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**Rethinking Patent Centric Biomedical
Innovation: Towards an Alternative
Conceptual Framework Building**

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Thesis submitted for the degree of PhD

2018

School of Law

SOAS, University of London

Declaration for SOAS PhD thesis

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ACKNOWLEDGMENT

To my parents who have dedicated all of their love and supports to my intellectual enquiries. I see the most of humanity out of their kindness every day.

谨以此文献给我的父母 — 感谢他们全心的爱，激励我求知不辍。他们每天的善行善念令我感念人性的荣光。

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ABSTRACT

The entrenched conceptual construction of patent as an indispensable institution for biomedical innovation has been embedded in the principal legal, policy and political discourses, with considerable controversies over the last decades. The development of a patent system for biomedical inventions has been considered a hybrid of political, economic and social processes, in which the conventional justifications on patent have been constantly contested. Yet, the increasing number of patents on biomedical inventions involving low levels of innovative values alongside highly specialised patenting techniques and practices have evolved into a relatively closed system in which the production of the notion of newness is subject to a particular understanding and conception of innovation. This practice has increasingly enclosed medical research tools and methods, which are traditionally open; influenced the norms and behaviours of other actors in the overall biomedical innovation process, such as the physicians and scientists; and reinforced the political rhetoric of having patent as an indispensable means to biomedical innovation.

Although mechanisms to mitigate the tension have been explored including the use of patent flexibilities and alternative management of intellectual assets, but the central questions remain regarding the extent to which the nature of medicines can be reappraised and the role of law can be re-approached beyond a proprietary-centric worldview. This includes how biomedical innovation can be reimaged and rethought by relocating innovation communities and the public outside of industry-concentrated discourses. To achieve this, this thesis investigates what a possible alternative conceptual framework would need to be to alter the patent-centric paradigm for biomedical innovation.

The thesis explores an alternative conceptual framework for biomedical innovation by adopting a critical approach. It takes an interdisciplinary approach by resorting to the theoretical framework of co-production in science and technology studies, critical legal studies, and critical international relations studies as the main methodological resources. The first part of the thesis critically examines the central thesis of patent law's function in terms of innovation and openness in the context of health by looking at its manifestation at both theoretical and practical levels. The second part of the thesis refers to the co-production framework to examine the epistemic formation of the idea of 'patent as innovation' through the working of expertise and legal professions, which intertwines with the ideological motives and political discourses. The third part of the thesis then reviews the ideas and initiatives of alternative knowledge making and innovation management in both the biomedical and other fields, and explores the key elements of an alternative conceptual biomedical innovation framework in contrast of the hegemonic idea of the patent-centric approach. The thesis argues that the reimagination of alternative conceptual biomedical innovation framework entails a plurality of norms, repositioning the role of professions and expertise with user innovators and the public, thereby highlighting the need to explore self-governance and socially-motivated and determined mechanisms in relation to innovation.

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LIST OF ABBREVIATIONS

ABS	Access and Benefit Sharing Mechanism
ACPAA	All-China Patent Agent Association
AIPPI	International Association for the Protection of Intellectual Property
ANT	Actor-Network Theory
APAA	Asian Patent Attorney Association
BIOS	Biological Innovation for Open Society
BVGH	Bio Venture for Global Health
CAMBIA	Centre for Application of Molecular Biology in International Agriculture
CBD	Convention on Biological Diversity
CIPA	Chartered Institute of Patent Attorneys
CLS	Critical Legal Studies
DNA	Deoxyribonucleic Acid
DNDi	Drug for Neglected Diseases Initiative
DNP+	Delhi Network of Positive People
EBA	Enlarged Board of Appeal of the European Patent Office
EPC	European Patent Convention
EPI	Institute of Professional Representatives before the European Patent Office
EPLAW	European Patent Lawyers Association
EPO	European Patent Organization/ European Patent Office
EWHC	High Court of Justice of England and Wales
FRAND	Fair, Reasonable and Non-discriminatory principles
FTA	Free Trade Agreement
FTPL	Fix the Patent Law Coalition
GMO	Genetic Modified Organism
GP	General Practice
GPL	General Public License
GPLPG	General Public License for Plant Germplasm
GSK	Glaxo Smith Klein
HGP	Human Genome Project
IAD	Institutional Analysis and Development framework
ICC	International Chamber of Commerce
IFPMA	International Federation of Pharmaceutical Manufacturers Association
IGPA	International Generic Pharmaceutical Alliance
IP	Intellectual Property
IPC	Intellectual Property Committee
ITPC	International Treatment Preparedness Coalition
JAX	Jackson Laboratories of Bar Harbour
JPAA	Japan Patent Attorneys Association
KEI	Knowledge Ecology International
LDC	Least Developed Countries
LMC	Local Medical Committees (of England)
LMIC	Low-Middle Income Countries

MMV	Medicines for Malaria Venture
MOU	Memorandum of Understanding
MSF	Médecins Sans Frontières
MTA	Material Transfer Agreement
NAPP	National Association of Patent Practitioners (US)
NIH	National Institute of Health
NTD	Neglected Tropical Diseases
OECD	Organization for Economic Cooperation and Development
OS	Open Source
OSDD	Open Source Drug Discovery
PBC	People's Business Commission
PCT	Patent Cooperation Treaty
PhRMA	The Pharmaceutical Research and Manufacturers of America
PLT	Patent Law Treaty
R&D	Research and Development
STEM	Science, Technology, Economics, Mathematics
STS	Science and Technology Studies
TAC	Treatment Action Campaign
TBA	Technical Board of Appeal of the European Patent Office
TDI	Tropical Disease Initiative
TRIPS	Agreements on Trade-related Intellectual Property Rights
TPP	Trans-Pacific Partnership Agreement
TWN	Third World Network
UK	United Kingdom
UN HRC	United National Human Rights Council
UPOV	International Convention of the Protection of New Variety of Plants
USPTO	Patent and Trademark Office of the United States of America
WHO	World Health Organization
WIPO	World Intellectual Property Organization
WIPO SCP	World Intellectual Property Organization, Standing Committee on the Law of Patents
WTO	World Trade Organization

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EISAI/Second medical indication [1979-85] EPOR B241

BAYER/Nimodipin (I) T 17/81 [1979-85] EPOR B320

ROUSSEL-UCLAF/Tetrahydropyridinyl-Indole Derivatives [1979-85] EPOR B448

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Genentech 1 / Polypeptide Expression [1989] 1 EPOR 1

Genentech Inc's Patent [1989] RPC 147

Biogen Inc v Medeva PLC [1997] RPC 1

MedImmune, Inc v Genentech, Inc., 549 U.S. 118 (2007)

Novartis AG v. Union of India & Others [2013] Supreme Court of India

Mylan and Actavis v Warner-Lambert [2015] EWHC 2548 (Pat)*Unwired Planet*

International v Huawei Technologies Co Ltd [2017] EWHC 711 (Pat)

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'I hope there is no suffering of sickness in the world, even if my medicines are kept in dust on the shelf.' (但愿世间无疾苦, 何妨架上药生尘)

--- *Anonymous Chinese medicine doctors' motto (17-18th century)*

INTRODUCTION

I. Background: The Global Expansion of Patent Law and the Biomedical Innovation Paradox

It has been observed that intellectual property in general, and patent law in particular, has become a contingent site of conflicts, suppressions and resistances at global and local levels in the era of the knowledge society.¹ One of the manifestations of such conflicts is the contentious issue that arises regarding the patent-centric paradigm of innovation in medicines.

One of the central rhetoric of the patent system confirms its function as encouraging innovation in exchange for granting a profitable temporary monopoly, so that the majority of society will eventually benefit from scientific and technological progress. However, the reality is that the field of health and medicines has increasingly become sceptical about such an argument despite the fact that the numbers of patents related to medicines are increasing.² A few recent examples can be cited. For instance, while anti-microbial resistance has become a global health threat, especially in relation to the

¹ Sebastian Haunss, *Conflict in the Knowledge Society: The Contentious Politics of Intellectual Property* (CUP 2013).

² WIPO 'World Intellectual Property Indicators'
<http://www.wipo.int/edocs/pubdocs/en/wipo_pub_941_2014.pdf> accessed 12 May 2015.

recently identified typhoid superbug in humans,³ innovation delivered in this field has steadily declined over the past three decades.⁴ Before the most recent outbreak of Ebola in West African countries that travelled across continents, discoveries and developments of a cure for this old disease have been shelved.⁵ The question of whether a stronger patent system can really drive more innovations in reaction to health challenges is pertinent.

From an academic perspective, although the pharmaceutical sector has often been seen as one among others who rely strongly on the patent system in contrast to other industries,⁶ critiques concerning the Tragedy of Anti-commons⁷ suggest that the privatization of biomedical research through patenting has had the paradoxical consequence of stifling innovation.⁸ Researchers have also pointed out that while the narrative of patents creating an innovation incentive has never been firmly demonstrated in reality, it has, however, supported the formation of the current global patent regime

³ NHS Choice, 'Scientists "Amazed" at the Spread of Typhoid Super Bug' <<http://www.nhs.uk/news/2015/05May/Pages/Scientists-amazed-at-spread-of-typhoid-superbug.aspx>> accessed 12 May 2015.

⁴ Brad Spellberg and others, 'The Epidemic of Antibiotic-Resistant Infections: A Call to Action for the Medical Community from the Infectious Diseases Society of America' <<http://cid.oxfordjournals.org/content/46/2/155.full.pdf+html?sid=f3703aa3-6de8-4095-a63a-7042add23eeb>> accessed 12 May 2015. See also Gregory W Daniel and others, 'Antimicrobial Resistance: Antibiotics Stewardship and Innovation' (2014) Brookings <<http://www.brookings.edu/research/articles/2014/06/12-antibiotic-stewardship-and-innovation>> accessed 12 May 2015; Universities Allied for Essential Medicines (UAEM), 'Tackling the Antimicrobial Resistance Innovation Crisis' <<http://uaem.org/cms/assets/uploads/2014/05/UAEM-AMR-Policy-Briefing.pdf>> accessed 9 March 2015.

⁵ James Surowieki, 'Ebolanomics' (New Yorker 25 August 2014) <<http://www.newyorker.com/magazine/2014/08/25/ebolanomics>> access 12 May 2015.

⁶ Edwin Mansfield, 'Patent and Innovation: An Empirical Study' (1986) 32(2) *Management Science* 173; Richard Levin and others, 'Appropriating Returns from Industry Research and Development' (1987) 3 Brookings Paper on Economic Activity 783; Stuart Macdonald, 'Exploring the Hidden Cost of Patents' in Peter Drahos and Ruth Mayne (eds), *Global Intellectual Property Rights: Knowledge, Access and Development* (Palgrave Macmillan 2002) 13.

⁷ Michael A Heller, 'The Tragedy of Anticommons: Property in the Transition from Marx to Market' (1998) 111(3) *Harvard Law Review* 621.

⁸ Michael A Heller and Rebecca S Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' (1998) 280 *Science* 698.

while also enabling the complex patent portfolio to be used increasingly as a purely business strategy.⁹

It is also worth noting that the controversy and scepticism regarding the role of patents in health-related innovation is not a new one. For instance, research has provided a historical play-back of the interactions between patent law development and the early industrial developments in the field of synthetic chemical pharmaceuticals.¹⁰ Germany, at the time of the early nineteenth century the pioneer in the field of chemical and pharmaceutical manufacturing, had not introduced patent on products but only on processes due to a strong industrial lobby.¹¹ Germany is now a strong patent supporter. A couple of other European countries have undergone a similar history when patent had formerly been subject to strong resistance. For instance, Switzerland did not introduce patent on chemical processes until the beginning of the 20th century due to a long-term concern regarding losing competitiveness to German companies.¹² The dynamics between industry and medical practitioners in the European and North American contexts concerning the scope of patent law have also been subject to fierce debate. For instance, the literature has discussed physicians' resistance in terms of their overall suspicions regarding patenting medical treatment methods.¹³

⁹ Michael Blakeney, 'Biotechnological Patenting and Innovation' in Martin J Adelman and others (eds), *Patents and Technological Progress in a Globalized World: Liber Amicorum Joseph Straus* (Springer 2009).

¹⁰ Graham Dutfield, *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History* (1st edn, Ashgate 2003); Graham Dutfield, *Intellectual Property Rights and the Life Science Industries: Past, Present and Future* (2nd edn, World Scientific 2009).

¹¹ *ibid.*

¹² *ibid.* 83.

¹³ Katherine J Strandburg, 'Derogatory to Professional Characters: The Evolution of Physician Anti-patenting Norms' in Kate Darling and Aaron Perzanowski (eds), *Creativity Without Law: Challenging the Assumptions of Intellectual Property* (New York University Press 2017) 63.

Very similar tensions and debates have re-emerged in the context of more and more developing countries marching toward stronger patent systems as part of their plans to join the global free trade club, with the ambition of building stronger national economies and becoming more innovative. Whether or not such vision is a promising prospect or more of an ideological fallacy is highly debatable and has also been covered by remarkable body of research.¹⁴ Keeping in mind this scholarly trend, which has at least re-informed the very feature of patent law as a dialectical and self-referring system that changes constantly according to historical and technological conditions,¹⁵ the primary intention of this research is to critically examine the conceptual elements of patent law in the context of biomedical innovation.

Returning to the contemporary discussion, while different justifications of patent have long been controversial,¹⁶ from an industrial perspective today patent remains the strongest form of intellectual property protection that fosters commercial profits. Taking the established patent-centric paradigm in innovation in medicines on the one hand, the

¹⁴ A rich body of literature has emerged in the last two decades concerning the challenges facing developing countries when the introduction of stronger intellectual property law was pressed through political and trade channels. Research of this kind has adopted legal, social, economic and historical approaches, reviewing the political, social and economic impact on developing countries in terms of coping with various developmental issues including health and proposing possible options, especially regarding the use of flexible mechanisms contained in patent law. See, for example, Peter Drahos and Ruth Mayne (eds), *Global Intellectual Property Rights: Knowledge, Access and Development* (Palgrave Macmillan 2002); Philippe Cullet, 'Human Rights and Intellectual Property Protection in the TRIPS Era' [2007] 29(2) Human Rights Quarterly 403; Philippe Cullet, *Intellectual Property Protection and Sustainable Development* (LexisNexis Butterworths 2005); Carlos M Correa, *Designing Intellectual Property Policies in Developing Countries* (TWN 2010); Martin Khor, *Intellectual Property, Biodiversity, and Sustainable Development: The TRIPS Agreement and the Issues to be Resolved* (Zed Books 2002); Neil Weinstock Netanel (ed), *The Development Agenda: Global Intellectual Property and Developing Countries* (OUP 2009); Carlos M Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre 2000); Carlos M Correa, *Intellectual Property Rights, the WTO and Developing Countries: The TRIPS Agreement and Policy Options* (Zed/TWN 2000).

¹⁵ Analysis of this aspect could be found from researches such as Christopher May and Susan K Sell, *Intellectual Property Rights: A Critical History* (Lynne Rienner Publishers, 2006); Susan K Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights* (CUP 2003).

¹⁶ Sigrid Sterckx, 'The Ethics of Patent: Uneasy Justification' in Peter Drahos (ed), *Death of Patent* (Lawtext Publishing and Queens Mary Intellectual Property Research Centre 2005) 175.

expansion of the patent regime has further triumphed at both international and national levels, especially in the aftermath of the Agreements on Trade-related Intellectual Property Rights (TRIPS) under the auspices of World Trade Organization (WTO). According to Drahos, ‘there are probably less than five countries where one cannot obtain a patent’.¹⁷ TRIPS, viewed as a global-level capitalist project,¹⁸ has formally transformed the narrative of intellectual property as an integrated issue of international trade and investment, which has reinforced the global expansion of a neo-liberal agenda while also strengthening the impact of the established paradigm of patent as an indispensable vehicle for innovation and growth. Beyond TRIPS, patent protection remains one of the contentious topics in free trade agreement (FTA) negotiations, with a requirement for additional protection beyond the minimum standards of TRIPS often imposed by negotiating parties from economically-enhanced nations.

One profound theory in this regard is the justification of patent as a critical driving force and incentive for innovation, which is seen as a vital element to achieve competitive capacities in a global market based increasingly on an ‘information economy’.¹⁹ Such a justification has been identified in various scholarly discourses concerning intellectual property.²⁰ However, sceptics have argued that overly expansive rights will result in little innovation²¹ while strong patent could reduce both innovation and welfare.²² In

¹⁷ Peter Drahos, *The Global Governance of Knowledge: Patent Offices and their Clients* (CUP 2010) 2.

¹⁸ Christopher May, *The Global Political Economy of Intellectual Property Rights: A New Approach* (2nd edn, Routledge 2010) 148.

¹⁹ Carl Shapiro, ‘Competition Policy in the Information Economy’, (August 1999) <<http://faculty.haas.berkeley.edu/shapiro/comppolicy.htm#II>> accessed 10 March 2015.

²⁰ Niva Elkin-Koren and Eli M Salzberger, *The Law and Economics of Intellectual Property in the Digital Age: The Limits of Analysis* (Routledge 2013) 4.

²¹ Kenneth Joseph Arrow, ‘Economic Welfare and the Allocation of Resources for Invention’ in National Bureau of Economic Research (ed), *The Rate and Direction of Inventive Activity: Economic and Social Factors* (National Bureau of Economic Research 1962) 609.

²² Josh Lerner, ‘Patent Protection and Innovation over 150 Years’ (NBER 2002) <<http://www.nber.org/papers/w8977>> accessed 20 January 2015.

addition to the effects of TRIPS, there are two more important factors that need to be noted in order to gain an overview of the expansion of the patent law regime.

First of all, TRIPS is not the first or only international legal instrument concerning patent protection, albeit perhaps the strongest one with a comprehensive mechanism to ensure that it is undertaken by every WTO member while safeguarded by a quasi-judicial dispute settlement procedure that supports its national enforcement. Beside TRIPS, the Paris Convention for the Protection of Industrial Property (Paris Convention) under the auspices of the World Intellectual Property Organization (WIPO) has established the major international legal standards for the protection of patent, including those concerning inventions, utility models and designs. Although the Paris Convention includes fewer enforcement measures compared to TRIPS, its substantive rules and procedures have been incorporated by national patent laws including those that came before the TRIPS era.

In addition, TRIPS – as it is claimed to be fully commensurate with Paris Convention – has reinforced the realization of provisions under the Paris Convention. Furthermore, the Patent Cooperation Treaty (PCT)²³ together with the Patent Law Treaty (PLT),²⁴ which are also administrated by the WIPO, have contributed to the establishment of the global administrative and governance network on patent protection.²⁵ Under the WIPO system, the standardized classification of patent, international application procedures,

²³ WIPO Patent Cooperation Treaty (adopted on 19 June 1970, amended on 28 September 1979, modified on 3 February 1984 and 3 October 2001, entered into force on 1 April 2002).

²⁴ WIPO Patent Law Treaty (adopted on 1 June 2000, entered into force on 28 April 2005). It is worth noting here that the harmonization of patent standards through WIPO has not stopped at the formal procedure level. Beyond PLT, controversies remain in terms of the draft Substantive Patent Law Treaty which is now pending with the Standing Committee on the Law of Patents in WIPO due to member states' strongly diverging views concerning the impact of such substantive law integration.

²⁵ Peter Drahos, *The Global Governance of Knowledge: Patent Offices and their Clients* (CUP 2010).

supplemented by substantive technical exchange, training and technical assistance programmes, have facilitated the rise of patent offices around the world reinforcing the patent-centric paradigm on innovation, progress and growth.²⁶

In the field of biomedical innovation, additional legal instruments also stand out in the WIPO system. For instance, the Budapest Treaty on the International Recognition of the Deposit of Microorganism for the Purpose of Patent Protection (Budapest Treaty)²⁷ under WIPO, which has been seen as one of the major international law instruments explicitly deal with patenting on living matters,²⁸ requires the deposit of microorganisms and disclosure of such information in patent applications with the contracting members.²⁹ Processing and synthesising from microorganisms in nature has played a substantial role in the discovery and development of modern Western medicines, a notable examples as the discovery of penicillin.³⁰ Although the Budapest Treaty has not been not ratified by many developing countries and is also not specifically promoted by TRIPS, researchers have noted that the patent protection rules inserted through bilateral FTAs has reinforced the expansion of the Budapest system concerning microorganism patenting.³¹ Although the issues of microorganism patenting is not particularly

²⁶ *ibid.* See also: Hon Gerald J Mossinghoff, 'Patent Harmonization through the United Nations: International Progress or Deadlock?' [2004] 86 J Pat & Trademark Off Soc'y 5.

²⁷ WIPO Budapest Treaty on the International Recognition of the Deposit of Microorganism for the Purpose of Patent Protection (28 April 1977, and amended on 26 September 1980). The treaty now has 79 contracting parties.

²⁸ Anne Eckstein, *The Patentability of Living Matters* (European Information Service 2001).

²⁹ The development of the Budapest system had close links with the historical and technological context of the biotechnology industry's emergence and its implications for medical research and development.

³⁰ Graham Dutfield, *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History* (1st edn, Ashgate 2003).

³¹ Research on the Budapest Treaty and its relationship with and impact on biotechnology and developing countries can be found in, for example: Jonathan Curci, 'The New Challenges to The International Patentability of Biotechnology: Legal Relations Between The WTO Treaty on Trade-Related Aspects of Intellectual Property Rights and the Convention on Biological Diversity' [2005] 2 Int'l L. & Mgmt Rev 1; John Edward Schneider, 'Microorganisms and the Patent Office: To Deposit or Not to Deposit, That is the Question' [1984] 52(4) Fordham Law Review
<<http://ir.lawnet.fordham.edu/cgi/viewcontent.cgi?article=2578&context=flr>> accessed 13 May 2015;

addressed in this research, when looking at the use of microorganisms as a technological means in biomedical research, the overall conceptual questions of patent's centrality in innovation remains relevant.

Secondly, there are co-existing proprietary-based or related legal institutions that exist in parallel, interact, or are in conflict with the patent regime, which adds to the complexity of the biomedical innovation legal landscape. For instance, plants and animals are traditionally and conventionally not considered as patentable in most countries.³² In reality, however, there has been a constant tendency to trespass the scope of the exceptions. It has been observed that the International Convention on the Protection of New Variety of Plants (UPOV Convention),³³ which provides a *sui generis* system on plant breeders' rights, has been moving closer to proprietary-based protection similar to the utility patent under TRIPS.³⁴ Some jurisdictions where the exception of patenting on plant and plant varieties has been long established have also faced the expansive challenges posed by judicial bodies and legislation's gradual changes in jurisprudence.³⁵

Virginia H Meyer, 'Problems and Issues in Depositing Microorganisms for Patent Purposes' [1983] 65 *Journal of the Patent Office Society* 455.

³² Exceptions are evident where there are explicit legislations such as the Plant Patent Act 1930 in the US.

³³ International Convention for the Protection of New Variety of Plants (UPOV) (adopted on 2 December 1961, entered into force in August 10, 1968, revised on 10 November 1972, on 23 October 1978, and on 19 March 1991).

³⁴ Community Plants Variety Office, 'Relation between PVP and Patent on Biotechnology' <<http://www.cpvo.europa.eu/documents/articles/BK%20Bangkok%20November%202003.pdf>> accessed 10 May 2015.

³⁵ For example, a considerable amount of research has been conducted on the jurisprudences developed by the Enlarged Board of Appeal of European Patent Office and the EC Directive on the Legal Protection on Biotechnological Inventions (Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions), on the issue of patentability concerning living matter including plant and plant varieties. Detailed analyses of this can be found in Sigrid Sterckx and Julian Cockbain, *Exclusions from Patentability: How Far Has the European Patent Office Eroded Boundaries?* (CUP 2012); Geertrui van Overwalle, 'Reshaping Bio-Patents: Measures to Restore Trust in the Patent System' in Han Somsen (ed), *The Regulatory Challenge of Biotechnology: Human Genetics, Food and Patents* (Edward Elgar 2007) 238.

The therapeutic and medicinal knowledge and usage of plants and animals has played and continues to play a central role in innovation activities related to traditional medicines, and also enjoys a crucial role in a completely different setting – the screening for lead substance in the biopharmaceutical industry’s research and development processes, which has opened up an entire area of legal controversy related to the bio-prospecting and bio-piracy of traditional knowledge. Legal responses to these issues can be navigated through the provisions and mechanisms developed under the Convention on Biological Diversity (CBD)³⁶ and its Nagoya Protocol,³⁷ as well as the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, which intended to explore a *sui generis* protection of traditional knowledge that is significantly distinguished from the intellectual property system.

The fundamental conceptual issue here lies in the notion that traditional knowledge’s driving of innovation operates in a distinctive way and does not ‘fit in the western paradigm of science’.³⁸ The objectives of protecting traditional knowledge are both to defend such a system from misappropriation by using the means of intellectual property while providing an enabling legal framework for knowledge production and its diffusion and development with its own features. Challenges remain in terms of achieving full realization of such protection in law, especially when facing the patent-centric paradigm and its ideological and practical approach to innovation in general. For instance, one of the challenges here is the issue of accommodating a sufficient disclosure doctrine under

³⁶ The Convention on Biological Diversity (adopted 5 June 1992, entered into force 29 December 1993).

³⁷ Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity (adopted 29 October 2010, entered into force 12 October 2014).

³⁸ Philippe Cullet, *Intellectual Property Protection and Sustainable Development* (LexisNexis Butterworths 2005).

patent law with the access and benefit-sharing mechanism enshrined under the CBD framework.³⁹

To sum up, the global expansion of patent law has been undertaken using international law and international trade platforms, with TRIPS together with the WIPO-administrated treaties reinforced by the well-established patent-centric innovation paradigm. This expansion has also taken shape in the interaction or conflict between TRIPS and other co-existing legal institutions related to traditional knowledge and genetic resources. The conceptual controversy regarding the notion of science, technology and knowledge has been reflected in the manoeuvring of patent law in the overall context of innovation discourses.

Considerable critiques have been developed both academically and practically concerning the conflict between the strong proprietary protection of patent and insufficient innovation to address health needs, and the flexibility contained in the current patent law system that can be used facilitate health objectives. Another line of critique focuses on alternative business models of innovation by looking at economic incentives based on public and consolidated funding for research in order to mitigate the

³⁹ A rich literature has contributed to the normative discussions in both WIPO and WTO. For instance, under the WTO, the proposal has been made by members to amend TRIPS by incorporating a mandatory disclosure obligation of origin when a patent application concerns the uses of genetic resources. Responses can also be found in national patent laws such as in Brazil, India, China, Norway, Switzerland and others, where amendments have been introduced in making disclosure of origin a stricter obligation for patent applicants. Research, discussion and analyses on the issue of mandatory disclosure of origin can be found in *WIPO Technical Study on Patent Disclosure Requirement Related to Genetic Resources and Traditional Knowledge* (2004) <http://www.wipo.int/edocs/pubdocs/en/tk/786/wipo_pub_786.pdf> accessed 10 May 2015; Joshua D Sarnoff and Carlos M Correa, *Analysis of Options for Implementing Disclosure of Origin Requirements in Intellectual Property Applications* (UNCTAD Report 2004) <http://unctad.org/en/Docs/ditcted200514_en.pdf> accessed 10 May 2015; Jonathan Carr, 'Agreements That Divide: TRIPS vs. CBD and Proposals for Mandatory Disclosure of Source and Origin of Genetic Resources in Patent Applications' (2008) 18(1) *J of Transnational Law & Policy* 131 <http://archive.law.fsu.edu/journals/transnational/vol18_1/carr.pdf> accessed 10 May 2015.

dilemmas posed by profit-driven innovation.⁴⁰ However, both major critiques bear similar limitations in that they fail to address directly the central conceptual problems in patent law that keep evolving, regardless of external critiques on the failure of the system to generate much-needed innovation. For instance, proposed alternative business model which leverage public funding remain based in a narrative premised on the perception that innovation is predominantly achieved by certain private sectors. Meanwhile, funding, in the context of innovation discourse, would yet again be directed to those who have already benefited disproportionately from patent's proprietary function. Other proposals such as the collective management of patent might provide a tactical reconciliation while remaining silent about the central conceptual problems regarding how innovation is constructed or misconstrued through law. Thus, more fundamental issues remain in terms of how biomedical innovation is produced technically, socially and politically, and the extent to which a legal regime such as patent has dealt with it. Therefore, there is a need to explore conceptual frameworks that might act as an alternative to the established paradigm of patent-centric innovation.

⁴⁰ For more detailed discussion and analysis in this regard, see the large body of literature drawn from both academic research and policy reports from different international bodies, for instance: World Health Organization (WHO), *Public Health, Innovation and Intellectual Property* (2002) <<http://www.who.int/intellectualproperty/en/>> accessed 02 May 2012; James Love, 'Measures to Enhance Access to Medical Technologies and New Methods of Stimulating Medical R&D' [2007] 40 UC Davis Review 679; Tim Hubbard and James Love, 'A New Trade Framework for Global Health R&D' [2004] 2(2) PLoS Biology 147; Nicoletta Dentico and Nathen Ford, 'The Courage to Change the Rules: A Proposal for Essential Health R&D Treaty' [2005] 2(2) PLoS Medicine 96; German Velásquez, 'Rethinking the R&D Model for Pharmaceutical Products: A Binding Global Convention' [2012] 8 South Centre Policy Brief <http://www.sciencespo.fr/psia/sites/sciencespo.fr/psia/files/RP42_Rethinking-global-health_EN.pdf> accessed 30 August 2018; Erin Shinneman, 'Owing Global Knowledge: The Rise of Open Innovation and the Future of Patent Law' [2010] 35 Brooklyn Journal of International Law 935; John-Arne Røttingen and others, 'Global-health Research Architecture—Time for Mergers?' [2009] 373 The Lancet 193.

II. Innovation, Knowledge, and the Patent-centric Approach to Innovation

Before discussing patent law's approach to biomedical innovation, it is necessary to first outline what is understood by innovation in a non-legal context. It is worth noting that, as the central theme in intellectual property law research, the concept of innovation has often been approached without defined it in the first place, especially in legal terms.

It has, however, been noted that there is no one precise and fixed definition of the concept of 'innovation'.⁴¹ The Oxford Dictionary provides a loosely constructed definition of 'innovation' as 'the action or process of innovating',⁴² while 'innovate' itself is defined as 'making changes to something established, especially by introducing new methods, ideas and products.'⁴³ It is generally understood as the process of turning a new technology into a commercial product.⁴⁴ In Joseph Schumpeter's typologies of innovation in entrepreneurship and economics, the term also involves an opening up of a new market or new ways of supplying raw materials.⁴⁵ In addition, innovation has also been defined in other ways, for instance, it has been understood as 'straddl[ing] the worlds of mental and physical activity',⁴⁶ while its approach to 'newness' and 'uncertainty' are 'much more concerned with the future than it is with the present'.⁴⁷

⁴¹ Doris Estelle Long, 'Crossing the Innovation Divide' (2008) 81 Temp L Rev 507.

⁴² Oxford Dictionary Online 'Innovation'

<<http://www.oxforddictionaries.com/definition/english/innovation?q=innovation>> accessed 8 May 2015.

⁴³ Oxford Dictionary Online, 'Innovate'

<<http://www.oxforddictionaries.com/definition/english/innovate?q=innovate>> accessed 8 May 2015.

⁴⁴ Rebecca S Eisenberg, 'Patents and the Progress of Science: Exclusive Rights and Experimental Use' [1989] 56 U Chi L Rev 1017, 1038-39.

⁴⁵ In Schumpeter, the introduction of new products or processes is the major means of translating economically valuable inventions into innovations as a central circular process of a capitalist economy. Ref. Joseph A. Schumpeter, *Capitalism, Socialism and Democracy* (Harper and Row 1942) 83.

⁴⁶ William Kingston, *Innovation, Creativity and Law* (Kluwer Academic Publishers 1990) 8-9.

⁴⁷ *ibid.*

In addition, there are notable cultural and social dimensions in which innovation is understood and discussed, especially in the context of creativity in the knowledge production process.⁴⁸ The feature of building something new upon existing knowledge and information also marks the cumulative character of innovation according to many studies,⁴⁹ and thus touches upon the controversy of adequate legal response, especially as pursued through intellectual property protection.⁵⁰ Furthermore, it has been noted that the common understanding of innovation in the technological and economic senses is the result of a narrow conception promoted by Western countries.⁵¹ This approach has largely neglected innovations that are located or derived from ‘tradition-based knowledge, works and practices’.⁵²

The belief that patent is an indispensable aspect of innovation is problematic on both theoretical and practical levels. At a theoretical level, the patent-centric approach to innovation is situated primarily in the incentive narrative of patent driving innovation.⁵³ As such, this theoretical paradigm implies a few underlying presumptions. First, innovation is largely seen as conducted by private entities with clear commercial intentions. Secondly, the economic consideration of incentive – especially in the sense of recouping any investment in the innovation process – is responding largely to the particular interests of the pharmaceutical industry, which has been commonly

⁴⁸ Peter Lee, ‘Social Innovation’ [2014] 92 Wash UL Rev 1; Robert Keith Sawyer, ‘Creativity, Innovation and Obviousness’ [2008] Lewis & Clark L Rev 461.

⁴⁹ Graham Dutfield and Uma Suthersanen, ‘The Innovation Dilemma: Intellectual Property and the Historical Legacy of Cumulative Creativity’ [2004] 4 IPQ 379-421.

⁵⁰ *ibid.* It is also worth noting the differences between discussions of cumulative innovation and the issue of patenting incremental inventions. The former focuses on mapping the practical challenges of balancing patent law’s recognition of newness in the face of a shrinking public domain for further innovation building on existing knowledge. The latter, on the other hand, has been used in the context of justifying lax patent criteria which serve as a major factor behind the patent thicket effects in the pharmaceutical sector.

⁵¹ William Kingston, *Innovation, Creativity and Law* (Kluwer Academic Publishers 1990) 9.

⁵² Long (n 41).

⁵³ Elkin-Koren and Salzberger (n 20) 9.

understood as a sector operating with high capital flow, risk and profitability levels respectively. Thirdly, patent law is seen as indispensable in achieving an incentive effect due to its enforceable power of legalizing the patent holder's market monopoly.

In addition, the paradigm has a narrow understanding of innovation and is disconnected from both the broader literature on the failure of the current model to address non-commercial actors and users' conceptions of innovation. In the context of biomedical innovation, physicians, clinical doctors and medical scientists remain active innovators⁵⁴ while remaining marginalised in the biomedical innovation discourse where the patent-centric paradigm prioritises the commercial holders of patent as the perceived primary force behind innovation.⁵⁵ In addition, at least two conceptual levels are ignored when the incentive narrative becomes a political rhetoric. First, patent law does not define innovation as a legal term but defines inventions, making innovation a fluid and undetermined idea that does not have a legal effect in patent. Second, while Schumpeterian evolutionary economics remains a leading theory to be resorted to when innovation is perceived as vital for economic growth, Schumpeter's analysis never touched on patent's role in relation to innovation.⁵⁶ It is not an isolated case when

⁵⁴ Innovation literature has investigated the critical role of physicians in innovations concerning diagnostic devices, second medical indication and others. This level of innovation has been sidestepped and marginalized while patent exclusivity is prioritised by commercial holders. Discussions on physician innovators can be found in, for instance, Stefan Bechtold, 'Physicians as User Innovators' in Rochelle Cooper Dreyfuss and Jane C Ginsburg (eds), *Intellectual Property at the Edge* (CUP 2014) 343; Harold J. DeMonaco, Ayfer Ali and Eric von Hippel, 'The Major Role of Clinicians in the Discovery of Off-label Drug Therapies' [2006] 26(3) *Pharmacotherapy* 323; Eric von Hippel, Harold DeMonaco and Jeroen PJ de Jong, 'Market Failure in the Diffusion of Clinician-developed Innovations: The Case of Off-label Drug Discoveries' [2017] 44(1) *Science and Public Policy* 121; Aron K Chatterji and Kira Fabrizio, 'Professional User as a Source of Innovation: The Role of Physician Innovation in the Medical Device Industry' [2007] <https://faculty.fuqua.duke.edu/~ronnie/bio/ChatterjiFabrizio_July2nd.pdf> accessed 15 July 2018.

⁵⁵ The literature discusses the different treatment of different pharmaceutical sectors under patent law, which has in turn reinforced the understanding of commercially-motivated innovation in health. See, for instance, Graham Dutfield, 'Healthcare Innovation and Patent Law's "Pharmaceutical Privilege"' [2017] 12 *Health Economics, Policy and Law* 453.

⁵⁶ Mark Blaug, 'Why Did Schumpeter Neglect Intellectual Property Rights?' [2005] 2(1) *Review of*

patent's 'incentive to innovate' justification has never been indisputably endorsed and concluded by economists. More detailed discussions of these problems are provided in Chapter 1.

At a practical level, the patent-centric innovation paradigm on medical products can be seen as reflecting three major perspectives. Firstly, due to the shared belief of relying on patent to secure market competitiveness and profitability, patent thicket and patent ever-greening have become common practices across the pharmaceutical industry.⁵⁷ The former refers to the phenomenon of a remarkable number of patent on one single pharmaceutical product while the latter describes the action and strategy of seeking a maximum level of patenting on every single technological feature of a product in order to delay the 'patent cliff' effect – a situation in which the expiration of primary patent on flagship products would result in steep loss of market share over a short period of time due to the quick entry of multiple competitors.

Secondly, a similar strategy and phenomenon has also been observed in biotechnology and genetic technology-based innovation practices led by industry, while patent is considered as a default legal mechanism to pursue. Despite the remarkable differences in technological features between chemical- and biological-based research and

Economic Research on Copyright Issues 69.

⁵⁷ A considerable amount of the literature has analyzed the issues of patent thicket and evergreening in the context of pharmaceutical innovation. Examples of some of the most recent analyses can be found in: Carl Shapiro, 'Navigating Patent Thicket: Cross Licensing, Patent Pool and Standard Setting' in Adam B. Jaffe and others (eds), *Innovation Policy and Economy* (MIT Press 2001) <<http://www.nber.org/chapters/c10778.pdf>> accessed 8 May 2015; Amy Kapczynski and others, 'Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of "Secondary" Pharmaceutical Patents' [2012] 7(12) PLoS ONE <<http://www.plosone.org/article/fetchObject.action?uri=info:doi/10.1371/journal.pone.0049470&representation=PDF>> accessed 08 May 2015.

development practices, patenting remains the central indicator in labelling certain actors as innovators and others as imitators.

Thirdly, the established and shared paradigm used by industry actors has penetrated into other actors in the innovation process, including scientists and legal professionals. For instance, researchers have reviewed the impact of the introduction of the Bayh-Dole Act⁵⁸ in the United States on publicly-funded research communities, activities and outcomes, with critiques on the influence of the industrial preferences of proprietary protection in research collaborations concerning the impartiality and ethics of public research communities.⁵⁹ The paradigm has also been reinforced by evolving techniques, doctrines and strategies initiated and developed by patent law professionals. Chapter 3 looks at this aspect more closely.

In addition, a historical account of industrial and technological changes and their interaction with the patent law institution also helps in furthering the understanding of the formation of the patent-centric paradigm of innovation in health and medicines at a practical level and as presented in its contemporary forms. For instance, researchers have traced back the origin of the modern chemical industry's development and its consequential impact on the emergence of pharmaceutical science and manufactures.⁶⁰

The role of patent had been used instrumentally at different stages of different countries'

⁵⁸ Patent and Trademark Law Amendment Act, United States, Pub L No 96-517, 94 Stat 3015 (1980) (codified as amended at 35 USC §§ 200-211, 301-307 (2004)). The major controversies around Bayh-Dole Act concern its encouragement of public research institutes and publicly-funded scientific researchers seeking patent protections on their inventions generated by public sponsorship.

⁵⁹ Analyses and critiques of this can be found in: Rebecca S Eisenberg, 'Public Research and Private Development: Patents and Technology Transfer in Government-Sponsored Research' [1996] 82 VA L Rev 1663; David C Mowery and others, *Ivory Tower and Industrial Innovation: University-Industry Technology Transfer Before and After the Bayh-Dole Act* (Stanford University Press 2004); Roberto Mazzoleni, 'Patents and University-Industry Interactions in Pharmaceutical Research Before 1962: An Investigation of the Historical Justifications for Bayh-Dole' [2010] 10 J High Tech L 168.

⁶⁰ Important research can be found in, for example, Graham Dutfield, *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History* (1st edn, Ashgate 2003).

industrial development, which remained the status quo until dramatic changes in the legal landscape, especially after the establishment of the WTO and the introduction of TRIPS.^{61 62}

A concept closely related with innovation is the notion of knowledge, its creation and dissemination. Reviewing the evolution of intellectual property theory, from its early stage as a privilege to its contemporary form as a vested property right, reflects the embedded understanding of knowledge in its empirical sense and the commodification of the process of knowledge.⁶³ The perceived differences between an abstract idea and the embodiment of the same idea under current patent law practices are no longer straightforward. The material aspect of embodiments that are eligible for patent law protection can be established largely through the drafting skill of a lawyer.⁶⁴ However, whether that constructed embodiment carries any scientific and technological reality and useful source of knowledge is questionable.⁶⁵ The alienation of the information system in patent from the reality of science and society has resulted in a re-discussion of the nature of knowledge especially in the literature on innovation, including the scholarship concerned with the reconceptualization of knowledge commons.⁶⁶

⁶¹ WTO Agreement on Trade-related Intellectual Property Rights (adopted 15 April 1994, entered into force 1 January 1995) LT/UR/A-1C/IP/1.

⁶² Dutfield (n 60).

⁶³ Laurelyn Whitt, *Science, Colonialism, and Indigenous Peoples: The Cultural Politics of Law and Knowledge* (CUP 2009).

⁶⁴ Some typical examples of relevant debates can be found in discussions of patenting computer software and business methods. In the field of pharmaceutical and biological patenting, the boundary has also been challenged, for instance, in cases related to living matters or products of nature.

⁶⁵ Alan Pottage and Brad Sherman, 'On the Prehistory of Intellectual Property' in Alain Pottage and Brad Sherman (eds) *Concepts of Property in Intellectual Property Law* (CUP 2013) 27.

⁶⁶ Brett M Frischmann, Michael J Madison and Katherine J Strandburg (eds), *Governing Knowledge Commons* (OUP 2014).

III. Patent Law Doctrines and Discontent with Biomedical Innovation

In September 2015, Mr Justice Arnold of the High Court of Justice of England and Wales made a final decision on the case *Mylan and Actavis v Warner-Lambert*,⁶⁷ invalidating a Pfizer patent⁶⁸ concerned with the so-called ‘second medical use’ of the medicine Pregabalin under the brand name Lyrica, which has been used in treating epilepsy, anxiety disorders and neuropathic pain. The case involves two disputes, namely invalidation claimed by Mylan and Actavis, and infringement claims by Warner-Lambert, a subsidiary of Pfizer. Regarding the invalidation dispute, the final ruling held that the patent is non-obvious in its inventiveness test, yet invalid due to insufficiency in its specification. On the infringement dispute, the Justice found no infringement stands in the case. The 174 page court decision also documented in nearly 100 paragraphs the steps and effects of Pfizer’s warning and threat to sue for infringement health authorities, general practice doctors, pharmacists, hospitals, pharmacies and customers across the UK, attempting to stop the prescription and use of generic versions of the off-patent Pregabalin.⁶⁹

For those who are familiar with the evolution of modern patent law, these 100 paragraphs in the Lyrica decision recall some historical debates. For instance, during the patent law reform process in Britain in the 1930-1940s, the representative body of the British Medical Association adopted the following resolution in 1931, stating:

⁶⁷ Mylan and Actavis v Warner-Lambert [2015] EWHC 2548 (Pat). <<http://www.bailii.org/ew/cases/EWHC/Patents/2015/2548.html>> accessed 09 June 2015.

⁶⁸ European Patent (UK) No 0 934 061 entitled ‘Isobutyrgaba and Its Derivatives for the Treatment of Pain’.

