by many, especially indigenous drug manufacturers, as an encumbrance to the development of a robust pharmaceutical sector and achievement of pharmaceutical autonomy. In response, India amended its patent law in 1970 and removed product patents on medicines and agro-chemicals. It also limited the protection term for processes to seven years. The Indian patent reform, it has been argued, was an icon of the thinking that prevailed in terms of patent reform.²¹

Brazil, though one of the original members of the Paris Convention, was dissatisfied with the Convention due to the rampant abuses of patent monopolies by foreign pharmaceutical companies.²² As a result, the country demanded for a patent system both at home and at the UN that is favourable to its economic development, including proper controls against abuse,

²⁰ Sudip Chaudhuri, *The WTO and India's Pharmaceuticals Industry: Patent Protection, TRIPS, and Developing Countries* (Oxford University Press 2006) 54.

²¹ Pedro Roffe and Gina Vea, 'The WIPO Development Agenda in an Historical and Political Context', *The Development Agenda: Global Intellectual Property and Developing Countries* (Oxford University Press 2008) 92.

²² AK Menescal, 'Changing WIPO's Ways? The 2004 Development Agenda in Historical Perspective.' (2005) *Journal of World Intellectual Property* 763.

thereby putting ‘development’ issues and ‘public interest concerns’ on the international IP agenda.²³ Whilst the country was not successful in pushing forward this counter-hegemonic stance at the UN, it succeeded at home in revising the Brazilian patent law in 1971 and removed patent protection for both pharmaceutical products and processes. The Brazilian and Indian examples provide attempts by Third World countries to make modern technology more freely accessible for commercial development within their respective countries. Abolishing patent protection in the case of Brazil and severely limiting the patent framework in the case of India represent a radical departure from the traditional concept that patent ownership rights should be afforded the highest degree of protection.²⁴

Whilst Nigeria also experienced high incidents of monopoly abuse,²⁵ the first post-colonial patent law was a response to the *Rhone - SA Poulenc and May & Baker v Lodeka Pharmacy* case.²⁶ The then military government implemented the first post-colonial patent law to allow the Nigerian government to purchase patented pharmaceutical products and to also exempt the government from infringement of a patent granted with respect to the articles concerned or the liability to pay royalties or compensation to the patentee.²⁷ In this regard, the PDA did not take into account the country’s development level at the time, leading to an absence of relevant underlying policy for using the patent regime to attain certain development purposes.

Another significant piece that fomented the circulation and emergence of counter-hegemonic narratives on IP systems is associated with the general disillusionment of the many newly colonized states of the Third World with the international system of the UN. This is particularly so with the failure of the NIEO. The NIEO reflected efforts by developing countries to assert greater control over technology transfer, multinational enterprises, and other economic activities related to economic development.²⁸ The failure to achieve the objectives of the NIEO as well as the unsuccessful Brazilian attempt to introduce a Development Agenda in the WIPO forced both Brazil and India to look inwards and adjust their IP laws to suit their national interests.

Meanwhile in Nigeria, the discovery of oil in commercial quantities, especially the oil boom of the 1970s, drastically changed the structure of the economy.²⁹ Specifically, it increased the

²³ *ibid.*

²⁴ Frederick M Abbott, ‘Intellectual Property, International Protection’ (Florida State University - College of Law 2009) 2.

²⁵ Owen T Adikibi, ‘The Multinational Corporation and Monopoly of Patents in Nigeria’ (1988) 16 *World Development* 512.

²⁶ (1965) LLR 9.

²⁷ Patents (Limitation) Decree No 8 (1968), s 1(3).

²⁸ Okediji (n 3) 332; Nils Gilman, ‘The New International Economic Order: A Reintroduction’ (2015) 6 *Humanity*.

²⁹ Bill Freund, ‘Oil Boom and Crisis in Contemporary Nigeria’ (1978) 5 *Review of African Political Economy* 91, 92.

importation of finished goods, which severely weakened the industrial sector. Thus, while Brazil and India had to look inwards to develop policies that would encourage technology transfer and industrial development, Nigeria relied on the windfall from oil to grow its economy and did not implement a strategic and deliberate development policy towards ensuring the transfer and development of technological capacities.

Moreover, the influx of foreign drug companies to Nigeria³⁰ – a by-product of the oil boom – created an illusion of industrial growth and expansion. Analyses in Chapter 5 showed that the growth was largely ephemeral as it was largely characterised by foreign-owned and foreign-managed industries, often dependent on imported raw materials and engaged in aggressive transfer pricing and money laundering schemes.³¹ This became obvious when the oil boom ended and the introduction of austerity measures, which negatively affected purchasing power of Nigerians, forced foreign pharmaceutical companies to divest from the country.

The thesis therefore argued that the oil windfall robbed the Nigerian state of an opportunity to develop a fine-tuned IPR system and to successfully build domestic capabilities in the highly competitive pharmaceutical industry. Thus, while the 1970s witnessed a wave of legal reforms in Brazil and India that created a counter-narrative on patents that translated into important changes in IP-related legislations, the counter-hegemonic movement was absent in Nigeria because of the windfall from oil, preventing the state from seriously engaging in patent reform or using patents to effect development.

3) How do non-state actors – private sector and civil society groups – challenge and/or influence this understanding and conceptualisation of patents into law and policy?

This thesis has shown how counter-hegemonic campaigns and activism by non-state actors, referred to in this thesis to mean the private sector and civil society groups, achieved a reform of patent laws in Brazil and India.

As mentioned earlier, Brazil phased into the TRIPS Agreement early without using the transition period accorded to developing countries. It also implemented standards which many believed to be higher than what is required by the TRIPS Agreement. However, the HIV/AIDS epidemic amplified the engagement of civil society groups that couched their

³⁰ Kristin Peterson, *Speculative Markets: Drug Circuits and Derivative Life in Nigeria* (Duke University 2014) 41 (*Speculative Markets*).

³¹ SI Ebohon, 'Globalization, Technology Transfer and the Knowledge Gap: Case Study of the Global Pharmaceutical Industry in Nigeria' (2012) 11 *Global Journal of Social Sciences* 27; Raymond Baker, 'Plundering a Continent' (*Global Financial Integrity*, 2012) <<http://www.gfintegrity.org/press-release/plundering-a-continent/>> accessed 29 March 2016.

activism on the terms of the constitutional right to health.³² These groups played a key role in producing knowledge, expertise, and awareness regarding the impact of patents on access to ARV drugs. To effect the required change and response, these groups adopted several tactics such as policy advocacy, HIV/AIDS de-stigmatization campaigns, and legal suits against government policies that negate the government's health care responsibilities. This led to the introduction of Law 9313/96 (Sarney Law), which guarantees free access to ARVs for AIDS treatment for all people in Brazil living with HIV/AIDS.³³

It can be argued that the legal battle waged by civil society groups, especially in relation to the right to health as codified in the Brazilian Constitution, was decisive behind the change in Brazil's patent law. If anything, it led to a more structured and organised response by the government. In fact, the policy of universal ARV access was initially undermined by the early implementation of the TRIPS Agreement as it meant the country cannot copy drugs patented elsewhere and should therefore purchase the required ARV drugs at full price. By expressing the threat to the AIDS programme during campaigns and protests as a patent issue due to the price of expansive patented drugs, civil society movements forced the government to break patents and issue a CL for the ARV medicine *Efavirenz*.³⁴

In India, the primacy of local industry vis-à-vis the patent law has seen indigenous drug manufacturers play an active role in the initial post-colonial patent amendment as well as in the post-TRIPS Agreement era. The country's unique position as a supplier of generic drugs to the world was achieved as a result of the changes to its patent law in 1970. The post-TRIPS era deepened popular activism of Indian civil society groups, which became dominant prior to the final amendment of India's patent law in 2005 to comply with its TRIPS obligation. Since the final amendment of the IPA in 2005, new social movements, radical legal decisions, and business partnerships have led to the development of novel conceptions of patents advanced by the different actors. For example, CSO groups are actively pushing forward a rights-based patent regime that enables the provision of drugs at affordable prices to the people of India.³⁵ They have adopted patent opposition strategies against what they see as frivolous patent applications or applications deemed injurious to public health. The courts have also become the battleground in the development and expansion of patent law and policies. The private

³² Renata Reis, Veriano Terto Jr, and Maria Cristina Pimenta, *Intellectual Property Rights and Access to ARV Medicines* (ABIA 2009); Gabriela Chaves, Marcela Vieira, and Renata Reis, *Access to Medicines and Intellectual Property in Brazil: Reflections and Strategies of Civil Society* (1st edn, 2008) <http://www.scielo.br/pdf/sur/v5n8/en_v5n8a09.pdf> accessed 21 May 2015.