⁶⁹ *Mylan and Actavis v Warner-Lambert* [2015] EWHC 2548 (Pat). <<http://www.bailii.org/ew/cases/EWHC/Patents/2015/2548.html>> para 459-558.

...that the association approves the traditional professional usage in accordance with which it is unethical for any medical practitioner who discovers or invents any substance, process, apparatus, or principle likely to be of value in the treatment of patients to act against the public interests by unduly restricting the use and knowledge of such discovery or invention for his own personal advantage.⁷⁰

The Association accordingly submitted the suggestion to the Law Reform Committee at the time to seek a mechanism for managing such patent by a public body.⁷¹

It is maybe exaggerating to conclude that Justice Arnold ruled the case only in light of the public interest, but the decision does help in lifting the undue restriction that Pfizer has been strenuously attempting to impose on a public health system. There was no public statement from a professional body in Britain on this decision with critiques on the intersection of patent and public health interests in as witnessed decades previously. Time has moved on and the country has become a strong patent supporter at large.

The central technical reasoning of the case relates to a type of so-called ‘second medical use’ in the Swiss form of patent claim. The ‘second medical use’ refers broadly to claiming an invention on discovering that an old medicine can be used in treating a new disease, one of the types of patent applications that have been categorized as ‘ever-greening’, which has long been controversial in terms of whether it merits a legal recognition as something new that can be patented. Pfizer, as is the case with all other major pharmaceutical companies, has been relying on such a strategy to secure its market

⁷⁰ R Smither, ‘Patent Protection for Inventions Relating to Medical Treatment of Human and Animals: A Study with Recommendations’ (The Common Law Institute of Intellectual Property 1991) 45.

⁷¹ *ibid.*

position, as in the notorious case of its flagship product Viagra. As a typical ‘second medical use’ product, Viagra has brought Pfizer billions of dollars in profits, and in the meantime dozens of patent litigations from its competitors around the world have challenged its ‘second medical use’ assertion. The debates around issues such as ‘second medical use’ often touch on the central doctrines of patent law in terms of its approach to recognizing whether or not something can be endorsed as a patentable invention.

Across the continent, another case that has remained at the centre of attention was decided by the Supreme Court of India in 2013 in *Novartis AG v Union of India & Others*, over a patent concerning a beta-crystalline form of Imatinib Mesylate, a medicine under the brand name Glivec, used in treating myeloid leukaemia and tumours.⁷² The Court directly ruled out the inventiveness of the crystalline form claim by adopting Section 3(d) under the India Patent Act 1970, amended as of 2005. The case has triggered heated debates in the field from both industrial and public health perspectives, also partly due to India’s unique position as a generic pharmaceutical producer at a global level. According to Section 3(d), unless proven to have significant enhancement, nothing shall be granted patent if it involves merely a change in the known substance,⁷³ which is essentially a way of preventing an ‘ever-greening’ strategy that has been commonly used by industry. Glivec, as a crystalline form of a known medicine,

⁷² *Novartis v Union of India* [2013] Supreme Court of India, Civil Appeal Nos. 2706-2716 of 2013, < <https://indiankanoon.org/doc/165776436/> > accessed 20 June 2016.

⁷³ Section 3(d) of the Patent Act 1975 India reads that ‘(d) 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 one new reactant.

Explanation. -For the purposes of this clause, salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance shall be considered to be the same substance, unless they differ significantly in properties with regard to efficacy...’.

has been considered as lacking that level of enhancement that would merit a patent protection under Indian law.

The two cases share some central inquiries that are relevant to this research. Firstly, there is the issue of how the legal conceptualisation and construction of innovation differs from how innovation is understood in other senses. Secondly, there is the question of the role legal professionals have played in constructing, interpreting and reinterpreting the notion of innovation in patent law.

For the first inquiry, it is worth noting that patent law does not define ‘innovation’ *per se* as a starting point in its positivistic sense, but rather concentrates on patentable inventions. The patentability standards framework subjects the legal determination of newness and usefulness to the specific formality, technological, spatial and temporal conditions, which are often known as novelty, inventiveness and industrial applicability that have to be disclosed in a manner sufficient to be recognized by law.⁷⁴

It is necessary to review how patent is operated within the system defining the boundary of newness over time and across technological transitions. This controversial aspect touches on patentability criteria concerning medicines, including chemical and biological drugs, diagnostic tools, and supporting technologies.

Overall, the patentability criteria reflect considerable uncertainty and are indeterminate in their actual applications. For example, the most important party in the patent field is a ‘fictitious person skilled in the art’.⁷⁵ The actual person who assesses the

⁷⁴ The standard of inventiveness is also often referred to as the “doctrine of non-obviousness”. The requirement for industrial application is also referred to sometimes as “utility in determining the patentability of a given subject matter”.

⁷⁵ Hans-Rainer Jaenichen and others, *From Clones to Claims: The European Patent Office’s Case Law on the Patentability of Biotechnology Inventions in Comparison to the United States and Japanese*

understanding of such a hypothetical person is often the patent examiner or members of patent appellant bodies and judges. The actual level of knowledge and experiences of this group of professionals could make the legal construction of the person skilled in the art highly uncertain and fluid.

In addition, the issue of obviousness has played an important role in the debates on pharmaceutical patents, especially related to the issues of patent thickets and ever-greening as mentioned above. The assessment in this regard, however, varies substantially from country to country, which leaves the conceptual issue regarding the boundary of inventiveness in patent law unfinished.

Thirdly, the boundary of eligibility, namely acceptances and exclusions of patentable subject matters under patent law has also resulted in controversies and challenges. The tendency to expand the scope of patentable subject matters has been a constant debate, one heavily associated with the pace of technological changes in society. Controversies also arise concerning patenting research and diagnostic tools. For instance, medical treatment methods and tools have long been excluded from patent, however recent years have seen jurisprudence developments that have directly challenged the previous scope of the law in terms of exclusions.⁷⁶

For the second set of inquiries, it is important to draw on the intersection of law and science and technology alongside further analysis of the role of active professionals in forming the notion of innovation through law. In the research on legal professionals, the literature on patent attorneys and examiners is comparatively rare. Recent literature has

Practices (4th edn, Carl Heymanns Verlag 2006) 49.

⁷⁶ Florian Leverve and Jeremy Phillips, *The Exclusion of Surgical, Therapeutical and Diagnostic Inventions from Patentability under Article 52 (4) of the European Patent Convention* (Intellectual Property Institute Report 2008).

started emerging that looks at the issue more closely, but many examples focus rather narrowly on patent holders' perspective.⁷⁷ In this dissertation, the role of expertise and professionals will be discussed in relation to two aspects. Firstly, the making meaning of patent law texts and patent documents is represented as a grant process of co-production of law, science and technologies, in which legal professionals – particularly patent attorneys – have played a critical role in constructing and sustaining the system. Secondly, with legal expertise reinforcing a particular vision of how knowledge is produced and shared and how the meaning of newness is to be understood, the broader community of innovators – especially physicians and scientists – have been marginalised. Even though inventors other than corporate patent holders are entitled to retain moral rights in patent documents,⁷⁸ their political positioning is considerably weaker in the current debates on patent's central role in biomedical innovation. This dissertation engages these elements by exploring the building of an alternative conceptual framework.

IV. Methodology

Building a conceptual framework has been defined as an approach to working out 'a network...of interlinked concepts that together provide a comprehensive understanding

⁷⁷ For instance, the literature has started discussing the need for patent attorneys with a scientific background to understand the law better, and the necessity to have attorneys playing participatory roles in innovation strategy processes and not merely act as service providers in order to identify the best road to winning patent applications. Some examples of this kind of research can be found in: John M Golden, 'Construing Patent Claims According to Their Interpretive Community: A Call for an Attorney-Plus-Artisan Perspective' [2008] 21 U Harv JLT 321; Srikumaran Melethil, 'Patent Issues in Drug Development: Perspectives of a Pharmaceutical Scientist-Attorney' [2005] 7(3) AAPS Journal 723; Cameron Walker, 'Finding a Balance' [2014] 511 Nature 621.

⁷⁸ Graham Dutfield, 'Collective Invention and Patent Law Individualism, 1877-2012; or, the Curious Persistence of Inventor's Moral Right' in Stathis Arapostathis and Graham Dutfield (eds), *Knowledge Management and Intellectual Property: Concepts, Actors and Practices* (Edward Elgar 2013) 109.

of a phenomenon or phenomena'.⁷⁹ The thesis intends to keep in line with this definition of conceptual framework building in determining the methodologies.

In this regard, the methodological approach of the thesis is largely inspired by Critical Legal Studies, especially associated with the branch of critical legal scholarship that seeks re-construction as the outcome of their criticism.⁸⁰ In addition, an interdisciplinary approach will be used by engaging with the theoretical approach of critical international political economy scholarship, by revealing the dialectical features of international law and exploring its path to transformation. The research will be conducted through a desk review of law sources and secondary literature. As such, the methodological choice is expected to support the critique, reinterpretation and transformative argumentation that the thesis intends to achieve.

i. Critical Legal Studies and Its Application to the Thesis

In order to answer the central research question concerning the extent to which an alternative conceptual framework could be built in order to respond to the insufficiencies of the current patent law doctrine in terms of promoting biomedical innovation, the thesis starts with a critical analysis of the patent law paradigm in the field of innovation drawing largely from utilitarian theory. In this regard, instead of looking at law as a self-contained system from a doctrinal point of view, the thesis approaches patent law from a contextual perspective.

⁷⁹ Yosef Jabareen, 'Building a Conceptual Framework: Philosophy, Definitions, and Procedure' [2009] 8(4) International Journal of Qualitative Methods

<<http://ejournals.library.ualberta.ca/index.php/IJQM/article/view/6118>> accessed 15 May 2015.

⁸⁰ Robert Mangabeira Unger, *The Critical Legal Studies Movement* (Harvard University Press 1986) 18, 25.

Firstly, via critiques, the thesis refers to the critical legal scholarship in its attempt to alert us to the law's contradictions as 'dissatisfaction' with the 'injustices perpetrated by law, and with the orthodox legal tradition that either explained away or ignored law's failure'.⁸¹ In addition, it has been observed that there is a close link between the methodological approach of critical legal studies and the view on the different functions of law,⁸² which informs the choice of the methods used in the context of this research. The phenomenon of the politicization of patent law that has been observed,⁸³ especially in the context of trade globalization, has revealed the injustice of using patent law as an instrument to reinforce the political economy agenda at a global level. This inherent injustice manifests itself in neglected innovation for diseases suffered by those who do not have sufficient market power. In addition, the contradictory practices of using patent for maximizing commercial gain further illustrates current patent law's internal conflicts and contradictions. These conflicts are typically reflected either in the legal fictions of defining biomedical innovations in the context of changing technologies, or by the concentrated power exercised by a particular group of actors in the broader innovation community while patent law has also been used as a political vehicle to sustain particular ideological agendas. This level of dilemma is difficult to analyse using positivistic methods, as the tendency to ignore the objective influence and perceived political neutrality⁸⁴ of positivist approach can easily veil the nexus of the instrumental rhetoric that uses patent for innovation and the political economy agenda that lies behind it.

⁸¹ Costas Douzinas and Adam Gearey, *Critical Jurisprudence: The Political Philosophy of Justice* (Hart Publishing 2005) 240-7.

⁸² Mark van Hoecke (ed), *Methodologies of Legal Research: Which Kind of Method for What Kind of Discipline* (Hart Publishing 2011) 110.

⁸³ Sebastian Haunss, *Conflict in the Knowledge Society: The Contentious Politics of Intellectual Property* (CUP 2013) 4.

⁸⁴ Michael Salter and Julie Mason, *Writing Law Dissertations: An Introduction and Guide to the Conduct of Legal Research* (Pearson Longman 2007).

Secondly, and reinforcing the above point, the thesis critically reviews the central theoretical enquiry of how the seemingly homogeneous understanding of the role of patent in driving innovation has been formed. In this regard, by recognizing the predominance of law and economic studies in intellectual property law and policy discourses on this question, the thesis tracks and critically reviews the dogmatic features of law and economic approaches in order to summarize the major inabilities of such approaches in terms of exploring alternative conceptual framework building.

Thirdly, the thesis also outlines a historical account of patent law, especially its dialectical evolution strongly linked to policy choices in the light of industrial development. The importance of including this level of critique is to contest the tendency to interpret and justify patent from natural rights and human rights perspectives which, from a critical historical vantage point, does not have solid ground. A rich literature has also been developed in relation to this issue by looking at intellectual property system as a whole and patent more specifically.⁸⁵ Contesting the connotations of patent as a fixed formality based on a historical critique prepares the thesis to go further in reinterpreting the concept of openness while simultaneously discussing the patent paradigm's transformation.

Fourthly, the thesis will develop a critique formed from within the patent law regime by discussing the extent to which the positive principles and institutions of patent law are able to adjust distortions in the context of biomedical innovation. In this sense, an interpretative engagement will look at the objectivity of the patent system, its legitimacy and contentious challenges to it, and the functions and limitations of the flexible

⁸⁵ Christopher May and Susan K Sell, *Intellectual Property Rights: A Critical History* (Lynne Rienner Publishers 2006).

mechanisms contained in patent law in relation to biomedical innovation. This critical dimension refers to the structuralist aspects of the relevant legal scholarship,⁸⁶ which could help feeding back to and informing the role of law. In this respect, the critique engages directly with patent law's legal framework, in which the construction of 'new' through patentability criteria, flexibilities for research activities, and the notion of balance have attempted to deal with the inherent political struggles. However, these efforts could not avoid finding the limitations revealed in questioning the underlying justification of the patent system and seeking transformative alternatives. In addition, the thesis also discusses further challenges to such limitations when patent has been constructed as a binding institution through international law, especially under the WTO's TRIPS agreement.

The above critiques use a critical legal scholar's notion of analysing inherent inconsistencies and contradictions, and looking for a path to reconstruction. This approach links the problems in law with broader social theory, thereby forming the basis for discussions based on reinterpretations and transformations.

ii. Reinterpretation and Transformation: An Interdisciplinary Approach

Despite its radical origin in challenging liberal legal theories, critical legal studies have also developed reconstructive thinking,⁸⁷ an approach in which Unger's arguments on construction and social transformation have been especially prominent.⁸⁸ In terms of approaching alternative conceptual framework building, the thesis takes above

⁸⁶ Douzinas and Gearey (n 81).

⁸⁷ Peter Fitzpatrick, 'Distance Relations: The New Constructionism in Critical and Socio-legal Studies' in Philip A Thomas (eds), *Socio-Legal Studies* (Aldershot 1997). See also Ian Ward, *Introduction to Critical Legal Theory* (Routledge Cavendish Publishing 2004).

⁸⁸ Unger (n 80).

dimensions of critical legal research to be a key nexus linking two academic fields, namely science and technologies studies (STS) and critical international political economy.

Firstly, the thesis advances the critiques on the role of legal professionals and patent's construction of meaning by engaging with STS and its co-production idiom. As an emerging field of intellectual inquiry, the notion of co-production draws on multiple disciplines, namely law, sociology, science and politics in investigating the way in which particular understandings, institutions and identities have been formed.⁸⁹ By relating itself to critical studies, co-production claims to be a branch of STS scholarship with a more direct engagement with political conflicts in the context of making, using and governing science and technologies, in contrast to other STS branches which may suffer from being overly symmetrical in their analysis, particularly in relation to power and politics.⁹⁰ The co-production framework has provided scholars with a useful way of interrogating the interactional and dialectical interplay in knowledge and expertise related to medicines, medical practices, law and institutional arrangements in the field of biomedical innovation.

Secondly, the thesis further develops the transformation framework by referring to critical political economy scholars, in particular the triangulation approach introduced by the neo-Gramscian Robert Cox.⁹¹ This approach argues that the path to transformation is a collective process involving interaction between ideas, material

⁸⁹ Sheila Jasanoff, 'The Idiom of Co-Production' in Sheila Jasanoff (ed), *States of Knowledge* (Routledge 2004).

⁹⁰ *ibid.*

⁹¹ Robert W Cox, 'Social Forces, States, and World Orders: Beyond International Relations Theory (1981)' in Robert W Cox and TJ Sinclair (eds), *Approaches to World Order* (CUP 1996).

conditions and institutions.⁹² The reinforcing or weakening of each dimension would lead to the progressive transformation of the total regime. Such a notion reflects the consistent debates and challenges facing the overall patent law regime in respect of biomedical innovation. Cox's account of transformation highlights the importance of looking from below and outside of existing normative orders,⁹³ thereby allowing a reimagining of the role of norms and law in developing alternative conceptual frameworks.

To mitigate the limitation of being international relations-oriented and probably somewhat structuralist in terms of a triangulation approach, combination with a co-production framework provides both a macro and micro level perspective in this dissertation's discussion of alternative conceptual framework building, especially in the later chapters.

iii. Exploring Key Elements for Building an Alternative Conceptual Framework

After the above theoretical discussion, the thesis examines how the key transformative elements explored here connect with how the patent paradigm influences and works in reality. Firstly, the thesis discusses the ideal dimension in which the normative meaning of medicine and biomedical knowledge can alter the definition as prevails in the patent-centric model. This dissertation discusses the divisions between the material and behavioural aspects of medicine, the traditional and modern dichotomy of medicine in predominant patent law order, and explores the notion that this divisions can be mitigated. In this sense, three main normative discussions in which medicine and knowledge have been dealt with without necessarily constructing rivalry and exclusivity

⁹² *ibid.*

⁹³ *ibid.*

are examined, namely the commons studies on biomedical knowledge, the mechanism of access and benefit sharing, and the human rights framework concerning the right to health and the right to science and knowledge.

Secondly, the thesis discusses the role and norm-based governance of broader innovator communities, and the relationship between patent and those initiatives claiming to be open innovation-orientated in the field of neglected diseases. These two lines of analysis intend to provide further support to the institutional dimension of the transformative conceptual framework building. The thesis suggests the reengagement of the community of innovators in order to explore the route of transformation, outside of the conventional patent holder-centred approach as defined in patent law. This implies re-examining the professional culture and norms governing patent law practitioners and medical practitioners in order to pursue an alternative objective of openness. In relation to openness, the thesis looks at the normative aspect of R&D for neglected diseases, discussing the notion of ‘neglected’ in a societal sense and its connection with the reinterpretation of openness in light of the concept of human rights, empowerment and capabilities. In addition, the actual policies involved in dealing with the patent regime in open innovation initiatives are fluid and depend on the actors and participants involved.

Secondly, the thesis discusses the role and effect of expertise and the professions in the context of constructing the legal meaning in patent papers related to biomedical innovation. This level of analysis is based on critiques of the role of legal professionals – in particular patent attorneys – in constructing patenting documents and claims’ specific language system, and the implications of this for the discourse of biomedical innovation. The thesis will later engage with the literature on innovation beyond patent

holders, especially regarding the role of clinicians and scientists in biomedical innovations. Among these groups of actors, the interactions and conflicts between professional and communal cultures invite the exploration of possible forms and norms while reimagined concepts of innovation entail a request for innovation's democratization.

In addition, the thesis discusses the major aspects arising from the analysis of the patent paradigm in relation to biomedical innovation's progressive transformation. Referring to the central methodological approach adopted here, which uses critical legal studies' reconstructive orientation, STS's co-production idiom and critical political economy's transformative framework, the thesis discusses the extent to which these transformative elements provide feedback and impact on the role of law. Such an analysis maintains reference to the critical perspective of patent law as a dialectical institution while progressive transformation would, potentially, be triggered by redefining notions of openness in innovation, while sidestepping patent and reengaging with public and broader innovation communities would require a reimagined normative intent.

iv. Sources and Materials

In order to apply the methodological approach outlined above, the thesis will engage with three major types of sources and materials.

Firstly, in supporting the critical analysis of patent law's internal contradictions special attention will be paid to reviewing and analysing formal sources of law. Treaties under the auspices of the WTO and WIPO will be the major sources of international law reviewed here. In the sections concerning traditional medical knowledge and practices, sources of international law under the auspices of the CBD and WHO will also be

discussed. In addition, national patent laws and selected leading cases will be referred to when reviewing the development and controversies of the predominant patent law doctrines in defining health-related innovations and their changing historical, technological and political contexts.

Secondly, reviewing the secondary literature and data will be the major methods adopted in this thesis. In order to support the analysis of the central research questions, the literature reviewed will include scholarly works on international law, intellectual property law (especially patent law), critical international political economy, legal and economic studies, science and technology studies, and studies of traditional knowledge whose research focuses on innovation, biomedical patents and globalization.

The author of the thesis has obtained sources and materials through using library and online research databases. The major information resources used to gather the literature and legal sources have included: the School of Oriental and African Studies library; the Global Law Library, Institute of Advanced Legal Studies; the British Library; the London School of Hygiene and Tropical Medicines library, the World Intellectual Property Organization library; and the University of Geneva library. In terms of online research databases, Westlaw, LexisNexis, JUSTO, Heinonline and other online literature, e-books and databases with university-based library credentials constitute the major electronic literature and resources used in this thesis. Internet search and online literature published by international organizations and other research institutes related to this research have also been used as source material.

V. Scope of the Research

The research will focus on a critical review of the conceptual issues between patent law doctrine and biomedical innovation to explore the construction of an alternative conceptual framework. At the theoretical level, the utilitarian justification of patent and the legal and economic-based arguments will be this dissertation's major focus. Patentability criteria doctrines that have been developed by legislation and leading cases concerned with the invention of biomedical products and diagnostic tools will be discussed in contrast to the notion and practices of innovation in non-law settings, especially in relation to scientific communities and medical knowledge systems outside the realm of patent. The existing legal framework at international level aims to redistribute and facilitate the dissemination of knowledge and technologies within and outside of patent law, such as the exemptions from patent, open licensing, access and benefit sharing and technology transfer will also be analysed in the context of the dissertation's central concerns. The research will cite legislation and cases from different jurisdictions when they represent archetypal conceptual issues, without focusing on particular countries or regions in its analysis. In addition, the use of 'biomedical innovation' is intended to refer to the broad sense of biomedical research including 'activities and applications of basic sciences (e.g. biochemistry, anatomy) to the diagnostic and treatment of patients'.⁹⁴ The meaning of biomedical innovations as used in this research is inclusive and broadly related to both synthetic and biological medicines, diagnostic tools and methods.

⁹⁴ 'Biomedical' in Rebecca Sell and others (eds), *Dictionary of Medical Terms* (Barron's Educational Series 2012) 70.

Chapter 1 of the thesis will analyse the major patent law doctrines in an attempt to balance openness and innovation in a positive law context while taking its discontents into account. It will critically review the major patent law justifications and doctrines related to health innovation. In this regard, primary justification of patent law, especially the incentive narratives closely derived from legal and economic perspectives, will be analysed closely. In addition, the patentability criteria used in defining newness and innovation, general exceptions in medical tools and methods, and research and experimental exemptions are also examined. The thesis will also discuss mechanisms within patent law that aim to encourage knowledge diffusion (especially licensing and pooling), while examining their major limitations in the context of health innovation.

Chapter 2 reviews the constructing of innovation through patent law. It refers to a few schools of scholarships, in particular drawing on the STS concept of co-production. The chapter begins by outlining the notion of co-production and disciplinary conflict between patent law and science and research. It also refers to broader notions from Socio-Legal Studies and the Actor Network Theory with a focus on the relationship between law and other social and scientific interpretations of patent.

Chapter 3 discusses the influence of professions and expertise. In particular it will look at how patent attorneys are recognized and positioned within the broader context of legal professionals, keeping in mind the co-production framework. The chapter maps the conceptual and historical emergence of the patent attorney as a specialised profession and in the field of biomedical innovations. It first reviews the qualification mechanism for patent attorneys specializing in biotechnology and pharmaceutical sciences, looking at the disciplinary transformation and institutional-level co-production, especially concerning the question of how innovation is looked at, defined and assessed. The

chapter also discusses the different approaches to legal practices within the law profession and the implications of this for patent attorneys.

Chapter 4 reviews the interaction of ideological motives, expertise and community imaginaries in the process of the micro level construction and reproduction of the concept of newness in the context of biomedical research. It first discusses the role of text and expertise in forming patent's community imaginary and reflects on the construction of a known subject's new meaning. It further interrogates the ideological motives in the process of reproducing the meanings of innovation in the context of enclosing research tools through patenting on life forms in the genomic era. The chapter also discusses the roles of communities of non-patent expertise in the context of biomedical innovation, especially medical practitioners. Having contributed and performed innovation regularly, these communities are marginalised by the current patent-centric paradigm. In this regard, the analysis developed in this thesis will pave the way for Part III's conceptual discussion where the roles and interplay of communities can be reimagined, thereby moving towards an alternative innovation framework.

Chapter 5 draws on the critical conceptual reviews in Part I of the thesis and outlines the main aspects of the alternative conceptual framework for biomedical innovation alongside the patent paradigm. It examines the theoretical applicability of the triangulation framework and its combined use with the co-production approach in the building of a transformative conceptual framework. It then discusses the conceptual divisions and the need to unify the concept of medicine and biomedical knowledge. To explore the ideal dimension of the alternative conceptual framework, it reviews studies of the medical knowledge commons, access and benefit sharing and the human rights framework concerning health, science and knowledge. Thereinafter it discusses the

reinterpretation and reformation of communities and collective production of knowledge in the context of biomedical innovation.

Chapter 6 discusses the possible frameworks for rethinking the issue through the lens of broader innovators communities and rethinks the norm-based approach to openness in medical science and research. It examines the impact of patent law proliferation on the culture of science and research and examines the question and concept of openness as a possible pathway. The chapter also discusses the reciprocal effect of materials, ideas and institutions in the context of medical science and research while confronting the issues of patent law proliferations and the need to reconfigure the concept of innovation and its relationship with patent.

PART I

Chapter 1: Patent Law Justifications and Discontents in Biomedical Innovation

1.1 Enclosing Knowledge and the Conflict of Cultures in Science and Technologies: Some Pre-conceptual Discussions

1.1.1 Knowledge and the Proprietary Enclosure

Researchers have pointed out that one central economic argument underpins making intellectual subjects a form of property is the constructed scarcity of knowledge, so that the legal institution of intellectual property can be established via an analogy based on the law of real properties.⁹⁵ This line of analysis highlights one critical feature of ‘knowledge’ as a non-rivalry resource,⁹⁶ whose value is not be exhausted after being used by different members of society. On the other hand, once constructed as a scare resource, the non-rival nature of knowledge has also been used to justify the necessity of solving the problem of free-riding in the context of intellectual property studies.⁹⁷ Nonetheless, both scenarios leave open the question what the meaning of knowledge exactly entails.

Without going into the details of the overall debates on legal philosophy’s attitudes towards knowledge in this research, it is appropriate to locate the notion of knowledge in the context of intellectual property law in general and patent law in particular, given

⁹⁵ A rich literature has contributed to this viewpoint. Some typical critical analyses could be inferred from, for example, Christopher May and Susan K Sell, *Intellectual Property Rights: A Critical History* (Lynne Rienner Publishers 2006).

⁹⁶ *ibid.*

⁹⁷ William M Landes and Richard A Posner, *The Economic Structure of Intellectual Property Law* (The Belknap Press of Harvard University Press 2003).

that this branch of law has been formed as a direct agent in regulating and governing the production, dissemination and reproduction of knowledge in contemporary society.

The evolution of intellectual property theory, from its early stages as a privilege to its contemporary form as a vested property right, has largely reflected the embedded understanding of knowledge in its empirical sense alongside the commodification of the process of knowledge.⁹⁸ Patent lawyers could possibly point out here that the law protects not the abstract idea but only its embodiments, thus knowledge *per se* is not really subject to exclusivity but rather is a carrier of it. However, literature has emerged that investigates the legal exercise of attaching meanings to patent text and codes, which may not contain or reflect scientific or technological realities.⁹⁹ It has also been argued that the materiality of present patent practice is represented more as the patent texts themselves, constituting ‘the materiality of text’.¹⁰⁰ The presumed line between the tangible and intangible, material and immaterial in patent law becomes blurred. The textual construction of meaning in patent, on the other hand, weakens the communicative function of patent documents outside of professional circles, making it rarely understandable for non-patent-practitioners. Thus, producing legally acceptable patent documents may become a system in itself, which might not carry meaningful knowledge that one would anticipate obtaining while respecting the legally-granted exclusivity

⁹⁸ Laurelyn Whitt, *Science, Colonialism, and Indigenous Peoples: The Cultural Politics of Law and Knowledge* (CUP 2009). See also. Mario Biagioli, ‘Patent Specification and Political Representation: How Patent Became Rights’, in Mario Biagioli and others (eds), *Making and Unmaking Intellectual Property: Creative Production in Legal and Cultural Perspective* (University of Chicago Press 2011) 25-40.

⁹⁹ Hyo Yoon Kang, ‘Science Inside Law: The Making of a New Patent Class in the International Patent Classification’ [2012]25(4) *Science in Context* <<http://dx.doi.org/10.1017/S0269889712000233>>551, accessed 20 May 2018; Alan Pottage and Brad Sherman, ‘On the Prehistory of Intellectual Property’ in Alain Pottage and Brad Sherman (eds), *Concepts of Property in Intellectual Property Law* (CUP 2013) 12.

¹⁰⁰ Alan Pottage and Brad Sherman, ‘On the Prehistory of Intellectual Property’ in Alain Pottage and Brad Sherman (eds), *Concepts of Property in Intellectual Property Law* (CUP 2013) 27.

rights enjoyed by the patent holders. The particularly constituted system of documents in turn facilitates the expansive private property rights dimension in the understanding of patent vis-à-vis knowledge, and have triggered a number of critiques, including those concerning the reconceptualization of knowledge commons.¹⁰¹

An additional point on the concept of knowledge should also be made concerning its perceived intent in Western contexts and the interaction with non-Western cultures, which remains one of the central issues in the context of discussing medical innovation based on traditional knowledge.¹⁰² The author has acknowledges that the use of Western versus non-Western could be contestable in terms of neglecting the actual diversity of societies and cultures in non-Western settings and also given the presumption of homogeneity in the West. For both convenience and the main purpose of the research, the dichotomy in this sense would be used to refer largely to the phenomenon of the constructed logic of innovation based on a certain type of knowledge, science and technology that has been presented by the intellectual property law system, contrary to the different types of knowledge and innovation systems operating outside of such logic.

By acknowledging the difficulty of exhausting the conceptual presentations and discourses of knowledge in different cultures, the author choose one such example from the work of the Chinese philosopher Zhang Dongsun, who intended to provide a critique and consolidation of the theory of knowledge proposed by Western philosophies and the

¹⁰¹ Brett M Frischmann, Michael J Madison and Katherine J Strandburg (eds), *Governing Knowledge Commons* (OUP 2014).

¹⁰² See, for example, Philippe Cullet, *Intellectual Property Protection and Sustainable Development* (LexisNexis Butterworths 2005); Christopher May and Susan K Sell, *Intellectual Property Rights: A Critical History* (Lynne Rienner Publishers 2006); Graham Dutfield, *Intellectual Property, Biogenetic Resources and Traditional Knowledge* (Earthscan 2004).

Chinese epistemological approach to knowledge.¹⁰³ While Zhang's analysis is located in the comparison between China and the West, reviewers have observed the broader implications of his conclusions in studying the plurality of epistemology and knowledge.¹⁰⁴ Accordingly in Zhang, 'the theory of knowledge and cultural history must be treated simultaneously',¹⁰⁵ and in this sense 'Western philosophy is nothing but a particular form of knowledge characteristics of and for the use of Western culture'.¹⁰⁶

1.1.2 Science and Technologies: A Cultural Conflict with Patent Law over Openness?

The Western-oriented knowledge system has been progressed hand-in-hand with notions of science and technology in contemporary society. It is important to emphasise that the notion of science has played a critical role in supporting the existence and development of the patent system. One example reflecting the elaboration of the term 'science' in supporting the legitimacy of intellectual property law is the constitutional legitimacy of providing intellectual property protection by the Congress to promote the useful art and the progress of science in the United States.¹⁰⁷

¹⁰³ Zhang Dongsun, 'Thought, Language and Culture' (1946) 10 *Sociology World* (张东荪, '思想语言与文化', 《社会科学界》1946年), Translated and available online at <http://www.vordenker.de/downloads/chang-tung-sun_thought-language-culture.pdf> accessed 11 May 2015.

¹⁰⁴ See, for example, Haridas T Muzumdar, 'A Chinese Philosopher's Theory of Knowledge' (1956) 19(1) *Midwest Sociologist* 12; Jana Rošker, 'Epistemology in Chinese Philosophy' (2014) *Stanford Encyclopaedia of Philosophy* <<http://plato.stanford.edu/entries/chinese-epistemology/>> accessed 11 May 2015.

¹⁰⁵ Zhang (n 103).

¹⁰⁶ *ibid.*

¹⁰⁷ Article 1 Section 8 Clause 8: 'The Congress shall have power ... to promote the progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries,' Constitution of the United States 1787.

Research has also pointed out that science and technology have contributed to a number of characteristics of contemporary societies, namely the

...uncertainty, unaccountability and speed that contribute, at the level of personal experience, to feelings of being perpetually off balance, the reduction of individuals to standard classifications that demarcate the normal from the deviant and authorize varieties of social control, the scepticism, alienation and distrust that threaten the legitimacy of public action, and the oscillation between visions of doom and vision of progress that destabilize the future.¹⁰⁸

While science and technologies might bear a certain similarity to law in its normative-based mode of operating,¹⁰⁹ jurists could possibly quick reflect here that majority of such characteristics mentioned above are what law would normally dislike and would attempt to eliminate, reduce or stabilize, which is equally the case from the standpoint of patent law. Amongst other analyses in this regard, it is pointed out that

Whereas scientific research can engage with the turbulent or violent history of innovation and controversy... law has a homeostatic quality which is produced by the obligation to keep the fragile tissue of rules and texts intact, and to ensure that one is understood by everyone at all times...

¹⁰⁸ Sheila Jasanoff, 'Ordering Knowledge, Ordering Society' in Sheila Jasanoff (ed), *States of Knowledge* (Routledge 2004) 13.

¹⁰⁹ Bruno Latour, *The Making of Law: An Ethnography of the Conseil D'État* (Marina Brilman and Alain Pottage trs, Polity 2002).

A premium is put on legal stability but there is no such thing as scientific stability.¹¹⁰

Referring these distinctions back to the realm of patent law, the construction and development of doctrines – especially those related to the scope of patentable subject matter and patentability criteria in the context of evolving technological realities – are of particular importance for this research. In particular, unpacking the articulation concerning patent law’s role in encouraging innovation for health will lead us to questions such as how innovation is legally constructed and the compatibility of such constructions in terms of the broader notion of newness in biomedical science.

In addition, the problem of a Western-centric approach remains in relation to conceptions of science and technology, arbitrarily creating the superiority of certain types of knowledge organization and use as ‘scientific’ or ‘modern’, while others become ‘non-scientific’ or ‘traditional’.¹¹¹ This presents an inherent controversy in terms of dealing with innovation derived from traditional knowledge within patent’s established paradigm. This level of controversy is also reflected in the context of knowledge diffusion. In this regard scholars have criticised the rigid Eurocentric framework of science diffusion,¹¹² pointed out that Western science and technologies develop and mark their own identities in the process of encountering other cultures,¹¹³ instead of being seen as an end. The view on Western science and technologies as

¹¹⁰ *ibid* 242.

¹¹¹ Graham Dutfield, ‘TK Unlimited: The Emerging but Incoherent International Law of Traditional Knowledge Protection’ [2017] 20 *J World Intellect Prop* 144.

¹¹² Alexis De Greiff A and Mauricio Nieto Olarte, ‘What We Still Do Not Know about North-South Technoscientific Exchange: North-Centrism, Scientific Diffusion, and the Social Studies of Science’ in Ronald E Doel and Thomas Soderqvist (eds), *The Historiography of Contemporary Science, Technology and Medicine: Writing Recent Science* (Routledge 2006) 21.

¹¹³ *ibid* 242-243.

superior has also contributed to the deterioration and deprivation of other systems of knowledge through developing control and domination, especially by means of colonization.¹¹⁴

These commentaries and analyses are helpful for enquiries concerning the contingency between the patent-centric paradigm and innovations based on non-Western knowledge systems. Scholars has questioned the compatibility of the intellectual property law system with indigenous knowledge system.¹¹⁵ The efforts to construct a suitable protection of indigenous knowledge under the intellectual property law regime would be nothing more than a process of epistemological assimilation.¹¹⁶

It is also helpful to keep these conceptual issues in mind when analysing the effects of patent law's global expansion and its impact on the innovation paradigm in health and medicines.

In additional to the above-mentioned contingencies between the disciplinary cultures of science and technology and those of law, as well as the controversy involved in defining 'science' as a Western-centric concept when developing patent law doctrines, there is

¹¹⁴ *ibid.*

¹¹⁵ Darrel Posey and Graham Dutfield, *Beyond Intellectual Property: Toward Traditional Resource Rights for Indigenous Peoples and Local Communities* (International Development Research Centre 1996) 92; Chidi Oguamanam, 'Localizing Intellectual Property in the Globalization Epoch: The Integration of Indigenous Knowledge' [2004] 11(2) *Indiana Journal of Global Legal Studies* 135; Laurelyn Whitt, *Science, Colonialism and Indigenous People* (CUP 2014).

¹¹⁶ This aspect of the literature discusses the imperial and colonial nature of the use of intellectual property law in the context of indigenous knowledge. The intertwined use of law and science could justify the appropriation of traditional and genetic resources by the Western-dominant research agenda at the global level, such as the Human Genome Diversity Project, while forming a type of biocolonialism. See: Laurelyn Whitt, *Science, Colonialism and Indigenous People* (CUP 2014) 167, 175; Chidi Oguamanam, 'Localizing Intellectual Property in the Globalization Epoch: The Integration of Indigenous Knowledge' [2004] 11(2) *Indiana Journal of Global Legal Studies* 135, 150, 168.

one additional critical-level of discussion related to the conceptual problem of patent law in the context of health innovation, which is the issue of openness.

In the context of innovation debates in general, the notion of openness has become increasingly significant, especially when accompanied by the ‘open innovation’¹¹⁷ concept proposed by Henry Chesbrough which refers to the trend of changing a business model of innovation from a corporate perspective. Chesbrough defines the notion of openness as ‘a paradigm that assumes that firms can and should use external ideas as well as internal ideas, and internal and external paths to market, as the firms look to advance their technology,’¹¹⁸ particularly when used in contrast to the closed mode of innovation traditionally carried out by a company’s research and development (R&D) department. Open innovation in his sense refers to a process of absorption of external resources and expertise during the innovation process, and a process of ‘sharing risk and sharing rewards’.¹¹⁹ Nonetheless, whether the meaning of openness used in Chesbrough’s sense is equivalent with its usage on other occasions in the innovation debate, is a different question.

The notion of being open can be understood quite differently depending on the context of the language and discourse used, including, for example, ‘being allowed to access’, ‘uncovered’, ‘free’ and/or ‘made available’.¹²⁰ Putting each of these variables into the context of discussions on biomedical innovation potentially leads to different scenarios

¹¹⁷ Henry Chesbrough, *Open Innovation: The New Imperative for Creating and Profiting from Technology* (Harvard Business School Press 2003).

¹¹⁸ *ibid.*

¹¹⁹ *ibid.*

¹²⁰ Oxford Dictionary Online, ‘Open’
<http://www.oxforddictionaries.com/definition/english/open?q=openness#open__120> accessed 14 May 2015.

regarding how openness would and should be understood and unpacked. In addition, the notion of openness in the sense of ‘making something available’ or ‘allowing access’ might indicate a presupposed ownership starting from which openness could be achieved. On another hand, if understood as reflecting a status of ‘uncovered’ and ‘free’, then a rather dynamic and participatory situation might be initially envisaged.

In the practical field, the notion of open innovation has been increasingly used by both commercial and non-commercial entities. According to research supported by the Organization for Economic Cooperation and Development (OECD), by analysing data related to licensing, R&D investment and co-inventions across industries, the research considers open innovation to be on the rise, while the pharmaceutical sector had been considered among the highest users of the model.¹²¹ Conceptually, however, it has also been pointed out that it remains difficult to offer a clear account as to what open innovation’s exact definition is.¹²²

One of the critical elements related to the notion of open innovation is the extent to which its emerging paradigm would help in shifting the patent centric dilemma as briefly outlined above. The answer to such a question remains uncertain as many of those initiatives labelled as open innovation are operating within the realm of or at the margin of the patent-centric paradigm while locating the notion of openness as not more than being collaborative. It has been argued by some recent scholars that the centralized

¹²¹ Koen de Backer and others, ‘Open Innovation in a Global Perspective: What Do Existing Data Tell Us?’ in *OECD Science, Technology and Industry Working Papers 2008/04* (OECD 2008) <<http://dx.doi.org/10.1787/230073468188> > accessed 10 May 2015> accessed 14 May 2015.

¹²² WHO, *Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination* (Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination 2012).

nature of the patent system might ultimately be harmful for the overall open innovation movement which has developed its model on a rather decentralized scenario.¹²³

Referring to the much more advanced open source movement in the field of computer software development, one which has been often compared with the potential for a similar institution in the field of biomedical innovations, it is also important to recall two elements that the movement currently operates on the basis of. One is that the notion of openness in the context of open source software in computer science does not mean financially free, but rather implies a culture of sharing between the members who have committed themselves and who are thereby certified under the open source license terms.¹²⁴ Second, the model itself is centrally coordinated, license-based and not patent free.¹²⁵ While the open source movement has inspired some initiatives in the field of biomedical innovations, critics remain cautious about their compatibility.¹²⁶ A more detailed account on the element of openness, and the transformative potential of referring to open source concept in biomedical innovation will be explored in later Chapter 6 of the thesis.

Two more brief notes need to be made here regarding the concept of openness in this research. First, in the current patent law system, openness can refer to the requirement of disclosure of invention. Disclosure of invention is one of the basic requirements for patentability assessment, and has been used as one of the major justifications of the

¹²³ Clark D Asay, 'Enable Patentless Innovation' [2015] 74 Maryland Law Review 431.

¹²⁴ Janet Hope, 'Open Source Genetics: Conceptual Framework' in Geertrui van Overwalle (ed), *Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open Source Models and Liability Regimes* (CUP 2009) 171.

¹²⁵ Arti K Rai, 'Critical Commentary on "Open Source" in the Life Science' in Geertrui van Overwalle (ed), *Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open Source Models and Liability Regimes* (CUP 2009) 213.

¹²⁶ *ibid.*

advantageousness of patent law in contrast to trade secret protections.¹²⁷ This level of meaning is different from how openness is understood in the context of open innovation or open source. More discussions will be offered in this regard, especially as related to the realization of disclosure requirement under the current patent law doctrine and related controversies in the context of biomedical innovations.

Secondly, more nuanced discussions might be formulated when putting the notion of openness in the context of scientific or medical practitioners' communities respectively. For instance, and as observed by researchers, the communality culture within the conventional scientific community might be in inherent conflict with the patent scenario which is based on partial disclosure.¹²⁸ Thus, working on an alternative conceptual framework would require further enquiries regarding how openness could be altered and interpreted in the context of biomedical innovation.

1.2 Theorizing Innovation in Patent Law Justifications and Its Limitations

1.2.1 Deontological Justification of Patent and Its Limitations

Typical justifications of patent can be categorized in two broad groups, namely deontological and consequentialist justifications.¹²⁹ Deontological justification has a clear natural rights orientation, including using the Lockean theory of private property and adapting it in terms of the privatization of intellectual objects.¹³⁰ Thus, the result of

¹²⁷ Edwin C Hettinger, 'Justifying Intellectual Property' [1989] 18(1) *Philosophy and Public Affairs* 31.

¹²⁸ Henry Etzkowitz and Andrew Webster, 'Science as Intellectual Property' in Sheila Jasanoff and others (eds), *Handbook of Science and Technology Studies* (SAGE 1995) 480.