³³ A Nunn, E Da Fonseca, and S Gruskin, 'Changing Global Essential Medicines Norms to Improve Access to AIDS Treatment: Lessons from Brazil' (2009) 4 *Global Public Health* 134.

³⁴ Chaves, Vieira, and Reis (n 32).

³⁵ Julia George, 'India, Intellectual Property and Access to Medicines: Developments and Civil Society Initiatives in India', *Intellectual Property Rights and Access to ARV Medicines* (1st edn, ABIA 2009).

sector is also employing various tactics to increase its space within post-TRIPS India. In seeking out favourable rules via pre-emptive injunctions and legal tie-ups through VLs and outright purchase of competitor firms, MNCs are gaining control of generic markets and are pursuing capitalist goals that are contrary to CSO and, sometimes, state objectives.

However, the thesis finds that the non-state actors' contestation and engagement in Brazil and India are absent in Nigeria. This is due to various factors including the legal indeterminacies, market failure, and poor economic policies affecting Nigeria's drug sector in terms of growth and presence of sectorial actors in the pharmaceutical industry.³⁶ Moreover, years under a military regime blunted CSO activism, while the presence of donor organisations further weakened the ability of CSOs to participate in patent law making. As a result, these actors that normatively would have played an important role in the cognitive shaping of and knowledge production on patent law are not doing so.

Specifically, the thesis showed that pharmaceutical technology imported by foreign drug makers operating in Nigeria in the early 1960s and 1970s was not adapted to the local situation and therefore did not lead to any significant transfer of technology, which would have led to local industrialisation. However, government policies such as the Indigenisation Decree – instituted to reconfigure the dominance of the foreign nationals in the Nigerian economy – failed to increase technology transfer. This is because the Indigenisation Decree was improperly implemented and instead encouraged the transfer of company ownership to individuals connected to the ruling class but who had no prior experience in running a drug manufacturing plant. Furthermore, the ISI policy enforced at the time made the importation of raw materials expensive and made local production unsustainable. This forced the drug manufacturers to resort to importing finished goods instead of engaging in local manufacturing. On the other hand, the SAP – introduced to curtail fiscal mismanagement triggered by the oil boom and bust of the 1970s and the 1980s – eviscerated the pharmaceutical manufacturing companies, in turn weakening the ability of the pharmaceutical manufacturing sector to engage in domestic inventiveness.

The inability of local civil society actors to engage with patent law also explains the absence of an organised pressure group, determined to make the government reformulate patent policy in such a way that it can enhance the indigenous pharmaceutical sector while

³⁶ Peterson, *Speculative Markets* (n 30); Kristin Peterson, 'On the Monopoly: Speculation, Pharmaceutical Markets, and Intellectual Property Law in Nigeria' (2014) 41 *American Ethnologist* ('On the Monopoly'); Kristin Peterson, 'Intellectual Property Designs: Drugs, Governance, and Nigerian (Non-) Compliance with the World Trade Organization', *Rethinking Biomedicine and Governance in Africa: Contributions from Anthropology* (1st edn, Transcript Verlag 2012) ('IP Designs'); Ebohon (n 31).

simultaneously protecting public interest. This relates back to the concerted effort of civil society activism in Brazil and India, especially the active role which civil society played in reshaping these countries' IP laws.

6.2 Contribution to Research

The thesis has revealed a previously unknown factor on the patent regime in Nigeria – the effect of the absence of a local pharmaceutical manufacturing sector and civil society organisations in patent law making and structural reform. The expansive comparative coverage given to patent jurisprudence of selected jurisdictions and juxtaposing it to the Nigerian situation clearly epitomizes the lacuna. Thus, while certain scholars have argued that the impact of the TRIPS Agreement on medicine access in Nigeria is negligent,³⁷ this thesis adds to the discourse by revealing *how* this happens. Why is this important? The analyses of American MNCs in Chapter 2, the Brazilian context in Chapter 3, and the Indian setting in Chapter 4 showed how actors successfully embedded themselves in the making and reform of patent law in those jurisdictions. Conversely, the absence of patent in Nigerian law and development policies underscores the instrumental role of these non-state actors in structural patent reform. Such analyses provide insight and better understanding regarding the importance of these actors to patent law making, the transformation of the discourse, and the discourse they oppose.