¹²⁹ Horacio M Spector, 'An Outline of a Theory Justifying Intellectual and Industrial Property Rights' [1989] 11(8) *European Intellectual Property Review* 270.

¹³⁰ Sigrid Sterckx, 'The Ethics of Patent: Uneasy Justification' in Peter Drahos (ed), *Death of Patent* (Lawtext Publishing and Queens Mary Intellectual Property Research Centre 2005) 175; Peter Drahos, *A Philosophy of Intellectual Property* (Ashgate 1996) 41.

labour has to be owned and rewarded by means of property rights, which are deemed as fundamental to individual liberty. It has been observed that deontological justification finds its tradition in a more European context,¹³¹ with the recent positive statutory example from the recognition of intellectual property as a fundamental right enshrined under the Charter of Fundamental Rights of the European Union.¹³²

Criticisms of this strand of justification can be found by locating patent law in a historical and practical context. Contrary to the notion of having patent as an essential part of personhood, the granting of patent is historically conditional and pragmatic. It is always subject to policy considerations, legally constructed qualifications, while the rights derived from a patent are also spatial and temporally specific.¹³³ More importantly, it is worth noting that hardly any conceptual analysis on innovation or newness have been forthcoming regarding this strand of justification. As obtaining ownership is linked with personal integrity in this justification, it could be supported without necessarily being subject to the more objective assessment of whether the results of labour are considered as new in comparison with other creations by other people. The typical proviso from Nozick on Lockean theory in patent has applied ‘enough and as good’ conditions¹³⁴ that have been mostly used to explain the limitations on patent term and

¹³¹ Niva Elkin-Koren and Eli M Salzberger, *The Law and Economics of Intellectual Property in the Digital Age: The Limits of Analysis* (Routledge 2013) 4.

¹³² Ping Xiong, *An International Law Perspective on the Protection of Human Rights in the TRIPS Agreement: An Interpretation of the TRIPS Agreement in Relation to the Right to Health* (Martinus Nijhoff Publishers 2012) 54. Article 17.2 of the Charter of Fundamental Rights of the European Union (2000/C 364/01).

¹³³ Peter Drahos, *A Philosophy of Intellectual Property* (Ashgate 1996) 45.

¹³⁴ Sigrid Sterckx, ‘The Ethics of Patent: Uneasy Justification’ in Peter Drahos (ed), *Death of Patent* (Lawtext Publishing and Queens Mary Intellectual Property Research Centre 2005) 182.

the non-rival value of the intellectual objects when used by others. However, theorizing innovation remains absent in this proviso.

1.2.2 Consequentialist Justification of Patent and Reflections by Law and Economics

Differentiated from deontological justification, consequentialist justifications involve economic and technological dimensions in their analyses and focus on the consequences of not having a patent system. At the centre of this group of justifications is the utilitarian theory originating from Jeremy Bentham, who described his idea of granting patent for a limited number of years as one of the critical means to increase wealth:

With respect to a great number of inventions in the arts, an exclusive privilege is absolutely necessary, in order that what is sown may be reaped. In new inventions, protection against imitators is not less necessary than in established manufactures protection against thieves. *He who has no hope that he shall reap, will not take the trouble to sow.* But that which one man has invented, all the world can imitate. *Without the assistance of the laws, the inventor would almost always be driven out of the market by his rival, who finding himself, without any expense, in possession of a discovery which has cost the inventor much time and expense, would be able to deprive him of all his deserved advantages, by selling at a lower price. An exclusive privilege is of all rewards the best proportioned, the most natural, and the least burdensome.*¹³⁵

¹³⁵ Jeremy Bentham, *A Manual of Political Economy* (1st edn, the MSS 1785) 71 < <http://socserv.mcmaster.ca/econ/ugcm/3113/bentham/manualpoliticeconomy.pdf> > accessed 20 March 2015.

Here, law is instrumental and only used to fix the privilege for wealth generation, which bears utility function according to Bentham and would result in pleasure for individuals.¹³⁶ Bentham's original analysis has inspired the major consequentialist arguments based on the incentive function of patent law, including the argument of incentive to invent and innovate, and the argument of incentive to disclosure.¹³⁷ It has been observed that this strand of justification has been the most predominant.¹³⁸ Although it remains unclear how innovation was conceptualized *per se* from Bentham's first account, it has provided a basic economic logic in utilitarian sense, which had further paved the way for the law and economics' understanding of patent law in relation to innovation. Law and economic analyses, on the other hand, have been seen as having superseded other discourses on patent and have presumptions to providing a grand theory in normative terms.¹³⁹ This aspect will be further discussed in the next section.

Nonetheless, incentive theses have been criticised in various ways. For instance, while the incentive to disclosure argument envisages an exchange for knowledge diffusion with a time-bound monopoly, the information that is actually disclosed in the patent documents have been observed as insufficient for the public¹⁴⁰ or distorted through patent applications' drafting techniques.¹⁴¹ Argument of incentive to invent and innovate,

¹³⁶ DJ Manning, *The Mind of Jeremy Bentham* (Greenwood Press Publishers 1968) 33-36.

¹³⁷ Sterckx (n 134) 193.

¹³⁸ Elkin-Koren and Salzberger (n 131) 57.

¹³⁹ *ibid.*

¹⁴⁰ Rebecca S Eisenberg, 'Proprietary Rights and the Norms of Science in Biotechnology Research' [1987] 97 *Yale LJ* 177, 184-87.

¹⁴¹ Peter Drahos and John Braithwaite, *Information Feudalism: Who Owns Knowledge Economy?* (Earthscan 2002) 47 <<https://www.anu.edu.au/fellows/pdrahos/books/Information%20Feudalism.pdf>> access 10 March 2015; Peter Drahos, *The Global Governance of Knowledge: Patent Offices and Their Clients* (CUP 2010) 79-90; Graham Dutfield, *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History* (1st edn, Ashgate 2003).

on the other hand, has been criticised as problematically and counterintuitively restricting the use of inventions by creating a monopoly itself,¹⁴² causing inefficiencies by diverting resources to for-profit research predominately, thereby increasing the social cost of maintaining such a system¹⁴³ and undermining other innovators other than patent holders, thus wasting time and effort in redundant productivity.¹⁴⁴

For the purpose of this study, the question to be further reviewed is the extent to which innovation has been theorized in the argument of incentive to invent and innovate. In this regard, it is necessary to have a closer look at the incentive narrative and its critiques related to Law and Economics studies, whose analysis has been reflecting specifically the utilitarian logic and dominant in law and policy discourses of patent.

1.3 Incentive Narrative on Patent and Its Critiques with a Focus on Law and Economics Studies

The law and economics movement emerged in the 1960-1970s as one of the offspring of legal realism, with critical legal studies acting as a parallel (and rival movement).¹⁴⁵ Historically, legal realism challenged legal positivism's dogmatic understanding of law and provided a contextual and pragmatic approach to law thereby revealing the gaps between formalist law and realities that are often influenced by ideologies and politics.¹⁴⁶ Continuing this tradition of realism, law and economics studies further

¹⁴² Rebecca S Eisenberg, 'Patents and the Progress of Science: Exclusive Rights and Experimental Use' [1989] 56(3) U of Chi LR 1017, 1026.

¹⁴³ *ibid* 1027.

¹⁴⁴ *ibid* 1028.

¹⁴⁵ Elkin-Koren and Salzberger (n 131)16-17.

¹⁴⁶ *ibid*.

highlight the intersection between law and economics,¹⁴⁷ especially when using analytical tools from economics in explaining legal issues. Often associated with a right wing political ideology, law and economics have also been observed as operating mostly on the basis of the liberal foundations of law in contrast to critical legal studies who is often considered as a leftist legal approach.¹⁴⁸ The liberal orientation in general has also played an important role in using legal and economic arguments in the process of patent law expansion in the context of trade globalization, which is one critical backdrop of this dissertation's discussion of biomedical innovation.

1.3.1 Economics Accounts

To better understand how innovation in connection with patent has been approached in law and economics studies, it is necessary to first look at how it has been dealt with in economic studies. Two issues are to be discussed in this regard, namely the different views of using patent as an incentive, and the analysis of innovation itself.

First, it is worth noting that, despite of the dominant liberal economic influence in the patent law literature, there is in fact no theoretical consensus in economic studies regarding whether patent is a suitable incentive. Some examples of the classic arguments are summarized below:

¹⁴⁷ *ibid.*21.

¹⁴⁸ *ibid.*17.

Table 1: Role of Patent in Innovation According to Leading Economic Theories

<i>Role of patent</i>	<i>Examples of leading scholars</i>
Patent is necessary to recoup risk and expenses, otherwise invention activities will, in general, decline.	Jeremy Bentham ¹⁴⁹ John Stuart Mill ¹⁵⁰
Patent is wasteful as it is based on a deliberately created scarcity. Inventions will happen even without a patent. High cost for invention is only a minority case.	Arnold Plant ¹⁵¹ Yoram Barzel ¹⁵²
Patent is less optimal in allocating resources for inventive activities than finance provided by government or other non-for-profit agencies.	Kenneth Arrow ¹⁵³

This is far from a linear or complete categorization as shown above, as some authors have also been cited by later researchers for different purposes. For instance, while Arrow concluded that having public funding provides a better invention incentive, his other analyses in the same study has also been cited as key arguments justifying the necessity of having a patent when facing the paradox of information.¹⁵⁴ While this study does not intend to provide any further detailed review of mainstream economics studies,

¹⁴⁹ *ibid.*

¹⁵⁰ John Stuart Mill, *Principles of Political Economy* (7th edn, Longmans, first published in 1848, Green and Co 1909) Chapter V.X.12 and 25 <<http://www.econlib.org/library/Mill/mlPCover.html>> accessed 18 March 2015.

¹⁵¹ Arnold Plant, ‘The Economic Theory Concerning Patents for Inventions’ [1934] 1(1) *Economica* 30.

¹⁵² Yoram Barzel, ‘Optimal Timing of Innovations’ [1968] 50(3) *Rev of Economics and Statistics* 348, 352, fn 10-11.

¹⁵³ Kenneth Arrow, ‘Economic Welfare and the Allocation of Resources for Invention’ in Universities-National Bureau (ed), *The Rate and Direction of Inventive Activity: Economic and Social Factors* (first published by Economics Division, RAND Corporation 1959, Princeton University Press 1962) 609 <<http://www.rand.org/content/dam/rand/pubs/papers/2006/P1856.pdf>> accessed 22 March 2015.

¹⁵⁴ See, for instance, F Scott Kieff, ‘On the Economics of Patent Law and Policy’ in Toshiko Takenaka (ed), *Patent Law and Theory: A Handbook of Contemporary Research* (Edward Elgar 2008) 4-5.

the divergent views on the role of patent in generating inventive activities have clearly suggested economists' sceptical or 'at least unconvinced'¹⁵⁵ attitude.

Secondly, a further look at the more direct analysis of innovation is necessary. In this regard, the work of Joseph Schumpeter is of special importance, as it introduced the notion of 'creative destruction'¹⁵⁶ as an essential fact of a capitalist economy. Schumpeter's major contribution is summarized below:

1. Distinction between invention and innovation: inventions created by genuine inventors might not necessarily become innovations immediately within a non-profitable environment.¹⁵⁷
2. Typology of innovation in connection with technological progress and economic change: 'new combinations'¹⁵⁸ could therefore be formed based on new consumer goods, new methods of production, new markets and new organizations.¹⁵⁹
3. Entrepreneurs drive creative destruction at a constant pace to support their existence in a capitalist economy: largely sharing a Marxist analysis of the role of coercive law of competition in compelling individual capitalists to innovate in order to survive the efforts of rivals, Schumpeter differentiated himself from neo-classical economics by considering dynamic entrepreneurs as the central movers of innovation and economic change.¹⁶⁰

¹⁵⁵ Elkin-Koren and Salzberger (n 131) 9.

¹⁵⁶ Joseph A Schumpeter, *Capitalism, Socialism and Democracy* (Harper and Row 1942) 83.

¹⁵⁷ Heinz D Kurz, *Innovation, Knowledge and Growth: Adam Smith, Schumpeter and the Moderns* (Routledge 2012) 25, 31. According to Kurz, this view has been influenced by similar analysis by Karl Marx and before that by Adam Smith and David Ricardo.

¹⁵⁸ *ibid* 69.

¹⁵⁹ Schumpeter (n 156).

¹⁶⁰ Schumpeter (n 156) 'Introduction'. In the 'Introduction' section, Richard Swedberg discusses the central role of the entrepreneur in Schumpeter's economic theory. Accordingly, social change begins with the entrepreneurs' active actions. The emphasis on the role of entrepreneur has also been mentioned by Friedrich von Wieser, Schumpeter's teacher. It has been observed by Swedberg in his new introduction to Schumpeter's book that the latter's theory is centred on entrepreneurs and views their actions as the beginning of economic life changes.

Schumpeter's studies highlighted the critical role of technological change in the process of creative destruction, which is essential for encouraging new productivity, ensuring entrepreneurs' renewed rivalry capacity and dismissing old forms of technological and economic means that would often cause unemployment. Such a process is rather circular than unidirectional, and would repeat itself periodically as long as capitalist systems operate. Schumpeter's work has been seen as an exceptional case in modern economic studies, one that has provided a systematic framework concerning the dynamic interaction between innovation and economic growth.¹⁶¹

It is worth noting that though the Schumpeterian approach to innovation reinforces the discourse of economics, his works have not established any connection with patent law's function in this context.¹⁶² Further, it has also been observed that many neo-Schumpeterian economists, who take into account more informal factors in innovation, consider it as an exaggeration to theorise intellectual property as a primary driving force for innovation.¹⁶³

1.3.2 Law and Economics Accounts and Their Major Critiques

In contrast to economists' rather fluid attitudes toward resorting to patent as an incentive for innovation, mainstream law and economics scholars seem more enthusiastic in terms of confirming the efficiency of patent law in this sense.¹⁶⁴ One can partially trace back the reason for this by looking at how the law and economics movement has evolved since the 1960s and given its interaction with the emergence of different branches of

¹⁶¹ *ibid.* See also Elkin-Koren and Salzberger (n 131) 8.

¹⁶² Mark Blaug, 'Why Did Schumpeter Neglect Intellectual Property Rights?' (2005) 2(1) *Rev of Economic Research on Copyright Issues* 69.

¹⁶³ Elkin-Koren and Salzberger (n 131) 27.

¹⁶⁴ *ibid.* 9.

economics over time.¹⁶⁵ Despite adding or modifying certain elements of its analytical parameters, the different branches, broadly representing three generations of law and economics studies,¹⁶⁶ have shared a number of commonalities, including major shortcomings in their application of patent law's incentive narrative regarding innovation. Two major aspects of criticisms of these shortcomings are especially relevant to this dissertation.

First of all, the most severe critiques relate to problems with the assumption of efficiency and rationality. As law and economics studies intend to develop a grand theory whereby all legal issues can be explained and analysed using economic methods,¹⁶⁷ it has been observed that most such studies share the main normative objective of efficiency in their analytical framework,¹⁶⁸ including the literature concerning patent law and its incentive function.¹⁶⁹ In addition, the primary underlying assumption is that the preferences of actors are made on the basis of rationality. Rationality, from a utilitarian perspective, always pursues the maximum level of satisfaction,¹⁷⁰ which in mainstream law and economics narratives more rigidly refers to wealth.¹⁷¹ Wealth maximization, seen as the

¹⁶⁵ *ibid.* 21-27. It provides a good overview of the three generations of law and economics studies, transitioning from the traditional Chicago school featured in its theoretical framework based on the neo-classic economic model, through the neo-institutional economics-influenced branch incorporating variables from political structures, agencies and non-commercial entities, moving toward the emerging behaviour and development law and economics analysis that started examining the role of technology.

¹⁶⁶ *ibid.*

¹⁶⁷ Elkin-Koren and Salzberger (n 131) 4.

¹⁶⁸ *ibid.* 23.

¹⁶⁹ William M Landes and Richard A Posner, 'The Economics of Patent Law' in William M Landes and Richard A Posner, *The Economic Structure of Intellectual Property Law* (Belknap Press of Harvard University Press 2003) 294-334.

¹⁷⁰ Nicholas Mercuro and Steven G Medema, *Economics and the Law: From Posner to Post-Modernism* (Princeton University Press 1997) 57.

¹⁷¹ A link could be identified here with the orthodox Benthamist analysis of utility maximization. However, while Bentham focused on wealth increase in his justification of patent, his overall notion of utilities is probably broader than wealth in general.

manifesto of efficiency, especially in Posner,¹⁷² has thus been considered the central mission of law, including concerning patent.¹⁷³

Major critiques have particularly questioned the normative merits of efficiency, especially interpreted in the sense of achieving wealth maximization alongside the assumption of rationality. For instance, boiling down the issue of rationality in a legal context to a mere economic question has been seen as not providing the whole truth of the political implications of reinforcing the agenda to minimise the notion of social interactions in law.¹⁷⁴ In addition, while law and economics analyses might aim to create an eventual efficiency code whereby partial equilibrium in individual cases would accumulate into a totality of ground rules, such objectives would not work because the diverse options for efficient solutions would, in reality, make the effort of locating one equilibrium rule for all legal cases completely indeterminate.¹⁷⁵ Furthermore, it is a fundamental flaw to make wealth maximization a social goal of law in itself,¹⁷⁶ because the presupposed entirely rational and objective individuals are not real, and the legal process is comprised of far more diversified and complex human factors, including those individuals driven by motivations and non-motivations.¹⁷⁷ It also raises an ethical

¹⁷² Richard A Posner, *The Problems of Jurisprudence* (Harvard University Press, 1990) 382.

¹⁷³ *ibid.*

¹⁷⁴ Frank Michelman, 'Politics and Values and What's Really Wrong with Rationality Review?' [1979] 13 *Creighton Law Review* 478, 506.

¹⁷⁵ Duncan Kennedy, 'Law-and-Economics from the Perspective of Critical Legal Studies' in Peter Newman (ed), *The New Palgrave Dictionary of Economics and the Law* (Macmillan Reference 1998) 471.

¹⁷⁶ Ronald M Dworkin, 'Is Wealth a Value?' [1980] 9(2) *J of Legal Studies* 191, 220.

¹⁷⁷ *ibid* 221-222.

difficulty in terms of affirming fundamental rights on the basis of measuring different abilities to pay.¹⁷⁸

In the context of the incentive narrative relating to patent law, the assumption of achieving optimal efficiency with patent is equally contestable because only a very specific neo-classical economic model would help to support such a conclusion, while considerable scepticism and variables have been largely omitted in law and economics studies.¹⁷⁹ The rigid application of neo-classical economic logic in this regard also has a far-reaching impact on the expansion of patent regime in the name of promoting free trade, which is based largely on neoliberal ideology in the international political arena.

In addition, critiques have pointed out that mainstream law and economics studies have become more irrelevant to the real world of law.¹⁸⁰ While the law and economics movement emerged as one of the critical departures from legal positivism, it has, however, transformed into another type of dogmatic legal theory.¹⁸¹ This is partly due to the same problem mentioned above, namely that the overreliance on the presupposed normative objective and a neoliberal economic model has limited its methodological capacity, which has been highly focused on microeconomic and mathematical modelling.¹⁸² In particular, with the overall presumption of achieving efficient law in terms of promoting wealth maximization going unchallenged, mainstream writings have contributed more to explain *de lege lata* of legal rules and institutions and is, thus,

¹⁷⁸ *ibid* 206-207, 224.

¹⁷⁹ Elkin-Koren and Salzberg (n 131) 27.

¹⁸⁰ *ibid.* 37.

¹⁸¹ *ibid.*

¹⁸² *ibid.*

positivist in itself.¹⁸³ For the purpose of this study, law and economics studies' rigid approach to patent's incentive role in innovation also invites some additional critiques.

Firstly, within law and economics studies, the changing technological conditions for innovation have not been brought into complete consideration in its analysis of patent law. On the one hand, it has been observed that the notion of technological change has become increasingly significant for the development of law and economics research in relation to intellectual property law.¹⁸⁴ On the other hand, however, economics itself has not yet reached a general theory of innovation, even with the exception of the Schumpeterian analysis innovation from a rather non-neoliberal perspective.¹⁸⁵ Without resorting to alternatives, law and economics studies continue to use an older methodological framework derived from neoclassical economics.¹⁸⁶ This is also reflected in the fact that not many law and economics studies have made direct reference to either Schumpeterian¹⁸⁷ or neo-Schumpeterian literature¹⁸⁸ in relation to innovation, which might have meant that the analytical framework became more adaptive.

Secondly, the complex, interactive and reciprocal relations between science, technology and the law are not captured in law and economics studies related to patent and innovation, which also results in its limitations in furthering discussion on the issue of essential health innovations, a dimension this study addresses. Essentially, due to the

¹⁸³ Christophe J Bruce, 'A Positive Analysis of Methodology in Law and Economics Literature' [1989] 12(2) Hamline Law Review 197, 198.

¹⁸⁴ Elkin-Koren and Salzberg (n 131) 26.

¹⁸⁵ *ibid.* 27.

¹⁸⁶ *ibid.*

¹⁸⁷ Robert P Merges, 'Commercial Success and Patent Standards: Economic Perspectives on Innovation' [1988] 76 Cal L Rev 803, 844 < <http://scholarship.law.berkeley.edu/facpubs/1505> > accessed 01 March 2015.

¹⁸⁸ Elkin-Koren and Salzberg (n 131) 27.

theoretical and analytical problems mentioned above, law and economics studies attempts to provide a rather linear, objective and predictable picture of the intersection between law and economics, which is incomplete. For instance, from a historical perspective, the emergence of modern patent law is by no means a unidirectional evolutionary process.¹⁸⁹ In addition, the development of the key patent law principles and institutions dominating the positivist law narrative on innovation, nowadays largely reflects co-production between sciences, technologies and law in a given context.¹⁹⁰ Furthermore, the disciplinary interaction between law and science and technology,¹⁹¹ and the role of scientists in patent's incentive narrative would be important in exploring variants and alternatives in the context of insufficient innovation for non-profitable goods. All these more nuanced aspects are missing in mainstream law and economics studies.

Thirdly, such dogmatic assumptions omit various critical elements¹⁹² in innovation practices including sociological, psychological, spiritual, political issues which are dynamic in nature and unable to be captured in a fixed economic formula. The law and economics positivist analytical approach implies rather straightforward effects based on a presupposed rationality, which oversimplifies a real life context. Some of the recent intellectual property literature has proposed certain alternatives including, for instance, that in order to replace law and economics justifications, a well-being approach should

¹⁸⁹ Christopher May and Susan K Sell, *Intellectual Property Rights: A Critical History* (Lynne Rienner Publishers 2006).

¹⁹⁰ Sheila Jasanoff, 'The Idiom of Co-Production' in Sheila Jasanoff (ed), *States of Knowledge* (Routledge 2004) 1-13.

¹⁹¹ Etzkowitz and Webster (n 128).

¹⁹² *ibid.*

be adapted.¹⁹³ Scholars also suggest that cultural elements in innovation should be examined,¹⁹⁴ the instrumentalist nature of patent should be affirmed and the public welfare purposes of the patent system need to be further investigated.¹⁹⁵ These lines of critiques, although valuable, involve looking for solutions within the system rather than seeking critical transformation from the outside.

Fourthly, a rather micro-level focused and positivist-oriented law and economics analysis of patent law would not go far in discussing the systemic impact on and conflict with broader ethical, social, political and legal values¹⁹⁶ at a global level, analyses that would be relevant to innovation's normative discourse. Even in legal positivist analyses, the answers to questions regarding the level, scope and duration of patent protection remain indeterminate.¹⁹⁷ While the underlying neoclassical economic assumptions might be explanatory in terms of the distortion between a lack of innovation in certain essential health needs and the expansion of the patent regime in the name of global free trade,¹⁹⁸ such assumptions simultaneously limit the ability of law and economics studies in extending its reach to transformative discussions given its unchallenged theoretical basis.

¹⁹³ Estelle Derclaye and Tim Taylor, 'Happy IP: Replacing the Law and Economics Justification for Intellectual Property Rights with a Well-being Approach' [2015] 37(4) EIPR 197; Estelle Derclaye and Tim Taylor, 'Happy IP: Aligning Intellectual Property Rights with Well-being' [2015] 1 I. P.Q. 1.

¹⁹⁴ Madhavi Sunder, *From Goods to a Good Life: Intellectual Property and Global Justice* (Yale University Press 2012).

¹⁹⁵ Drahos, *A Philosophy of Intellectual Property* (n 133) 199-224.

¹⁹⁶ Sebastian Haunss, *Conflict in the Knowledge Society: The Contentious Politics of Intellectual Property* (CUP 2013).

¹⁹⁷ Landes and Posner (n 97) 331-332.

¹⁹⁸ Susan K Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights* (CUP 2003); Christopher May and Susan K Sell, *Intellectual Property Rights: A Critical History* (Lynne Rienner Publishers 2006).

Finally, the uncritical facet of law and economics studies regarding patent provides no adequate conceptual framework capable of responding to the changing dynamic in innovation, the possible impact of the changing dynamic regarding insufficient innovation in health despite an increase number in patenting, and the eventual possible transformation of the paradigm. In particular, patent law has transited – through TRIPS – into a branch of law bearing dual features in terms of the character of both public international law and national private law. This shift has played an important role in reinforcing the hegemonic belief in patent’s indispensable role in incentivizing innovation at international level. The emergence of such a transition at international level was political.¹⁹⁹ The consequences of this and its further development at bilateral, multilateral, transnational and national levels remain one of the most contingent issues in current international political economy.²⁰⁰ While these tensions largely reflect the antagonism between different economic and political ideologies, and involve multiple influences that shape normative agendas and legal responses, the general right wing-inclined nature of law and economics studies makes it difficult for them to go beyond an interpretative contribution to the status quo.

The above discussion has revealed a number of contradictions in law and economics studies concerning the narrative of patent law’s incentive function concerning innovation. On the one hand, while there is no theoretical consensus within economics regarding whether patent provides a preferred and better incentive that generates innovation. On the other hand, mainstream law and economics studies have kept their

¹⁹⁹ Peter Drahos, ‘Global Property Rights in Information: The Story of TRIPS at the GATT’ [1995] 13(1) Prometheus 6.

²⁰⁰ Christopher May, *A Global Political Economy of Intellectual Property Rights: The New Enclosure?* (Routledge 2002).

primary analytical frames with one specific aspect of the utilitarian and neoliberal models, thus upholding and generalising the normative conclusions of patent's indispensable role in these models. Its dogmatic approach has not provided a plausible conceptual framework that could enable possible transformations that might address the dilemma of insufficient innovation for essential health needs with narrow profit margins.

It is worth recalling that a number of alternative ideas have been proposed in response to the distortion between the failure to promote innovation and the increase in the number of patent. However, some of these studies restricted their proposals without challenging an outstanding and problematic theoretical assumption. This, in my opinion, might be at risk of leaving the work half-finished. Therefore, critically reviewing the central theoretical presumption that has supported the formulation of the mainstream patent centric paradigm to biomedical innovation, would provide the basis for this dissertation's research, especially in terms of exploring the building of an alternative conceptual framework. To this end, a number of further questions need to be discussed in the later chapters. These questions include, for instance, how the interaction between scientific and technological changes in biomedical research and the positive patent law responses might or might not provide adequate transformative opportunities; what the effect of the emerging open innovation narrative might be in regard to the central paradigm of patent and innovation; and how the controversies and normative implications of the medical innovation system and practice outside of the patent-centric model might simultaneously provide opportunities for rethinking.

1.4 Patent Law Doctrines and Controversies in the Biomedical Innovation Paradigm

1.4.1 The Concept of Patent on Inventions and Intellectual Property

To further examine the controversies concerning biomedical innovation and the patent law doctrine, we need to return briefly to the basic concepts involved.

The English word ‘patent’ comes from the Latin term *patere*, which means ‘to be open’.²⁰¹ Legal historians have noted that the original meaning of patent referred specifically to the ‘open letter of privilege from the sovereign’.²⁰² The meaning of openness, however, represents a completely different dimension in medical science when the concept of patent is used, which instead refers to ‘open as in a patent *foramen ovale*, a hole in the heart’.²⁰³

Regarding the law in European context, it is common to refer to the Venetian Patent Act in 1474,²⁰⁴ one of the first statutes that consisted of a number of early notions that were later reflected in the contemporary patent system, including the recognition of public interests and the value of the given patent’s public disclosure.²⁰⁵ Letters patent was the major administrative instrument used in continental Europe and Britain from the 15th to

²⁰¹ Robert P Merges and others, *Intellectual Property in the New Technological Age* (Aspen Law & Business 2004) 12.

²⁰² *ibid.*

²⁰³ Geertrui van Overwalle (ed), *Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open Source Models and Liability Models* (CUP 2009) Introduction.

²⁰⁴ Venetian Statute on Industrial Brevets Venice 1474 <http://www.copyrighthistory.org/record/i_1474> accessed 02 May 2015.

²⁰⁵ Michael A Gollin, *Driving Innovation: Intellectual Property Strategies for a Dynamic World* (CUP 2008).

the 16th century,²⁰⁶ when Britain's Statutes of Monopolies²⁰⁷ came into force in 1623 which recognized the protection of patent as a form of legal monopoly. By contrast, the development of the modern patent system in the United States took a different route given the legitimacy of the Congress in providing intellectual property protection as laid down in the Constitution.²⁰⁸

The concept and value of patent in a legal sense developed further during the industrial revolution, when a number of specific legal doctrines started to take shape in English law. For instance, scholars have considered the establishment of the public interests doctrine to be a result of King James I's announcement in the Book of Bounty,²⁰⁹ while the doctrine of sufficient disclosure of patent specification was derived from a judgement made by Lord Mansfield in 1778.²¹⁰ In addition, the Great Exhibition in London in 1851 marked an important moment when the very first idea of an international legal framework on patent was discussed, which subsequently became the Paris Convention on the Protection of Industrial Property (the Paris Convention) under the auspices of World Intellectual Property Organization (WIPO).

Thus, the concept of patent as it is incorporated into law to date refers to a status of privilege granted with proprietary rights within a certain period of time. In the current

²⁰⁶ It is worth noting that letters patents have been maintained in UK until now, for instance to appoint judges, but no longer in the context of granting patents on inventions. See Philip W Grubb and Peter Thomsen, *Patents for Chemicals, Pharmaceuticals, and Biotechnology: Fundamentals of Global Law, Practice and Strategy* (5th edn, OUP 2010) 4.

²⁰⁷ Statute of Monopolies 1623 <<http://www.legislation.gov.uk/aep/Ja1/21/3/contents>> accessed 04 May 2015.

²⁰⁸ US Constitution (n 107).

²⁰⁹ Herbert Harding, *Patent Office Centenary: A Story of 100 Years in the Life and Work of the Patent Office* (Her Majesty's Stationery Office, 1953) 3. See also Philip Johnson, Ashley Roughton and Trevor Cook, *The Modern Law of Patents* (3rd edn, LexisNexis 2014) 1251.

²¹⁰ Harding, *Patent Office Centenary* (n 209) 4.

positive law sense, patent can be used for inventions, utility models or industrial designs, mostly enshrined in international laws such as those under the Paris Convention, while this research concentrates predominantly on patent on inventions.

Two points related to this need to be outlined here. Firstly, while the granted status of patent concerns inventions, there is, however, no clear definition of ‘invention’ itself in international law, mainly because of the difficulty of reaching a meaningful agreement.²¹¹ Instead, invention can be subject to patent protection only if it fulfils a specific set of criteria, also known as the patentability criteria, which recognise new and useful technical solutions. The composition, interpretation and jurisprudence developed based on the patentability criteria are among the central issues that concern patent practitioners and patent law jurists.

Secondly, there is an overall conceptual ambiguity with respect to intellectual property in general while patent is only one part of the problem. For instance, scholars have pointed out that when the concept of ‘intellectual property’ is used to refer to grouped doctrines related to copyright, patent, trademarks and others, such a constituency is not helpful in defining the concept clearly because the term does not ‘describe an easily identifiable object, emotion, belief or behaviour’.²¹² It has also been remarked that developing a general theory of intellectual property is difficult because such a theory would ‘belong to a number of disciplines because intellectual property deals with information, rights, economic growth and power, not to mention the many subplots which are part of the whole story of intellectual property’.²¹³

²¹¹ Johnson, Roughton and Cook, *The Modern Law of Patents* (n209) 21.

²¹² Alexandra George, *Constructing Intellectual Property* (CUP 2012) 32.

²¹³ Drahos, *A Philosophy of Intellectual Property* (n 133) 199.

More critically, when linking the conceptual issue of patent with the notion of innovation, it becomes contestable whether to endorse the patent-centric paradigm as a vested mode for innovation, partly because the history of the patent system does not in itself provide a linear path. For instance, instead of there being a clear cut consensus, the higher requirement for intellectual property norms as refracted through TRIPS and other FTA negotiations are shaped by ‘powerful private interests whose lobbying activists hold sway in legislative and regulatory initiatives in rich countries and international forums’.²¹⁴ In addition, suspicions of and opposition to patent’s function in driving innovation have accompanied the formation of the current patent system, in which radical legal changes took place including the complete abolition of the patent system in a number of European countries in the late 19th century due to the understanding that patent acted as an impediment to technological innovation.²¹⁵

However, looking at history does not necessarily suggest the direct abolition of the current patent system, especially when particular efficiencies at a global level still hold the water from certain economic perspectives,²¹⁶ while distributive effects still offer the possibility of mitigation via differential mechanisms and flexibilities contained in the current regime.²¹⁷ In addition, a literature has emerged over time on intellectual property’s reformative capacity in general, including but not limited to those scholars

²¹⁴ Keith E Maskus and Jerome H Reichman, ‘The Globalization of Private Knowledge Goods and the Privatization of Global Public Goods’ [2005] 7 *Journal of International Economic Law* 279, 282-283. It is also collected in Keith E Maskus and Jerome H Reichman (eds), *International Public Goods and Transfer of Technology Under a Globalized Intellectual Property Regime* (CUP 2005) 3, 7.

²¹⁵ Pottage and Sherman, ‘On the Prehistory of Intellectual Property’ in Howe H R and Griffiths J (eds), *Concepts of Property in Intellectual Property Law* (CUP 2013).

²¹⁶ Keith E Maskus, ‘TRIPS: Controversies and Potential Reform’ (2002) <http://www.researchgate.net/profile/Keith_Maskus/publication/253879873_TRIPS_Controversies_and_Potential_Reform/links/00b4952ebd023116d6000000.pdf> accessed 4 May 2015.

²¹⁷ *ibid.*

emphasizing the need to re-examine the concept of the public domain,²¹⁸ and the need to consider alternative ways to produce knowledge.²¹⁹

1.4.2 Major Controversies of Patent Law Doctrines in Relation to Biomedical Innovation

In addition to the above-mentioned major problems and critiques related to utilitarian justifications and law and economics studies of patent law, it is important to engage with controversies in the established doctrines of patent law in relation to the innovation paradigm dealing with medicines. Some of these concerns and critiques have been outlined briefly in the above sections touching on the patent-centric innovation paradigm and its conceptual, theoretical and practical underpinnings, particularly in regard to health and medicine. This section builds on and summarizes these major concerns in order to outline the research framework for the later chapters.

First of all, and recalling the major conceptual issues concerning knowledge, innovation and science outlined above, the private rights-centric and commercial motivation-based understanding of knowledge production, its sharing and advancement, is entirely biased. The presumptions of all inventors as commercially-oriented entities do not reflect the contextual and communally-oriented manner of innovation adopted by many communities with different cultural and epistemic contexts such as prevails among physicians. In addition, the determination of patentability, especially the inventive steps, by referencing the technological situation in a given field at a certain point in time while allowing the exclusive rights derived from this assessment to last unchanged in the

²¹⁸ Christopher May, *A Global Political Economy of Intellectual Property Rights: The New Enclosure?* (Routledge 2002). Charlotte Waelde and Hector McQueen (eds), *Intellectual Property: The Many Faces of the Public Domain* (Edward Elgar, 2007).

²¹⁹ Charlotte Waelde and Hector McQueen (eds), *Intellectual Property: The Many Faces of the Public Domain* (Edward Elgar, 2007).

following years of the patent term does not reflect the evolving, dynamic and communicative features of innovation. Furthermore, the controversies concerning patenting plants and animals provides direct conflict with innovation based on traditional medical knowledge and practices. Discussions on an alternative conceptual framework need to accommodate these controversies and analyse the conflict implicit in the current legal framework and the possible options to address these tensions.

Secondly, it is necessary to review closely how patent operates within the current system in terms of manoeuvring the boundary of ‘newness’ over time and across technological transitions, which has had a tangible impact on the biomedical innovation landscape. This aspect of the controversy touches on the establishment, application and changing of patentability criteria concerning medicines, diagnostic tools and their supporting technologies.

At a general level, the seemingly objective, neutral and technical set of patentability criteria contain harbour uncertainty and are indeterminate in terms of their actual applications. For example, it has been pointed out by researchers that the most important party in the patent field is none else than a hypothetical ‘fictitious person skilled in the art’.²²⁰ This person is essential in determining nearly all the core criteria of patentability in both patent examinations and judicial proceedings. Leaving the fixed definition of such a person open in order to accommodate different technologies – which might be meritorious in itself – the actual person who assesses the understanding of such a hypothetical person is often the patent examiner or members of patent appellant bodies. For patent examiners, to guess what this hypothetical person would say is, in reality, the

²²⁰ Hans-Rainer Jaenichen and others, *From Clones to Claims: The European Patent Office’s Case Law on the Patentability of Biotechnology Inventions in Comparison to the United States and Japanese Practices* (4th edn, Carl Heymanns Verlag 2006) 49.

process of looking for prior art (the same invention that has been published by someone else earlier), determining whether the information is disclosed sufficiently and, most importantly, to judge whether this is very obvious technically to this imaginary person skilled in the art. Thus, a series of practical factors will come into play with the legal requirement, including whether she has had enough access to worldwide scientific journals and databases, what level of education and expertise she has in assuming this responsibility, whether she has referred to the right technological standards in determining the obviousness. The legally-constructed definition of this hypothetical person in case law may also evolve and vary over time from an ordinary technician to ‘a team of cautious PhD, bench molecular biologists including laboratory assistants’.²²¹ All of these contain substantial levels of uncertainty, which makes the process of administering the patent application itself a fluid and subjective exercise.²²²

In addition, the issue of non-obviousness as a criterion to assess inventiveness has played an important role in debates on pharmaceutical patent, especially relating to the issue of patent thickets and ever-greening as mentioned previously. It has been frequently noted that the possibility of patenting improvements of an existing technology has been established since the patent disputes around Watt’s steam engine.²²³ Nonetheless, patenting derivative forms of known chemical substances have been noted as detrimental for follow-up innovations and obvious for skilled developers.²²⁴ The assessment in this

²²¹ *ibid.*

²²² The interplay between the doctrinal requirement of patent law and its realization in the day-to-day administrative work conducted in patent offices in different countries has been reviewed by Peter Drahos, *The Global Governance of Knowledge: Patent Offices and their Clients* (CUP 2010).

²²³ *Boulton & Watt v Bull* [1795].

²²⁴ A notable statutory example of this is Section 3(d) of India Patent Act 1970 as amended in 2005. According to the provision, derivatives of known substance are not patentable unless significant enhancement can be justified. This provision has been used by generic companies in India when challenging multinational producers who have used the tactic of patenting alternative forms of chemical

regard, however, varies largely from country to country, which leaves unfinished the conceptual issue regarding the boundary of inventiveness in patent law.

Thirdly, the boundary of eligibility – namely acceptances and exclusions of patentable subject matters under patent law – has also encountered controversies and challenges. The tendency to expanding the scope of patentable subject matters has been a constant debate, one associated with evolving technological change. Some of the most oft-cited examples illustrate the role of legal discourse in this regard, including Chief Justice Burger’s famous quote that patent should be in favour of ‘anything under the sun that is made by man’ in *Diamond v Chakrabarty*,²²⁵ which has implication for the debates on patenting living things in the context of biotechnology. Controversies also arise concerning patenting on research and diagnostic tools. For instance, medical treatment methods and tools have long been excluded from being patentable, but this has become far more heated and controversial in recent years due largely to debatable jurisprudences and evolving medical practices mixed with the increasing use of biogenetic technologies, while some researchers had observed that the technical side of changes have directly challenged the previous scope of law in terms of exclusions.²²⁶ Researchers have also examined the case law track record in the context of English patent law in dealing with medical diagnostic-related patent,²²⁷ commenting that a boundary has however been

compounds in order to extend market monopolies.

²²⁵ *Diamond v Chakrabarty* 447 US 303 (1980).

²²⁶ Florian Leverve and Jeremy Phillips, *The Exclusion of Surgical, Therapeutical and Diagnostic Inventions from Patentability under Article 52(4) of the European Patent Convention* (Intellectual Property Institute Report 2008).

²²⁷ Research and analyses of this kind could be found in, for example, Oliver Mills, *Biotechnological Inventions: Moral Restraints and Patent Law* (Ashgate 2005) Sigrid Sterckx and Julian Cockbain, *Exclusions from Patentability: How Far Has the European Patent Office Eroded Boundaries?* (Cambridge University Press 2012), showing how the established boundary of exception was modified. Leading cases cited and examined in this context include *Genentech I/Polypeptide Expression* ([1989] 1 EPOR 1), *Biogen Inc v Medeva PLC* ([1997] RPC 1), *Genentech Inc’s Patent* ([1989] RPC 147).

crossed and become blurred through the impact of European Union patent law cases alongside certain interpretations of patent claims.²²⁸ Research has also illuminated the need for further enquiries into the fluid meaning and boundaries of statutory exceptions permissible in patent for research purposes, which have been considered as essential in ensuring the flow of knowledge and generating new innovations.²²⁹

Fourthly, and as mentioned above, one of the controversies related to the doctrinal perspective on patent law and the innovation paradigm, is the dialectical, indeterminate and yet reciprocal relations between law, science and technologies that go with biomedical innovation. In this regard, research has offered insights concerning the tension between the emerging genetic technologies in the area of biomedical innovation and patent law doctrine,²³⁰ with examples cited such as controversies concerning the patenting of genes, genetically-modified living organisms and animals, as well as the impact of the patent paradigm on the innovation discourse during the human genome project.²³¹ The exploration of an alternative conceptual framework and its construction thus requires further research into the relationship between these elements, especially

²²⁸ *ibid.*

²²⁹ The literature on this aspect can be found in research and experimental exceptions including those concerning medical and laboratory use of patents. For some of the recent comprehensive analysis see Edson Beas Rodrigues Jr, *The General Exception Clauses of the TRIPS Agreements: Promoting Sustainable Development* (CUP 2012).

²³⁰ Considerable numbers of literature have been developed in this regard, including Geerturi van Overwalle, 'Reshaping Bio-Patents: Measures to Restore Trust in the Patent System' in Han Somsen (ed), *The Regulatory Challenge of Biotechnology: Human Genetics, Food and Patents* (Edward Elgar 2007); Geerturi van Overwalle (ed), *Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open-source Models and Liability Models* (CUP 2009).

²³¹ Critiques on patenting on biotechnologies in relation to the conflict with traditional knowledge and indigenous people could be found in Whitt L, *Science, Colonialism, and Indigenous Peoples: The Cultural Politics of Law and Knowledge* (CUP 2009); Charles McMains (ed), *Intellectual Property, Biotechnology & Traditional Knowledge* (Earthscan 2007); Graham Dutfield, *Intellectual Property, Biogenetic Resources and Traditional Knowledge* (Earthscan 2004).

regarding collectiveness in science and research in both experimental and traditional senses, and their implications for established paradigm and legal doctrines.