The primary aim of this study was to discover whether Nigeria could learn from Brazil and/or India on how to create and implement an IP framework, especially a patent regime that encourages, instead of hinders, development and public health management. The analyses demonstrate how Nigerian patent law can particularly benefit from India and Brazil's approach of promoting their IP frameworks. This is a great contribution to scholarship in this area and would contribute immensely to the reform and growth of Nigerian patent law and practice.

Furthermore, in exclusively focusing on law making in the Third World, this thesis unmask a competing narrative – a counter-narrative of sorts – to the current understanding of the international IP regime. Particularly, in successfully articulating and impelling a local counter-hegemonic discourse of global patent rules, the thesis showed how patent law making

³⁷ AO Oyewunmi, 'Health Access to Medicines and Intellectual Property Options for African Countries in Light of the WTO TRIPS Agreement' (2013) 1 Journal of International Law and Diplomacy; Okechukwu Timothy Umahi, 'Access to Medicines: The Colonial Impacts on Patent Law of Nigeria' <http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1975928> accessed 15 March 2015.

in Brazil and India are expanding the aperture on norms governing pharmaceutical patent regimes and discourses on access to essential medicines. This provides ways for governments of other Third World countries to exploit the residual flexibilities within the TRIPS Agreement.

Theoretically, the thesis has argued that TWAIL alone cannot explain how and why actors mobilise in a particular locality and not in others. The thesis showed that while Brazil, India, and Nigeria opposed the inclusion of an IP regime in the global trade framework at the Uruguay Round, only Brazil and India had gone ahead to local implement 'alternative' IP laws. Thus, this shows that TWAIL cannot uncover all the aspects of the Global South voice without the addition of nodal governance. Equally, the limitation of nodal governance lies in its inability to probe the structure, history, and processes of the (global) legal system within which it exists. Nodal governance needs TWAIL to ensure that the colonialism underpinning much of international law (and international IP law) is exposed in the interactions between the various nodes/actors. Thus, in combining TWAIL and nodal governance theory to illuminate the materialisation of the international in the local, the thesis showed the gamut of legal, historical, political, and economic forces that bring about the internationalisation of pharmaceutical patent law in the local forums of Brazil, India, and Nigeria.

6.3 Commonalities and Differences

Studying the patent regimes in Brazil, India, and Nigeria brought to the fore striking similarities between the three countries. First, these countries actively opposed the inclusion of IP in the international trade rules, with Brazil and India more so than Nigeria. Nevertheless, these countries were aware of the power of patents to affect development and the daily lives of their citizens. This is because these countries are regional powerhouses, which places greater demands on them in terms of competitive development in the knowledge-based economy and in upholding human rights obligations.

Compared to Nigeria, Brazil and India have local pharmaceutical companies, and have incorporated the TRIPS Agreement into local legislation as a result of being under constant pressure from the US. However, unlike in India where indigenous manufacturers were active from the onset, this was absent in Brazil. Nevertheless, it should be mentioned that Brazilian drug makers are beginning to take their place in national discourses on patents, drug manufacturing, and medicine access.

Another surprising factor was the limited influence of corruption in the patent discourse in these countries as corruption was not seen as an issue. This is different from the notion, usually from the Global North, of the endemic nature of corruption in these countries. This could be from the fact that corruption manifests differently than what is generally perceived as ‘corrupt’ by analysts in the West. For instance, the transfer of ownership from foreign owners to Nigerians connected to ruling elites is seen more as crony politics at work than corruption.

6.4 Recommendations for Nigeria

As this thesis has shown, both Brazil and India provide a comprehensive legal framework for IPR protection. Each of the countries implemented the TRIPS Agreement in a different manner and time. Each country had a different set of challenges, and a different strategy or model of protection. Both Brazil and India have opened their markets to foreign investments and competition, aiming to become part of the globalised prosperity envisaged with the creation of the WTO. In this regard, Nigeria has something to learn from these countries.

First, the lesson from the Brazilian and Indian IP law regime has shown that patent law and policy cannot be implemented in a vacuum and independent of the cultural, political, and economic lives of the country. It has many other components going far beyond the IPR regime. Brazil framed and marketed its patent regime as part of its health policy, whereas India mainly promoted its patent regime as an industrial tool and later on as a health policy. Nigeria should adopt a patent law bearing in mind its economic and social circumstances, technological capabilities, and industry profile. The thesis therefore recommends developing a patent regime framed as a health policy tool due to the various health challenges faced by Nigeria, especially with HIV/AIDS, malaria, and tuberculosis. Adopting a right to health frame, as Brazil did, will not only allow the country to invest in health care but to also collaborate with foreign MNCs through PPP agreements to locally develop and manufacture drugs in the country. Doing so would encourage technology transfer whilst developing the manufacturing sector.

Second, in terms of patents and access to medicines, Brazil and India have shown the way that policy makers have tailored the implementation of TRIPS obligations to fit their particular circumstances. This was absent in the first post-colonial patent law in Nigeria. As Nigeria is yet to fully implement the TRIPS Agreement, the thesis suggests framing a patent regime cognizant of Nigeria’s health challenges and needs as well as its development aspirations. Specifically, the thesis recommends that patent protection for pharmaceutical products and

processes be explicitly included in the list of patentable inventions in Section 1(4) of the PDA, and such right be enjoyable with discrimination as stipulated by Article 27 (1) of the TRIPS Agreement. In addition, the new policy should not be too restrictive to hinder innovation nor too wide to engender abuse. If anything, the TRIPS Agreement still allows some degree of flexibility for countries to determine how the criteria for patentability should be applied.³⁸ In this regard, Nigeria could borrow from India to exclude new uses of known products or processes in order to promote access to medicines and to ensure that only inventions which are new, involving an inventive step, and are capable of industrial application can be patented. This would also prevent ever-greening.

Third, the analyses of Nigerian patent law show that certain flexibilities afforded by the TRIPS Agreement, such as parallel importation, are omitted. In this regard, the thesis recommends the inclusion of a parallel importation clause. Particularly, it suggests the inclusion of a global parallel importation regime as national and regional parallel importation guidelines would be restrictive because they limit access to the same drugs distributed within the country and region. Global parallel importation, on the other hand, allows for shopping around for drug products and provides opportunities to purchase cheaper pharmaceuticals.

Fourth, the current patent law in Nigeria does not allow for substantive examination of patents. This thesis suggests an amendment of the patent law to include a substantial examination clause. This is to ensure that only inventions that meet patentability standards are approved. In addition, Nigeria should also borrow from Brazil and allow the participation of the health sector in the examination and analysis of pharmaceutical patents. This would ensure that a patent application is examined in light of its impact on public health. This is also in line with Article 8 of the TRIPS Agreement, which permits members to adopt measures necessary to protect public health when formulating domestic laws.

Finally, the thesis revealed the gap in communication among government regulatory agencies, which has created a system where contradiction and incoherence thrive. The thesis therefore recommends the institution of a committee similar to the Brazilian GIPI. This committee should consist of agencies and government departments whose oversight duties interface with the patent regime and should be required to meet on a monthly basis to ensure that each department or agency is well-informed of the workings and activities of the other. This will not only reduce fragmentation and policy contradiction but would also encourage the development of a cohesive patent regulatory strategy and effective enforcement mechanisms.

³⁸ TRIPS Agreement, art 27.

6.5 Suggestion for Future Research

While Chapter 5 on Nigeria revealed new insights for the research such as the influence of donor organisations on CSO engagement in patent law making, the research did not go into a deeper analysis of this donor presence due to the limited space in and scope of this thesis. In light of current discourse on aid,³⁹ the influence of donor organisations on patent law making becomes even more pertinent.

This thesis therefore recommends that further research be done in this regard. Particularly, examining how donor organisations currently engage patents and access to medicines in the countries under study would be illuminating. Furthermore, future studies could examine the role of these organisations in fostering competitive generic markets via patent pools. The finding could be compelling in understanding the broader effects these organisations have on international trade law and patent judicialization.

³⁹ Dambisa Moyo, *Dead Aid* (Farrar, Straus, and Giroux 2009).