Lastly, the role of active professionals in forming and changing the patent-centric-paradigm is another crosscutting issue related to any examination of the controversies of the patent law doctrine. As noted above, the realization and manipulation of these established legal doctrines are accomplished by the highly specialized professionals working within the current patent-centric paradigm, including patent attorneys and examiners. In research on legal professionals, the literature on patent attorneys and examiners are not substantial. However, there is a common perception that practising patent law is among the most complicated areas in the legal profession,²³² due largely to its requirement of high-level skills and specialities in the disciplines of both law and science. Therefore, the role of such professionals in producing the meanings of patent, and how that practice in turn contributes to the forming of patent-centric paradigms, are worthy of further exploration. Recent literature has started looking at the issue more closely, but many of these analyses remain focused on patent holders' perspectives.²³³ Further exploration of how patent law practitioners view, practise and create legal boundaries related to biomedical innovation is necessary.

²³² General comments and discussions of this kind could be found in B Joan Holdridge, 'Malpractice of Patent Attorneys' [1958] 7 Clev-Marshall L Rev 345; William T Braithwaite, 'How Is Technology Affecting the Practice and Profession of Law' [1991] 22 Tex Tech L Rev 1113.

²³³ For instance, the literature has started discussing the need for patent attorneys with scientific backgrounds to understand the law better, and the need to have attorneys play a more participatory role in the innovation strategy process and not merely act as service providers in order to identify early the best route-map to win a patent application. Some examples could be found in: John M. Golden, 'Construing Patent Claims According to Their Interpretive Community: A Call for an Attorney-Plus-Artisan Perspective' [2008] 21 U Harv JLT 321; Srikumaran Melethil, 'Patent Issues in Drug Development: Perspectives of a Pharmaceutical Scientist-Attorney' [2005] 7(3) AAPS Journal 723; Cameron Walker, 'Finding a Balance' (2014) 511 Nature 621.

1.5 Theoretical Limitations in Patent and Biomedical Innovation

The initial conceptual review on knowledge, innovation and patent law has revealed extenuating controversies in the field of biomedical innovation. As much as mainstream theoretical justifications on patent have failed to provide certainty regarding innovation, law and economics perspectives on incentive narrative and its role in patent remain unconvincing. The notion of innovation emerged in an economic context, and not legally defined. Even so, the benefits of innovation have been rhetorically used as a major justification for patent's dominant role in the field of biomedical innovation. Despite theoretical uncertainty and disagreements in the economic and legal literature on the role of patent, the political utilisation of patent in the international context as a means to expand the global economic agenda has continued unabated. Patent law, when pursuing legal certainty, has evolved its own techniques and viewpoints on what constitutes what is new and innovative. In the context of biomedical innovation, the above controversies need to be borne in mind. Building on the above review, further critiques are provided in the next chapter by resorting to the co-production idiom which further reveals the establishment of the cotemporary patent regime in relation to biomedical innovation.

Chapter 2: Constructing Biomedical Innovation Fallacy through Patent Law: Co-Production of Science, Technology and Law

The major controversies over the role of patent in relation to biomedical innovation are reflected on both conceptual and practical levels as broadly outlined in the introduction and Chapter 1. At the centre of the discontent lies the dialectical, indeterminate and yet reciprocal relations between law, science and technologies that have had influences on the actual operation of the patent law regime in regard to biomedical innovations. This chapter draws on the Science and Technologies Studies (STS) notion of co-production and goes on to discuss the interaction of law, science and technologies in constituting the boundaries of patenting biomedical innovations.

2.1 Co-Production in the Context of Biomedical Innovation and Patent Law

2.1.1 Science and Technology Studies

The notion of co-production originated mainly from scholars associated with STS. The starting point of this scholarly approach is commonly understood to be inspired by Thomas Kuhn's ground-breaking work *The Structure of Scientific Revolutions*.²³⁴ Kuhn's work provided two major conceptual starting points for studies on science and technology which have also been referred to by social science studies looking at the consequences of science and technology for society. The first conceptual issue is the notion of paradigm in Kuhn's conception concerning the scientists which states that:

²³⁴ Thomas Kuhn, *The Structure of Scientific Revolutions* (3rd edn, The University of Chicago Press 1996); Sergio Sismondo, 'Science and Technology Studies and an Engaged Program' in Edward J Hackett and others (eds), *Handbook of Science and Technology Studies* (3rd edn, MIT Press 2008) 14.

[T]heir achievement was sufficiently unprecedented to attract an enduring group of adherents away from competing modes of scientific activity. Simultaneously, it was sufficiently open-ended to leave all sorts of problems for the redefined group of practitioners to resolve.²³⁵

The adherence to and solidity of the existing norms of so-called ‘normal science’²³⁶ in Kuhn are both the preconditions and consequences of the paradigm’s formation and the paradigm shift in scientific practices. Such a notion has been borrowed in social science research, especially when referring to Kuhn’s view on paradigm as representing the ‘entire constellation of beliefs, values, techniques, and so on shared by the members of a given community’,²³⁷ which in turn provides the foundation for ‘paradigm shift’.²³⁸

Secondly, Kuhn’s work has been viewed as opening up the possibilities of the subsequent study of science as a kind of social activity.²³⁹ The interference of human epistemic and societal elements in making science has been studied using a variety of notions related to constructions and productions of science,²⁴⁰ and largely linked to the studies of sociology of knowledge from the 1970s onwards.²⁴¹

²³⁵ Thomas Kuhn, *Structure of Scientific Revolution* (3rd edn, The University of Chicago Press 1996) 10. Kuhn’s works have been widely accepted as the landmark reassessment of the history of science, where he rejected the linear narrative of scientific progress, and rather suggested revolution as the means of progress in scientific communities. His analysis on ‘paradigm shift’ occurring as a result of clash of the old sets of proofs and routines has been used widely by different disciplines in the context of the natural sciences and social sciences.

²³⁶ Thomas Kuhn, *Structure of Scientific Revolution* (3rd edn, The University of Chicago Press 1996).

²³⁷ *ibid* 175.

²³⁸ *ibid*.

²³⁹ Sergio Sismondo, ‘Science and Technology Studies and an Engaged Program’ in Edward J. Hackett and others (eds) *Handbook of Science and Technology Studies* (3rd edn, MIT Press 2008) 14.

²⁴⁰ *ibid*. Among the different streams of studies, some sociological and ethnographic studies are of particular interest for this research. For instance, the Actor Network Theory (ANT) led by Bruno Latour shed comparative views on science and law in the constructive processes. Bruno Latour, *The Making of Law: An Ethnography of the Conseil D’État* (Marina Brilman and Alain Pottage trs, Polity 2002).

²⁴¹ Bruno Latour, *The Making of Law: An Ethnography of the Conseil D’État* (Marina Brilman and Alain

This line of development has been seen as contributing to the discussion of social construction of realities in contrast to the traditional way of looking at science as a mere reflection of the natural world.²⁴² Research in the 1980s has also extended the discourse of social construction to the technological realm.²⁴³

Indeed, post-Kuhnian STS has developed into multiple streams based on an interdisciplinary set of intellectual inquiries. Broadly speaking, there are two branches in the current STS scholarship, namely, the interactionist approach to interpreting and understanding the evolution of scientific knowledge and technological artefacts, and the constructionist approach interrogating the accountability of science and technology in the public interest.²⁴⁴ It is the latter branch of STS research that is closely related to studies on politics and law in the context of science and technology including, for instance, the literature on evidence and expert witness in the judicial processes.²⁴⁵

However, it has also been noted that the division of the two branches might be artificial given increasing convergence between the fields of politics, law and expertise in the areas of scientific knowledge and technology, with social concerns and public interest issues going insufficiently addressed, thus an engaged programme is needed in order to mitigate such divisions.²⁴⁶ In this regard, an

Pottage trs, Polity 2002).

²⁴² Sergio Sismondo, *An Introduction to Science and Technology Studies* (Blackwell Publishing 2004) 64.

²⁴³ Trevor J Pinch and Wiebe E Bijker, 'The Social Construction of Facts and Artifacts: Or How the Sociology of Science and the Sociology of Technology Might Benefit Each Other', in Thomas P Hughes and Trevor Pinch (eds) *The Social Construction of Technological Systems: New Directions in the Sociology and History of Technology* (MIT Press 1987) 17–50.

²⁴⁴ Sismondo (n 242) 18.

²⁴⁵ Sheila Jasanoff, *Science at the Bar: Law, Science and Technology in America* (Harvard University Press 1995).

²⁴⁶ Sismondo (n 242) 18-20.

increasing amount of literature has emerged in recent years, including work by political and legal scholars exploring the general framework of studies on expertise and the relationship between democracy and science.²⁴⁷

2.1.2 The Notion of Co-production

In the broad spectrum of STS studies reviewed above, the notion of co-production initiated by Sheila Jasanoff has provided a helpful framework for the later discussion regarding the construction of patent law in the context of biomedical innovation.

For Jasanoff, science and technology operate as political agents,²⁴⁸ yet STS in general has not made a clear connection between ‘the micro-world of scientific practice and the macro-categories of political and social thought’.²⁴⁹ In order to further investigate the complex phenomenon of knowledge production, the concept, or rather idiom, of co-production has been invoked as an interpretative tool for ‘the accounts take on the normative concerns of political theory and moral philosophy by revealing unsuspected dimensions of ethics, values, lawfulness and

²⁴⁷ Different literatures have started to emerge over the last decade focusing on the impact of expertise on political and legal processes, their impact on democracy, and the question of legitimacy in technological decision making. Some of these have clear links with STS while some are rather interdisciplinary exhibiting influences from different schools of thought. Typical examples include: Sheila Jasanoff, *Science at the Bar: Law, Science and Technology in America* (Harvard University Press 1995); David Kennedy, *A World of Struggle: How Power, Law and Expertise Shape Global Political Economy* (Princeton University Press 2016); Harry M Collins and Robert Evans, ‘The Third Wave of Science Studies: Studies of Expertise and Experiences’ [2002] 32(2) *Social Studies of Science*, 235; Sheila Jasanoff, ‘(No?) Accounting for Expertise’ [2003] 30(3) *Science and Public Policy* 157; Michel Lynch and Simon Cole, ‘Science and Technology Studies on Trial: Dilemmas of Expertise’ [2005] 35(2) *Social Studies of Science* 269.

²⁴⁸ Sheila Jasanoff, ‘Ordering Knowledge, Ordering Society’, in Sheila Jasanoff (ed) *States of Knowledge: The Co-Production of Science and Social Order* (Routledge 2004) 14.

²⁴⁹ *ibid* 18.

power within the epistemic, material and social formations that constitute science and technology.²⁵⁰

Co-production relates closely to the notions of the interdependence of social, material and nature such as those of Latour's Actor-Network Theory (ANT). Latour's ANT argues for the pervasive phenomenon of interdependence and the exercise of powers with social norms being incorporated in material subjects, and institutions, such as capitalism, represent nature similar to how scientists do in laboratories.²⁵¹ Despite its remarkable contribution in the academic field, ANT has also been criticised for being short of macro-level thinking and as overly materialistic and flat given its micro-level focus, sharp distinction between human and non-human,²⁵² and shying away from confronting political conflicts.²⁵³ Related to but departing from ANT, co-production looks at the constant interplay of the social dimension and the cognitive and normative dimensions in science and technology discourses.²⁵⁴ In another word, these interplays and effects are symmetrical and simultaneous, and present a critique of the realist ideology 'that persistently separates the domains of nature, facts, objectivity, reason and policy from those of culture, values, subjectivity, emotion and politics'.²⁵⁵

Illustrating such process can also be made in a context in which scientific practitioners may proactively create and maintain a polity where their intellectual products can be produced, which in turn becomes a political element of the broader

²⁵⁰ Sheilla Jasanoff, 'The Idiom of Co-Production', in Sheilla Jasanoff (ed) *States of Knowledge: The Co-Production of Science and Social Order* (Routledge 2004) 4.

²⁵¹ *ibid* 22, for the comments on ANT.

²⁵² Sismondo (n 242), Chapter 7 Actor-Network Theory, 65-74.

²⁵³ Jasanoff (n 250) 27.

²⁵⁴ *ibid*.

²⁵⁵ *ibid* 3.

polity.²⁵⁶ The notion of symmetry in co-production does not exclude the stage of power in the process. Rather, it hopes to further interrogate ‘why the products of science and technology acquire such deep holds on people's normative instincts as well as their cognitive faculties’.²⁵⁷

The idiom of co-production has been seen as moving STS away from the determinist idea of having either the social or the scientific as the determinant, but rather highlights that social, political and scientific dimensions simultaneously underwrite each other's existence in the co-production process.²⁵⁸ This provides a new approach to political power while ‘the often invisible role of knowledge, expertise, technical practices and material objects in shaping, sustaining, subverting or transforming relations of authority’ is revealed.²⁵⁹ Thus, power is not exercised in one institution or actor, but may be co-produced within interactive assumptions and practices relating to science and technology.²⁶⁰

2.1.3 Co-Production of Science, Technology and Law: The Application to Biomedical Innovation and Patent Law Discussion

The applicability of STS and the co-production idiom in legal studies is in line with Latour's analogical study of science and law while science and technology might bear a certain level of similarities to law in its normative mode of operating,²⁶¹ although the meaning of norms is very different in the two

²⁵⁶ Jasanoff (n 248) 30.

²⁵⁷ Jasanoff (n 248) 38.

²⁵⁸ Alan Erwin, ‘STS Perspectives of Scientific Governance’, in Edward J Hackett and others (eds.) *Handbook of Science and Technology Studies* (3rd edn, MIT Press 2008) 590.

²⁵⁹ Jasanoff (n 250) 1-12. See also Erwin (n 258) 589.

²⁶⁰ Erwin (n 258) 589.

²⁶¹ Latour (n 241).

disciplinary cultures.²⁶² In addition, although STS was not a product of legal scholarship *per se*, it has been observed that the notion of co-production and the broader interests of the sociology of science and technology have shared a number of commonalities with Critical Legal Studies (CLS) in destabilising the authority of rule-makings while being sensitive to the social and epistemic foundation of legal orders.²⁶³ The shared spirits have been summarised as follows:

The CLS project with regard to the law paralleled that of STS with regard to science... in its focus on the indeterminacy of rules..., its emphasis on contradictions and dualities that legal doctrine cannot resolve..., and its awareness that the law does not simply respond to social needs but creates the very conditions from which those needs arise...²⁶⁴

Despite the commonalities, there has not been a systemic convergence of the two academic schools during the heyday of CLS.²⁶⁵ However, the two critical traditions continue to illuminate contemporary inquiries on science and law.

Using STS and the notion of co-production in legal studies can be loosely categorised as part of the ‘second wave’ of STS,²⁶⁶ there being three groups of literature to date, all attempts to investigate the interplay of science, technology and law in the latter’s normative context. The first literature concerns the issue of scientific evidence and expert witnesses in legal processes.²⁶⁷ The second line of

²⁶² *ibid* 242.

²⁶³ Sheila Jasanoff, ‘Making Order: Law and Science in Action’ in Edward J Hackett and others (eds.) *Handbook of Science and Technology Studies* (3rd edn, MIT Press 2008) 773.

²⁶⁴ *ibid*.

²⁶⁵ *ibid*.

²⁶⁶ Harry M Collins and Robert Evans, ‘The Third Wave of Science Studies: Studies of Expertise and Experiences’ [2002] 32(2) *Social Studies of Science* 235, 239.

²⁶⁷ This line of literature includes: Sheila Jasanoff, *Science at the Bar: Law, Science and Technology in America* (Harvard University Press 1995); Roger Smith and Brian Wynne (eds), *Expert Evidence:*

literature reviews the role of scientific knowledge in environmental law, policy making, and risk management.²⁶⁸ The third strain of literature – and the most relevant to this research – concerns intellectual property law, particularly the interaction of science and patent in general, the political conflicts related to the boundaries of patenting, the role of expertise in patent politics, and the impact of patenting on scientific research in universities and research institutions.²⁶⁹

The existing STS literatures on patent and science, and life science in particular, provide a helpful foundation to explore the further usage of STS and the notion of co-production in this research. Firstly, and as discussed in the previous chapter, discontents concerning innovation insufficiency in the health context and given the predominantly utilitarian interpretation and reinterpretation of the role of patent, cannot be solved without resorting to an alternative conceptual pathway based on problematizing and explanations. In another word, the determinist view of the relationship between patent and innovation which trapped the narrative in a

Interpreting Science in the Law (Routledge 1989); Michael Lynch, 'Circumscribing Expertise: Membership Categories in Courtroom Testimony' in Sheila Jasanoff (ed), *States of Knowledge: The Co-production of Science and Social Order* (Routledge 2004).

²⁶⁸ See, for instance, Robert V Percival and others, *Environmental Regulation: Law, Science and Policy* (6th edn, Aspen 2009); Clark Miller, 'Hybrid Management: Boundary Organizations, Science Policy, and the Environmental Governance in the Climate Regime' [2001] 26(4) *Science, Technology & Human Values* 478.

²⁶⁹ There is a considerable line of STS literature relating to patent on life science and research. See: Kathryn Packer and Andrew Webster, 'Patenting Culture in Science: Reinventing the Scientific Wheel of Credibility' [1996] 21 *Science, Technology & Human Values* 427; John P. Walsh, Charlene Cho, and Wesley M. Cohen, 'The View from the Bench: Patents, Material Transfers and Biomedical Science' [2005] 309 *Science* 2002; Wesley Cohen and Stephen Merrill (eds) *Patents in the Knowledge-Based Economy* (National Academies Press 2003); Jason Owen-Smith and Walter W Powell, 'The Expanding Role of University Patenting in the Life Sciences: Assessing the Importance of Experience and Connectivity' [2003] 32(9) *Research Policy* 1695; Mildred K Cho and others, 'Effects of Gene Patents and Licenses on the Provision of Clinical Genetic Testing Services' [2003] 5 *Journal of Molecular Diagnosis* 5; Rebecca Eisenberg, 'Patent Swords and Shields' [2003] 299 *Science* 1018; Rebecca Henderson, Adam B Jaffe and Manuel Trajtenberg, 'Universities as a Source of Commercial Technology: A Detailed Analysis of University Patenting, 1965–1988' [1998] 80(1) *Review of Economics and Statistics* 119; Charles Weiner, 'Universities, Professors, and Patents: A Continuing Controversy' [1986] 1 *Technology Review* 33; Jane Calvert 'Genomic Patenting and the Utility Requirement' [2004] 23(3) *New Genetics and Society* 301.

legal and economic circularity has largely ignored the cognitive and political dimensions of innovation. The notion of co-production could help revealing the practices and assumptions of actors and legal institutions which have helped form the current state of the patent-centric viewpoint on innovation.

In addition, it also helps furthering the discussion of the conflict and interplay of disciplinary cultures while science, technologies and law are rewriting each other's normative orders in the context of biomedical innovation. Two dimensions of these discussions are relevant here. First of all, the internal evolution of patent law doctrines is a manifestation of co-production of scientific knowledge and legal knowledge. In the pharmaceutical and biomedical contexts, the ways in which novelty and inventiveness are constructed in the process of law are themselves a co-production process. In a simplified sense, new technologies or improvements of old technologies seek further power through patenting techniques that are endorsed via law, while the legal rules evolve simultaneously, thereby becoming the new normative guide for concurrent or later scientific and technological practices. The stages of power might become further nuanced when patent seeks global outreach while international and intra-national inequalities in industrial development remain. Secondly, expertise plays a vital role in such co-production processes at different normative levels. In addition, the epistemic and practical factors of various professions may consciously or subconsciously drive the constant co-production.

These aspects will be further explored in this chapter's later sections by reviewing the historical evolution and contemporary development of medical science and

patent law, and in a later chapter 3 when further interrogating the question of expertise.

2.2 Evolution of Contemporary Medical Sciences and Technologies and the Cooperation of Patent

2.2.1 Medicines Discovery: A Journey from Nature to Laboratories

2.2.1.1 Overview

Research has proposed a co-evolutionary relationship between science, patent and business in the aftermath of the 20th century life science industry.²⁷⁰ Although this industry has occupied the major space of pharmaceutical development recently, a further brief retracing of the evolution of contemporary medicines and pharmaceuticals would be helpful in interrogating co-production features in relation to patent law. It is immediately noticeable that the institutions concerned – the life science industry, modern medicines and patent laws – have largely originated from Western contexts, albeit herb-based medical knowledge may have shared some commonalities with non-Western settings. For the purpose of this chapter, this section will focus mainly on Western medicines in terms of their close correlation with the development of modern patent law.²⁷¹

The notion of medicines and pharmaceuticals are often interchangeable in the context of looking them as products of pharmacists or industries.²⁷² In addition, medicine as a

²⁷⁰ Graham Dutfield, *Intellectual Property Rights and the Life Science Industries: Past, Present and Future* (2nd edn, World Scientific Publishing 2009) 35.

²⁷¹ The problems with the modern medicine as a concept in relation to the general meaning of medicine will be discussed in more details in later Chapter 5.

²⁷² Stuard Anderson (ed), *Making Medicines: A Brief History of Pharmacy and Pharmaceuticals* (Pharmaceutical Press 2005) 5.

concept also refers to the science and practice of diagnostic, prevention and treatment of diseases.²⁷³ Medicine's dual feature as being both a material and behaviour subject is critical to the understanding of the enclosure effect of patent towards medicine. In this sense, not only medicine as material but also medicine as a system of practice have been subject to patenting discussions. There is also a broader historical account of medicines, including those discovered, made and used during the pre-industrial era. It has been observed that the initial success of modern medicines' discovery and research has not been dependent on the rapid publication of scientific results, but rather has drawn from knowledge and experiences accumulated over centuries, and has always been a result of communicative social and cultural factors.²⁷⁴

The journey of modern medicines has largely followed two major interactive lines of development, namely medicines from naturally-occurring prototypes and synthetic medicines.²⁷⁵ These prototypes involve techniques of extraction and isolation of active alkaloid and glycosides mostly from plants with therapeutic functions.²⁷⁶ Since the 20th century and given the development of other disciplines such as microbiology, isolation from microorganisms for antibiotics and other biochemical sources have become a new phenomenon.²⁷⁷ On the other hand, the evolution of synthetic medicines has been closely related to the development of dyestuffs industries in Europe which is seen as resulting in the rise of organic chemistry in the late 19th century.²⁷⁸ Organic chemistry

²⁷³ 'Medicine' in *Oxford Concise Medical Dictionary* (8th edn, OUP 2014) online version <<http://www.oxfordreference.com/view/10.1093/acref/9780199557141.001.0001/acref-9780199557141-e-6016?rskey=KQ7QiP&result=6559>> accessed 20 March 2018.

²⁷⁴ Walter Sneader, *Drug Discovery: A History* (John Wiley & Sons 2005) 1.

²⁷⁵ *ibid.*

²⁷⁶ *ibid.* 5.

²⁷⁷ *ibid.*

²⁷⁸ *ibid.* 4. See also: Graham Dutfield, *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History* (1st edn, Ashgate 2003) 73.

makes it possible to conduct drug discoveries without necessarily relying on natural products.²⁷⁹ In the meanwhile, prototyping from nature continued in parallel, and the later biotechnologies and genetic engineering have added further nuanced drug discoveries.

Nevertheless, the rise of organic chemistry first in the dyestuffs industry and later on in pharmaceuticals has provided an important departure point, if not a linear one, regarding the sites where drug discovery were conducted since the late 19th century. The previously dominant position of universities in drug discovery started to be shared by large corporations' laboratories.²⁸⁰ The mixed nature of the sites have also resulted in the rise of medicine-related patenting.

2.2.1.2 Early Examples of Patenting of Medicines

Both prototyping from nature and synthesis via organic chemistry triggered patenting behaviours. On the organic chemistry front, William Perkin obtained a patent in 1856 for the first generation of coal tar dye.²⁸¹ The change of technologies triggered severe competition between the European chemical industries while the use of patent law has been one of the tools used in obtaining competitive status. As research has observed, given the German advantage in leading chemical industry development, its patent law at the time offered only process patent, thereby allowing quicker innovation and an enhanced commercial status when compared to its British and French rivals.²⁸² More importantly, Perkin's invention stimulated the emergence of new science-based

²⁷⁹ Sneader (n 274) 4.

²⁸⁰ *ibid.*

²⁸¹ Graham Dutfield, *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History* (1st edn, Ashgate 2003) 73.

²⁸² *ibid.* 79.

industries including pharmaceuticals²⁸³ while the extent of patent had since become a site of constant lobbying.

Another famous story relating to prototyping is the case of aspirin, one of the first patented pharmaceutical products.²⁸⁴ While the therapeutic function of willow bark, from which aspirin, a crystalline form of the active compound, was isolated, was known in ancient Greek and Rome, scientific experiments and human actions have changed its status of being. On the one hand, scientists at different times tested the therapeutic function of willow bark, however patent was resorted to nearly 150 years later when the first scientific ‘discovery’ of such a function was announced.²⁸⁵ On the other hand, aspirin presented one of the first cases in which intellectual property on pharmaceuticals had been used intensively for commercial interests. Bayer, as the holder of the aspirin brand, has been observed as such an example for its early awareness that ‘drugs that were no more than modest improvements on competing ones could sell well with an aggressive marketing and intellectual property strategy’.²⁸⁶ This is very much still the case today.

2.2.1.3 Further developments

As science and technologies evolved new understandings of the human body and medicines, new subjects have also emerged that gradually became a subject for patenting or patenting-related debate. For instance, the development of biotechnologies and especially the mapping of the human genome have been considered as the future

²⁸³ Dutfield (n 270) 12.

²⁸⁴ *ibid.*

²⁸⁵ Dutfield (n 270) 13-20.

²⁸⁶ Dutfield (n 270) 16.

pathway for drug discovery.²⁸⁷ Predictably, new approaches to drug development will increase in using ‘the emerging technological expertise from pharmacogenetics, pharmacogenomics and functional genomics to dissect, predict and monitor the nature of the individual response to medications.’²⁸⁸ This approach will potentially lead to the era of personalised medicines following quicker and smaller clinical trials.²⁸⁹ Indeed, the topic of personalised medicines – sometimes referred to as precision medicines – has become a subject for policy and regulatory bodies.²⁹⁰ Facing the wave of personalised medicines, however, questions have been raised about the possible overarching impact on the cost of healthcare and the unclear public health objectives.²⁹¹ While the field itself is still developing, it has already triggered enthusiastic discussions²⁹² among

²⁸⁷ Thomas Reiss, ‘Drug Discovery of the Future: the Implication of the Human Genome Project’ [2001] 19(12) *Trends in Biotechnology* 496; Francis S. Collins, ‘Medical and Societal Consequences of the Human Genome Project’ [1999] 341 *N Engl J Med* 28; Francis S Collins and Victor A McKusick, ‘Implications of Human Genome Project for Medical Science’ [2001] 285 (5) *JAMA* 540.

²⁸⁸ Gerard Emilien, Michel Ponchon, Carlos Caldas and others, ‘Impact of Genomics on Drug Discovery and Clinical Medicine’ [2000] 93 *QJ Med*, 391

<<http://qjmed.oxfordjournals.org/content/qjmed/93/7/391.full.pdf>> accessed 08 June 2016.

²⁸⁹ *ibid.*

²⁹⁰ For instance, NHS England issued a Personalised Medicines Strategy in September 2015, <<https://www.england.nhs.uk/wp-content/uploads/2015/09/item5-board-29-09-15.pdf>> accessed 08 June 2016; The European Commission launched a policy on personalised medicines under its research and innovation framework in 2013

<<http://ec.europa.eu/research/health/index.cfm?pg=policy&policyname=personalised>> accessed 08 June 2016; The US FDA has also pledged a new policy framework on precision

medicines<<http://www.fda.gov/ScienceResearch/SpecialTopics/PrecisionMedicine/default.htm>> accessed 08 June 2016.

²⁹¹ Michael J Joyner and Nigel Paneth ‘Seven questions for personalized medicine’ [2005] 314(10), *Journal of the American Medical Association* 999.

²⁹² For instance, online blog discussions and opinion pieces from non-academic sources could be found in: Jeremy, ‘Taking it Personal: Patent, Medicines and Genetic Market’ (IPKat, 17 August 2012) <<http://ipkitten.blogspot.ch/2012/08/taking-it-personally-patents-medicines.html>> accessed 10 August 2016; Suleman Ali on IPKat, ‘Personalised Medicines: a Presidential Initiative, Inherent Treatment, Mayo and Akamai’ (IPKat, 15 May 2015) <<http://ipkitten.blogspot.ch/2015/02/personalised-medicines-presidential.html>> accessed 10 August 2016; Steven M Amundson, ‘Personalised Medicine and Patent Eligibility’ (*Genetic Engineering and Biotechnology News*, 17 September 2013) <<http://www.genengnews.com/gen-articles/personalized-medicine-and-patent-eligibility/4992/>>

accessed 10 August 2016; Mewburn Ellis LLP, ‘Patent Claims for Personalised Medicines’ (7 February 2013)<<http://www.lexology.com/library/detail.aspx?g=f8823215-8dc0-42fe-838c-4656b4e300c0>> accessed 10 August 2016.

practitioners regarding the prospects for future patenting, especially in light of the patent invalidation based on the understanding of an individual patient's metabolite reaction to the drug falling within the 'law of nature' exclusion in *Mayo v Prometheus*.²⁹³ Scholar has also discussed the increased possibility of seeking patent on the second medical use and the method of medical treatment in the context of personalised medicines²⁹⁴, challenges the approach of giving privilege to pharmaceutical patent and the possibility to curtail such privilege when public interests are affected.²⁹⁵

In addition, new controversies have also arisen when the evolving discourse on patenting has gone side by side with technological progress. For instance, these new controversies include, but are not limited to, those around patent on genetically-modified subjects such as the case of *Oncomice*²⁹⁶ and around recombinant DNA methods such as the *Genentech* patent,²⁹⁷ which have renewed the co-produced discourse between the science of medicines and patent law.

This broad brush overview of the historical trails of modern medicines discovery and its relevance to patent offer a general picture of co-production in the sense that the use and resort to patent law has been going together with technological progress and commercial prospects regarding medicines. In turn, the patent system has been adjusting its boundaries in terms of reflecting or rejecting claims of interests that are often associated with large industries. This process is far from linear and remains highly indeterminate.

²⁹³ *Mayo Collaborative Services v Prometheus Laboratories Inc* No 10-1150 US Supreme Court. Full text of the judgement available at: <<http://www.supremecourt.gov/opinions/11pdf/10-1150.pdf>>

²⁹⁴ Graham Dutfield, 'Healthcare Innovation and Patent Law's "Pharmaceutical Privilege"' [2017] 12 Health Economics, Policy and Law 453 <<https://doi.org/10.1017/S1744133117000111>> accessed 10 May 2018.

²⁹⁵ *ibid.*

²⁹⁶ US Patent No 4736 866, issued in 1998.

²⁹⁷ *MedImmune, Inc v Genentech, Inc*, 549 US 118 (2007).

However, what is more certain is that alongside this interactional process of co-production, the normative system of patent in regard to pharmaceuticals has shifted.

2.2.2 Development of Modern Patent Law and the Boundary of Protections on Medical Innovations

In the context of co-producing normative orders alongside the evolution of pharmaceutical and biological science and technologies, the boundary of patent law in protecting biomedical innovations had been changing constantly or, more precisely, expanding. At the same time, it is also untrue to portray this process of change in the patent system as a passive one. Instead, the system is very proactive in embracing technological shifts, either in an effective or controversial way. Many of these reactions and changes are driven by expertise and professionals, which will be discussed at greater length in the next chapter. Simultaneously, the legal framework itself has revealed the effects of co-producing.

2.2.2.1 International legal framework

As mentioned in previous chapters, the origin of modern patent law was closely linked to the industrial revolution. Patent was initially used as a means of attracting technology transfer to local artisans. Being a legal monopoly and privilege initiated in particular from the Statute of Monopoly in 1623 in England, patent law remained largely a field of domestic law until the late 20th century.

WIPO system

Convention on the Protection for Industrial Property (Paris Convention)

The 19th century's creation of the Paris Convention on the Protection for Industrial Property (Paris Convention)²⁹⁸ triggered the first generation of international treaties relating to patent. The development of treaty law in this area also contributed to the final establishment of the World Intellectual Property Organisation (WIPO) in 1970s.²⁹⁹ The text of the Paris Convention has no mention of the notion of 'medicine', 'pharmaceutical', or 'health'. It sets up general rules of patenting for the reference of national legislations. In addition, Article 25 of the Paris Convention illustrates the approach of its domestic implementation, whereby '[a]ny country party to this Convention undertakes to adopt, in accordance with its constitution, the measures necessary to ensure the application of this Convention.'³⁰⁰ This approach has left significant flexibility for its member states to determine the necessary level of patent protection applicable in a given context.

The Paris Convention was not an end in itself, as WIPO's industrialised members wanted to move the boundary of patent towards a more cosmopolitan interpretation. Consequently, the Patent Cooperation Treaty (PCT)³⁰¹ together with the Patent Law Treaty (PLT),³⁰² which are also administrated by the WIPO, have contributed

²⁹⁸ WIPO, Paris Convention on the Protection for Industrial Property, entered into force in March 1883, revised up to September 1979.

²⁹⁹ Convention Establishing the World Intellectual Property Organization (WIPO), entered into force in April 1970.

³⁰⁰ Art 25, Paris Convention.

³⁰¹ WIPO Patent Cooperation Treaty (adopted on 19 June 1970, amended on 28 September 1979, modified on 3 February 1984 and 3 October 2001, entered into force on 1 April 2002).

³⁰² WIPO Patent Law Treaty (adopted on 1 June 2000, entered into force on 28 April 2005). It is worth noting here that the harmonization of patent standards through WIPO had not stopped at the formal procedure level. Beyond PLT, controversies have dogged the draft Substantive Patent Law Treaty which is now pending with the Standing Committee on the Law of Patents in WIPO due to severe divergent

substantially to the establishment of the global administrative and governance network on patent protection.³⁰³ Within the WIPO-administered system, the standardized classification of patent, international application procedures, supplemented by substantive technical exchange, training and technical assistance programmes, have facilitated the rise of patent offices around the world as the nested agent reinforcing the patent-centric paradigm on innovation, progress and growth.³⁰⁴

A few detailed issues touched on by the Paris Convention are worth mentioning in the context of this research. Firstly, the concept of priority rights was first established through the Paris Convention, and later developed in the PCT system. Article 4.A (2) of the Paris Convention requires a mutual recognition of filing while the person who has filed in a member country can claim the right of priority when subsequently filing in the next member country, and be treated as equivalent to a national filing. Article 4.C further defines that the right of priority starts from the date of the first filing and will last for 12 months for patent. The PCT system further amended this mechanism by creating a commonly-recognised system of patent numbers that would identify the filing tracks in order to receive benefits of priority rights for the applicant.

Priority right is a pure legal construction that aims to stabilize the possibility of concurrent patent applications by independent research entities in different countries, thereby providing a fixed time as the benchmark for assessing novelty criteria. As scientific research and discovery are based largely on traditionally openly shared knowledge and information in respective disciplines, it is far from impossible to have

views from member states on the impact of such substantive law integration.

³⁰³ Peter Drahos, *The Global Governance of Knowledge: Patent Offices and Their Clients* (CUP 2010).

³⁰⁴ *ibid.* See also: Honorable Gerald J Mossinghoff, 'Patent Harmonization through the United Nations: International Progress or Deadlock?' (2004) 86 J Pat & Trademark Off Soc'y 5.

multiple scientists and researchers working on a similar or the same subject without knowing each other. A breakthrough could happen to anyone and anywhere, but patent likely goes to the first one who submits their application. The priority of being the first could then be extended at international level through the priority rights mechanism created by law. This incentive to race to be the first filing has had a far-reaching impact on industries' patenting behaviours while also affecting scientists' conception of patenting. For instance, in the context of pharmaceutical patenting, the timeline of filing the first patent has been pushed further up the drug discovery chain, in order to ensure early occupation of spaces in the patent world. Such practices have been facilitated by legal techniques in patent claim drafting, for instance those concerning the so-called 'Markush claim' type of drafting while a vague and broad group of potential compounds could be included in claims regarding a general chemical structure. Although there are possible remedies if one could not obtain priority right due to a slightly late filing, such as seeking the right of prior use, losing priority status still involves considerable economic loss for industry applicants. This sense of time pressure has also been transferred to the university or, broadly speaking, the academic research context when more and more academic scientists and researchers are under the constant pressure from their universities' technology transfer offices to apply for patent early rather than prioritising the submission to peer review publications, which was the norm previously.

The second issue worth noting is that the Paris Convention has initiated the mechanism of divisional filing of patent. Article 4.G of the Paris Convention states that

- (1) If the examination reveals that an application for a patent contains more than one invention, the applicant may divide the application into a certain

number of divisional applications and preserve as the date of each the date of the initial application and the benefit of the right of priority, if any.

(2) The applicant may also, on his own initiative, divide a patent application and preserve as the date of each divisional application the date of the initial application and the benefit of the right of priority, if any. Each country of the Union shall have the right to determine the conditions under which such division shall be authorized.³⁰⁵

Divisional applications have been used intensively in the context of pharmaceutical patenting. It has been a common strategy to bargain with the patent examination bodies by starting with a broad scope of claims, subsequently narrowing it down either through revision or divisional filings. This is another legal construction attempting to reinforce the principle of ‘one patent, one technical solution/invention’. Yet, the intention of streamlining the patent scopes through this construction can be manipulated by applicants as a way of delaying rivals and creating patent thickets, thereby blurring the actual boundary for other concurrent or follow-up researchers.

Patent Cooperation Treaty

Mechanisms on patent protection designed under the Paris Convention have been taken further given the additional rules adopted under WIPO auspices. In particular, the Patent Cooperation Treaty (PCT)³⁰⁶ together with the Patent Law Treaty (PLT)³⁰⁷ which are also WIPO administered, have contributed substantially to the establishment of the

³⁰⁵ Article 4.G of the Paris Convention

³⁰⁶ WIPO Patent Cooperation Treaty (adopted on 19 June 1970, amended on 28 September 1979, modified on 3 February 1984 and 3 October 2001, entered into force on 1 April 2002).

³⁰⁷ WIPO Patent Law Treaty (adopted on 1 June 2000, entered into force on 28 April 2005).

global administrative and governance network on patent protection.³⁰⁸ Within this system overseen by WIPO, the standardized classification of patents, international application procedures, supplemented by substantive technical exchange, training and technical assistance programmes, have facilitated the rise of patent offices around the world as the nested agent reinforcing the patent-centric paradigm on innovation, progress and growth.³⁰⁹ While PLT has yet to enter into force, the PCT system on the other hand has been up and running and enjoying a considerable degree of acceptance among WIPO members, becoming one of the central functional aspects of WIPO that interacts not only with its member countries' patent offices, but more importantly with industries that use PCT in extending the reach of their patents in global markets.

Budapest Treaty on the International Recognition of the Deposit of Microorganism for the Purpose of Patent Protection

In the field of innovation related to health and medicines, additional legal instruments also stand out in the WIPO system. For instance, the Budapest Treaty on the International Recognition of the Deposit of Microorganism for the Purpose of Patent Protection (Budapest Treaty)³¹⁰ under WIPO, which has been seen as the only treaty that deals explicitly with patents on living matter,³¹¹ has ended the time when microorganisms were excluded from patenting in the contracting members' jurisdictions.³¹² Processing and synthesising from microorganisms in nature had played

³⁰⁸ Peter Drahos. *The Global Governance of Knowledge: Patent Offices and Their Clients* (CUP 2010).

³⁰⁹ *ibid.*

³¹⁰ WIPO Budapest Treaty on the International Recognition of the Deposit of Microorganism for the Purpose of Patent Protection (28 April 1977, and amended on 26 September, 1980). The treaty now has 79 contracting parties.

³¹¹ Anne Eckstein, *The Patentability of Living Matters* (European Information Service 2001).

³¹² The development of the Budapest system had close links with the historical and technological context of the emerging biotechnology industry and has had implications for medical research and development.

a substantive role in modern Western medicines' discovery and development with one of the notable examples being the discovery of penicillin.³¹³ Although the Budapest Treaty is not ratified by many developing countries and also not promoted specifically, researchers have noted that the patent protection rules inserted through bilateral FTAs have reinforced the expansion of the Budapest system concerning microorganism patenting.³¹⁴

In addition to the formal legal instruments, WIPO also houses several normative and non-normative platforms in which the questions related to biomedical innovation and patenting are tagged. Notably, the Standing Committee on the Law of Patent (SCP) has long been a platform of technical and policy debates among WIPO members concerning the extent to which international harmonisation on patenting standards should be pursued, including those related to biomedical subject matters. SCP also holds a standing item of discussion concerning patent and health in general and mostly policy oriented manner. In addition, WIPO hosts the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (IGC). IGC is mandated to conduct text-based negotiation towards an international legal framework on the protection of traditional knowledge, genetic resources and traditional cultural expressions.³¹⁵ As noted by researchers, the establishment of IGC was seen as a response

³¹³ Graham Dutfield, *Intellectual Property Rights and the Life Science Industries: A Twentieth Century History* (1st edn, Ashgate 2003).

³¹⁴ Research on the Budapest Treaty and its relationship to and impact on biotechnology and developing countries can be found in Jonathan Curci, 'The New Challenges to the International Patentability of Biotechnology: Legal Relations Between the WTO Treaty on Trade-Related Aspects of Intellectual Property Rights and The Convention on Biological Diversity' [2005] 2 Int'l L & Mgmt Rev 1; John Edward Schneider, 'Microorganisms and the Patent Office: To Deposit or Not To Deposit, That is the Question' [1984] 52(4) Fordham Law Review
<<http://ir.lawnet.fordham.edu/cgi/viewcontent.cgi?article=2578&context=flr>> accessed 13 May 2015; Virginia H Meyer, 'Problems and Issues in Depositing Microorganisms for Patent Purposes' [1983] 65 Journal of the Patent Office Society 455.

³¹⁵ WIPO, Matters Concerning the Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore (Assemblies of Member States of WIPO Fifty-Seventh

to the failure of accommodating traditional knowledge in the intellectual property system as it is.³¹⁶ However, IGC also started working against the background of normative development elsewhere, especially the Convention on Biological Diversity (CBD) that pursues an alternative normative approach to protecting genetic resources and traditional knowledge. Although the detailed discussion on traditional knowledge protection goes beyond the scope of this research, traditional medical knowledge and genetic resources that can yield therapeutic effects are within the remits of both IGC and CBD mechanisms and therefore relevant to the discussion on the possible alternative conceptual framework building in later chapters (Chapter 5 especially).

WTO and the Global Trade Regime

If WIPO had been the central stage of patent rule making at international level throughout the golden age of the industrial revolution and most of the early 20th century, the post-war emergence of free trade ideology has rather radically changed the normative and political landscape regarding patent law, while also affecting pharmaceuticals and biologicals.

The history of the Agreements on Trade-related Aspects of Intellectual Property Rights (TRIPS) negotiation at the time the World Trade Organization (WTO) was created is a history of the exercise of power in its vertical and horizontal senses. Horizontal power bargaining took place between countries and trade regions of different economic status, while vertical power bargaining happened when a group of industries, often through

Session, October 2-11 2017) <http://www.wipo.int/export/sites/www/tk/en/igc/pdf/igc_mandate_2018-2019.pdf> accessed 20 June 2018.

³¹⁶ Chidi Oguamanam, 'Ramifications of the WIPO IGC for IP and development' in Daniel F. Robinson, Ahmed Abdel-Latif, Pedro Roffe (eds) *Protecting Traditional Knowledge: The WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore* (Routledge 2017) 339.

their lawyers, intervened in the negotiation agenda and process. The birth of TRIPS was an example of the intertwined effects of vertical lobbying led by an industry-backed Intellectual Property Committee (IPC).³¹⁷ The emergence of TRIPS as a reflection of the global political economy³¹⁸ at the time has also presented a complex nested effects of technology, capital, power and law, which has also implicated pharmaceuticals. TRIPS has formally transformed the narrative of intellectual property as an integrated issue of international trade and investment, which on the one hand reinforced the global expansion of a neoliberal economic agenda, and on the other strengthened the impact of the established paradigm of having patent as an indispensable means of innovation and growth.