Appendix 1: List of Interviewees (Brazil)

Interviewee	Name of Organization and Professional Title	Date Interviewed
Prof. Richard Parker	President, Brazil Interdisciplinary AIDS Association (ABIA), Rio de Janeiro	3 June 2014
Felipe Carvalho	Médecins Sans Frontières (MSF), Rio de Janeiro	20 May 2014
Jose Carlos Cavalcanti	CAMEX (Foreign Trade Chamber, IP Negotiations Department), Brasilia	28 May 2014
Pedro Paranagua	Advisor to the ruling Workers Party, Chamber of Deputies, Brasilia	27 May 2014
Pedro Villardi	Working Group on Intellectual Property of the Brazilian Network for the Integration of People (GTPI), Rio de Janeiro	18 May 2014
Murilo Lubambo	Trade Policy Coordinator, Ministry of Finance	27 May 2014
Pedro Barbosa	Attorney, Denis Borges Barbosa Advogados, Rio de Janeiro	5 June, 2014
Dr. Monica Caetano	National Agency for Sanitary Surveillance (ANVISA)	5 June 2014
Gabriela Chaves	FIOcruz Foundation, Rio de Janeiro	13 June 2014
Fabio Mesquita	Director, Department of STDs, AIDS and Viral Hepatitis, Ministry of Health, Brasilia	29 May 2014
Marcela Viera	Country Coordinator, REBRIP, Rio de Janeiro	4 June 2014
Marcia Maria Nunes de Barros	Federal District Judge, Rio de Janeiro	11 June 2014
Mayara Santos	Deputy Head, Intellectual Property Division, Ministry of External Relations	25 May 2014
Reinaldo Guimarães	Vice President, Associação Brasileira das Indústrias de Química Fina, Biotecnologia e Suas Especialidades (ABIFINA), Rio de Janeiro	4 June 2014
Renata Reis	Independent researcher and activist	13 June 2014
Juliana Gomes	Social Issues Division, Ministry of External Relations	28 May 2014
Jorge Avila	Director, National Institute for Industrial Property (INPI)	Denied
Regina Lucia P. Cohen	Director, Movement National Das Cidades Positive, Brasilia	27 May 2014
Prof. Maria Inês Toledo	School of Health Sciences, University of Brasilia	28 May 2014
Prof. Veriano Terto	Instituto de Estudos em Saúde Coletiva - IESC/UFRJ	5 June 2014

Appendix 2: List of Interviewees (India)

Interviewee	Name of Organization and Professional Title	Date Interviewed
T. C. James	President, NIPO, Delhi	26 August 2014
D. G. Shah	Indian Pharmaceutical Alliance, Mumbai	26 September 2014
Leena Menghaney	Médecins Sans Frontières, Delhi	25 August 2014
Prof. Shamnad Basheer	Spicy IP, Kolkata	26 August 2014
Dr. K. S. Kardam	Senior Joint Controller of Patents and Designs, Indian Patent Office, Delhi	Denied
Prof. Biswajit Dhar	Center for Economic Studies and Planning, JNU, Delhi	11 September 2014
Vikas Ahuja	Delhi Network of Positive People, Delhi	29 August 2014
Shri Anshu Prakash	Joint Secretary, Ministry of Health	Cancelled
Chandni Raina	Department of Commerce, Ministry of Trade and Commerce	Denied
Gopakumar Nair	Indian Drug Manufacturers' Association, Mumbai	24 September 2014
Rajana Smectask	Director General, Organization of Pharmaceutical Producers in India, Mumbai	24 September 2014
Amit Sen Gupta	National Working Group Patent Law, Delhi	3 September 2014
K. M. Gopakumar	Third World Network, Delhi	15 September 2014
Colins Gonzales	Human Rights Law Network, Delhi	19 September 2014
Zakir Thomas	Council of Scientific and Industrial Research (CSIR)	16 September 2014
B. S. Chimni	Professor, Centre for International Legal Studies, School of International Studies, JNU, Delhi	26 August 2014
Dr. Shakthivel Selvaraj	Public Health Foundation of India (PHFI), Delhi	9 September 2014
Prof. Raghuram	IP University, Delhi	01 September 2014
Justice Prabha Sridevan	Madras High Court, Chennai	17 September 2014
Dinesh Abrol	Indian Institute of Science and Technology, Delhi	8 September 2014