Significantly, TRIPS confirms its commensurability with the Paris Convention,³¹⁹ and yet bears a number of substantive norms that go beyond the WIPO system. There are two specific issues under TRIPS worth mentioning for the purpose of this research. The first issue concerns the protection of test data, notably under Article 39 of TRIPS. In the overall context of protecting undisclosed information, Article 39.3 of TRIPS reads that

3. Members, when requiring, as a condition of approving the marketing of pharmaceutical or of agricultural chemical products which utilize new chemical entities, the submission of undisclosed test or other data, the origination of which involves a considerable effort, shall protect such data

³¹⁷ Susan K Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights* (CUP 2003).

³¹⁸ Christopher May, *A Global Political Economy of Intellectual Property Rights: The New Enclosures?* (1st edn, Routledge 2000).

³¹⁹ Article 2 of TRIPS specifies that nothing in it will derogate the existing obligations of the members that are under the other WIPO administrated treaties, including the Paris Convention.

Article 2.2 of TRIPS: 'Nothing in Parts I to IV of this Agreement shall derogate from existing obligations that Members may have to each other under the Paris Convention, the Berne Convention, the Rome Convention and the Treaty on Intellectual Property in Respect of Integrated Circuits.'

against unfair commercial use. In addition, Members shall protect such data against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.

The large-scale pharmaceutical industry often uses this as the legal grounds for exclusive protection while test data cannot be used in regulatory processes. However, it has been observed that both the negotiating history and the WTO's official interpretation have not confirmed the understanding that Art 39.3 can lead to obligations of exclusive protection.³²⁰ WTO members can voluntarily commit to an exclusive protection during the accession procedure, while data exclusivity has also been promoted and endorsed through bilateral and regional trade agreements which the WTO has no official mandate to regulate.

Enclosing test data triggered long-lasting controversies including ethics queries and follow-up innovation. On the one hand, testing data is the genuine record of individuals' participation in the biomedical development process and has a clear public interest value in terms of making the data and its use transparent and accountable.³²¹ On the other hand, success and failure documented through testing data are important resources for follow-up innovation and improvements, and once enclosed would cause an unnecessary waste of resources and redundant research. Whether Article 39.3 of TRIPS invokes an exclusivity rights out of the test data protection has long been an issue of controversy. Research has revealed that the negotiation history of this provision does not support the view that the objective of Article 39.3 is to establish the exclusivity rights out of data.³²²

³²⁰ Carlos Correa, 'Implication of Bilateral Trade Agreements on Access to Medicines' [2006] 84(5) Bull World Health Organ 399; Susan Sell, 'TRIPS-Plus Free Trade Agreements and Access to Medicines' [2007] 28(1) Liverpool Law Review 41.

³²¹ EMA regulation and advocacy for test data transparency

³²² Carlos Correa, 'Protection of Data Submitted for The Registration of Pharmaceuticals: Implementing

Rather, it aims to charge unfair competition practices.³²³ Nevertheless, WTO has not so far provided authoritative interpretation in this regard. The ambiguity of Article 39.3 of TRIPS remains. In the meanwhile, data exclusivity has taken other forums of norm-making, notably in the recently concluded Trans-Pacific Partnership Agreement (TPP) requiring 5-8 years of exclusivity for biological medicines, resulting in further layers of uncertainty in relation to future biomedical innovations, especially those taking place in developing country members.

The second issue is research and experimental exception, ensuring behaviours under this category would not be considered as patent infringement. The mechanism of exceptions is considered as a type of ‘*ex post* adjustment of the scope of patent.’³²⁴ Among the other grounds of exceptions, the research-use exception has been considered as one of the most popular exemplars in national laws in different forms.³²⁵ Such exceptions usually ‘allow third parties to carry out scientific experiments with the protected patents, without prior permission of the patent owner’,³²⁶ so in certain contexts it is also referred as ‘experimental use exceptions’.

Clauses concerning research use exceptions in national law are often deemed to be in line with Article 30 of TRIPS.³²⁷ Linking with Article 7 of TRIPS,³²⁸ the use of research

the Standards of The TRIPS Agreement’ (South Centre 2002) <
http://www.who.int/medicines/areas/policy/protection_of_data.pdf> accessed 1 August 2018.

³²³ *ibid.*

³²⁴ Rochelle Dreyfuss, ‘Unique Works/Unique Challenges at the Intellectual Property/Competition Law Interface’ [2005] Law and Economics Research Paper <
https://papers.ssrn.com/sol3/papers.cfm?abstract_id=763688> accessed 20 July 2016.

³²⁵ Edson Beas Rodrigues Jr., *The General Exception Clauses of the TRIPS Agreements: Promoting Sustainable Development* (CUP 2012) 180.

³²⁶ *ibid.*

³²⁷ Carlos M. Correa, *Designing Intellectual Property Policies in Developing Countries* (Third World Network 2010) 21.

³²⁸ WTO, *Agreements on Trade-related Intellectual Property Rights*, (Marrakesh, 1994), Article 7: ‘Objectives: The protection and enforcement of intellectual property rights should contribute to the promotion of technological innovation and to the transfer and dissemination of technology, to the mutual

or experimental exceptions could also be identified as a way of achieving the promotion of ‘technological innovation’³²⁹ and ‘balance of rights and obligations’.³³⁰ Research has also pointed out that research use exceptions can be justified from the perspective of promoting the broader objective of promoting infusion of innovations under patent law³³¹ and to provide spaces for society to generate new knowledge and improvements of patented subject matters.³³²

Nonetheless, Article 30 of TRIPS does not contain substantive wordings regarding research/experimental use exception *per se*, which leaves national laws to determine the exact scope of such a provision. This level of flexibility has in turn created a point of uncertainty in national laws as many such provisions are considered as too limited or even non-functional.³³³ In particular, many such provisions would lead to interpreting certain research activities as for commercial purposes, so that the exceptions are not applicable³³⁴ and entities would turn to seek licensing negotiations with patent owners.³³⁵ The imbalance between the over-protection of patent owners and restricted applicability of research exceptions is potentially become an obstacle to innovation, especially in sectors such as biomedicine.³³⁶

advantage of producers and users of technological knowledge and in a manner conducive to social and economic welfare, and to a balance of rights and obligations.’

³²⁹ *ibid.*

³³⁰ *ibid.*

³³¹ Shannad Basheer and Prashant Reddy, ‘The “Experimental Use” Exception through a Developmental Lens’ [2010] 50(4) IDEA: The Intellectual Property Law Review 836.

³³² Edson Beas Rodrigues Jr., *The General Exception Clauses of the TRIPS Agreements: Promoting Sustainable Development* (CUP 2012) 180.

³³³ *ibid* 181.

³³⁴ *ibid* 187.

³³⁵ *ibid.*

³³⁶ *ibid* 189.

Beyond TRIPS, patent protection remains one of the outstanding topics in FTA negotiations, with a requirement for additional protection beyond the minimum TRIPS standards often imposed by negotiating parties from economically-enhanced nations.

Other Co-existing International Laws

In addition to the WIPO and WTO systems, there are co-existing proprietary-based or related legal institutions that are interacting or in conflict with the patent regime.

For instance, plants and animals are traditionally and conventionally not considered patentable in most countries.³³⁷ The reality has, however, presented a constant tendency to trespass such a boundary of exception. It has been observed that the International Convention of the Protection of New Variety of Plants (UPOV Convention),³³⁸ which provides a *sui generis* system on a plant breeder's right, has been moving closer to the proprietary-based protection similar to the utility patent under TRIPS.³³⁹ Some jurisdictions where exception of patenting on plant and plant varieties has been long established have also faced the expansive challenges posed by gradual changes in jurisprudence by judicial bodies and legislatures.³⁴⁰

³³⁷ Exceptions can be found where there are explicit legislation such as the Plant Patent Act 1930 in the US.

³³⁸ UPOV International Convention of the Protection of New Variety of Plants (adopted on 2 December 1961, entered into force in 10 August 1968, revised on 10 November 1972, on 23 October 1978, and on 19 March 1991).

³³⁹ Community Plants Variety Office, 'Relation between PVP and Patent on Biotechnology' <<http://www.cpvo.europa.eu/documents/articles/BK%20Bangkok%20November%202003.pdf>> accessed 10 May 2015.

³⁴⁰ For example, a considerable body of research has been conducted on the jurisprudence developed by the Enlarged Board of Appeal of European Patent Office and the EC Directive on the Legal Protection on Biotechnological Inventions (Directive 98/44/EC of the European Parliament and of the Council of 6 July 1998 on the legal protection of biotechnological inventions), on the issues of patentability concerning living matter including plant and plant varieties. Detailed analyses of this can be found in: Sigrid Sterckx and Julian Cockbain, *Exclusions from Patentability: How Far Has the European Patent Office Eroded Boundaries?* (CUP 2012); Geertrui van Overwalle, 'Reshaping Bio-Patents: Measures to Restore Trust in

The therapeutic and medicinal knowledge and usage of plants and animals has played and continues to play a central role in innovation activities related to traditional medicines and also has a crucial role in a completely different setting – the screening for lead substance in biopharmaceutical industries’ research and development (R&D) processes, which has resulted in an entire area of legal controversy related to the bio-prospecting and bio-piracy on traditional knowledge. Legal responses to these issues can be navigated through the mechanisms developed under the Convention on Biological Diversity (CBD)³⁴¹ and its Nagoya Protocol,³⁴² as well as the WIPO Intergovernmental Committee on Intellectual Property and Genetic Resources, Traditional Knowledge and Folklore, which has attempted to explore a *sui generis* protection of traditional knowledge that is significantly distinguishable from the intellectual property system.

The current legal framework at an international level provides a complex picture of patenting in relation to science and technologies in relation to biomedical innovation. A number of legal constructions have been created, developed and expanded as a means of extending corporate power, rather than stimulating quick innovation in scientific communities. The co-producing of this normative complexity by public and private, inter- and intra-treaties, technological neutral and technological political approaches etc., reflected the prevailing power realities in the discourse of patent and innovation. This complexity does not stop at the international normative context, but has further manifested itself in at least two dimensions. One concerns the further uncertainty and complexity involved when the current framework is translated into national legal

the Patent System’ in Han Somsen (ed), *The Regulatory Challenge of Biotechnology: Human Genetics, Food and Patents* (Edward Elgar 2007).

³⁴¹ The Convention on Biological Diversity (adopted 5 June 1992, entered into force 29 December 1993).

³⁴² Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits arising from their Utilization to The Convention on Biological Diversity (adopted 29 October 2010, entered into force 12 October 2014).

systems. Another is the different layer of complexity impacting the internal operation of patent law. The section below further illustrates two more thematic issues related to the latter dimension that have cross-cutting effects on the science and technology's path in the shadow of the patent regime.

2.2.2.2 Non-patentable Subject Matters: Surgical, Diagnostic and Therapeutic Treatment Methods

Article 27.3(a) of TRIPS states that 'diagnostic, therapeutic and surgical methods for the treatment of humans or animals' may be excluded from being patentable, paving the way for countries to adapt this flexibility in their national law practices, and as a consequence many countries have excluded these methods from being eligible for patent.

The justification of such exclusion has been linked to the notion of the higher duty of doctors³⁴³ and the long recognized professional ethics of the medical practitioner that should not be obscured by proprietary enclosure. Specifically, the Hippocratic Oath requires medical practitioners to 'practice and prescribe to the best of [their] ability for the good of [their] patients, and to try to avoid harming them...' and to 'keep the good of the patient as the highest priority'.³⁴⁴ This justification has been confirmed in legal practice when such methods are excluded as non-patentable. For instance, in the G0002/08 *Dosage Regime/Abbott Respiratory* case, the Enlarged Board of Appeal of the European Patent Office states that

³⁴³ Florian Leverve and Jeremy Phillips, 'The Exclusion of Surgical, Therapeutic and Diagnostic Inventions from Patentability under Article 52(4) of the European Patent Convention' (Intellectual Property Institute 2008) 3.

³⁴⁴ *ibid.*

...the exclusion...seemed actually to be based on socio-ethical and public health considerations... In fact physicians should be free to take all actions they considered suitable to prevent or to cure a disease, and in this exercise they should remain uninhibited by patents.³⁴⁵

Similar reasoning can also be found in

- 2005, G-1/04 Diagnostic methods: ‘... the exclusion from patentability of medical methods under... seems actually to be based on socio-ethical and public health considerations... medical and veterinary practitioners should be free to take the actions they consider suited to diagnose illness by means of investigative methods. Consequently, the policy... appears to be aimed at ensuring that those who carry out diagnostic methods as part of the medical treatment of humans or veterinary treatment of animals are not inhibited by patents’ (cf. T 116/85, Pigs I/Wellcome, G-1/04/348).³⁴⁶
- 2010, G-1/07 Treatment by surgery/MEDI-PHYSICS: ‘the principle has been confirmed that medical and veterinary practitioners’ freedom to use the best available treatment to the benefit of their patients uninhibited by any worry that some treatment might be covered by a patent is protected by excluding these activities from patentability... the real reason for excluding the defined methods from patentability were socio-ethical considerations and consideration of public health, ... medical and veterinary practitioners should be free to use their skills and knowledge of the best available treatments to

³⁴⁵ G0002/08 *Dosage Regime/Abbott Respiratory* <https://www.epo.org/law-practice/case-law-appeals/recent/g080002ex1.html>

³⁴⁶ Sigrid Sterckx and Julian Cockbain, *Exclusions from Patentability: How Far has the European Patent Office Eroded Boundaries?* (CUP 2012) 135-172.

achieve the utmost benefit for their patients uninhibited by any worry that some treatment might be covered by a patent...’³⁴⁷

The practices of physicians remain an important source of accumulating medical knowledge, thus the exclusion of methods as such also has a far-reaching impact on scientific development regarding medicines.

2.2.2.3 Patentability: Example of Second Medical Use

While exclusion from eligibility has reflected the policy influence in patent law making and practice, the extent of patentability criteria and examination determines the actual boundary of protection in a given technological context. In this regard, the discussion of how the concept of ‘new’ has been constructed is of specific interest to this research.

As mentioned in the Introduction, the notion of what constitutes ‘new’ is collectively represented in patent law system as a co-produced conceptual framework in which the three basic criteria – novelty, inventiveness and industrial applicability –work together in the construction. In particular, there are spatial and temporal elements concerning the legal fixation of criteria related to ‘new’ mostly through assessing the novelty and inventiveness. Novelty stands against the ‘prior art’ that existed before the recognised date of filing or the date of priority. Timing is important. As discussed above regarding the issue of priority right, among the simultaneous inventors, the person who filed patent might be one day earlier than the others, thus becoming the patentee in the end, regardless whether in reality the other inventors who remained in their laboratories having had an earlier breakthrough. The novelty rule is built on the assumption that at a legally-accepted point in time the invention remained unknown to the public in a given

³⁴⁷ *ibid.*

space. Inventiveness, on the other hand, is also based on retrospective assumptions of time and personnel. As discussed in the previous chapter, it involves the imaginary concept of a ‘person skilled in the art’, and assuming such person would be able to look back in time to the point when the invention was achieved, and make a technical assessment whether the solution was obvious to her/him.

The constructions of the two criteria present a telling co-production process while the tendency of the law toward fixation and stability and the characteristic of science’s uncertainty meet in a rather imaginary field in regulating a technological subject together. Whether such an exercise produces consistent outcomes is a fluid question as the inherent power asymmetry of actors, policy and political influences often results in varied decisions.

One example of such an exercise is found in the context of second medical use patents. After the original product claim on a given chemical substance, one can often claim the first discovery of the therapeutic use of this substance, thereby triggering the first medical use patents as allowed by Article 54(4) under European Patent Convention (EPC) 2000.³⁴⁸ However, second medical use of the same substance that has obtained patent twice is not a universally accepted patent policy. In particular, the lack of novelty has often been used as the major argument against second medical use patents.³⁴⁹ Notwithstanding this, legal construction has stepped in again with the creation of the

³⁴⁸ In the context of the patentability of the method of treatment, Article 54(4) of EPC 2000 states that patentability shall not be excluded for ‘any substance or composition, comprised in the state of the art, for use in a method’, in which the ‘method’ refers to ‘methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods; under Article 53(c).’

³⁴⁹ Sigrid Sterckx and Julian Cockbain, *Exclusions from Patentability: How Far has the European Patent Office Eroded Boundaries?* (CUP 2012) 135,163.

Swiss-style claim, turning a publicly-oriented debate into a techno-centric one. As first recognised in the EISAI decision G 5/83 by the Enlarged Board of Appeal of European Patent Office (EPO) in 1984, the typical Swiss style claim is drafted in a specific format: ‘*The use of compound X in the manufacture of medicament for the treatment of disease Y.*’³⁵⁰ The EISAI decision attempted a balance between maintaining the non-patentability of the method of treatment according to the EPC and the interest of the industry in obtaining some protection on second medical use. Therefore, the inserted notion of ‘manufacture’ attempts to silence the very controversy of clinical practice in relation to an old medicine and creates a ‘new’ category.

The impact of this kind of practice on different actors is evident the decision made by the High Court of England and Wales in 2015 on *Mylan and Actavis v Warner-Lambert*,³⁵¹ which concerns the invalidation of a second medical use patents³⁵² on pregabalin, a drug sold under the brand name Lyrica and used to treat epilepsy, anxiety disorders and neuropathic pain. As mentioned briefly in the introduction chapter, there are over 100 paragraphs of text in the High Court decision revealing the activities and interactions between the company Pfizer and nearly all sectors and medical practitioners in the entire UK public health system.³⁵³ The company’s public warning and threats triggered medical practitioners’ resistance. In May 2015, before the High Court decision

³⁵⁰ EISAI, G0005/83 (Second medical use), Para.19 reads: ‘As indicated in the Enlarged Board of Appeal’s communication dated 31 July 1984, having regard to the statement of practice of the Swiss Federal Intellectual Property Office, the Enlarged Board has also given careful consideration to the possibility of protecting second (and subsequent) medical indications by means of a claim directed to the use of a substance or composition for the manufacture of a medicament for a specified (new) therapeutic application. Such claims do not conflict with Article 52(4) EPC or Article 57 EPC but there may be a problem concerning the novelty of the invention.’

³⁵¹ *Mylan and Actavis v Warner-Lambert*, [2015] EWHC 2548 (Pat). See <http://www.bailii.org/ew/cases/EWHC/Patents/2015/2548.html> accessed 18 July 2017.

³⁵² European Patent (UK) No. 0 934 061 entitled ‘Isobuytlgaba and its derivatives for the treatment of pain’.

³⁵³ See paragraph 459-558 of the decision.

was made, a motion was tabled in the annual Local Medical Committees (LMCs) conference stating that

...conference believes that generic prescribing should always result in the lowest acquisition cost for the NHS, and that:

- i) category M³⁵⁴ classification distorts the market and should be ended;
- ii) price stability for generic products should be maintained;
- iii) *legislation is urgently needed to end patent protection for specific indications for pharmaceuticals*; [emphasis added]
- iv) direct intervention to ensure continuity of supply of widely used generic products is required.³⁵⁵

It is hard to prove that the High Court ruling had been influenced by the actions taken by GP doctors in this regard. However, the calls from the GP community reinforced the objection that has been long standing against the granting of second medical use patents on medicines given its negative impact on public health. The constructing of artificial newness through claim drafting rather than actual technological improvements once again revealed a co-production exercise in which the cognitive power of language plays an important role in facilitating the interplay of law and technology in meeting the conventionally time-sensitive novelty test. Second medical use patents is only one example of how old technological subjects can be reactivated without any change and continues to gain ground in terms of commercial competition. This strategy is known as

³⁵⁴ Category M refers to the scheme of fixed reimbursement prices for 500 medicines that was introduced under the Drug Tariffs 2005 of the UK. The scheme has triggered controversy for its possibility of retaining high prices of medicines and causing inequality of services between different geographic areas. Ref. comments on the category M practice by the Pharmaceutical Services Negotiating Committee <<https://psnc.org.uk/funding-and-statistics/funding-distribution/retained-margin-category-m/>>, accessed 25 November 2018.

³⁵⁵ Pulse Today, 'LMC Vote to End Patent' <<http://www.pulsetoday.co.uk/clinical/prescribing/gps-vote-to-end-patent-protection-after-nhs-england-enforced-branded-pregabalin-prescribing/20010048.fullarticle>>, accessed 20 July 2017.

‘ever-greening’, with its metaphoric effect of going beyond the time limit on the enjoyment of exclusivity that is established by law. In addition, the achievement of ever-greening itself simultaneously relies on the pathways provided by law.

2.3 Remarks: Revisiting the Two Cultures

At the centre of this chapter’s discussion is the contentious relationship between science, technology and law in the context of constructing the notion of innovation for pharmaceuticals. As observed by scholars, ‘science and property, formerly independent and even opposed concepts referring to distinctively different kinds of activities and social spheres, have been made contingent upon each other through the concept of intellectual property rights’.³⁵⁶ This kind of relationship has become routine in the co-production processes while science, technology, property law and patent have started simultaneously rewriting each other’s normative ordering. The indeterminate feature of such processes reveals the clash of linear explanations of the commonality and differences between disciplinary cultures that are now melting in the field of patenting. On the other hand, the process has also revealed a deep conflict concerning boundaries, a tension which placed certain public interests in danger. Despite co-produced rules and institutions, the overall functions of expertise playing a vital role in the co-production exercise. In this regard, questions regarding the extent to which the domination of patenting has changed the normative context and behaviours in the scientific communities’ biomedical research and how patent law practitioners have contributed to this construction in their actions, will be further explored in Chapter 3.

³⁵⁶ Henry Etzkowitz and Andrew Webster, ‘Science as Intellectual Property’ in Sheila Jasanoff and others (eds), *Handbook of Science and Technology Studies* (SAGE 1995) 480.

PART II

Chapter 3: The Role of Legal Profession and Expertise in Patent and Biomedical Innovation Discourse

As the previous chapter detailed, the development of an international-level legal framework for patent on medical technologies has revealed the macro-level political discourse relating to innovation, economic rationales, and the notion of scientific and technological advancement and development. At the micro level, co-production occurs when inventions are written into patent documents for legal recognition, thereby representing the disciplinary interplay between law, science and technology. This is constructed within the specific techniques of legal professions, especially patent attorneys, who have a concurrent knowledge and disciplinary awareness of law and biomedical science. Individual patent attorneys are not always politically motivated in their routine patent law practices. Rather, a politically-motivated network of expertise can actively generate and sustain a particular vision of patent and innovation in normative discussions. On the other hand, it is also problematic to presume the homogeneity of motives on the part of patent law professionals in the context of patenting on biomedical innovations, because as much as the law provides a platform for constructing a hegemonic understanding of innovation, it simultaneously provides a site of resistance and contestation. Therefore, the role of the patent law profession should not be overlooked in discussions of alternative conceptual frameworks for biomedical innovation, as such professionals have contributed substantively to the epistemic dimension in terms of the way in which biomedical knowledge and innovation is dealt with by law. To extend this discussion, this chapter will examine the role of legal

profession and expertise, with a focus on patent attorneys, in the patent and biomedical innovation discourse.

3.1 Experts and Expertise in Knowledge Making and Their Relevance to Biomedical Innovation Debates

The discussion of the role of the patent law profession can be located in the broader literature concerning experts and expertise. The literature has illuminated the role of experts and expertise in the context of knowledge creation and policy making from anthropological, sociological, legal and political economy perspectives, including those from STS scholars.³⁵⁷ Studies have also discussed how expertise is developed in the defined context while social norms and networks construct the way of how technological systems, facts and normal science are practised.³⁵⁸

In the context of the making of global affairs and legal orders, expertise has been seen as ‘specialised knowledge’³⁵⁹ that can be held by anyone who, through relationship with others, can contribute to a certain form of decision making. By staging the discussion of expertise against the backdrop of resistance and struggle, the use of expertise can be a

³⁵⁷ Some examples of influential studies on expert and expertise include: Max Weber ‘The Vocation of Science’, in Sam Whimster (ed), *The Essential Weber: A Reader* (Routledge 2004); Etienne Wenger, *Communities of Practice* (CUP 1998); K Anders Ericson, Neil Charness and Paul Feltovich, *The Cambridge Handbook of Expertise and Expert Performance* (CUP 2006). Legal scholars have also examined the role of expertise in international law and policy makings. See: David Kennedy, *The Dark Sides of Virtue: Reassessing International Humanitarianism* (Princeton University Press 2004); David Kennedy, *A World of Struggle: How Power, Law and Expertise Shape Global Political Economy* (Princeton University Press 2016).

³⁵⁸ Studies of this kind include for instance: Bruno Latour and Steve Woolgar, *Laboratory Life: The Construction of Scientific Facts* (2nd edn, Princeton University Press 1986), Sheila Jasanoff, *Science at the Bar: Law, Science and Technology in America* (Harvard University Press 1995), Sheila Jasanoff, ‘The Idiom of Co-Production’, in Sheila Jasanoff (ed), *States of Knowledge: The Co-Production of Science and Social Order* (Routledge 2004); Wiede E Bijker and others (eds), *The Social Construction of Technological Systems: New Directions in the Sociology and History of Technology* (The MIT Press, 2012), Thomas Kuhn, *The Structure of Scientific Revolution* (3rd edn, The University of Chicago Press, 1996).

³⁵⁹ David Kennedy, *A World of Struggle: How Power, Law and Expertise Shape Global Political Economy* (Princeton University Press 2016) 108.

tactic and imaginary deployed in developing the idea of ‘global problems’,³⁶⁰ although solutions might be found in local contexts instead. While everyone can hold a certain level of expertise in a given context, the important role of professionals has been considered as introducing the focus and redefining the width and depth of the discussions in both broader contexts and while developing common sense understandings.³⁶¹ However, this does not mean that the emerging of professionals has stabilised disputes, because professional communities may consist of their members’ different concerns and opinions, which can further complicate a discourse with other players in a given context.³⁶² In terms of law and science, resorting to scientific expertise has long been practised as part of truth-finding in courtrooms.³⁶³ The production of scientific facts in a legal context, however, has been considered as subject to ‘economic and sociological constraints’.³⁶⁴ Instead of a linear notion of a cultural clash between law and science, co-production rather suggests that the two boundaries could be constitutive in fact-making in legal contexts.³⁶⁵

Bringing these lines of thinking into the context of this research, the tension between patent regime expansion and the insufficient outcome of and access to biomedical innovation has been presented as a global macro-level problem, a context in which the debate concerns how international law and governance structures can be used in rebalancing power relations between countries with different economic and technological capacities. At the micro level, patent law keeps its internal evolution

³⁶⁰ *ibid* 95.

³⁶¹ *ibid*.

³⁶² *ibid*.

³⁶³ Sheila Jasanoff, *Science at the Bar: Law, Science and Technology in America* (Harvard University Press 1995) 42.

³⁶⁴ *ibid* 67.

³⁶⁵ *ibid* 8.

relevant to the understanding of innovation through constantly setting the scope of protections in the process of patent prosecution, examination, and dispute proceedings. At a micro level, the exercise also adds to the culture of patenting in the scientific community and the development of deep professionalism in patent law practice. Each of these levels involves the network and interaction of different communities with expertise in the fields of law, medicine, politics, economics, public health, social movements and others. The subject, scope and extent to which biomedical innovation is subject to patent protection are being constantly determined and re-determined in the process of interactions between medical practitioners (such as physicians and pharmacists), biomedical scientists, legal professionals (including patent attorneys and lawyers, patent examiners, judges and academic lawyers). In this process, the legal expertise and knowledge could be dominate and at the centre of defining the structure, communicative route and normativity. For instance, a study on the process of introducing a new patent class into the WIPO international patent classification (IPC) system has shown that the materials of patent documents, rather than the scientific and technological content in these documents, are the primary focus in this exercise, which forms a legal epistemic in the context of patent administration.³⁶⁶

Moreover, legal expertise itself can be further divided depending on the specialties of the lawyers engaged in the debate.³⁶⁷ In the context of patenting and biomedical innovation, lawyers can reflect diverse views and interests depending on their clients or

³⁶⁶ Hyo Yoon Kang, 'Science inside Law: The Making of a New Patent Class in the International Patent Classification' [2012] 25(4) *Science in Context* 551 <<http://dx.doi.org/10.1017/S0269889712000233>>, accessed 20 May 2018.

³⁶⁷ In Kennedy, the example of lawyers' taking of global political economy is one such example while the global knowledge practice among lawyers shows distinctive focuses depending on which area of law they are focusing on. See David Kennedy, *A World of Struggle: How Power, Law and Expertise Shape Global Political Economy* (Princeton University Press 2016) 130-133.

associated entities. In addition, the work of patent attorneys are of particular interest here, as they function as the active creators of documents that represent the invention concerned in order to seek a patent based on biomedical innovation. Individual patent attorneys may not be visible in the macro level political discourse, but rather play an indispensable role in driving the internal evolution of the patent law system alongside other legal professionals. On the other hand, the collective entity and the network of professional knowledge sharing between patent attorneys, can be evidenced in more substantive participation in high-level normative debates regarding how biomedical innovation should be dealt with in legal terms. The exercise of expertise in this sense has been substantively facilitated by the deep professionalism developed in the context of making patent practitioners part of the profession, which will be discussed in more detail in later sections.

3.2 The Legal Profession and Patent Attorneys

3.2.1 Studies of the Legal Profession

Lawyers are one of the oldest professions and the role has been studied by sociological works in particular.³⁶⁸ Despite the fact that how to define a profession is still debated,³⁶⁹ the classical understanding of ‘profession’ relies on the individual’s institutional function as an intermediary between individuals, the state and the market with distinctive expertise,³⁷⁰ and embodying stable and distinctive social groups with high levels of knowledge and expertise.³⁷¹ However, this approach has been found to be uncritical

³⁶⁸ Andrew Boon, *Lawyers’ Ethics and Professional Responsibility* (Hart Publishing 2015) 38-39.

³⁶⁹ Mike Saks, ‘Defining a Profession: The Role of Knowledge and Expertise’ [2012] 2(1) *Professions & Professionalism* 1-10.

³⁷⁰ Emile Durkheim, *The Division of Labour in Society* (The Free Press 1964). See also Hilary Sommerlad and others (eds.) *The Future of Legal Education and the Legal Profession* (Hart Publishing 2015).

³⁷¹ *ibid.*

regarding the ideological and political dimensions that knowledge and expertise play in making professions and their relationship with the wider society. In this regard, Weber shed more light on the interactional effect between lawyers and their social context.³⁷² Marx also looked at the legal profession as a reflection of bourgeois prejudice in capitalist society.³⁷³ In addition, the idea of lawyers as a profession independent from the judiciary has been seen as a reflection of political liberalism and the safeguarding of the rule of law.³⁷⁴

In the context of the study of legal profession specifically, three main approaches have been observed. The structural and functional approach states that achieving functional specificity is a shared principle based on which professions can establish authority.³⁷⁵ This approach focuses on social structures and normative standards related to the functions of the legal profession, and the orientation of the legal profession towards collective mobility in social status and market control.³⁷⁶ Key elements such as legal education, licensing and professional ethics are crucial in creating market control and demand for legal services.³⁷⁷ The second approach looks at the social interactions in legal practices. These interactions are either related to lawyers and clients, between lawyers, or concerning lawyers and other competing professional communities.³⁷⁸ Social interaction paves the way to professionalise certain vocations whose social status

³⁷² *ibid.*

³⁷³ Karl Marx and Frederic Engels, *Collected Works*, Vol 40 (International Publisher 1976) 494-495. See also Andrew Boon, *Lawyers' Ethics and Professional Responsibility* (Hart Publishing 2015) 38-39.

³⁷⁴ Terence C Halliday and Lucien Karpik, *Lawyers and the Rise of Western Political Liberalism* (Clarendon Press 1997), Robert W Gordon, 'Independence of Lawyers' [1988] 66 Boston University Law Review 1.

³⁷⁵ Robert Dingwall and Philip Lewis, *The Sociology of Professions: Lawyers, Doctors and Others* (Quid Pro 2014) 3.

³⁷⁶ Sida Liu, 'The Legal Profession as a Social Process: A Theory on Lawyers and Globalisation' [2013] 38(3) *Law & Social Inquiry* 670, 672.

³⁷⁷ *ibid.* See also Richard L Abel, *The Legal Profession in England and Wales* (Blackwell 1988) 158.

³⁷⁸ Liu, (n 376).

can be redefined.³⁷⁹ The third approach studies lawyers' collective actions and influences outside of the legal sphere, examining their work in influencing and changing political spaces and languages, through studies of cause-lawyering and political lawyering.³⁸⁰ With their respective focuses, they all point toward lawyers' engagement and impact outside of the domain of law itself.³⁸¹ The last two approaches are particularly relevant to the discussion of patent law practitioners in the context of this research. Indeed, politically- and ideologically-related insights are relevant when the value and norms of biomedical innovation have been constituted using a dominant vision backed by neoliberal ideology in the global context, as the previous chapters have reviewed.

Firstly, and from a historical perspective, the origin of lawyers as a distinctive profession in Western society can be traced back to the middle ages,³⁸² before the emergence of modern capitalist society. However, the flourishing of the legal profession has followed in the traces of mercantilism and capitalism.³⁸³ Colonial history also witnessed the transplanting of the system of legal professions to the colonies together with the establishment of legal institutions as part of the overall colonial process.³⁸⁴ The emergence of specialised patent lawyers in a Western context has also followed similar timelines, as the section below discusses.

³⁷⁹ Mike Saks, 'Defining a Profession: The Role of Knowledge and Expertise' [2012] 2(1) *Professions & Professionalism* 1.

³⁸⁰ Liu, (n 376).

³⁸¹ *ibid.*

³⁸² Anton-Herman Chroust, 'Legal Profession in Ancient Republic Rome' [1954] 30(1) *Notre Dame L Rev.* available at: <<http://scholarship.law.nd.edu/ndlr/vol30/iss1/5/>> accessed 30 July 2017; James A Brundage, *The Medieval Origins of Legal Profession* (The University of Chicago Press 2008).

³⁸³ *ibid.* See also Paul A Brand, 'The Original of English Legal Profession' [1987] 5(1) *Law and History Review*, 31-50.

³⁸⁴ Duman Daniel, *The English and Colonial Bars in the Nineteenth Century* (Croom Helm 1983).

Secondly, the high level of specialised knowledge and expertise of a profession often implies society's expectations of particular and elevated levels of virtue and ethics.³⁸⁵ To preserve professionalism, the work of lawyers is expected to be neutral in order to be able to represent morally indefensible individuals.³⁸⁶ Furthermore, client-centred ethical standards are also seen as indispensable to ensuring professionalism in a deliberately-removed manner, which is independent and free from the influence of the state and its representatives and agencies, the judiciary, political parties and the public, so that equal treatment of all types of clients could be guaranteed.³⁸⁷ This deliberation as such also finds common ground in the example of patent attorneys. In addition, patent attorneys also bring with them another level of ethical conspicuousness from their earlier background as scientists and engineers.

Furthermore, the independence of lawyers has been supported and safeguarded by a distinctive privilege lawyers are entitled to and enjoy, namely to be able to work in confidence with their clients. For instance, in the case of England, and as a core principle developed by common law, legal professional privilege has been specified by statute.³⁸⁸ Professional privilege is a powerful defence to exempt the lawyer and their client from being required to give evidence about what has been communicated and exchanged between them.³⁸⁹ This aspect is relevant to patent attorneys, who have a unique status in the broader legal profession. The extent to which patent attorneys may enjoy the same level of professional privilege as other lawyers depends on how the patent attorney is recognised and regulated in a given jurisdiction. Confidentiality, the key guarantee of

³⁸⁵ Boon (n 368) 31.

³⁸⁶ *ibid.*

³⁸⁷ *ibid.*

³⁸⁸ The Police and Criminal Evidence Act 1984 Section 10(1).

³⁸⁹ Boon (n 368) 184.

the enjoyment of professional privilege, may mean conceptual conflicts with the notion of disclosure and diffusion in a patenting process, thereby restraining the individual inventors – and especially academic scientists – from discussing and sharing their work in progress with their peers.

3.2.2 Challenges of Legal Professionalism

In addition, traditional professional values, ethics and privilege, which are largely built upon the homogeneous identity of legal profession as a distinctive social group, can face at least two levels of overall challenges nowadays. The first concerns the heated discussions of recent years regarding the decline in legal professionalism in the face of an increasingly enterprise-oriented culture in legal services. The emergence of corporate firms and lawyers, whose practice serve only certain interest groups, have been seen as embodying ‘the erosion of classical professionalism’³⁹⁰ while fracturing the ‘homogeneity of the profession’.³⁹¹ Multinational law firms have become more powerful and influential in public spaces compared to the traditional associative body of individual and independent lawyers.³⁹² Secondly, internal changes in the profession also introduce the difficult question concerning the degree to which a lawyer should bear responsibilities in the public interest.

The two levels of challenges outlined above are also highly relevant to the discussions of patent attorneys in the context of biomedical innovation and patenting. Firstly, and as the section below discusses, the clients of patent attorneys have changed over the process

³⁹⁰ Hilary Sommerlad and others, ‘The Future of Legal Education and the Legal Profession’, in Hilary Sommerlad and others (eds) *The Future of Legal Education and the Legal Profession* (Hart Publishing, 2015) 9.

³⁹¹ *ibid.*

³⁹² *ibid.*

of patent law's development. While early patent attorneys, even before they had become a profession, worked mostly with individual inventors, professionalised patent attorneys now have a highly diversified group of clients including corporate-focused patent firms and attorneys. As examined in the previous chapter, the current international level-tensions surfaced following the globalization of the trade agenda, while intellectual property had been brought in through TRIPS as a result of lawyers' work representing the interests of multinational corporations.³⁹³ In addition, patent attorneys have contributed to circumventing the statutory exclusion of patentable subject matters through claim drafting techniques.³⁹⁴ At the same time, some patent attorneys, together with other lawyers, have also engaged actively in debate on the public interest in intellectual property law, in turn launching patent oppositions and litigations concerning pharmaceutical, biological or life form patents alongside civil society organizations.³⁹⁵ Thus, the professionalism developed on the part of patent attorneys could be said to be both intensified, given further integration with commercially-driven interests; and segmented, with subversive individuals and groups choosing to practice in the patent law system for the public interest.

Having reviewed the studies of the legal profession and their relevance to the discussion of patent attorneys in the context of this research, the rest of the chapter looks at the

³⁹³ Susan K Sell, *Private Power, Public Law: The Globalization of Intellectual Property Rights* (CUP 2003) 173.

³⁹⁴ Peter Drahos, *The Global Governance of Knowledge: Patent Offices and their Clients* (CUP 2010) 52.

³⁹⁵ Some examples of patent attorneys' public interest-oriented practices can be found in patent oppositions on pharmaceutical and life-form patents brought or supported by the US patent attorney Daniel Ravicher's Public Patent Foundation, British barrister Daniel Alexander's work with German civil society's 'No Patent on Life', the US-based public interest law group I-MAK and India public interest law group Lawyers Collective. See: Shobita Parthasarathy, *Patent Politics: Life Forms, Markets and the Public Interest in the United States and Europe* (The University of Chicago Press 2017) 134-135, 137-139, 141; Shobita Parthasarathy, 'Breaking the Expertise Barrier: Understanding Activist Challenges to Science and Technology Policy Domains' [2010] 37(5) *Science & Public Policy* 335, 360; Fran Quigley, 'Patent Fights: Taking on Big Pharma' (07 November 2017) *Health and Human Rights Journal* <<https://www.hhrjournal.org/2017/11/patent-fighters-taking-on-big-pharma/>> accessed 15 April 2018.

making of a patent attorney as a process of co-production, and the effect of professional networks of patent attorneys in a transnational context alongside the resulting impact on the discussions of biomedical innovation and patenting.

3.3 Making the Patent Profession in the Biomedical Field

3.3.1 The Emergence of the Patent Attorney as a Profession

Comparing to studies of the legal profession in general, the literature concerning patent attorneys is relatively scarce. In the available literature, legal historians have attributed the emergence of the patent agent or attorney in the English and the US patent system to the change in regulatory requirements for patent registration procedures, when patent specification, the role of patent examiner, and more sophisticated formative requirements were introduced.³⁹⁶ This transformation has been seen as triggering the emergence of the patent agent or patent attorney as an occupation and eventually a profession.³⁹⁷

It has been observed that the early appearance of a specialised group of patent agents could be traced back to 18th century England after the patent specification requirement was introduced into law.³⁹⁸ The requirement was understood as having been first introduced regarding the issuance of letter patent with an added clause stating that the letter patent could become void if the inventor did not describe in writing the specifics

³⁹⁶ *ibid.* See also: Christine MacLeod, *Inventing the Industrial Revolution: The English Patent System 1660-1800* (1st edn, Carl Heymanns Verlag 1988); Kara W Swanson, 'The Emergence of Professional Patent Practitioner' [2009] 50(3) *Technology and Culture* 519, 523; Sean Bottomley, *The British Patent System During the Industrial Revolution 1700-1852: From Privilege to Property* (CUP 2014) 73.

³⁹⁷ Sean Bottomley, *The British Patent System during the Industrial Revolution 1700-1852: From Privilege to Property* (CUP 2014) 73.

³⁹⁸ Mario Biagioli, 'Patent Specification and Political Representation: How Patent Became Rights', in Maria Biagioli and others (eds) *Making and Unmaking Intellectual Property: Creative Production in Legal and Cultural Perspective* (The University of Chicago Press 2011).

and performance of the invention.³⁹⁹ The principle was further established through a 1778 decision made by Lord Mansfield when a patent was annulled due to lack of ‘specification’.⁴⁰⁰ The reasoning concerning patent specifications was based on the theory of the social contract of patent, while the necessity of specifications was to provide appropriate teaching to others, thereby ensuring that the public shall benefit from the invention.⁴⁰¹ Similar provisions emerged in the same period in some other countries, such as the requirement for written descriptions under the US Patent Act 1790 and the French Patent Law 1791,⁴⁰² and the introduction of the patent examiner under the US Patent Act 1836.⁴⁰³ The introduction of specification requirements and patent examination procedures have fundamentally shifted the central focus of patent application and the relationship between the patent office and inventors. The merits of obtaining a patent were once demonstrated by the material and mechanical model of the operation of an invention, and the requirement of mandatory technology transfers to local artisans.⁴⁰⁴ By contrast, after the specification requirement assumed a more central role, the focus of patent applications and examinations shifted slowly towards how the invention is written.⁴⁰⁵

This shift has been considered as reconceptualising the invention and moving away ‘from actual machine to inventive idea’.⁴⁰⁶ This has triggered institutional changes in

³⁹⁹ Herbert Harding, *Patent Office Centenary: A Story of 100 Years in the Life and Work of the Patent Office* (Her Majesty’s Stationery Office 1953) 4.

⁴⁰⁰ *Liardet v Johnson* (1778) 1 HPC 198. Sean Bottomley, *The British Patent System During the Industrial Revolution 1700-1852: From Privilege to Property* (CUP 2014) 88.

⁴⁰¹ *Liardet v Johnson* (1778) 1 HPC 198.

⁴⁰² Biagioli, ‘Patent Specification and Political Representation’ (n398) 27.

⁴⁰³ Kara W Swanson, ‘The Emergence of Professional Patent Practitioner’ [2009] 50(3) *Technology and Culture* 519, 525.

⁴⁰⁴ Biagioli, ‘Patent Specification and Political Representation’ (n398) 32

⁴⁰⁵ Alain Pottage and Brat Sherman, ‘Chapter 7: Textual Machines’ in Alain Pottage and Brat Sherman (eds), *Figure of Invention: A History of Modern Patent Law* (OUP 2013) 127.

⁴⁰⁶ Biagioli, ‘Patent Specification and Political Representation’ (n 398398) 32.

the patent law system with both the invention and the person have moving from a system of presentation to a system of representation.⁴⁰⁷ For instance, following the enactment of the Patent Law Amendment Act 1852 in England, the patent office was divided for the first time into the Patent Division and the Specification Division.⁴⁰⁸ The way of writing up the specification and the fulfilment of the writing template, format and style have taken up the space of patent prosecution practices while inventors needed specialised assistance in getting this right.⁴⁰⁹ Likewise, research has identified a booming ‘how-to’ patent advice literature in the US in the late nineteenth century, which created a market demand for specialised services.⁴¹⁰ It has been observed that

The proliferating how-to literature demonstrated a growing consensus that any savvy inventor would use a patent practitioner as his agent in dealing with the patent office, leaving his ‘mental acts’ to be described to the examiner by someone with experience in patent drafting, a specialised form of ghost-writing.⁴¹¹

Positive commentaries have found that the work of patent agents helped to eliminate the gaps between the bureaucracy and individual inventors in the patent administration process,⁴¹² thereby making patent applications more accessible and convenient.⁴¹³ The regulatory change and the effect of using specialised services in the patent prosecution

⁴⁰⁷ *ibid* 34.

⁴⁰⁸ *ibid*.

⁴⁰⁹ Herbert Harding, *Patent Office Centenary: A Story of 100 Years in the Life and Work of the Patent Office* (Her Majesty’s Stationery Office 1953) 10-12.

⁴¹⁰ Kara W Swanson, ‘Authoring an Invention: Patent Production in the Nineteenth-century United States’, in Maria Biagioli and others (eds) *Making and Unmaking Intellectual Property: Creative Production in Legal and Cultural Perspective* (The University of Chicago Press 2011) 46.

⁴¹¹ *ibid*.

⁴¹² Bottomley (n397)73.

⁴¹³ *ibid*.

process had given birth to the professionalization of patent practices and patent attorneys as a distinct group emerged as a specialised profession.

It is worth noting, however, that not every country has gone through a similar history where the patent attorney's role evolved as a consequence of voluntary and dynamic shifts in the patent system at a local level. For instance, during the colonial era, patent attorneys started emerging as a result of the adaptation of patent legislation led by the colonisers, as took place in Australia in the late 1800s.⁴¹⁴ Other countries may see the patent attorney as a profession promoted by the state's interest in systemic law and economic reform. For instance, China's first generation of patent attorneys was trained by the government only in the late 1980s when the country adapted a Western-style of patent law in 1984 following the beginning of the economic reform era and under pressure from the US in bilateral trade and market access negotiations.⁴¹⁵ Regardless of their institutional origins, professionalised patent attorneys share a similar notion and practice in making patents, while inventions are represented using a specifically-crafted type of language.⁴¹⁶ This level of commonality can be substantively attributed to the increasing exchange of information and collaboration regarding patent law practices and

⁴¹⁴ Barton Hack, *A History of the Patent Profession in Colonial Australia: Presented at the Annual Conference of the Institute of Patent Attorneys of Australia* (Clement Hack & Co 1984).

⁴¹⁵ Peter Yu, 'The Transplant and Transformation of Intellectual Property Law in China' in Nari Lee, Niklas Bruun and Li Mingde (eds), *Governance of Intellectual Property Rights in China And Europe* (Edward Elgar 2016) 20; Warren H. Maruyama, 'U.S.–China IPR Negotiations: Trade, Intellectual Property, and the Rule of Law in a Global Economy' in Mark A Cohen, A Elizabeth Bang and Stephanie J Mitchel (eds), *Chinese Intellectual Property Law and Practice* (Kluwer Law International 1999) 186; Wu Handong, 'One Hundred Years of Progress: The Development of Intellectual Property System in China' [2009] 1 WIPO J 117; Li Wei, 'The Reference to the US for Patent Attorney System Development in China' Chinese Intellectual Property Newspaper (16 September 2009) (李薇, '中国专利代理人制度的美国借鉴' 中国知识产权报, 2009年9月16日). See also: Li Wei, 'Patent Agent Systems in China and the US' [2009] 31 China Intellectual Property <<http://www.chinaipmagazine.com/en/journal-show.asp?id=506>> accessed 01 August 2018.

⁴¹⁶ Alain Pottage and Brat Sherman, 'Textual Machines' in Alain Pottage and Brat Sherman (eds), *Figure of Invention: A History of Modern Patent Law* (OUP 2013) 118, 127.

the increasing assimilation of patent administration in national systems, all in the context of globalization which has been considered as reflecting an ‘invisible harmonization’ of the patent regime.⁴¹⁷

3.3.2 Qualifications and Expertise

In addition to the rather pragmatic institutional-level advent, the making of the patent attorney profession also carries with it a unique qualification requirement compared to other sub-groups in the legal profession.

The position of patent attorney varies between jurisdictions, but all share the features of a highly-specialised group or a small sub-branch of the general legal profession. When recognised as part of the broader legal profession, patent attorneys may enjoy nearly the same level of regulatory and professional privilege as other lawyers. For instance, both the European Patent Convention (EPC)⁴¹⁸ and the UK Copyrights, Designs and Patent Act 1988 extend a privileged status to patent attorneys.⁴¹⁹ The UK Legal Services Act 2007 posits the ‘patent attorney’ under the category of ‘other lawyers’,⁴²⁰ joining the trademark attorney as the two specialised intellectual property practitioners recognised by statute. The UK Chartered Institute of Patent Attorneys (CIPA), the approved regulatory body for the patent professions, has categorised different titles in patent law practices,⁴²¹ while ‘patent attorney’ is specifically defined as ‘a member of a small

⁴¹⁷ Drahos, *The Global Governance of Knowledge* (n 394).

⁴¹⁸ Rule 153(1) of European Patent Convention, entered into force in December 2007.

⁴¹⁹ Section 280 of UK Copyrights, Designs and Patent Act 1988.

⁴²⁰ Article 185, Legal Services Act 2007, UK.

⁴²¹ See Chartered Institute of Patent Attorneys, ‘Patent Attorneys and other Advisors’, available at: <<http://www.cipa.org.uk/need-advice/patent-attorneys-and-other-advisors/>>. Accordingly, the categories of practitioners include: Patent Attorneys; Chartered Patent Attorneys; European Patent Attorneys; Registered Trade Mark Attorneys; European Trade Mark Attorneys; Patent Attorney Litigators; Solicitors; Barristers; and Invention Promoters or Invention Brokers.

profession qualified by examination in the intellectual property law of the United Kingdom and abroad. Patent attorneys are specially trained and experienced in the art of drafting patents and in knowledge of intellectual property law.⁴²² In another context, the patent attorney may not enjoy the same level of status as lawyers, especially in terms of professional privilege. For example, the patent attorney is not regarded as a variety of lawyer in India and thus does not enjoy professional privilege before the law.⁴²³ Even under the English system, a patent attorney's entitlement to professional privilege only started from the Civil Evidence Act 1968.⁴²⁴

The divergence regarding patent attorneys' entitlement to professional privilege reflects the long-term contingency in terms of the relationship between specialised patent attorneys and the rest of the legal profession. The early literature described this relationship as that between 'cousins',⁴²⁵ and advocated for law school education to accommodate both.⁴²⁶ The notion that patent lawyers are primary engineers and secondary lawyers has also been observed as a common perception among general legal practitioners, according to a later study on the patent bar in the US.⁴²⁷ Due to the specialised skills, qualification process and scope of the work involved, there are further divisions of labour between patent practitioners, with some concentrating on patent

⁴²² *ibid.*

⁴²³ The rule was developed under *Wilden Pump Engineering Co v Fusfield*. The Evidence Act 1872 of India established that barristers, attorney, pleader and vakil are entitled to professional privilege. See: Compilation of laws and practices regarding the scope of client attorney privilege and its application to patent advisors: India, WIPO, SCP Electronic Forum, available at: http://www.wipo.int/export/sites/www/scp/en/confidentiality_advisors_clients/docs/03_india.pdf.

⁴²⁴ Section 15, Civil Evidence Act 1968.

⁴²⁵ Richard Spensor, 'The Patent Lawyer and The General Practitioner' (1933) Penn Law Legal Scholarship Depository
<http://scholarship.law.upenn.edu/cgi/viewcontent.cgi?article=8616&context=penn_law_review>
accessed 15 June 2017

⁴²⁶ *ibid.*

⁴²⁷ JM Conley and Lynn Mather, 'Scientists at the Bar: The Professional World of Patent Lawyers' in Leslie C Levin and Lynn Mather (eds), *Lawyers in Practice: Ethical Decision Making in Context* (The University of Chicago Press 2012).

prosecution and others on litigation. This makes the composition of this branch of the profession more diverse as patent litigators in many jurisdictions remain open for general lawyers without a scientific background. In contrast, patent prosecutors must have scientific backgrounds and are positions often taken up exclusively by patent attorneys. During a study on US patent lawyers, this dynamic was captured by an interview quote stating that ‘there are completely different skill sets involved in prosecution and litigation. Hardly anyone does both... prosecutors talk science and don’t know how to talk law... they’re the pocket protector crowd.’⁴²⁸ While first trained intensively as scientists and engineers, patent attorneys – especially those who focus on prosecutions – often study law later in the process of changing career from science to patent practice.⁴²⁹ Patent prosecutors work primarily with patent offices and clients directly on drafting and scoping patent claims and documents, while patent litigators work with other lawyers and the court.⁴³⁰

Under the English system, to be qualified as a patent attorney requires the person to be eligible and to complete a series of examination and qualification processes. Only graduates with STEM degrees – i.e. science, technology, engineering and mathematics – are eligible to enter the field.⁴³¹ A law degree is not required it can be studied later. Patent attorney is an attractive profession for many STEM graduates as the financial outlook is outstanding.⁴³² To be qualified, many countries require the candidate to pass a qualification exam and to receive practical qualification by working in a firm for a

⁴²⁸ *ibid.*

⁴²⁹ *ibid.*

⁴³⁰ *ibid.*

⁴³¹ See Qualification Exams, CIPA, available at: <<http://www.cipa.org.uk/patent-examination-board/faq/qualifying-examinations/>>.

⁴³² CIPA Career Guide 2015-16, 13. The guide states that ‘in the patent profession, you could earn up to £55,000 before you’ve even finished your exams.’ Often, a PhD degree in STEM would bring additional benefits and presumably a quicker career path in the firm.

period of time. The exam, taking the example of the UK, includes two parts of knowledge and skills, namely knowledge of intellectual property law and patent practice skills including claim constructions, patent litigation and other practices,⁴³³ with the pass rate ranging between 10-30%.⁴³⁴ The high threshold and low pass rate have lifted the status of the profession itself, and it has been observed that patent lawyers and attorneys are among the best remunerated group of professionals in the legal field.⁴³⁵

Once entered, the divisions of the practices are categorised according to the field of technology concerned, in which pharmaceuticals and biomedicine fall into the life science category in most UK big city firms. The CIPA Life Science Committee identifies its scope of concern as

...any matter of law or practice requiring knowledge of life sciences, which includes pharmaceuticals and biotechnology, or relating to IP protection of biological material or the production or use thereof, including Plant Breeders Rights and supplementary protection certificates (SPCs); also consideration of the interaction of the Biodiversity Convention and medicine regulatory and competition law with IP law.⁴³⁶

⁴³³ Past exam materials, CIPA, available at: <<http://www.cipa.org.uk/patent-examination-board/support/examination-information/past-examination-materials-qualifying-examinations/>>.

⁴³⁴ UK Patent Exam Success for Trainees and Single Qualified Patent Attorneys, available at: <<https://www.marks-clerk.com/Home/Knowledge-News/News/UK-patent-exam-success-2015.aspx#.WC1Q4rJ97Dc>>.

⁴³⁵ John M Conley and others, 'Scientists at the Bar: The Professional World of Patent Lawyers', in Lynn Mather (ed), *Lawyers in Practice: Ethical Decision Making in Context* (The University of Chicago Press 2012) 251. See also: CIPA Graduate Career Guide to Chartered Patent Attorneys 2015/2016 (Insidecareer 2015) 8.

⁴³⁶ CIPA Life Science Committee: <<http://www.cipa.org.uk/about-us/people/cipa-committees/laws-committees/life-sciences-committee/>>.

Entering into this field is a journey of transformation into a ‘hybrid’⁴³⁷ or a ‘mixture’⁴³⁸ of expertise, while interdisciplinary communications and interplays between law, science and technology take place at both personal and professional levels. The qualification process also involves turning, merging and redeveloping a scientist, engineer or biologist’s professional and ethical orientations to those of a patent attorney while consolidating their background techno-scientific knowledge with foregrounded legal expertise.⁴³⁹ The UK CIPA career offers an accessible illustration of this phenomenon:

Patent attorneys are a unique interdisciplinary mixture, operating in the areas where law, commerce and technology overlap. They need to have the ability to comprehend both the scientific and technical factors involved and the legal and commercial aspects. The patent attorney must be skilled in language, both oral and written, and be able to act as a bridge between various parties...⁴⁴⁰

It also provides a more substantive depiction of the type of expertise and skills required in performing a patent attorney’s work, which has been plainly referred to by the Legal Service Act as including: ‘(a) applying for or obtaining patents, or (b) conducting proceedings before the comptroller relating to applications for, or otherwise in connection with, patents.’⁴⁴¹

The development of a profession emerging out of patent practitioners is a historical and pragmatic phenomenon. Taking the example of the early emergence of the patent

⁴³⁷ Kara W Swanson, ‘The Emergence of Professional Patent Practitioner’ (2009) 50(3) *Technology and Culture* 519.

⁴³⁸ CIPA Career Guide 2015-16, 11.

⁴³⁹ Conley and others (n427) 250.

⁴⁴⁰ CIPA Graduate Career Guide to Chartered Patent Attorneys 2015/2016 (Insidecareer 2015) 6.

⁴⁴¹ See Section 275A (7), The Legal Services Act 2007, UK.

attorney in England, this was shaped by the industrial revolution's social and technological transitions. The requirement for modelling the invention in physical terms and the actual local training and technology transfer involved in the patent application process was replaced with by a representation-based system. In addition, textual and written specifications have become the central theme of the patent administration process. Individual practitioners in 18th century England had grown up with a highly specialised ability to provide service. However, they did not come to the game as lawyers. As observed previously, the first patent-preparation firms in England emerged in the 1830s and 1840s, but they were formed and staffed by engineers.⁴⁴² These tendencies continued with intensified specialisation and deep professionalism, while the patent attorney has come to play a central role in creating and sustaining a unique linguistic system of representation within the patent system through patent claim drafting and prosecution practices. While individual and micro-level practices are facilitated as such by professional networks and institutions at a transnational level, the notions and knowledge created by a specific group of professional practices can go beyond individual cases and jurisdictions by engaging in the political discourse concerning patent and innovation as the section below discusses.

3.4 Networking and the Patent Law Professions in the Context of the Patent and Biomedical Innovation Debate

The observation of the emergence of the patent attorney as a sub-branch of the legal profession is important for any investigation of the construction of the epistemic dimension in the discourse concerning biomedical innovation. According to this line of

⁴⁴² See: Harry I Dutton, *The Patent System and Inventive Activity during the Industrial Revolution 1750-1852* (Manchester University Press 1984); Dirk van Zyl Smit, 'Professional Patent Agents and the Development of the English Patent System' [1985] 13 *International Journal of the Sociology of Law* 79.

argument, patent has been considered as the key – if not the only – indicator of innovation. This perceived function of patent is highly contestable as the previous chapter has revealed, yet it enjoys widespread currency. In the field of biomedical innovation, the current discourse has overly focused on economic causation and mitigation, while the mechanics of how patent came to be understood and constructed as the indispensable vehicle for technological innovation is often overlooked.

There are also mismatches between the notions of what constitutes ‘new’ and ‘advancement’ in the conventional innovation discourse and the actual work of patent law respectively. First of all, ‘innovation’ *per se* is not a legal concept. Whether or not the function of the patent system or a particular patent is formidable or beneficial in terms of innovation, is mostly not a concern in the determination whether something merits a patent protection according to the law. Instead, modern patent law has developed a matrix of determination by looking at a set of criteria based on novelty, inventiveness, and industrial applicability or utility. Instead of looking at an ‘innovation’, patent law practice looks instead at an ‘invention,’ that is one technical solution intended to establish legal recognitions. It has been noted that patents are ‘poor proxies for innovation’,⁴⁴³ while studies have shown, for example, that only less than one-third of the active patent portfolio in large technology companies pertains to products on the market and an even smaller percentage of patents are actually related to technological advancements in any given field.⁴⁴⁴

⁴⁴³ Tim Lenoir and Eric Giannella, ‘Technological Platforms and the Layers of Patent Data’, in Mario Biagioli and others (eds), *Making and Unmaking Intellectual Property: Creative Production in Legal and Cultural Perspective* (The University of Chicago Press 2011) 363.

⁴⁴⁴ *ibid.*

The large number of patents that exist in a given field may well be the result of a sophisticated construction of recognizable patent claims alongside skilful negotiations in the professional practice of patent law, a process marked by the constant interplay of different levels of expertise. However, whether the statistics reflect ground-breaking advancements in a particular field is an entirely different issue. In the field of patents concerning pharmaceuticals, for instance, although there was an average of 2.3% steady growth in patent applications from 2004-2015,⁴⁴⁵ only 1.2% of new chemical entities for pharmaceutical use were approved in the same period of time.⁴⁴⁶ Indeed, the patent thicket around a competitive product may well represent the intelligent paperwork produced by a network of professional patent practitioners.

Meanwhile, when patent law practice operates within its own logic, the innovation discourse takes place in different forums and adopts the notion of patent ‘as indispensable for innovation’ without necessarily looking at how patent law works in its closed format. For instance, the discourse on patent and health in the Standing Committee on the Law of Patent (SCP) under the auspices of the World Intellectual Property Organisation (WIPO), was crafted by geopolitical manoeuvring and the avoidance of specification. The professional practice of patent law takes place in the shadow and backdrop of these discourses, without necessarily presenting itself visibly. Patent practitioners are located in the network of patent and health discourse actors as the shadow definers. Figure 1 tries to capture examples of the major networks where the

⁴⁴⁵ World Intellectual Property Organization, World Intellectual Property Indicator 2015, available at: <http://www.wipo.int/edocs/pubdocs/en/wipo_pub_941_2016.pdf> 49.

⁴⁴⁶ Belen Pedrique and others, ‘The Drug and Vaccine Landscape for Neglected Diseases (2000-11): A Systematic Assessment’ [2013] 1(6) *Lancet* 371.

notion of patent and, *inter alia*, biomedical innovation, takes place and the situatedness of its professional circles.

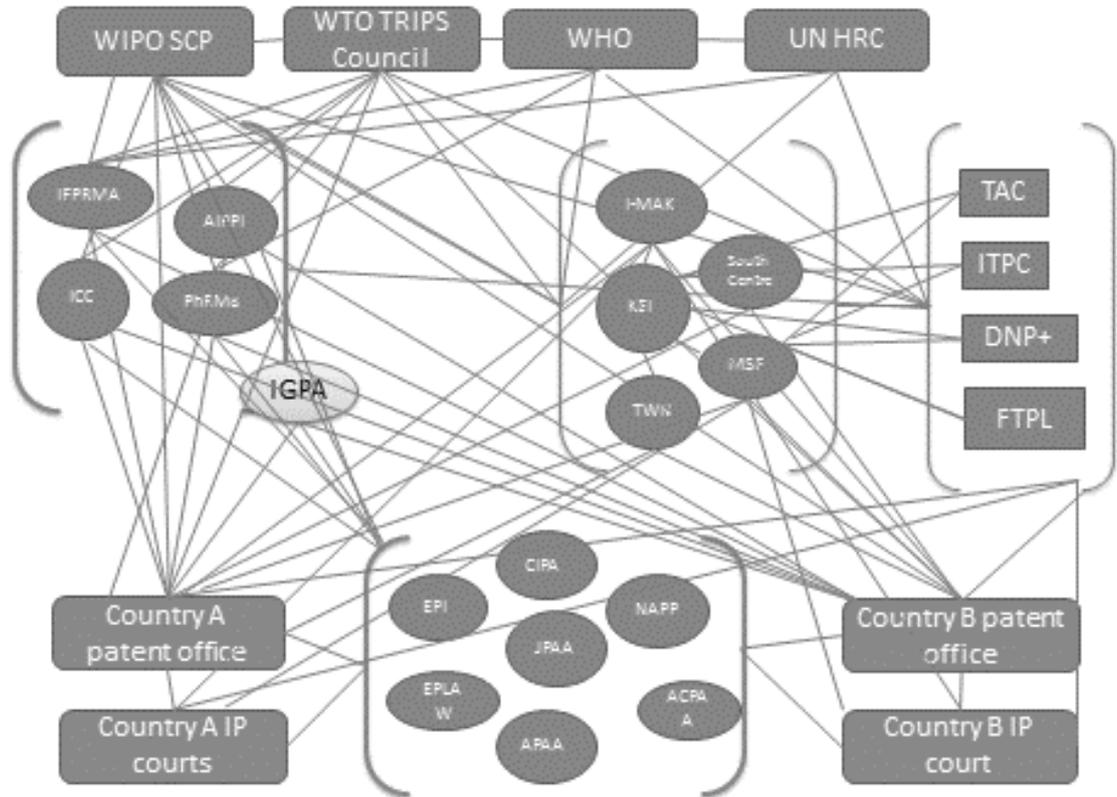


Figure 1: Network of Knowledge and Expertise on Patent and Health Discourse

On top of the chart are the major international forums where the issues of patent and health innovations are discussed. In the middle, there are three major influence groups with the industrial and commercial associations on the left, international non-governmental organisations in the middle, and the patient-led national and community movements to the right. The groups in the middle at the bottom of the chart include the major professional associations of patent attorneys and practitioners in major jurisdictions which contribute to the majority number of patent filings in the world.

What I intend to present here is a general scenario of how knowledge and expertise travel through the closed professional circle towards the major discursive and normative spaces at international level dealing with patent and health innovation. The chart illustrates this trend while professional groups' high density of knowledge and expertise regarding patent law is disproportionally aimed towards and interacts with both industrial representative groups and patent practices at national (and regional) levels. This could be presumed to be the consequence of practitioners' mandates and clients-oriented professional mission; it simultaneously reflects an absence of engagement with other stakeholders.

The trend here might invite questions regarding whether this disengagement was derived merely from patent attorneys' professional culture or rather back on a general lack of interest in social and public interest perspectives. Furthermore, while professional culture might possibly explain the phenomenon, questions remain about how such a professional culture was formed in the first place and how the process of entering this professional circle has impacted on individual practitioners' conception of the issue. As the previous chapter has argued, the sphere of patent creation is essentially a constant co-production process involving science, technology and law, while the making of practitioners in this process also comes under the same co-production rubric.

The transnational features of knowledge and expertise exchange has reinforced specialised patent law professionals' networks and sense of community. In addition, the origin and development of the patent attorney is also distinctive when compared with other legal professions. Recalling the observations and critiques that have arisen in recent research on the legal profession, a deepened enterprise-oriented culture is

considered a challenge to a declining professionalism⁴⁴⁷ while the extent to which the public interest should be a concern in legal services poses a constant dilemma to legal professionals in general. These challenges and questions bear direct relevance to patent attorneys. The inherent commercial orientation of patent drafting and prosecution practices make these questions even more difficult to answer. Apart from the *ordre public* doctrine which is generally recognised by international and national patent laws, other issues of public interest are vaguely and rarely defined or required in patent law practices. In the context of biomedical innovation, whether the improvement treatment outcome (though it may not be essential) is considered a type of public interest in contrast to certain patient groups who have no access to adapted innovations suiting their situation, or whether it should be the other way around, are questions to which it is often hard to identify straightforward answers. When performing services, the professional requirement to pursue the maximum possible opportunities regarding obtaining and maintaining patents, drives patent documents' drafting and prosecution to reach for an even higher level of specificity and complexity, meaning that textual discourse and interpretation triumph over the actual problems that need to be solved. The next chapter will discuss further how textual production has deepened the gap between law and society in the context of the biomedical innovation debate. Building on discussion of patent law specialists' expertise, it will also look at the broader communities around innovation, some of which may have been marginalised for a long period.

⁴⁴⁷ Hilary Sommerlad and others, 'The Future of Legal Education and the Legal Profession', in Hilary Sommerlad and others (eds) *The Future of Legal Education and the Legal Profession* (Hart Publishing, 2015) 9.

3.5 Towards an Alternative Professional Culture

The discussion on the role of patent law professionals, especially patent attorneys, is important in the context of identifying an alternative conceptual framework to biomedical innovation's patent-centric paradigm. The highly skilled work of patent attorneys and other patent law practitioners constitute the epistemic aspect of patent's current conceptualisation, which remains contestable. Critiques on the deficiency of the conceptual justification of patent as an indispensable institution that stimulates biomedical innovation have focused on two primary threads, namely debunking the economic underpinning and revealing the justification's empirical insufficiency. However, the making and transmitting of the meaning of newness and innovation are often overlooked in political and policy contexts. Legal historians have traced back the evolution of modern patent law in a Western context, particularly in Europe and the US, and demonstrated the process of transformation in which patent law shifted from a privilege-based system to a system of rights and entitlement. This transformation took place in the context of systemic technological changes, especially during the industrial revolution. This process also brought about significant changes in patent administration's regulatory and institutional infrastructure, with the introduction of patent specification and a substantive examination process. These changes have been considered as triggering the emergence of the specialised vocation of the patent agent, which later developed into a unique branch of the legal profession. Having knowledge of and skills relating to biomedical science, technology and law, patent attorneys perform day-to-day production of inventions' texts and meaning, mostly through patent claim drafting and prosecutions. In addition, the globalization of legal services and the increasing level of corporate-focused legal services have enabled professional skills and knowledge to be exchanged in transnational contexts. The network and associations

between patent attorneys in this transnational context have contributed to and formed an integral part of the discourse of biomedical innovation and patent.

Both the institutional establishment and political engagement of patent attorneys, as discussed in this chapter, have presented a co-production trait, in which knowledge of law is constitutive and interactional with the background knowledge of biomedical science and technologies. Transitioning from a scientist or engineer to a patent attorney has been bound by shared professional norms and client-centred ethics. This is prominent when corporate clients' access to specialized services has become substantively more accessible, raising questions concerning the declination of the legal profession as a distinctive and independent group free from impact of political, commercial and other interests. At the same time, studies on patent law practitioners have presented a non-linear picture where subversive patent attorneys and legal practitioners have joined forces to challenge technical grounds and boundaries from within the patent law realm. The mainstream homogeneity narrative of patent's indispensable role in biomedical innovation alongside the questioning of expansive patent's impact on the public interest have become a site of conflict and segmentation within the legal profession as well as the patent law-centred debate. This internal tension may offer a critical opportunity for an alternative conceptualization and re-imagination, as Part III will further discuss. Building on the above critiques, the next chapter will discuss the law in the context of making meanings and texts in relation to biomedical innovation and its impact on non-corporate innovators.

Chapter 4: Reproducing Meaning or Adding New Knowledge? Ideologies, Expertise and Community Imaginaries in Biomedical Patent Making

As discussed in the previous chapter, the emergence of a specialised branch of the legal profession in patent has brought about substantive changes in the institutional and epistemic landscape regarding the debate on patent and innovations. Although the individual and day-to-day work of a patent attorney may not always be politically driven, the transnational skill sharing network has enabled the patent practitioner's political and normative engagement in the context of the biomedical innovation debate. Patent attorneys who have rebelled, on the other hand, have indicated the need to reengage the public in those debates concerning pharmaceuticals as well as biological and life form patents. These traits have revealed the interactional co-production at personal and normative levels alongside multiple sites of conflicts. This chapter will further deploy the concept of co-production to discuss the making of meanings of newness in the context of patenting on biomedical innovations. It reviews the collective imaginary on patents in regard to biomedical innovation, the constitutive effects of patent law on scientific norms and discusses the construction of the new by citing examples of patenting on old medicines and the enclosure of biomedical research tools. The further critique of these contradictions is expected to help opening up the discussion on the elements required for reimagining biomedical innovation, which Part III will continue discussing.

4.1 Text, Meanings and the Patent Proliferation

Several distinctive features mark the high level of specialisation in modern patent law practices. Among others, specialised attorneys' increasingly sophisticated and commonly-shared techniques of patent claim construction, and the distant relationship between the physical specification of the invention and the textual specification of patent claims together present a modern imaginary of patent as the key indicator of innovation. The concentration of expert knowledge in these contexts make patent a nearly untouchable symbol. Around this, actors in science, technology and law are organised and re-organised to make sense of an imagined polity where the value of knowledge is presented and measured in a particular manner. Interrogating the process of the formation of this polity may help to reveal the way in which traditional norms have changed, and the elements based on which the pattern of change can be reconstructed alongside alternative conceptualisations that might be explored.

Scholars have interrogated how a particular subject comes to form a social identifier for a particular community,⁴⁴⁸ in which the context moves from physical to imaginary, thereby enabling the possibility of using a 'single theoretical framework' for a given community to hold a firm sense of belonging.⁴⁴⁹ Drawing on Benedict Anderson's study of nationhood building, the role of text through the dissemination of print media which meant that people who had no previous connections came to a shared imagination of commonality.⁴⁵⁰ Text carries both substantive and political functions in building this

⁴⁴⁸ For instance, Benedict Anderson argues that nationality has been a distinctive social identifier which also sees the formation of imagined political communities. See Benedict Anderson, *Imagined Communities: Reflection on the Origins and Spread of Nationalism* (Verso 1983).

⁴⁴⁹ *ibid.* See also: Sheila Jasanoff, 'Image and Imagination: The Formation of Global Environmental Consciousness', in C Miller and P Edwards (eds), *Changing the Atmosphere: Expert Knowledge and Environmental Governance* (MIT Press 2001).

⁴⁵⁰ *ibid.*

shared vision and behaviour in the process of building a political community. Scholars in science and technology studies (STS) have also examined the use of text in the representation of scientific meanings and natural subjects in political discourse.⁴⁵¹

The recent works of Jasanoff, in particular, have reviewed the often-omitted interplay between societal and non-material traces and modern technology innovation in institutional accounts of innovation.⁴⁵² Although institutions such as intellectual property law and patent provoke the technological meaningfulness in modern lives, it has been argued that modern technological innovations have rather often followed on the heels of science fiction and rooted in social constructions,⁴⁵³ whereas it is the needs, desires and choices of human society that would ultimately give meaning to technological advancement.⁴⁵⁴ Technologies, in this sense, are always ‘integral components of social order’.⁴⁵⁵ Using patent law as the institution to make sense of the material aspects of innovation has also resulted in a dilemma. On one hand, the preference for coherence and certainty in law forces the creation of specific language or coding systems to justify a presumed material value of patent on paper, regardless of whether human needs can be fulfilled in reality and in the final analysis. On the other hand, the scope of protection created through the paperwork in turn redefines the legitimacy concerning creative works done by others in the same technological and scientific field.

⁴⁵¹ *ibid.*

⁴⁵² Sheila Jasanoff, ‘Future Imperfect: Science, Technology and the Imagination of Modernity’ in Sheila Jasanoff, *Dreamscapes of Modernity: Sociotechnical Imaginary and the Fabrication of Power* (The University of Chicago Press 2015).

⁴⁵³ *ibid.*

⁴⁵⁴ *ibid.*

⁴⁵⁵ *ibid.*

The thickness of social – namely, the foundational and contextual aspects upon which scientific developments were associated and invited by human needs – in the historical account of patent system concerning science and technological innovations, can be traced primarily through the requirement for technology transfer as well as the detailed demonstration of the invention’s actual application in real life. These were measures deployed to ensure and guarantee the presumed social benefits of granting patent. Following the process of separating the patent specifications on paper from real life experiences, social thickness is lost in the textual imagination, thereby created a unique coding and language system that only certain groups of people would be able to interpret and understand. The increasing sense of commonality and belonging through these shared textual implications contributed significantly to patent proliferation, an entry code to a specifically-defined modern community. The imaginary process implied in inventing a new language to describe technologies and scientific subjects through patent has also profoundly influenced the norms in terms of the way in which knowledge should be generated, shared and evaluated.

4.2 Changing Norms: Science in Textual Constructions of Patent Meanings

4.2.1 Traditional Norms of Science

As discussed in the previous chapters, disciplinary cultures’ encounters and interactions take place in the context of converting an established scientist into a skilful patent attorney, who then contributes to the day-to-day co-production process of representing inventions through creating and negotiating patent texts. This encounter has also been discussed when constructed doctrines have continuously interrupted the innovation’

users, for instance medical practitioners.⁴⁵⁶ Disruptive technologies used in biomedical research increased the excitement involved in creating new interpretations of law and governing rules while the realm of patent law is constantly changing. However, while these encounters have been viewed from a legal standpoint, profound changes concerning the knowledge production structure, norms and behaviours in science as a whole have also taken place simultaneously. A brief recap of the main changes in this regard is necessary before moving on to a discussion of alternative imaginaries.

It has been observed that the traditional norms of science are at odd with the idea of appropriation of knowledge through exclusion and proprietary protections.⁴⁵⁷ Research looking at the historiography of Western science recalls that a community of gentlemen scientists shaped the primary norms of science during the Enlightenment while free exchange of information was central to the scientific endeavour.⁴⁵⁸ For instance, during the 17th century, the Royal Society of London for the Improvement of Natural Knowledge held to the principle that scientific credibility arises from ‘public scrutiny of

⁴⁵⁶ Katherine J Strandburg, ‘Legal but Unacceptable: Pallin v. Singer and Physician Patenting Norms’ in Rochelle Cooper Dreyfuss and Jane C. Ginsburg (eds), *Intellectual Property at the Edge* (CUP 2014) 321.

⁴⁵⁷ For the literature related to the origins and evolution of scientific norms and the intersection with intellectual property, see: Robert Merton, *The Sociology of Science: Theoretical and Empirical Investigations* (The University of Chicago Press 1973); Karl Popper, *The Open Society and Its Enemies* (Routledge, 1947); Rebecca S Eisenberg, ‘Proprietary Rights and the Norms of Science in Biotechnology Research’ [1987]97(2) Yale LJ 177-231; Henry Etzkowitz, ‘Entrepreneurial Science in the Academy: A Case of the Transformation of Norms’ [1989] 36(1) Social Problems 14-29; Rebecca Eisenberg, ‘Patenting Research Tools and the Law’, in National Research Council (ed) *Intellectual Property Rights and Research Tools in Molecular Biology* (Washington DC 1997), available at: <<http://www.nap.edu/readingroom/books/property/4.html#chap4>>; Jeffrey L Fox ‘Can Academia Adapt to Biotechnology’s Lure?’ (October 12, 1981) Chemical and Engineering News 39-44; James Boyle ‘The Second Enclosure Movement and the Construction of the Public Domain’ (2001) Presented at the Conference on the Public Domain, Duke University School of Law, 9-11 November 2001, available at: <<https://scholarship.law.duke.edu/cgi/viewcontent.cgi?article=1273&context=lcp>>; D Blumenthal and others ‘Withholding Research Results in Academic Life Science’ [1997] 277(15) Journal of the American Medical Association 1224-1228.

⁴⁵⁸ Janet Hope, *Biobazaar: The Open Source Revolution and Biotechnology* (Harvard University Press 2006)30.

experimental methods and results'.⁴⁵⁹ High levels of independence, scepticism and refutation of prevailing authorities were accepted and shared.⁴⁶⁰ Preserving norms required both an elevated level of scientific objectivity while researchers were able to carry on amid criticism and substantial publicity.⁴⁶¹ When illustrating his notion of the 'publicity of scientific method', the contemporary philosopher Karl Popper also argued that two central elements – approaching free criticism and avoiding cross-purposes – are constituting the objectivity of scientific methods and knowledge productions.⁴⁶² Objectivity, through publicity, ensures free and public scrutiny of scientific experiments while everyone could try and fail once the techniques were acquired. At the same time, public institutions such as laboratories and universities would continue progress amid the social aspects of their research.⁴⁶³ Popper went on to advocate that '[O]nly political power, when it is used to suppress free criticism, or when it fails to protect it, can impair the functioning of these institutions, on which all progress, scientific, technological, and political, ultimately depends.'⁴⁶⁴

The element of publicity has been a critical characteristic of science. Publicity helps to preserve objectivity in that, as a scientist, it is normal to be exposed to different types of (partial) criticism, publically from scientific peer or beyond, which is a reciprocal process of seeking truth and driving progress. Publicity was enabled when the norms of science were socially shared and supported by institutional governance on scientific knowledge production. Research on the sociology of science has further categorised four conventional interaction norms governing science's institutional goals, including

⁴⁵⁹ *ibid* 29.

⁴⁶⁰ *ibid*.

⁴⁶¹ Karl R Popper, *The Open Society and its Enemies* (Routledge 1947) 200-212.

⁴⁶² *ibid*.

⁴⁶³ *ibid*.

⁴⁶⁴ *ibid* 206.

universalism, communism, disinterestedness and organisational scepticism.⁴⁶⁵ The meanings of the four norms⁴⁶⁶ have presented an overall picture of scientific social relations in which scientists are both individuals and a virtual collective community. In particular, the consideration of scientific knowledge production and truth seeking as a continual process of social collaboration between the scientific community is essential as it determines traditional scientific operations' mechanisms of governance and reward.⁴⁶⁷ Public scrutiny, peer pressure to achieve originality, professional recognition and a rapid publication rate were therefore the mechanisms of governance and reward,⁴⁶⁸ through which the scientific community's social collaboration and progress could continue while at the same time innovations were contributing to the public good.⁴⁶⁹ It has been argued that a strong sense of communal and openness has reinforced the open source movement in modern information science and should be applicable in broader scientific fields such as biomedical innovation.⁴⁷⁰ This element will be illustrated further in Chapter 6.

4.2.2 Contemporary Intellectual Property and the New Norms in Science

With the development and expansion of the modern patent law regime, traditional scientific norms have been challenged and transformed, especially following the introduction of Patent and Trademark Amendment Act in the United States of America

⁴⁶⁵ Robert Merton, *The Sociology of Science: Theoretical and Empirical Investigations* (The University of Chicago Press 1973) 267. See also: Rebecca S Eisenberg, 'Proprietary Rights and the Norms of Science in Biotechnology Research' (1987) 97(2) Yale LJ 177-231.

⁴⁶⁶ Rebecca S Eisenberg 'Proprietary Rights and the Norms of Science in Biotechnology Research' (1987) 97(2) Yale LJ 183.

⁴⁶⁷ *ibid.*

⁴⁶⁸ *ibid.*

⁴⁶⁹ *ibid.*

⁴⁷⁰ Hope, *Biobazaar* (n 458) 31.

(USA),⁴⁷¹ also known as Bayh-Dole Act, concerning intellectual property ownership derived from publicly-funded research, especially in research institutions and universities. The Bayh-Dole Act covers all fields of scientific research including biomedicine and allows private patenting on publicly-funded research and exclusive licensing hereinafter, which has triggered long-term controversies and debates. A large body of researchers have observed and critically reviewed the impact of the Bayh-Dole Act and its derivatives in other countries when the model has been advertised and transplanted as a means of accelerating innovation, which is essentially a commercialisation of publicly-funded research, while implying institutional, behavioural and normative changes in scientific communities.⁴⁷² In particular, given the establishment of technology transfer offices in universities and research institutions, the norms of patenting and commercialisation-oriented research strategies have grown rapidly.⁴⁷³ Meanwhile, changes that have occurred in the field of science in general also have direct implications for biomedical research and development.

⁴⁷¹ Patent and Trademark Law Amendment Act, Pub.L. 96-517, December 12, 1980.

⁴⁷² There is a large body of research reviewing the impact of the Bayh-Dole Act and similar regulations in other countries when transplanted, based primarily on the regulatory and governance frameworks for public research and development See: Arti K Rai and Rebecca Eisenberg, 'Bayh-Dole Reform and the Progress of Biomedicine' [2003] 66(1) *Law and Contemporary Problems* 289; Sara Boettiger and Alan B Bennett 'Bayh-Dole: If We Knew Then What We Know Now' [2006] 24(3) *Nature Biotechnology* 320; Thomas B Astebro and others, 'Academic Entrepreneurship: Bayh-Dole Versus the "Professor's Privilege"' (February 2016); HEC Paris Research Paper No. SPE-2015-1118, <<https://ssrn.com/abstract=2677283> or <http://dx.doi.org/10.2139/ssrn.2677283>> accessed 06 August 2018; Joanne Waldstreicher, 'Managing Conflicts of Interest in Industry-Sponsored Clinical Research: More Physician Engagement Is Required' [2017] 317(17) *JAMA* 1751; Jason F Perkins 'The Bayh-Dole Act, Technology Transfer and the Public Interest' [2014] 28(2) *Industry and Higher Education* 143-151; Anthony D So and others, 'Is Bayh-Dole Good for Developing Countries? Lessons Learned from the US Experience' [2008] 6(10) *PLoS Biol* e262 < <https://doi.org/10.1371/journal.pbio.0060262> > accessed 10 August 2017; Michael S Kinch, 'A History of Drug Development in Four Acts' [2015] 20(10) *Drug Discovery Today* 1163; William O'Brien, 'March-in Rights under the Bayh-Dole Act: The NIH's Paper Tiger?' [2013] 43 *Seton Hall L Rev* 1403.

⁴⁷³ *ibid.* See also: Hope, *Biobazaar* (n 458)32.

Some researchers have argued that the main sites of conflicts derived from the above-mentioned changes are positioned between the scientific norms and reward mechanisms.⁴⁷⁴ While the incentives created by intellectual property are material – especially the attraction to commercialization via academic-industry partnerships – the lines between basic and applied science started to blur.⁴⁷⁵ While the traditional reward systems such as peer-reviewed publications and professional recognition remain valid, additional rewards derived from patent-based commercialisation have added complexity. Typically, in order to retain the right to claim priority in prospective patent applications, scientists are advised by technology transfer offices to delay the timing for publication.⁴⁷⁶ New research tools associated with biological materials could also make publishing alone insufficient given the need to access to the full information that goes beyond the texts; key data and materials might be retained by the publishing scientist due to an institutional intellectual property policy or restrictions emanating from the research partnership agreements.⁴⁷⁷ Furthermore, copyright policies of scientific journals may also limit the availability of publications, which would indirectly help the rhetoric of patenting to argue that patent is a much more desirable way to publicise and disseminate knowledge.

The tensions regarding publications' timing and channels in the context of the increase in patenting culture in science are worth examining further. As discussed in Chapter 1, the value of disclosure is one of the mainstream justifications for patent law in the

⁴⁷⁴ Rebecca Eisenberg 'Proprietary Rights and the Norms of Science in Biotechnology Research' [1987] 97(2) Yale LJ 177.

⁴⁷⁵ *ibid.*

⁴⁷⁶ *ibid.*

⁴⁷⁷ *ibid.* See also Rebecca Eisenberg, 'Patenting Research Tools and the Law', in National Research Council (ed) *Intellectual Property Rights and Research Tools in Molecular Biology* (Washington DC 1997), available at: <<http://www.nap.edu/readingroom/books/property/4.html#chap4>> accessed 20 July 2017.

context of innovation. Yet, the meaning of disclosure under patent law intersects with, but differentiates from, the meaning of publicity under the norms of science. In principle, the sufficient disclosure requirement under patent law is rigorous, asking for a level of disclosure sufficient to enable a person skilled in the art to replicate the invention described without missing or misleading information. In theory, the disclosure requirement in patent should be so rigorous that it is stricter than the disclosure requirement when publishing in a scientific journal.⁴⁷⁸ With patenting becoming mainstream in the scientific community and patent documents potentially revealing full technical solutions under the sufficient disclosure requirement, reading and analysing patent documents has also become one of the main sources of information for researchers. In fact, researchers in the fields of biotechnology and chemistry have been found to be the most frequent and active readers of patent documents and citations in this regard.⁴⁷⁹

However, legal and professional techniques have developed sophisticated means of circumventing sufficient disclosure requirements such as claiming partial completion of research, continually claiming additional protection while time goes by and as research progresses, citing partial or incorrect data, hiding important new indications for future patent applications, or dividing claims into multiple applications. The full landscape of patenting regarding a given technological issue or scientific object might be less straightforward than what the theoretical justification on patent wanted to see. Experienced, resourceful and skilful research teams and scientists might be able to navigate the thicket and unveil all the tricks of skilful patent drafters, and work around

⁴⁷⁸ Rebecca Eisenberg, 'Patenting Research Tools and the Law', in National Research Council (ed) *Intellectual Property Rights and Research Tools in Molecular Biology* (Washington DC 1997), available at: <<http://www.nap.edu/readingroom/books/property/4.html#chap4>> accessed 20 July 2017

⁴⁷⁹ Lisa Larrimore Ouellette, 'Who Reads Patents?' (2017) 35 *Nature Biotechnology* 421.

such blockages in their own research activities. However, this is very different from the ideal type of publicity that the conventional scientific norms intend to achieve. As mentioned above, publicity was envisaged in the context of an open society while public scrutiny, criticism and free exchange of information are promoted and ensured. This is a rather political concept because in order to preserve the ability to publicise research and receive criticism, scientists are supposed to both engage and maintain distance from each other and from the non-scientific population. A certain level of integral democracy in the scientific community and the surrounding social and regulatory context is therefore essential.