Appendix 3 - List of Interviewees (Nigeria)

Interviewee	Name of Organization and Professional Title	Date Interviewed
Dr. Bravo Otohabru	Procurement Officer, National Agency for the Control of AIDS (NACA)	3 December 2014
Ope Abegunde	Assistant Director, Policy and Strategy, National Agency for the Control of AIDS (NACA)	4 February 2015
Tile Tano	Deputy Director, Ministry of Health	25 November 2014
Ruth Okoye	TRIPS Division, Ministry of Trade and Investment	5 December 2014
Onyejekwu Simeon	Principal Trade Officer, WTO Department, Ministry of Trade and Investment	5 December 2014
Ezikpe Egbuta Kalu.	Trade Policy and Former Trade Negotiator, Ministry of Trade and Investment	21 December 2014
Aisha Salim	Patent Examiner, Patent Office	29 January 2015
Barrister Salman Mann	Director, Commercial Law (Trademarks and Patents)	5 December 2014
Ali Ibrahim	Deputy Director, i/c Pharmacovigilance/Post Marketing Surveillance, National Agency for Food and Drug Administration and Control (NAFDAC)	11 March 2015
Barrister Shafiu Adamu Yauri	Registrar (Trademarks and Patents)	26 November 2014
Corinna Heineke	GIZ Nigeria	17 February 2015
Engr. Nwosa Lucky	Director, Technology Transfer and Research (TAR), National Office for Technology Acquisition and Promotion (NOTAP), Abuja	22 January 2015
Interviewee A	WHO official	18 November 2014
Interviewee B	Health activist	29 January 2015
Prof. Adebambo Adewapo	Director, Intellectual Property Law, Institute of Advanced Legal Studies	3 February 2015
Dr. Kelechi Ohiri	Director, Saving One Million Lives Initiative	27 January 2015
Mr. Oloyole	National AIDS and STI Control Program (NESCOP)	5 February 2015
Prof. Chidi Odinkalu	Chairperson, National Human Rights Commission (NHRC)	26 June 2015
Yetunde Ali	BIOFEM Pharmaceutical Company, Lagos	12 July 2016
Mike Ajufor	Evans Pharmaceutical Plc	13 July 2016
Abraham Okeke	Swisspharma Plc	15 July 2016
Interviewee C	Official, Pharmaceutical Manufacturers Group of Manufacturers Association of Nigeria	14 July 2016

Fieldwork Interview Questions

Aim: This brief interview seeks to excavate deeper insights into 4 main areas: understanding and conceptualization of patent, understanding of TRIPS Agreement, and influence local politics and participant.

Stakeholders/Respondents: Local CSOs, relevant government agencies, private sector (foreign and local pharmaceutical companies), judiciary (attorneys, judges).

Duration: 30-45 minutes

Questions

1. What is your understanding of the global machinery of intellectual property regime, specifically the TRIPS Agreement? Has this understanding changed over time? If so, why (or why not)?
2. How is this understanding implemented into law (government agencies only)?
3. What social capacities and institutions were instantiated with the A2M debate?
4. Does your organization intervene in and frame policy debates and processes regarding A2M and patents? If so, what ways? If not, why not? (PS and CSOs only)
5. How does your organization influence the public knowledge about patent?
6. How is the relationship between Government (and its agencies) and local CSOs/private sector?
7. Are you aware of how other countries, say, India and Brazil are dealing with the patent issue in relation to development and health? Why is/isn't Nigeria following that path? (**Nigeria only**)

Participant identification number where applicable:

Consent Form

Tentative Project Title: Emerging Third World Jurisprudence in Legislating Increased Access to Medicines

Name of Researcher: Amaka Vanni
(To be completed by participant)

1. I confirm that I have read and understood the information sheet for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily. ☐ Yes ☐ No
2. I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason. ☐ Yes ☐ No
3. I understand that any information given by me may be used in future reports, articles or presentations by the researcher. ☐ Yes ☐ No
4. I understand that my information will be held and processed confidentially. ☐ Yes ☐ No
5. I agree to take part in the above study and allow the interview to be audiotaped. ☐ Yes ☐ No
6. I understand that data from the interviews will be kept in a secure storage and accessible to the researcher. ☐ Yes ☐ No

Name of Participant

Date

Signature

Researcher

Date

Signature

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