Publicity through patenting also has a behavioural and cognitive influence on how research is presented. Despite the legal techniques discussed above, the objectives of patent drafting are intended to fit the research outcomes, including preliminary ones, into the established doctrinal framework where both time and space are artificially defined in order to facilitate some degree of certainty in administrative and legal decision making. Peer scientists would need to reverse this process in order to acquire a real time picture of the research after the patent application is published, which is normally 18 months after the date of priority under the PCT system and according to national laws.⁴⁸⁰ The published content in patent documents functions primarily in two ways, namely to prevent other scientists from replicating the experiment and to build on comments and criticisms, unless a robust research exemptions mechanism is in place, and to claim

⁴⁸⁰ The 18-month waiting period for the publication of patent applications is common among member states of the WIPO Patent Cooperation Treaty. Article 21.2(a) of PCT states that ‘Subject to the exceptions provided for in subparagraph (b) and in Article 64(3), the international publication of the international application shall be effected promptly after the expiration of 18 months from the priority date of that application.’ Article 29.3 states that ‘(3) The national law of any designated State may provide that, where the international publication has been effected, on the request of the applicant, before the expiration of 18 months from the priority date, the effects provided for in paragraph (1) shall be applicable only from the expiration of 18 months from the priority date’.

boundary of exclusivity regarding potential proprietary rights. Some jurisdictions also recognise provisional protection on patent-pending applications during the waiting period between the publication of the patent application and the final decision on granting and enabling earlier claims of exclusivity and retrospective claims for damage on infringement.⁴⁸¹

This orientation towards exclusivity and secrecy, despite making the documents available publically, is fundamentally different from the orientation of public debates and replication that are entailed in the conventional norms of science. The pre-determined timeframe and methods of expression also limit its manner and speed while the full and continual picture of a given piece of research could be presented, reviewed, tested, debated and improved. Making patent applications publically available, therefore, is far from ideal in fulfilling the objective of openness that the norms of science intend to follow. In parallel, the constant tension between the material and the social in the process of making, unmaking and enforcing patents on biomedical innovations remains

⁴⁸¹ For instance, the US, Patent and Trademark Law 35 U.S.C Article 154(d) permits the provisional protection of pending patent application. Article 154(d) reads that: ‘a patent shall include the right to obtain a reasonable royalty from any person who, during the period beginning on the date of publication of the application... and ending on the date the patent is issued

(i) makes, uses, offers for sale, or sells in the United States the invention as claimed in the published patent application or imports such an invention into the United States; or

(ii) if the invention as claimed in the published patent application is a process, uses, offers for sale, or sells in the United States or imports into the United States products made by that process as claimed in the published patent application; and

(B) had actual notice of the published patent application and, ...

(2) Right based on substantially identical inventions.

The right under paragraph (1) to obtain a reasonable royalty shall not be available under this subsection unless the invention as claimed in the patent is substantially identical to the invention as claimed in the published patent application.’

In the UK, Section 69.01-08 of the Patent Act 1977 entitles infringement claims to be brought upon the exploitation of a pending patent application, though this provisional right is only enforceable after the patent has been granted eventually. See: UK IPO, The Manual of Patent Practice, on Section 69.01-08 of Patent Act 1977, available at: <<https://www.gov.uk/guidance/manual-of-patent-practice-mopp/section-69-infringement-of-rights-conferred-by-publication-of-application>>, accessed 10 September 2016.

the case, which continues to play a critical role in evaluating and exploring the venue and possibilities of redefining the lost social integrity and norms of openness.

4.3 Ideological Motives, Patent and the Public

The historical literature has provided invaluable insights regarding the transformation of modern patent law and doctrines, while textual presentation has triumphed in shifting the patent system from a pragmatic business privilege-based system into a system secured by the notion of rights and entitlements.⁴⁸² Commentators consider this as demonstrating that the ‘patent system became postmodern, in the sense they are predicated solely upon internal network of text referents’.⁴⁸³ Diminishing attachments to material and physical utility in the patent system opened the door for protection over abstract subjects and ideas, in contrast to traditional understandings of patent law, and intellectual property at large, in which protection is concerned with the embodiment of ideas rather than the ideas themselves. While the law has responded and accommodated this transformation through technical paths, political and ideological orientations have been rather overlooked in most of the patent law literature. Whether the current self-referring and highly specialised system reflects any particular ideological intention, and the extent to which legal techniques in return have become necessary to pursue, are important inquiries to make, and have emerged in the recent literature outside of conventional patent law research.

⁴⁸² For the typical literature in this regard see the works of legal historians such as Mario Biagioli, ‘Patent Specification and Political Representation: How Patent became Rights’ in Peter Jaszi and Martha Woodmansee (eds) *Making and Unmaking Intellectual Property: Creative Production in Legal and Culture Perspective* (University of Chicago Press 2011); Mario Biagioli, ‘Patent Republic: Representing Inventions, Constructing Authors and Rights’ [2006] 73(4) *Social Research* 1129.

⁴⁸³ Philip Mirowski, *Science-Mart: Privatizing American Science* (Harvard University Press 2011) 191.

There are three lines of critique that are most relevant in illuminating different evidence and thought regarding exploring possible conceptual alternatives, especially in light of the discussion in Chapter 3 about the long lost social dimension in patent law practices in relation to biomedical research. Firstly, scholars have pointed out that while critiques concerning this lost social touch are prominent, it is also important to note that the presumed ‘social contract’ between inventors, patent holders and society has never been bargained for or signed.⁴⁸⁴ Furthermore, in contrast to the pre-modern patent law practice which has emphasised tirelessly the consideration of and requirements for technology transfer and local production capacity development as a sort of support for the theory of exchanging technological openness with time-bound legal monopoly, the expansion of the patent regime today is rather a consequence of a politically-driven process realising a global neoliberal agenda that can be seen as reflecting the process of privatizing science and knowledge.⁴⁸⁵

Secondly, the reasoning behind the social, moral and ethical dimensions in patent law have been conducted differently in different jurisdictions.⁴⁸⁶ In examining how the question of public interest is dealt with under the US and European systems, research has observed that underneath the seemingly hegemonic treatment of patent as an important economic driving force, there are very different political traditions in each

⁴⁸⁴ *ibid* 192.

⁴⁸⁵ *ibid*. See also Elizabeth Popp Berman, *Creating the Market University: How Academic Science became an Economic Engine* (Princeton University Press 2011); Rebecca Eisenberg, ‘Public Research and Private Development: Patent and Technology Transfer in Government-sponsored Research’ [1996] 82(8) *Virginia Law Review* 1662; Sheila Jasanoff, ‘Taking Life: Private Rights in Public Nature’ in Kaushik Sunder Rajan (ed) *Living Capital: Biotechnologies, Ethics and Governance in Global Market* (Duke University Press 2012) 155-183; Shobita Parthasarathy, *Patent Politics: Life Forms, Markets, and the Public Interests in the United States and Europe* (University of Chicago Press 2017).

⁴⁸⁶ Shobita Parthasarathy, *Patent Politics: Life Forms, Markets, and the Public Interests in the United States and Europe* (University of Chicago Press 2017). See also: Margo A Bagley, ‘Patent First, Ask Questions Later: Morality and Biotechnology in Patent Law’ [2003] 45(2) *William and Mary Law Review* 469; Margo A Bagley, ‘A Global Controversy: The Role of Morality in Biotechnology Patent Law’ *University of Virginia Law School Public Law and Legal Theory Working Paper Series*, Paper 57 (2007).

respective context that have played longstanding roles in major patent controversies and debates.⁴⁸⁷ At the centre of these differences are different understandings of the role of government towards the market and society. Accordingly and given the US tradition of preferring small government with a market-making function, the rationale of public interest in patent law is manifested and managed through a strong resort to techno-legal expertise and the judiciary's procedural objectivity,⁴⁸⁸ while less concerned with the inherent conflict between patent and social benefits. By contrast, the original privilege system of patent in Europe has nourished a tradition of being alert to the socioeconomic dimensions of patent as an inherent problem, while government plays a strong role in providing and ensuring public services and shaping the market.⁴⁸⁹ This has been projected largely in the arena of pharmaceutical patent controversies while different political framing and legal devices have been used respectively, such that while the European system introduced patent opposition and active compulsory license mechanisms concerning patents related to medical products, the US system adapted a rather reluctant and narrow approach.⁴⁹⁰ Although there has been a real convergence of the two major traditions, especially in the aftermath of the 1990s following substantial international trade integrations, these differences remain impactful in both the US and European jurisdictions, as well as in countries where local patent laws have been influenced by either or both. Legal techniques such as patentability criteria setting, limitation and exemptions of rights, and examination and oppositions procedures – are necessities in both traditions in order to realise particular political orientations while

⁴⁸⁷ Shobita Parthasarathy, *Patent Politics: Life Forms, Markets, and the Public Interests in the United States and Europe* (University of Chicago Press 2017).

⁴⁸⁸ *ibid* 48.

⁴⁸⁹ *ibid*.

⁴⁹⁰ *ibid*.

resisting alternative understandings of the relationship between patent, knowledge, science and society.

Thirdly, while the notion of science as a public good has long been used as one of the major defences to resist the process of commodification in which patent is used as one vital facilitator, it is, however, worth noting that the concept itself has been degraded and twisted not only by neoliberal actors but also in other interested social research.⁴⁹¹ The concept was first conceived in the 1950s led by Paul Samuelsson and has been since used by neoclassic economists as a tool to justify both governmental intervention in the market and the provision of certain commodities or goods that have different characteristics than others, especially knowledge and science that are non-rivalry and non-exhaustive. However, perhaps the attempt to use the concept of commodity to limit commodification was problematic in the first place, while the 1960s witnessed the total rejection of the concept of the public good by neoliberal scholars.⁴⁹² The dismissal of the public good in the context of science policy and regulation has also been observed by some researchers including by Michel Callon and his use of Actor-Network-Theory (ANT) where he argues that infinite interdependences between actors indicated that there is no hindrance for science to be transformed and merchandised while the non-rivalry feature does not exist in practice.⁴⁹³ While the analytical contribution as such had been welcomed as a helpful departure from the typical economics of science

⁴⁹¹ Philip Mirowski, *Science-Mart: Privatizing American Science* (Harvard University Press 2011) 58-66.

⁴⁹² *ibid.*

⁴⁹³ See: Michel Callon, 'Is Science a Public Good?' [1994] 19(4) *Science, Technology and Human Value* 395; Michel Callon, 'Actor-Network-Theory: The Market Test' in J Law and J Hassard (eds), *Actor Network Theory and After* (Blackwell Publishers 1998) 181-195; Michel Callon, 'Techno-Economic Network and Irreversibility' [1990] 38(S1) *The Sociology Review* 132; Michel Callon, 'From Science as an Economic Activity to Socioeconomics of Scientific Research: The Dynamic of Emergent and Consolidated Techno-economic Network' in Philip Mirowski and Esther-Mirjam Sent (eds), *Science Bought and Sold: Essays in the Economics of Science* (University of Chicago Press 2002) 277-317.

scholarship,⁴⁹⁴ it is also a rather disturbing observation to make that instead of liberal economists themselves in dismissing the public good aspect of science, social science researchers from are discussing issues similar to those preoccupying neoliberals,⁴⁹⁵ and may not illustrate the challenges facing the globalised privatization of science.⁴⁹⁶ Callon's account of science and economics recalls some major criticisms of ANT, especially for its lack of a macro-perspective and its overly-materialistic nature.⁴⁹⁷ Other STS approaches such as the co-production idiom have rather maintained the interrogation of power and authority in its analytical inquiries and do not deny the reversible interactions in conceptual and normative arenas.⁴⁹⁸ Nevertheless, the decline of the conceptual debate on the public good in economic studies and the rather voluntary reconciliation of the neoliberal dismissal of science as a public good by some social scientists are important reality checks when attempts need to be made in reconceiving the social and the public in the discourse on biomedical innovation. It is also important to note that despite the decline of consensus between social science researchers as mentioned above, and neoliberalism's dominance, research on the public good in the context of science and knowledge has not stopped, with further conceptual efforts being made to re-examine the public good from global perspectives in relation to health and knowledge.⁴⁹⁹ A later section of this chapter will discuss this further.

⁴⁹⁴ Philip Mirowski and Esther-Mirjam Sent (eds), *Science Bought and Sold: Essays in the Economics of Science* (University of Chicago Press 2002) 54-56.

⁴⁹⁵ Mirowski, *Science-Mart* (n 483)66.

⁴⁹⁶ Philip Mirowski and Esther-Mirjam Sent (eds), *Science Bought and Sold: Essays in the Economics of Science* (University of Chicago Press 2002) 56.

⁴⁹⁷ Sergio Sismondo, *An Introduction to Science and Technology Studies* (Blackwell Publishing 2004) 65-74.

⁴⁹⁸ Sheila Jasanoff, 'Ordering Knowledge, Ordering Society', in Sheila Jasanoff (ed), *States of Knowledge: The Co-Production of Science and Social Order* (Routledge 2004) 30, 38.

⁴⁹⁹ For literature in this vein see: Inge Kaul, Isabella Grunberg and Marc A Stern (eds), *Global Public Good: International Cooperation in the 21st Century* (OUP 1999) available at: <https://www.researchgate.net/profile/Eugenio_Bobenrieth/publication/46440722_The_Political_Economy_of_International_Environmental_Cooperation/links/55ddb07308ae79830bb531ed.pdf#page=488>

Looking at these critiques together, there are key lessons to be drawn for this research. Firstly, the reconstruction of the social could be largely resisted and restricted if it was pursued in terms of the patent law regime alone. The ideological orientation of privatising and commodifying science and knowledge would seek all possible techno-legal revenues to sustain its mission, while patent law is one of the tools that has been used.⁵⁰⁰ Furthermore, moving outside or side-lining patent is desirable in order to recreate the social dimension. Secondly, the reconstruction of the concept of public would require work between marginalised communities in the face of patent proliferation.

4.4 Making New, Making Conflict: Textual Constructions and the Social Intersection with Patent Claims on Biomedical Innovation

4.4.1 New Indications of an Old Medicine: Journeys to Sites of Conflict and Legal Responses

In the biomedical research and development context, chemical compounds can have been known for a long time before they are tested and found to have therapeutic properties that can be used as medicines. In other circumstances, the subsequent testing and use of a known compound previously developed for a different disease may also lead to the realisation of another medical need it could address. These two situations correspond to discussions related to so-called first medical use and second medical use

accessed 29 November 2017. In this collection of essays, specific discussions on health and knowledge could be found in Lincoln C Chen, Tim G Evans and Richard A Cash, 'Health as a Global Public Good', 284-306, and Joseph E Stiglitz, 'Knowledge as a Global Public Good', 308-326.

⁵⁰⁰ There is a rich literature on this issue from a commercially-oriented patent law perspective while critical appraisals have discussed the use of combined legal techniques and strategies to retain commercial objectives. In the context of privatising scientific research, especially in academic settings, patent is one of the legal tools used alongside others, typically including technology transfer agreements, material transfer agreements, trademarks, know-how and trade secrets.

patents. The extent to which the medical use (first and second) of a known substance can be subject to patent protection has long been a controversial issue in both legislative and judicial practices in different jurisdictions. Common arguments made by the supporters of medical use patents include that offering patentability to the use patent can encourage more research and testing on existing medicines to find new therapeutic properties so that the overall time spent on R&D for new treatments for diseases will reduce.⁵⁰¹ In addition, legally speaking, the medical use of a known substance should be patentable because the ‘use’ itself is novel compared to the state of art.⁵⁰² On the contrary, dissenting opinions regarding granting use patents on known substance often argue that it involves a discovery process⁵⁰³ rather than invention, which is by nature excluded from patent protection, and that the ‘use’ of a known substance contradicts the novelty requirement.⁵⁰⁴

Meanwhile, second medical use patent controversies can be approached by looking at the nature of ‘medical use’ which has traditionally been considered as equivalent to the ‘method of treatment’ and not eligible for patent protection. Article 27.3(a) of the TRIPS agreement allows WTO members to exclude ‘diagnostic, therapeutic and surgical methods for the treatment of humans or animals’⁵⁰⁵ from eligibility for patent protections.

⁵⁰¹ The literature used to support medical-use patents often deploys an argument based on ‘incentive for innovation’ to justify the expansion of patentability to medical use patent, including both first and second medical use. See, for example: Jean M Miller, ‘Patentability of a Second Indication of a Pharmaceutical in Europe’ [1985-86] 26 IDEA 15; Ralf Perrey and Konstanze Lenhard, ‘The Patentability of Inventions Relating to Medicine, Pharmaceuticals, and Biotechnology According to European Patent Practice’ [2007] 89(6) Journal of the Patent and Trademark Office Society 479.

⁵⁰² *ibid.*

⁵⁰³ Carlos Correa, *Integrating Public Health Concerns into Patent Legislation in Developing Countries* (South Centre 2000) 23.

⁵⁰⁴ Philip Grubb, *Patents for Chemicals, Pharmaceuticals and Biotechnology: Fundamentals of Global Law, Practice and Strategy* (Clarendon Press 1999).

⁵⁰⁵ Article 27.3 (a) of TRIPS Agreement.

Nonetheless, patent laws in practice have managed different ways of circumventing this exclusion through textual constructions of second medical use patent.

In the European context, debates around the patentability of the second medical use indication of a known substance emerged during the initial drafting process of the European Patent Convention (EPC).⁵⁰⁶ While the draft Convention excluded the patentability of ‘method of treatment’ in general, discussions became heated regarding whether an exception should be made to allow the medical use of a known substance to be made patentable.^{507 508 509} As a result, the EPC 1973 contained two important clauses relating to the issue of second medical use patents, recognised an exception for the ‘use’ a known substance or composition ‘comprised in the state of the art’ from the general exclusion of patentability on methods of surgical, therapeutic and diagnostic treatment.⁵¹⁰

⁵⁰⁶ Eddy D Ventose, ‘Patent Protection for Second and Further Medical Uses Under the European Patent Convention’ [2009] 6(1) Scripted 57.

⁵⁰⁷ *ibid.*

⁵⁰⁸ It was observed that there was a clear division of views between the industrial lobby groups and state delegates, as well as between different states’ delegations during the negotiation, with the majority of countries such as the UK, Netherlands and Denmark resisting the insertion of the use patent in its entirety in the first place, subsequently accepting the compromise in favour of a distinction between the first and second medical use of a known substance and a restrictive interpretation of second medical use patent to be granted under the European patent system. Other countries, especially Germany, supported the inclusion of a second medical use patent and much more relaxed interpretations.

⁵⁰⁹ See: Minutes of the 9h meeting of Working Party I held from 12 to 22 October, 1971, in Luxembourg, at para 92; Minutes of the 11h Meeting of the Working Party I held in Luxembourg from 28 February to 3 March, 1972, at para 9(a); Minutes of a 3rd Meeting of the Co-coordinating Committee, Luxembourg, 17, 23 and 24 June 1972, at para 5; System for the Grant of Patents, Parts I and III, Luxembourg, 24-25 January and 2-4 February 1972, at para 33; Minutes of a 6h Meeting of the Inter-Governmental Conference for the setting up of a European System for the Grant of Patents, Luxembourg, 19-30 June 1972, at para 31; Comments by the Netherlands Government on the proposed amendments concerning the draft convention and the draft implementing regulations, in particular, Article 52(5), Munich, 1 June 1973 at para 9; Minutes of the Munich Diplomatic for the Setting up of a European System for the Grant of Patents, Munich 10 September to 6 October 1973, at para 54.

⁵¹⁰ Article 52 (4) states that ‘[M]ethods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body *shall not be regarded as inventions* [emphasis added by the author] which are susceptible of industrial application within the meaning of paragraph 1. *This provision shall not apply to products, in particular substances or compositions, for*

Reviewing the drafting history, it is clear that the legal fixation of the debates around the scope and interpretation of the exclusions of patentability on methods of treatment were based largely on ‘social, ethical and political grounds’.^{511 512}

Early jurisprudence on the EPO case law also reinforced the restrictive interpretation of Article 54(5) in light of the general exclusion of Article 52(4). For instance, in *HOFFMAN-LA ROCHE/Pyrrolidine derivatives*,⁵¹³ the Technical Board of Appeal (TBA) of the European Patent Office (EPO) ruled that Article 54(5) established a new rule of novelty in that the discovery of a new therapeutic use of a known compound ‘should be rewarded with a purpose-limited substance claim under Article 54(5) EPC to cover the whole field of therapy’,⁵¹⁴ however, the novelty would be destroyed if the therapeutic use of a compound was already known, rendering the interpretation of Article 54(5) to be applicable only for first medical use claims.⁵¹⁵

It did not take long until the EPO’s change to second medical use arose in *EISAI/Second Medical Indication*⁵¹⁶ when the Enlarged Board of Appeal (EBA) answered the TBA’s question concerning if a patent ‘with claims directed to the use [can] be granted for the use of a substance or composition for the treatment of the human or animal body by

use in any of these methods.’ Article 54 (5) on ‘novelty’ reads that the provisions ‘shall not exclude the patentability of any substance or composition, comprised in the state of the art, for use in a method referred to in Article 52, paragraph 4, provided that its use for any method referred to in that paragraph is not comprised in the state of the art’, available at: <<https://www.epo.org/law-practice/legal-texts/html/epc/1973/e/ar54.html>>.

⁵¹¹ Sigrid Sterckx and Julian Cockbain, *Exclusions from Patentability: How Far Has the European Patent Office Eroded Boundaries?* (CUP 2012) 136.

⁵¹² Ventose (n 506).

⁵¹³ [1979-85] EPOR B591.

⁵¹⁴ *ibid.*

⁵¹⁵ T 43/82 *ROUSSEL-UCLAF/Tetrahydropyridinyl-Indole Derivatives* [1979-85] EPOR B448. In *BAYER/Nimodipin (I)* T 17/81 [1979-85] EPOR B320, the TBA retained the view that the general claims for the use of known substances are not permissible given the general exclusion of Article 52 (4).

⁵¹⁶ G 05/83, [1979-85] EPOR B241.

therapy?’⁵¹⁷ The EBA held that a purpose-limited claim of use was allowable when the claim covered a specific therapeutic purpose,⁵¹⁸ contrary to the earlier view of the TBA that the purpose-limited claim covered the entire range of therapeutic possibilities.⁵¹⁹ By eliminating the differences between a ‘use’ and a ‘method’ claim respectively, the EBA was considered as trying to balance the attempt to expand the ‘use’ claim under Article 54(5) and extend this to second medical use, thereby maintaining the general exclusion of the ‘method’ claim on medical treatment under Article 52(4).⁵²⁰ The dilemma also led the EBA to recognize a legal fiction of claim construction, the Swiss-type claim, named after the claim formulation sanctioned by the Swiss Federal Office for Intellectual Property at the time, thus bypassing the contradictions under the EPC on second medical use patent.

A typical Swiss-type claim has to be made by resorting to the structure of ‘*Use of substance X in the manufacture/preparation of a medicament for the treatment of condition Y*’. By introducing the language of ‘manufacture/preparation’, this type of claim can be considered as a ‘method’ claim of manufacture/preparation, but not method of treatment, and therefore does not fall within the scope of Article 52(4) exclusions.⁵²¹ On the other hand, the language of ‘use... for the treatment of condition Y’ matches the novelty exception under Article 54(5) about claims for the use of a known substance, which requires the claim to be directed to a new therapy.⁵²² The recognition of the Swiss-

⁵¹⁷ G 05/83, *EISAI/Second medical indication*, at para. 1

⁵¹⁸ G 05/83, *EISAI/Second medical indication*, at para 15; [1979-85] EPOR B241.

⁵¹⁹ *Ventose* (n 506).

⁵²⁰ Qadir Qeidary, ‘Emerging Issues: New Uses, Whether Threat or Chance, What is the Current And Appropriate Legal Treatment?’ [2015] 1 Okla JL & Tech 78.

⁵²¹ Ralf Perrey, Konstanze Lenhard, ‘The Patentability of Inventions Relating to Medicine, Pharmaceuticals, and Biotechnology According to European Patent Practice’ [2007] 89(6) *Journal of the Patent and Trademark Office Society* 57.

⁵²² *ibid.* See: G 05/83, *EISAI/Second medical indication*; [1979-85] EPOR B241.

type claim as an acceptable form of claim was a pragmatic compromise regarding incorporating second medical use patent without having to confront the question of whether or not such a patent is in conflict with the exclusion of method of treatment from being patentable. After the revision of EPC in 2000, new clauses such as Article 53(c) were introduced replacing Article 54(5) of EPO 1973 that provided further confirmation of the possibility of claim for second medical use patent protection.⁵²³ It is also worth noting that Article 53(c) of EPC 2000 replaced Article 52(4) of EPC 1973 on the general exclusion of patentability of method of treatment.⁵²⁴

The evolution of the rules reveals a process of bargaining between intertwined social, economic, political and legal interests. The construction and style of the text in the making of the claims are of ultimate significance in determining the fate of the patent application. Claim construction matters, not only in terms of securing a better chance of receiving affirmative results through patent examination, but also in procedural aspects in the context of infringement or invalidation suits. A right or wrong style of claim construction may literally relate to the same material fact, but would be treated differently because only the correct type of language can be used as the code to open the legal door to second medical use patenting.

⁵²³ EPO Guideline for Examination, 7.1 Second or Further Medical Use of a Known Pharmaceutical Products, available at: <https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_vi_7_1.htm> accessed 09 July 2017.

⁵²⁴ Article 52(4) EPC 1973 reads ‘Methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body shall not be regarded as inventions which are susceptible of industrial application within the meaning of paragraph 1. This provision shall not apply to products, in particular substances or compositions, for use in any of these methods.’ Article 53(c) EPC 2000 reads ‘methods for treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body; this provision shall not apply to products, in particular substances or compositions, for use in any of these methods’.

For example, under the EPO examination guideline, examples of claim language styles are cited (see below Table 1). Each example can lead to a particular patent examination result, potentially obtaining an independent patent, though all could relate to the same medicine, i.e. while Product X is useful for asthma, cancer and leukaemia at the same time, each disease indication could receive an independent patent.. Table 1 is derived from the EPO Guideline for Examination, which provides examples of the different types of structure of the claim and their effect on patentability assessment.⁵²⁵

Table 1: The Effect of the Different Claim Structure on Patentability
(Source: EPO Guidelines for Examination)⁵²⁶

#	Claim	Patentable?	Article
A	Use of product X for the treatment of asthma	No	53(c)
B	1. Product X for use as a medicament [X known as e.g. herbicide 2. Product according to claim 1 for use in the treatment of asthma	Yes (even if X is a known product, but its use in medicine is not known)	54(4)
C	Product X for use in the treatment of cancer*	Yes (even if case B is prior art, provided that such a claim is inventive over B and any other prior art)	54(5)
D	Product X for use in the treatment of leukaemia*	Yes (even if cases B and C are prior art, provided that D is inventive over B and C and any other prior art because leukaemia is a specific type of cancer)	54(5)

⁵²⁵ G-VI 7.1 Second or further medical use of known pharmaceutical products, EPO Guideline for Examination, <https://www.epo.org/law-practice/legal-texts/html/guidelines/e_g_vi_7_1.htm> accessed 09 May 2017.

⁵²⁶ *ibid.*

From a plain English point of view, examples B, C and D are redundant in referring to the fact that one medicine can be used to treat multiple diseases, which is common knowledge among medical practitioners. Non-patent specialist readers may not appreciate the subtle differences between the different types as they all look the same, but it is a legal fixation and expert-driven imaginary that give each of them exclusive meanings in form of new lives. The pre-defined language is authoritative in its fixed formation. When new language is developed and recognized authoritatively, the pattern of community recognition evident in patent practitioners and examiners also shifts and evolves. This type of claim may also determine the type of evidence and data needed in making the claim material rather than assumptive. The art of using expert language in underwriting new rules without needing to change the law immediately has frequently manifested itself in the co-production process undertaken by the patent professions in defining the boundary of newness. In the end, it is about how you write, more than what you write.

4.4.2 Prospect Innovation and Present Law: Time-Lapse and the Markush Claim Problem

Making a text highly technical and legally viable is at the centre of the making of a community with a consensual understanding of the technical side of patenting, which is deliberately distant from the meaning of ‘new’ and its real-life implications and social relevance. The technique as such also often bears a temporal element while law is introduced to recognize the properties’ future probability rather than their present status or use. In the context of chemical pharmaceutical inventions, one of the most extreme forms is the Markush claim, a type of claim constructed based on a general chemical structure that can include possibly millions of future chemical compounds, without

naming a specific compound with an actual therapeutic property at the time when the patent was filed.⁵²⁷ Recognizing the future possibility of the therapeutic function of a group of unstable experimental chemical entities has presented another technological and legal imaginary whose political settlement has been attempted through legal recognition.

Scholars have generally viewed the Markush claim as a result of legal compromise.⁵²⁸ Its early literature has also discussed the tension between forms and substances which the controversy's high stakes.⁵²⁹ While the Markush claim was seen as more of a procedural arrangement,⁵³⁰ its intersection and possible conflict with substantive legal doctrines, principles and patentability requirements becomes somewhat unavoidable.⁵³¹ Two main discussion threads are evident, including those engaging with the relationship between the Markush claim and the doctrine of equivalents,⁵³² and those discussing its intersection with the sufficient disclosure requirement in patentability.⁵³³ Research on the Markush claim patent and its relationship with the doctrine of equivalence has reviewed the statutory objectives of the doctrine while underlining that functional and substantive technological equivalents are required to satisfy the test in upholding any

⁵²⁷ R Austin, 'The Complete Markush Structure Search: Mission Impossible? (Paper at PIUG North East Workshop, 16 October 2001). In: <http://www.stninternational.de/training_center/chemistry/piug1.pdf>. See also: Andrew H Berks, 'Current State of the Art of Markush topological searching systems' [2001] 13 World Patent Information 5.

⁵²⁸ *Ex parte* Markush, 1925 Dec. Comm'r Pat. 126 (1924). See: Adam Sussman, 'Million-Card Monte: Reforming the Markush Claim Post-AIA to Save Synthetic Chemical Innovation' [2013] 12 J Marshall Rev Intell Prop L 720.

⁵²⁹ Mary Helen Sears, 'The Markush Patent Claim and Its Relationship with the Doctrine of Equivalence' [1959] 27 Geo Wash L Rev 327, 352.

⁵³⁰ *ibid.*

⁵³¹ *ibid.*

⁵³² *ibid.* See also: Martha G Pugh, 'The Doctrine of Equivalents: Asset of Liability to the Drafters of Claims' [1961] 43 J Pat Off Soc'y 614; EA Ustinova and OV Chelisheva, 'Are Markush Structures Matters of Chemistry and Law or Just Figments of Imagination?' [1996] 18(1) World Patent Information 23.

⁵³³ See Sneha Sharma and Manchikanti Padmavati, 'Duty of Disclosure During Patent Prosecution in India' [2015] 41 World Patent Information 31.

patent application concerned.⁵³⁴ Meanwhile, a Markush claim focuses instead on structural equivalents that do not represent substantive contributions or functions.⁵³⁵ Sufficient disclosure requirements, on the other hand, ask that the disclosure of technological information in a patent application should be detailed enough so that a person skilled in the art could reverse engineer the technologies described. This requirement does not diminish even after the patent examination practice had shifted from asking for concrete demonstrations of the mode to assessing the patent specifications on paper forms. The emergence of the Markush claim patent introduced a challengeable exception to the sufficient disclosure principle, while researchers have also pointed out that Markush does not satisfy the prior art teaching to a person skilled in the art and that it fails to provide sufficient disclosure that could satisfy the utility criteria of the invention concerned.⁵³⁶ It goes at odds also with one of the major justifications of the patent system, namely to have disclosure of inventions for the purpose of the wider social welfare in exchange for time-bound monopolies while going against the principle that one patent application should cover only one invention.

The making of the Markush claim could be traced back to the practice of the US Patent and Trademark Office (USPTO) in its 1924 leading decision concerning chemical compounds patent applications filed by Eugene Markush.⁵³⁷ While claiming alternative compounds in one single application was originally rejected by USPTO, Markush re-wrote the claim with one generic term supported by a particular format of text structured

⁵³⁴ Martha G Pugh, 'The Doctrine of Equivalents: Asset of Liability to the Drafters of Claims' [1961] 43 J Pat Off Soc'y 614; Mary Helen Sears, 'The Markush Patent Claim and Its Relationship with the Doctrine of Equivalence' [1959] 27 Geo Wash L Rev 327, 352.

⁵³⁵ *ibid.*

⁵³⁶ Sneha Sharma and Manchikanti Padmavati, 'Duty of Disclosure During Patent Prosecution in India' [2015] 41 World Patent Information 31.

⁵³⁷ *Ex parte* Markush, 1925 Dec. Comm'r Pat. 126 (1924).

as ‘*materials selected from the group consist of...*’⁵³⁸ This format was supported by USPTO and later became the standard text to be qualified as a Markush claim in both the US and other jurisdictions. A fully-fledged patent document written with Markush-type claims can be far more complex than this simple formulation.⁵³⁹

It has been observed that the original compromise or legal fiction of a Markush structure of claim drafting was limited to chemical applications only and also further limited by other patentability criteria including sufficient disclosure supported by the best mode demonstration written in patent specifications.⁵⁴⁰ Nonetheless, it has been seen as a hugely preferred claim construction in a commercial context, because by including vastly open future possibilities of specific chemical entities with a similar structure, the patent applicant could conveniently block multiple future competitors from develop any of the possible chemical entities derived from the generic structure.⁵⁴¹ In addition, a

⁵³⁸ *ibid.*

⁵³⁹ More examples of how the Markush claim’s language works together with drawings of general chemical structures can be found from examination guidelines of different countries where this type of claim is recognized.] For instance, examples of language construction can be found in the *PCT International Searching and Examination Guidelines* (2017), available at: <<http://www.wipo.int/export/sites/www/pct/en/texts/pdf/ispe.pdf>>. One of the examples in the PCT guidelines reads as below:

Claim 1: A pharmaceutical compound of the formula: A – B – C – D – E
wherein:

A is selected from C1-C10 alkyl or alkenyl or cycloalkyl, substituted or unsubstituted aryl or C5-C7 heterocycle having 1-3 heteroatoms selected from O and N;

B is selected from C1-C6 alkyl or alkenyl or alkynyl, amino, sulfoxy, C3-C8 ether or thioether;

C is selected from C5-C8 saturated or unsaturated heterocycle having 1-4 heteroatoms selected from O, S or N or is a substituted or unsubstituted phenyl;

D is selected from B or a C4-C8 carboxylic acid ester or amide;

and E is selected from substituted or unsubstituted phenyl, naphthyl, indolyl, pyridyl, or oxazolyl

This example has been commented on as being seemingly straightforward in language but actually very difficult to search and examine by patent offices. See: USPTO, ‘OG Notice Examination of Patent Application Include Claims containing Alternative Language’, 04 September 2007, available at: <<https://www.uspto.gov/web/offices/com/sol/og/2007/week36/patapps.htm>>.

⁵⁴⁰ For example, as required under the USPTO Supplementary Examination Guidelines for Determining Compliance with 35 U.S.C. 112 and for Treatment of Related Issues in Patent Applications, 76 Fed. Reg. 7162, 7166 (09 February 2011); *In re Gardner*, 427 F.2d 786, 788 (CCPA 1970).

⁵⁴¹ Lucille J Brown, ‘The Markush challenge’ [1991] 31 J Chem Info Comput Sci 2.

Markush-type textual formulation has also been widely applied to other technological fields and recognized over time by patent offices, despite its original relevance to chemical inventions only.⁵⁴² An early year review report from USPTO itself offers a vivid account of the extent to which Markush claims were embraced enthusiastically in patent practice:

The extent to which the patent professional...made use of the Markush formula indicated that *its application had gone far afield of the original intent. It was like a fire which had spread beyond control. It became the medium through which totally unrelated substances could be assembled under the guise of a genus.* If one member were found to be old or inoperative, that one was stricken from the group, and the diminished group reasserted with renewed vigor. In such a case the search required was for as many individual species as there were members recited in the group.⁵⁴³

Other commentaries in the early years after the Markush claim was first introduced in the US can also be found in patent offices' decisions. For instance, in a commentary released by the Commission of Patent, it was stated that

This [Markush] formula has been taken advantage of by many applicants to multiply their claims far beyond reasonable bounds. *The abuse of the Markush*

⁵⁴² *ibid.* See also, Kimberley J Prior, 'The USPTO's Historical Struggle with Markush Claim: Will the 2011 Guideline Provide Relief?' [2012] Law School Student Scholarship, Paper 114. <http://scholarship.shu.edu/student_scholarship/114> accessed 30 July 2017; Steve Gardner and Andy Vintner, 'Stronger Protection for New Drugs' [2010] May-June PHARMA 46. In the latter article by Gardner and Vintner, it is pointed out that the 'Markush patterns in some Composition of Matter filings have exploded to the point where it is effectively impossible to verify the millions of structures presented.'

⁵⁴³ VI Richard, 'Claims Under the Markush Formula' (1935) 17 J Pat Off Soc'y 179, 190. See also: USPTO, 'OG Notice Examination of Patent Application Include Claims Containing Alternative Language', 04 September 2007, <<https://www.uspto.gov/web/offices/com/sol/og/2007/week36/patapps.htm>> accessed 30 July 2017.

formula has, in many instances, been carried to such excess as to defeat the very purpose for which a set of claims is intended. In the mass of verbiage presented by the claims, the invention is effectively concealed rather than clearly pointed out. It is quite apparent that proper and sensible restrictions must be imposed on the use of this unusual form of claim, which is distinctly a child of emergency, and intended for special relief only.⁵⁴⁴

The ongoing controversy did not trigger a transformative change in the USPTO's treatment of Markush claims. One effort was made when the patent office reviewed the state of the art of the application of Markush claims in a 2007 official notice which, however, was not enacted afterward.⁵⁴⁵ In 2011, a Supplementary Examination Guideline was published by USPTO which was intended to solve some of the historical tensions between the statutory requirement of sufficient disclosure under US Patent Law, and related patent claim issues including those concerning Markush claims.⁵⁴⁶ Although the new guideline intended to address the practical difficulties and patent examiners' backlog in examining the ever-increasing complexity in Markush claims drafting on pharmaceutical and other technological fields by adapting rules of restriction and rejections, it has however been observed that this has not substantively changed the situation in terms of the prevalent use of Markush claims in itself.⁵⁴⁷

⁵⁴⁴ Ex parte Dahlen, 1934 Dec. Comm'r Pat 9, 10.

⁵⁴⁵ USPTO, 'OG Notice Examination of Patent Application Include Claims Containing Alternative Language', 04 September 2007, available at:

<<https://www.uspto.gov/web/offices/com/sol/og/2007/week36/patapps.htm>> accessed 09 June 2016.

⁵⁴⁶ USPTO Supplementary Examination Guidelines for Determining Compliance with 35 USC 112 and for Treatment of Related Issues in Patent Applications, 76 Fed Reg 7162, 7166 (09 February 2011).

⁵⁴⁷ Kimberley J Prior, 'The USPTO's Historical Struggle with the Markush Claim: Will the 2011 Guideline Provide Relief?' (2012) Law School Student Scholarship Paper 114. Available at: <http://scholarship.shu.edu/student_scholarship/114> accessed 09 July 2017.

While self-correcting and self-adjusting the unintended consequences of Markush claim patents in the US has not shown success, the construction technique and legal recognition have been carried on alongside the expansion of patent law in other countries.⁵⁴⁸ The pertinent tension concerning the practice of Markush claims has also been seen as negatively affecting future research and innovation,⁵⁴⁹ as the futuristic outlook of the claims indicate indefinite possibilities regarding infringement of an undefined group of imagined chemical entities.

4.5 Enclosing Research Tools in Biomedical Research and Its Discontents: A Brief Revisit

4.5.1 Legal Framework to Preserve Biomedical Research Tools from Patenting

The main legal framework enshrined in international laws on patent contains three groups of standard provisions that are relevant to preserving biomedical research tools and activities from being disrupted by patenting. The first group concerns the exceptions from patent eligibility, typically stated under Article 27.3 of the TRIPS agreement. Accordingly, WTO members can choose to exclude diagnostic, therapeutic and surgical methods for the treatment of human and animals, with plants and animals at large being excluded from patent eligibility. Methods of concern as such can be essential in preserving spaces for innovation and effective functioning in clinical practices. However, this is an optional, not mandatory, obligation. The construction of new types of patent

⁵⁴⁸ Carlos Correa, 'A Guide to Pharmaceutical Patent' (South Centre 2008), available at: <<http://www20.iadb.org/intal/catalogo/PE/2008/01916.pdf>> accessed 09 July 2017.

⁵⁴⁹ Harold C Wegner, *Patent Law in Biotechnology Chemicals and Pharmaceuticals* (Stockton Press New York 1992) 951.

claims have also successfully narrowed or nullified the intended preservation under this group of provisions at national levels.

The second group relates to provisions on research and experimental use exceptions aiming to enable research activities to be free from infringement risks when using possibly-patented subject matter. This intends to ‘allow third parties to carry out scientific experiments with the protected patents, without prior permission of the patent owner’,⁵⁵⁰ so in certain context this is also referred to as ‘experimental use exceptions’. Though this group of provisions have been incorporated into national laws to a considerable extent, research has observed rather indeterminate jurisprudences around its application and sometime restrictive scope for its implementation.⁵⁵¹

The third group of provisions concern the mechanisms required to solve conflicts arising from essential patents needed by inventors or manufacturers other than the patent holder. One mechanism is the use of compulsory license if the use of the patented subject matter is essential for subsequent inventions. A typical example of this can be found in Chinese patent law where compulsory license can be applied for if the patent concerned is essential for later inventors to use.⁵⁵² However, the clause in China has not yet been used to date. Another approach in line with this scenario relates to those mechanisms intending to solve the possible blockage caused by patented technologies when those technologies are essential for all developers of a given technological field in order to fulfil regulatory standards. Instead of invoking compulsory license, the approach to standard-essential patents focus on norms to be followed in voluntary licensing practices,

⁵⁵⁰ Edson Beas Rodrigues Jr., *The General Exception Clauses of the TRIPS Agreements: Promoting Sustainable Development* (CUP 2012) 180.

⁵⁵¹ *ibid.*

⁵⁵² Article 51 of the Law on Patent of People’s Republic of China. However, the provision has not been tested.

especially the so-called FRAND – fair, reasonable, and non-discriminatory – principles-based license negotiation and agreement. FRAND has been advocated prominently and has also been used in judicial decisions.⁵⁵³ However, as it is a voluntary mechanism by nature and concerns primarily the interests of the downstream developer in a commercial context, it has had very limited impact on upstream patenting on basic R&D.

Given the respective shortcomings of each of the main legal approaches to limit the scope of patent rights and to preserve spaces for research and follow-up development, internal correction and adjustment at the micro level may not be sufficient to transform overall proliferation at the macro level. In parallel to the use and development of the above mechanisms, the attempt and progress in terms of enclosing research tools in the biomedical field have continued, especially in light of the rapid development of biotechnology and genomic technologies used in contemporary biomedical research. The next section will recap briefly the major controversies around some breakthrough technologies that are essential in order to advance biomedical research while reviewing the role of major expert communities in the process.

4.5.2 From Chakrabarty to Oncomouse: Legal Devices and the Scientific Community's Reactions

Treating patent as a techno-legal construct has been reflected in a number of landmark legal changes in the US system, which consequentially have been referred, introduced,

⁵⁵³ For instance, the UK High Court of Justice made the first judgment on FRAND license in 2017 in *Unwired Planet International v Huawei Technologies Co* [2017] EWHC 711 (Pat) <<https://www.judiciary.gov.uk/wp-content/uploads/2017/04/unwired-planet-v-huawei-20170405.pdf>> accessed 20 July 2017. The Court reasoned the public interest scenario in a FRAND-based licensing arrangement, stating that, ‘While the inventor must be entitled to a fair return for the use of their invention, in order for the standard to permit interoperability the inventor must not be able to prevent others from using the patented invention incorporated in the standard as long as implementers take an appropriate licence and pay a fair royalty.’

and imposed in other jurisdictions where US influences are prominent. In relation to the context of biomedical innovation, it is the expansion of patentable subject matter and the legal devices used in commodifying research tools that have had profound implications. Two important changes took place in the 1980 and 1990s, namely the decision made on *Diamond v Chakrabarty*⁵⁵⁴ and the enactment of the Bayh-Dole Act,⁵⁵⁵ which have paved the way for the systematic transformation of the landscape of science regulation and governance US academics have to negotiate. In addition to the famous citation from the Chakrabarty decision that ‘anything under the sun that is made by man’⁵⁵⁶ should be patentable, the process of the case has presented a debate on the function of patent law in relation to society, one which has been dominated by the view that patent is an indisputable vehicle for economic growth and innovation. Research has observed that among the total fifteen amicus briefs submitted to the court in relation to the patentability of Chakrabarty’s bacterium, only one held a dissident opinion against the grant of patent.⁵⁵⁷ The majority of the amici are from the patent-law associations, the US biotechnology company Genentech, universities, scientific associations, the US Pharmaceutical Manufacturers Association, and a molecular biologist.⁵⁵⁸

⁵⁵⁴ *Diamond v Chakrabarty* 447 US 303 (1980).

⁵⁵⁵ Patent and Trademark Law Amendments Act (Pub L 96-517, 12 December 1980), changed the provisions on ownership of patents arising from inventions that are financially supported by the federal budget. Accordingly, universities, small businesses and non-profit organisations have the right to apply for patents on inventions developed with public funding. In exchange, they need to disclose patents filed under such a scheme while the public funding agencies reserve to exercise March-in rights to use the patent without the permission of the patent holder. This Act profoundly changed the relationship between the research institutions and government research funding agencies, who had previously had more authority to determine the manner of protection and dissemination of inventions derived from its grantees. Janet Hope, ‘Open Source Genetics: Conceptual Framework’ in Geertrui van Overwalle (ed), *Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open Source Models and Liability Regimes* (CUP 2009)

⁵⁵⁶ *Diamond v Chakrabarty* 447 US 303 (1980).

⁵⁵⁷ Shobita Parthasarathy, *Patent Politics: Life Forms, Markets, and the Public Interests in the United States and Europe* (University of Chicago Press 2017) 54.

⁵⁵⁸ *ibid.* *Diamond v Chakrabarty* 447 US 303 (1980) (No 79-136). Shobita Parthasarathy, *Patent Politics: Life Forms, Markets, and the Public Interests in the United States and Europe* (University of Chicago

The only amicus brief against the patentability of Chakrabarty's organism was submitted by the People's Business Commission (PBC), arguing that patent has long lasting moral and ecological implications and that patenting life should be a matter that the Congress, instead of the court, should consider.⁵⁵⁹ This minority view was not taken, while the court, based on dominant support for patentability from other amici, decided in favour of patenting Chakrabarty's bacterium, and considered that the question of patent's influence on society only exists in terms of driving innovation and introducing more products to the market.⁵⁶⁰

Of the participants and interest groups who joined this debate, it is interesting to bear in mind that academic scientists held views similar to the patent law community concerning the philosophical question of what patent does for society, and the consideration of innovation triumphed over the social and moral implications that might not be unfamiliar to patent law technicians. The proposal to reframe the patent system by recourse to moral integrity was disregarded as this was believed to fall outside the scope of the patent system's consideration.⁵⁶¹ The process of constituting the Chakrabarty decision is therefore not the result of a single cause, but rather reflects a collective consciousness promoting a specific understanding of the patent system, while expert legal, scientific and business groups have come up with a similar justification. However, it is also worth noting that while legal and business groups retail a

Press 2017) 54.

⁵⁵⁹ *ibid.*

⁵⁶⁰ *ibid.*

⁵⁶¹ For instance, Chief Justice Warren Burger rejected the view that patent would have other implications for society than those related to innovation and markets. He held to the argument that 'the grant or denial of patents on micro-organisms is not likely to put an end to genetic research or to its attendant risks. The large amount of research that has already occurred when no researcher had sure knowledge that patent protection would be available suggests that legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tide.' *Diamond v Chakrabarty* 447 US 303 (1980) 12.

homogeneous line across the later debates, the scientific community's reaction and participation have varied. Other interest groups such as public research institutions and government agencies were not visible in the Chakrabarty judicial discourse, but have played a role in other disputes concerning the patenting of research tools.

The Chakrabarty decision fundamentally changed the prospect of patenting in the biotechnology field at the time, while the technologies required to modify the genetic structure of life emerged in the context of biomedical research and it has since become more promising to receive a patent on genetically-modified subjects, including life forms.

As such one landmark event relates to the controversies around patenting a genetically-modified mouse breed, the Oncomouse.⁵⁶² Mouse breeds had been an essential part of biomedical research activities and, before Oncomouse came into play, attempts had been made among the mouse research community in the US to develop a standard breed that could be supplied to the scientific community.⁵⁶³ The main producer of mice bred for research use was Jackson Laboratories of Bar Harbor (JAX), who supplied low-cost mice for cancer research to universities and research laboratories, mostly under a non-profit operational model until the 1980s.⁵⁶⁴ The ecosystem between JAX and scientific community broke down when patent was granted to Harvard University's new

⁵⁶² A rich literature has emerged on the Oncomouse patent case. For instance, a close review of the debates can be found in Fiona Murray, 'Patenting Life: How the Oncomouse Patent Changed the Lives of Mice and Men' in Mario Biagioli, Peter Jaszi and Martha Woodmansee (eds), *Making and Unmaking Intellectual Property: Creative Production in Legal and Culture Perspective* (University of Chicago Press 2011); Sasha Blaug, and others, 'Managing Innovation: University-industry Partnership and the Licensing of the Harvard Oncomouse (2004) 22(6) *Nature Biotechnology* 761.

⁵⁶³ Fiona Murray, 'Patenting Life: How the Oncomouse Patent Changed the Lives of Mice and Men' in Peter Jaszi and Martha Woodmansee (eds), *Making and Unmaking Intellectual Property: Creative Production in Legal and Culture Perspective* (University of Chicago Press 2011).

⁵⁶⁴ Mirowski, *Science-Mart* (n 483) 161-162.

genetically-modified breed under a partially-funded DuPont research programme, also trademark protected as the Oncomouse.⁵⁶⁵ While the emergence of Oncomouse brought about the promise of a standardised breed for cancer research, especially breast cancer research, the patent tag resulted in very high access costs for research communities.⁵⁶⁶ As part of its business strategy, DuPont introduced systematic Material Transfer Agreements (MTAs) together with patent licensing, gradually crowding out the JAX model, and eventually forcing JAX to accommodate the new model of supply and abandoning its previous non-profit approach.⁵⁶⁷ The proactive enforcement actions taken by Harvard University have also been observed, especially when other countries patent offices, such as Canada, rejected the primary patent on Oncomouse.⁵⁶⁸

What is especially relevant to this research in the Oncomouse controversies are the roles and strategies adopted by major influence communities. Legal expertise had played a vital role in combining the use of patent and other legal instruments such as MTAs to redefine scientific communities' access landscape to an essential research tool. On the other hand, the scientific community directly affected by the shifting of mouse supply models had also been observed as playing a passive reconciling role in accommodating the changes brought about by the enclosure trend. Research has suggested that apart from the then director of the National Institute of Health (NIH) who argued against the DuPont/Harvard approach and managed to get a memorandum of understanding signed for NIH-funded research, there was not much resistance observed in the mass scientific community. Even the NIH MOU was more of a product of compromise as it did not change DuPont's major approach by asking for the signing of restrictive MTAs that

⁵⁶⁵ *ibid.*

⁵⁶⁶ *ibid.*

⁵⁶⁷ *ibid.*

⁵⁶⁸ *ibid.*

would require scientists to have a due diligence check by DuPont/Harvard for their future research involving any use of Oncomouse. This rather peculiar situation in terms of the scientific community's collective silence resulted in commentaries concluding that 'scientists are resilient and intelligent creatures' and are very capable of finding ways to 'get around any impediments that temporarily may seem to have been erected.'⁵⁶⁹

If the ideological underpinning had been the major driving force behind the use of different normative devices and nesting expertise to transform the public nature of scientific research, especially in an academic setting, it has also been argued that 'it was the process of science as a whole that mutated as a consequence of the last three decades of tinkering with IP on a global scale; that in turn reverberated back on the legal instruments themselves and eventually on the institutions devoted to escalated levels of commercial activity.'⁵⁷⁰

Those observations are of great importance to a closer examination of community rather than the legal professions in the current proliferation of patent as the major identifier of innovation in a biomedical context. However, it is also problematic to conclude the scientific community's reactions and engagement as a totality. In addition, other communities, such as the research funding agencies and public service providers, remain marginalised in the above examples, but might emerge in later controversies concerning the patenting of research tools.

⁵⁶⁹ *ibid* 172.

⁵⁷⁰ *ibid* 139.

4.6 Reconnecting Social Aspects to Biomedical Innovation Discussion

The lost social connection in patent claims' textualization has manifested itself in temporal and spatial dimensions while technological and legal imaginaries have come together to co-produce the identity of patent proliferation which merely represents a particular type of language shared by a particular community. This practice has sought political settlements through energetic commercial endorsement and legal recognition, and simultaneously leaving the social implications in several different contexts unaddressed, especially concerning medical practices.

In the case of second medical use patents, for example, it is common knowledge and practice among physicians in different countries to prescribe medicines for unapproved medical indication, which is also termed the 'off-label' use of medicines. Off-label prescription has been found in every medical speciality in practice.⁵⁷¹ Studies found that a high percentage of children (78.9%) discharged from paediatric hospitals were taking at least one off-label medication in the US.⁵⁷² In the UK, the General Medical Council, the regulator for medical doctors, has issued guidance on off-label prescriptions, allowing such practices to be conducted with adequate guidance.⁵⁷³

⁵⁷¹ Christopher M Wittich and others, 'Ten Common Questions (and Their Answers) About Off-label Drug Use' [2012] 87(10) *Mayo Clinic Proceedings* 982

<<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3538391/#bib11>> accessed 20 July 2016.

⁵⁷² Samir S Shah, Matthew Hall, Denis M Goodman, 'Off-label Drug Use in Hospitalized Children' [2007] 161(3) *Arch Pediatr Adolesc Med* 282.

⁵⁷³ UK General Medical Council, 'Prescribing Unlicensed Medicines', (2013) Good Practices of Prescribing and Managing Medicines and Devices, available at: <http://www.gmc-uk.org/guidance/ethical_guidance/14316.asp>

Accordingly, a doctor can perform off-label prescriptions under the following conditions:

- a. be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy;
- b. take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring, and any follow up treatment, or ensure that arrangements are made for another suitable doctor to do so;

In addition, in many countries, it is medical professionals' duty to prescribe medicines using their generic names rather than brand names,⁵⁷⁴ while the high professional standards safeguarding patients' confidentiality in some countries has also led to the separation of doctors' prescriptions from dispatching pharmacists with the prescriptions often coming without specific indications.⁵⁷⁵ The patent status of different indications outside of the licensed scope of a known medicine is not of a concern to medical practitioners when they perform their medical duties within the long established discretion supported by their professional expertise. The 'unlicensed' new indication, in this context, is known to the medical professions both as obvious knowledge and as a practice. Thus, the existence and enforcement of second medical use patent brings a disruptive and legally-constructed binary test which can subject medical practitioners to potential patent infringement. In the context of the European patent regime, four decades after the heated debate on the exclusion and adaptation of second medical use patent, the issue once again occupies the headlines concerning a series of patent disputes between the company Pfizer and its generic competitors. In *Warner-Lambert Company LLC v Generics (UK) Ltd (t/a Mylan) & Ors*,⁵⁷⁶ the UK Court of Appeal upheld the decision made by Justice Arnold concerning insufficiency of disclosure in the Swiss-type claim

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- c. make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing an unlicensed medicine.

⁵⁷⁴ In France, it is a legal requirement for medical doctors to prescribe using the International Non-proprietary Names (INN) of medicines. Article L.5121-1-2 of the French Public Health Code. See also: Nicolaj Kleist and others, 'Second Medical Use Patents for Medicinal Products in the EU: When is Being Skinny not Enough?' [2016] 5(173) *Pharmaceut Reg Affairs* <10.4172/2167-7689.1000173 > accessed 09 June 2017.

⁵⁷⁵ For instance, doctors in the UK are trained to prescribe medicines in their generic names, and no specific indications are normally written in a description for the dispensing pharmacists. See: Richard Croker and others, 'The Clinician Impact and Financial Cost to the NHS of Litigation over Pregabalin: A Cohort Study in English Primary Care' [2018] *BMJ Open* < <http://dx.doi.org/10.1136/bmjopen-2018-022416> > accessed 05 August 2018.

⁵⁷⁶ *Warner-Lambert Company LLC v Generics (UK) Ltd (t/a Mylan) & Ors* [2016] EWCA Civ 1006 (13 October 2016). The full text of the judgment is available at: <<http://www.bailii.org/ew/cases/EWCA/Civ/2016/1006.html>>, accessed 09 June 2017.

and hence rejected Pfizer' requirement for an interim injunction.⁵⁷⁷ However, the process of how this case unfolded has revealed the real life contingency whereby Pfizer has been requesting the entire UK public health system, including the NHS and national pharmacy network, to change their guidelines and prescription practices in medical contexts.⁵⁷⁸

One might start questioning the possibility of re-interpreting patent laws while social connections have been weakened following the specialisation of patent law and practices, a result derived from the constant underwriting and rewriting of science and technological norms via the manipulation of expertise and textual reorientation of patent's meaning. However, the system's rather unsuccessful attempt to self-correct, as shown in the context of revising examination guidelines on Markush claims in the US, has not provided a promising pathway. Instead, a more thorough re-imagination of an alternative framework is needed in order for the lost social dimension to reclaim its boundaries. Among others, the concept of community remains critical in order for alternative expertise and norms to be explored. Alongside a re-imagined legal community as such, it is equally important to look at communities consisting of scientists and medical practitioners, which will be further discussed in the later chapters of this research.

The multiple layers and processes of co-production occur in the material and conceptual spheres, where the knowledge and practices of scientists, clinicians, lawyers, hybrid-disciplined patent attorneys, patent examiners, judiciaries, civil society, the public and policy makers act upon each other. The supremacy of legal techniques plays a critical

⁵⁷⁷ *ibid.*

⁵⁷⁸ *ibid.*

role in alienating the social from technical in the process of patent proliferation in the current biomedical innovation field. There are also different types of expert knowledge, that are either not yet entering the field of formal law or may have been reinterpreted in order to fit them in. Some of that knowledge might have once been dominant, but has later become subordinate as a result of reinterpretation and relocation. The actors' hyper-interconnection and constant modification of norms and practices have presented a complex and antagonistic network and process such that one might see it as rather unsettled. However, this fluidity should not be appraised while historical, ideological and political underpinnings are critical defining aspects in terms of making sense of the process, and inspiring a possible re-imagination.

PART III

Chapter 5: Reimagining Biomedical Knowledge: A critical approach to an alternative biomedical innovation conceptual framework

The previous chapters have discussed the conceptual contradictions of the patent-centric approach to biomedical innovation and the role of the legal professions in constructing and textualising the meaning of newness through patent documents. Social, political, scientific, technological and legal norms work together in a constant co-production process, a context in which particular ideological intents and legal techniques have succeeded in achieving the proliferation of a patent law regime in the context of biomedical innovation. To address the tension between the commercially driven proliferation of patent and the insufficiency in innovation for health, legal scholars, activists and public policy experts have proposed and pursued a number of possible adjustments and reforms based on the current patent law regime at both international and national levels. The primary reformist approach includes two distinctive and interrelated strategies. The first concerns the use of flexibilities enshrined under the current patent law framework, which aim to strike a better balance between private rights and public needs alongside control over socially detrimental patenting practices.⁵⁷⁹ In terms of stimulating innovative activities, the main measures that can be used under the current patent law system include exclusions of patentable subject matters, streamlining patentability criteria, the research and experimental use exemption,⁵⁸⁰ and compulsory

⁵⁷⁹ In addition to reforming patent laws, related strategies also include rejecting the imposition of additional obligations through trade agreement negotiations or bilateral investment negotiations. The non-patent monopolies granted under other regulatory laws, such as those concerning clinical data protection and patent term restoration, are also part of this reform strategy.

⁵⁸⁰ Some of the recent literature discussing the exclusion, general exception, research and experimental use exemptions includes: Sigrid Sterckx and Julian Cockbain, *Exclusions from Patentability: How Far Has the European Patent Office Eroded Boundaries?* (CUP 2012); Edson Beas Rodrigues Jr, *The General*

licenses for follow-on research. The effectiveness of these measures, however, depends largely on the specific provisions and practices under national laws and can be limited if a narrow approach is adopted due to political considerations.⁵⁸¹ The second type of reform concerns the alternative ways of managing intellectual property, with an emphasis on the use of voluntary licensing mechanisms and patent pooling. In contrast to the first type of reform that relies on public authority to drive the legislative and policymaking process, the second species of reform relies primarily on patent holders' initiative, motivation, and the creative design of licensing terms in order to achieve a certain level of public benefit.⁵⁸² Since this type of reform may not challenge the substantive validity and legitimacy of the specific patents involved in the voluntary licensing and patent pooling initiative, its impact on building an alternative conceptual framework could be limited.

In terms of limitations, however, reformist approaches are still critical. The first type of reform keeps pushing the patent law system internal boundaries while creating political

Exception Clauses of the TRIPS Agreements: Promoting Sustainable Development (CUP 2012); Katherine Strandburg, 'What Does the Public Get: Experimental Use and the Patent Bargain' [2004] *Wis L Rev* 81; Rochelle Dreyfuss, 'Protecting the Public Domain of Science: Has the Time for an Experimental Use Defense Arrived?' [2004] *46 Ariz L Rev* 457.

⁵⁸¹ *ibid.*

⁵⁸² A rich body of literature has illuminated the merits and limitations of using voluntary license and patent pooling in the context of ensuring access to medicines. In recent years, there practices involving the alternative use of voluntary measures have emerged including the establishment of the Medicines Patent Pool (MPP), funded by Unitaid, a funding agency and host partner with the World Health Organization. In contrast to the conventional licensing and pooling practices, MPP practices have shown some different approaches in terms of public health orientation. However, it also faces challenges in relation to expanding the scope of coverage due to the fact that patent holding companies will still keep lucrative markets outside of the pooling practice. Literature on public-oriented licensing and pooling includes, for instance: Ellen 't Hoen and others, 'Driving a Decade of Change: HIV/AIDS, Patent and Access to Medicines for All' [2011] *14(15) Journal of International AIDS Society* <<https://jiasociety.biomedcentral.com/track/pdf/10.1186/1758-2652-14-15>> accessed 18 July 2018; Peter Beyer, 'Developing Socially Responsible Intellectual Property Licensing Policies: Non-exclusive Licensing Initiatives in Pharmaceutical Sector' in Jacques de Werra (ed), *Research Handbook on Intellectual Property Licensing* (Edward Elgar 2013) 227; Brook Baker, 'A Silver of Hope: Analysing Voluntary Licenses to Accelerate Affordable Access to Medicines' [2018] *10(2) Northeastern University Law Review* 226.

space for non-dominant actors and opinions to be presented in the formal settings of law and policymaking. The second type of reform concerning the use of alternatives such as voluntary licenses and patent pooling attempts to challenge patent holders' routinely exploitative practices and opens up certain spaces for public engagement. To achieve further systematic change, the reformist approach could be stronger given a further rethinking of the conceptualization of biomedical innovation and its normative implications. The dialectical way in which technological and scientific development have been accommodated by law – especially through patenting also indicate the plurality of approaches required to re-imagine biomedical innovation and its normative meanings. Building on the critiques developed in Chapters 3 and 4, Chapters 5 and 6 discuss the key aspects that are required to build an alternative conceptual framework for biomedical innovation. To start with, this chapter discusses the transformative perspective in the construction of an alternative conceptual framework and the possible ideas pertinent to the rethinking of medicines and medical knowledge in innovation's normative context.

5.1 Conceptual Frameworks Necessary for the Transformation of Biomedical Innovation

5.1.1 Critical Approaches to a Transformative and Triangulated Framework

Transformation – differing from reformation – concerns a critical approach that 'allows for a normative choice in favour of a social and political order different from the prevailing order'.⁵⁸³ As one of critical political economy scholars' focal points of enquiry, the notion of political and social transformation is characterised by the search

⁵⁸³ Robert W Cox, 'Social Forces, States, and World Orders: Beyond International Relations Theory (1981)' in Robert W Cox and Timothy J Sinclair (eds), *Approaches to World Order* (CUP 1996) 90.

for ‘revolutionary consciousness’.⁵⁸⁴ Antonio Gramsci highlighted the political possibility of revolutionary consciousness as reflecting a restructured worldview for social change.⁵⁸⁵ Accordingly, transformation occurs with a newly formed ‘historical bloc’⁵⁸⁶ – an organic situation and process of new domination – which in turn counters the previous hegemonic bloc.⁵⁸⁷

Inspired by Gramsci’s interpretation of transformation, the critical political economy scholar Robert Cox has proposed a triangulated transformation framework based on an interactive historical structure of ideas, material capabilities and institutions.⁵⁸⁸ Working in the context of international relations, Cox considers these three dimensions of forces as interacting in a historical and reciprocal manner, without any one of them acting as a one-way determinant, neither are they ‘categories with a predetermined hierarchy of relationships’.⁵⁸⁹ Associated with historical materialism, Cox adopts a critical approach in this framework by questioning the origin of the prevailing order,⁵⁹⁰ and informing actions to occur ‘from the bottom or from outside’⁵⁹¹ of conflicts in order to pursue transformation. Cox contrasts this critical method with the ‘problem-solving approach’⁵⁹² which, according to him, aims at fixing particular problems in order to

⁵⁸⁴ Fabio de Nardis and Loris Caruso, ‘Political Crisis and Social Transformation in Antonio Gramsci: Elements for a Sociology of Political Praxis’ [2011] 1(6) *International Journal of Humanity and Social Science* 13, 14.

⁵⁸⁵ *ibid.*

⁵⁸⁶ Gramsci’s concept of the historic bloc is central to his theory of hegemony. The process of forming hegemonic and counter-hegemonic forces relies on the working of a historical bloc – an organic situation of consensus and cohesion, rather than a fixed group of people. See Michele Filippini, ‘Ideology’ in Michele Filippini, *Using Gramsci: A New Approach* (Pluto Press 2017) 10, 18.

⁵⁸⁷ Filippini (n 586).

⁵⁸⁸ Cox, ‘Social Forces, States, and World Orders (n 583) 97-101.

⁵⁸⁹ *ibid* 98.

⁵⁹⁰ *ibid* 89.

⁵⁹¹ *ibid* 97.

⁵⁹² *ibid* 88-89. See also: Robert Cox, ‘An Alternative Approach to Multilateralism for the Twenty-first Century’ [1997] 3(1) *Global Governance*, 103, 104.

smooth tensions within the prevailing social and power relationships.⁵⁹³ It is, therefore, likely that certain laws and regulations could be used in a problem-solving logic, according to Cox, while transformational intention requires looking beyond what exists.⁵⁹⁴

Cox's triangular approach has been referred to by critical scholars, such as Christopher May and Susan Sell, in their research on intellectual property regime.⁵⁹⁵ This line of scholarship provides a historical account of the intellectual property regime whereby the latter represents the 'manifestations of structural power'⁵⁹⁶ while legal institutions such as WTO's TRIPs agreement merely represent a capitalist project that commodifies knowledge.⁵⁹⁷ Accordingly, the capitalist features of the intellectual property regime presume the inevitable introduction of markets in order to ensure efficiency in distributing knowledge and ideas.⁵⁹⁸ Inspired by Cox's triangular approach, May and Sell consider transformative interactions in ideas, materiality and institutional changes as critical for a transformation of the intellectual property regime, thereby moving it toward a state of openness.⁵⁹⁹

In terms of this research, the triangular approach as outlined above has merits and limitations. Firstly, at a theoretical level, it provides a transformative route without being

⁵⁹³ *ibid.*

⁵⁹⁴ Cox, 'Social Forces, States, and World Orders' (n 583) 88.

⁵⁹⁵ See Christopher May, *The Global Political Economy of Intellectual Property Rights: A New Approach* (2nd edn, Routledge 2010) 40, 48. See also Christopher May and Susan Sell, *Intellectual Property Rights: A Critical History* (Lynne Rienner Publishers 2005) 31-37.

⁵⁹⁶ Christopher May, *The Global Political Economy of Intellectual Property Rights: A New Approach* (2nd edn, Routledge 2010) 48.

⁵⁹⁷ *ibid.*

⁵⁹⁸ Christopher May, 'Learning to Love Patents: Capacity Building, Intellectual Property and the (Re)production of Governance Norms in the "Developing World"' in Edmund Amann (ed), *Regulating Development: Evidence from Africa and Latin America* (Edward Elgar 2006) 65, 70.

⁵⁹⁹ *ibid.*

bound by the prevailing patent law institutions and is especially relevant when acknowledging the limitations of reforming the system from within.

Secondly, although the triangulation framework is most invoked in the context of international relations, its theoretical openness offers the possibility of an alternative use, in particular given its dialectical and historical materialist focus and emphasis on exploring transformation from either the bottom or from outside of the prevailing regime. This provides a helpful pathway in terms of reconstructing the normative discussion of biomedical innovations. In this sense, the use of a triangular framework in relation to biomedical innovation implies re-examining the plurality of innovators, reclaiming social norms that do not rely on an individualistic enclosure of knowledge.

However, the triangular approach as used above also has some limitations in relation to this research. Firstly, although the Coxian critique of the limitations of problem-solving approach – including the use of laws and regulations – is relevant to the ideologically-driven global expansion of the patent law regime, it has overlooked the possible critical role of law in facilitating transformation, particularly when looking at law in a broader context beyond the prevailing order of intellectual property. It also neglects the political possibility of activist lawyers' role in facilitating social movements.⁶⁰⁰ In Cox's framework, social groups holding rival collective ideas might provide 'evidence of the potential for alternative paths of development'.⁶⁰¹ Therefore, legal professionals who challenge the technical rationale of patent while seeking different normative structures

⁶⁰⁰ A related discussion is included in Chapter 3 concerning the work of different groups of legal professionals, including those working towards challenging the legitimacy and validity of the patent-centric narrative in the context of medicines and biomedical technologies. A recent good critical review of the law, lawyers and social movements is Scott L Cummings, 'Social Movement Turn in Law' [2018] 43(2) *Law and Social Inquiry* 362.

⁶⁰¹ Cox (n 583) 99.

in areas such as biomedical innovation should also be part of the broader forces pursuing transformation.

Secondly, although the Coxian critique has rightly pointed out the practice of neutralising or depoliticising political conflicts in discussions of ‘technical matters’,⁶⁰² including using law as a tool for such neutralisation, this perspective keeps the discussion at the macro level. As discussed in Chapters 3 and 4, the micro-level production of the meaning of patentability criteria has contributed substantively to the proliferation of patent in biomedical innovation. Any discussion of an alternative conceptual framework would thus need to look at both levels. In this regard, however, the theoretical openness of the triangular framework still provides an opportunity for reinterpretation and adaptation.

To mitigate the limitations and strengthen the merits of the triangular approach for the purpose of this research, it is necessary to examine its commensurability with the notion of co-production.

5.1.2 Co-production and the Triangular Framework

Having noted the conceptual contribution of the co-production approach and the transformation triangular framework respectively, this section examines the complementarity of both for the purpose of this research.

Firstly, both the co-production and triangular framework approaches adopt a historical and critical standpoint, questioning the origin of the prevailing order as the entry point when identifying alternatives. However, they approach a historical critique very

⁶⁰² May, *The Global Political Economy of Intellectual Property Rights: A New Approach* (n 596) 148.

differently in terms of setting up their respective theoretical enquiries and investigations of the formation of a status quo. The triangular approach locates its investigation in its questioning of the formation of the world order by examining the relationships between the three levels of forces with noting the systemic means of production,⁶⁰³ yet it does not investigate the micro level of creation of the material conditions – typically science and technologies – as a result of social and political processes. It also does not debate how knowledge travels across the process involved in producing a particular idea and the institutions that might legitimize a material condition, nor how technologies can be presumed to act as a solution to social and political problems. By contrast, these questions are of concern in the STS's notion of co-production, which investigates how science and technologies are constitutive and interactional in epistemic, social and political contexts.⁶⁰⁴ Instead of looking at the realm of science and technology as a neutral field of enquiry, the co-production approach is open to interpreting how science and technology, as material conditions, are legitimized and shape the formation of a particular idea and the creation of a given institution. In this sense, the two approaches are complementary, while the co-production approach can offer micro level interpretation of the formation of ideas, materials and institutions under the triangular framework. This has the potential to enrich the exploration of transformation at a systemic level while simultaneously revealing that co-production takes place in the different dimensions of forces.

Secondly, both approaches recognise the reciprocal and multidimensional relationships between the major forces involved in making the world order, particularly in terms of

⁶⁰³ Cox (n 583) 100-101.

⁶⁰⁴ Sheila Jasanoff, 'The Idiom of Co-production' in Sheila Jasanoff (ed), *States of Knowledge: The Co-production of Science and Social Order* (Routledge 2004) 4.

the system of knowledge and science and technology's governing regime. This view of plurality contrasts with the realist ideology's binary views.⁶⁰⁵ For Cox, realism's problem-solving orientations⁶⁰⁶ are flawed, given that its historical account is limited to recognising that the systems are recurrent and that human nature is limited to common rationality.⁶⁰⁷ In addition, realism does not provide a framework for change, according to Cox. For Jasanoff, realist theory 'persistently separates the domains of nature, facts, objectivity, reason and policy from those of culture, values, subjectivity, emotion and politics',⁶⁰⁸ thus it does not provide a framework to rethink the formation of socio-technical subjects in human society, including the normative orders.⁶⁰⁹ These two critiques of realist theory harbour strong transformative intentions and are complementary in the sense that by, confronting the conflicts and interactional states of the current orders, they both intend to inform alternatives that do not stay within the perceived circle of recurrence.

The complementarities between co-production and triangular approaches provide important a platform for the alternative conceptual framework building discussed in this research. Consolidating both approaches, the constant interplay between ideal, institutional and material dimensions are not linear, but rather are the basis for the rewriting and underwriting of pre-existing rules and norms. Altering the weight of each of these dimensions has the potential to trigger the possibility of change. The indeterminacy as such lies in the acknowledgment of the dialectic and plurality of norms,

⁶⁰⁵ *ibid* 3. See also Cox, 'Social Forces, States, and World Orders' (n 583)92, 94.

⁶⁰⁶ Cox, 'Social Forces, States, and World Orders' (n 583)94.

⁶⁰⁷ *ibid*.

⁶⁰⁸ Jasanoff, 'The Idiom of Co-Production' (n 604) 3.

⁶⁰⁹ *ibid*. 2-3.

the rejection of the existence of a universally valid mode of production, and the search for change from below and from the outside.

5.1.3 Key Aspects of Building an Alternative Biomedical Innovation Conceptual Framework

Revisiting the dominant model that has patent as the central factor that justifies the exclusivity-based approach to stimulating innovation, three main conceptual elements sustaining the model developed here. The first element concerns the necessity of creating exclusivity and rivalry features of medical knowledge whereby incentives are provided to further incentivise activities, following the consequentialist justification logic for patent law.⁶¹⁰ The second element is the patent holder-centred approach in normative discussions,⁶¹¹ while the broader contribution of innovators other than patent holders is often marginalised or ignored. The third element concerns the manner in which society at large is able to participate in substantive patent law discussions in terms of its function in innovation. The high level of specificity in patent law makes it difficult to participate fully without being guided by specialist knowledge and expertise that are often held only by patent law practitioners. The underlying rationale of patent's contribution to the ultimate social welfare is therefore defined by specialised groups only.

⁶¹⁰ See critiques on the consequentialist justification on patent law and its limitations in Chapter 1.

⁶¹¹ As noted by a researcher, patent's focus on the rights of patent holders has resulted in the relevant actors' unequal rights. See Philippe Cullet, 'Human Rights and Intellectual Property Protection in the TRIPS Era' [2007] 29(2) Human Rights Quarterly 403, 413.

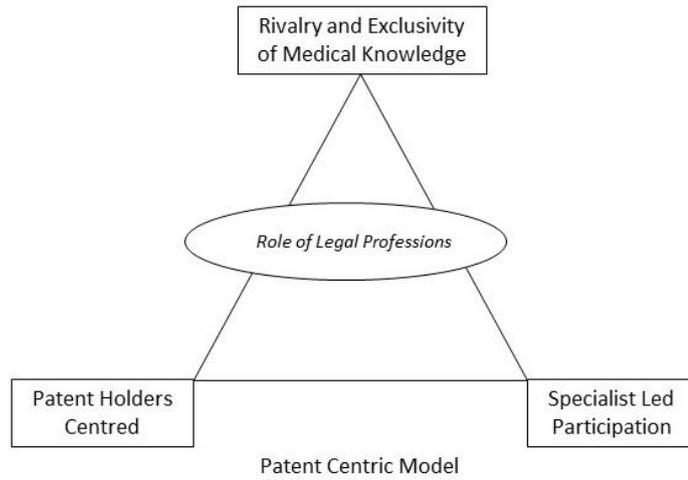


Figure 2: Key Aspects Supporting the Patent Centric Model

The key elements sustaining the current model also inform the means of rethinking alternatives. Keeping the above framework featuring a consolidated triangulation approach and co-production in mind, and building upon the critiques reviewed in earlier chapters, developing an alternative conceptual framework for biomedical innovation would include at least three levels of reconfiguration.

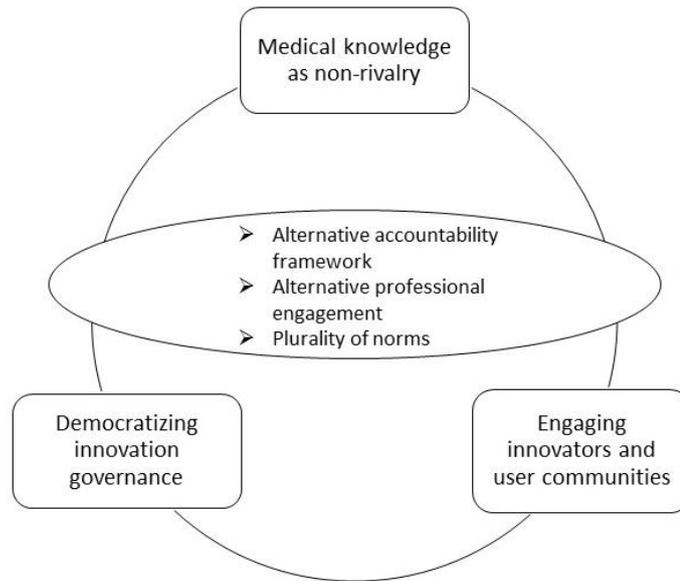


Figure 3: Key Elements for Alternative Conceptual Framework Building

Firstly, and in contrast to the belief in the necessity to construct rivalry and exclusivity on the knowledge that has supported the patenting regime, the meaning and value of medicines and biomedical knowledge should be revisited. Research have re-examined the knowledge production and management mechanisms. A number of discussions in this regard include understanding of knowledge as commons;⁶¹² invoking the collectiveness of knowledge in the context of the access and benefit sharing mechanism on traditional knowledge;⁶¹³ defining certain resources as the common heritage of

⁶¹² The leading literature of this line of thinking could be found in: Charlotte Hess and Elinor Ostrom (eds), *Understanding Knowledge as a Commons: From Theory to Practice* (MIT Press 2006); Katherine J Strandburg and others (eds), *Governing Medical Knowledge Commons* (CUP 2017).

⁶¹³ I refer to this line of argument in the literature, mostly in terms of challenging the Western-centric view of knowledge production in the context of normative discussions on the protection of biodiversity, genetic resources and traditional knowledge. Non-Western systems of knowledge have been considered as incompatible with the current regime of intellectual property. Access and benefit sharing was introduced as a *sui generis* mechanism to mitigate certain gaps. Conceptual discussions of the role of access and benefit sharing can be found in a rich literature, including: Kabir Bavikatte and Daniel F Robinson, 'Towards a People's History of the Law: Biocultural Jurisprudence and the Nagoya Protocol on Access and Benefit Sharing' [2011] 7(1) *Law, Environment and Development Journal* 35 <<http://www.lead-journal.org/content/11035.pdf>> accessed 20 April 2018; Graham Dutfield, 'Towards a Definition of

mankind or common resources,⁶¹⁴ and moving away from innovation monoculture of regulation by looking at a diversity of norms.⁶¹⁵ In addition, the literature has analysed the conceptual challenges and tensions between intellectual property law and human rights law in the context of discussing the human rights dimension of access to science and medicines.⁶¹⁶ These lines of research provide useful resources for a re-examination of the meaning of medicine and biomedical knowledge and relationship to human society.

Secondly, the marginalised in the biomedical context innovator communities, in contrast to industry patent holders, need to resurface in the conceptual discussion. As debated in the previous chapters, the epistemic and behavioural changes on the part of biomedical scientists could be attributed to multiple factors including changes in patent law and

Biocultural Heritage Innovations in Light of the Mainstream Innovation Literature' (3 April 2014) Institute of International Environment and Development <<http://pubs.iied.org/G03771/?a=G+Dutfield>> accessed 25 November 2017; Padmashree Gehl Sampath, *Regulating Bioprospecting: Institutions for Drug Research, Access and Benefit Sharing* (United Nations University Press 2005).

⁶¹⁴ The discussions on the common heritage of humankind were especially heated in the context of the use of human genome information for biomedical research. See, for example: Melisa L Surges, 'Who Should Hold Property Rights to the Human Genome?: An Application of the Common Heritage of Mankind' [1997] 13(1) *Am U Int'l* 219; Christina Byk, 'A Map to a New Treasure Island: The Human Genome and the Concept of Common Heritage' [1998] 23(3) *Journal of Medical Philosophy* 234; David B Rusnik, 'The Human Genome: Common Resource But Not Common Heritage' in Michiel Korthals and Robert J Bogers (eds), *Ethics for Life Scientists* (Springer 2004) 197; Pilar N Ossario, 'The Human Genome as Common Heritage: Common Sense or Legal Nonsense?' [2007] 35(3) *Journal of Law, Medicine and Ethics* 425.

⁶¹⁵ Kate Darling and Aaron Perzanowski (eds), *Creativity Without Law: Challenging the Assumptions of Intellectual Property* (New York University Press 2017).

⁶¹⁶ Aurora Plomer, 'The Human Rights Paradox: Rights of Access to Science and Intellectual Property Rights' [2013] 35(1) *Human Rights Quarterly* 143; Aurora Plomer, *Patent, Human Rights and Access to Science* (Edward Elgar 2015); Carlos Correa, 'Intellectual Property and Access to Science' South Centre Research Paper No. 69 (July 2016) <https://www.southcentre.int/wp-content/uploads/2016/07/RP69_IP-and-Access-to-Science_EN.pdf> accessed 18 June 2017; Christopher Geiger (ed), *Intellectual Property and Access to Science and Culture: Convergence or Conflict?* (ICTSD-CEIPI 2016) <https://www.ictsd.org/sites/default/files/research/ceipi-ictsd_3_0.pdf> accessed 18 June 2017.

research regulations,⁶¹⁷ the commodification of science,⁶¹⁸ the work of the specialised group of patent law practitioners,⁶¹⁹ and changes in research and development landscape, namely between academic scientists and commercial entities.⁶²⁰ While industrial entities hold the majority of the patents concerning biomedical technologies, the actual innovators of the same are rather broader. Scientists and physicians in particular remain the significant and active innovators.⁶²¹ Their position, even though retained in patent documents,⁶²² has been largely marginalised in the political discourse dealing with biomedical innovation and patenting. Shifting away from the dominant framing by industry patent holders requires re-inviting innovators in the broader community where knowledge creation norms can be shared and developed differently.

Thirdly, the debates emerging on democratizing innovation offer a critical space to reimagine an alternative conceptual framework for biomedical innovation. In addition

⁶¹⁷ David C Mowery and others (eds), *Ivory Tower and Industrial Innovation: University-Industry Technology Transfer Before and After the Bayh-Dole Act* (Stanford University Press 2004); Anthony D So and others, 'Is Bayh-Dole Good for Developing Countries? Lessons Learned from the US Experience' in A Cimoli and others (eds), *Intellectual Property Rights: Legal and Economic Challenges for Development* (OUP 2014).

⁶¹⁸ Philip Mirowski, *Science-mart: Privatizing American Science* (Harvard University Press 2011); Philip Mirowski and Esther-Mirjam Sent (eds), *Science Bought and Sold: Essays in the Economics of Science* (University of Chicago Press 2002).

⁶¹⁹ Alain Pottage and Brad Sherman (eds), *Figures of Invention: A History of Modern Patent Law* (OUP 2013); Hyo Yoon Kang, 'Science Inside Law: The Making of a New Patent Class in the International Patent Classification' [2012] 25(4) *Science in Context* <<http://dx.doi.org/10.1017/S0269889712000233>> 551, accessed 20 May 2018.

⁶²⁰ David C Mowery and others (eds), *Ivory Tower and Industrial Innovation: University-Industry Technology Transfer Before and After the Bayh-Dole Act* (Stanford University Press 2004); Philip Mirowski, *Science-mart: Privatizing American Science* (Harvard University Press 2011).

⁶²¹ Stephan Bechtold, 'Physicians as User Innovators' in Rochelle Cooper Dreyfuss and Jane C Ginsburg (eds), *Intellectual Property at the Edge* (CUP 2014) 343; Katherine Strandburg, 'Derogatory to Professional Character? The Evolution of Physician Anti-Patenting Norms' in Kate Darling and Aaron Perzanowski (eds), *Creativity Without Law: Challenging the Assumptions of Intellectual Property* (New York University Press 2017) 63; Harold J DeMonaco, Ayfer Ali and Eric von Hippel, 'The Major Role of Clinicians in the Discovery of Off-label Drug Therapies' [2006] 26(3) *Pharmacotherapy* 323.

⁶²² Graham Dutfield, 'Collective Invention and Patent Law Individualism, 1877-2012 – Or, the Curious Persistence of Inventor's Moral Right' in Stathis Arapostathis and Graham Dutfield (eds), *Knowledge Management and Intellectual Property: Concept, Actors and Practices from the Past to the Present* (Edward Elgar 2013) 109.

to reengaging the specialised groups of innovators mentioned above, it is also important to confront the question of the role of non-institutional researchers and citizens in the biomedical innovation context. In particular, the technological conditions for biomedical research have changed dramatically with the development of biotechnology and genetic technology, the understanding of disease-related human genome information and the advancement of information technologies for research. Decentralised and non-institutional research initiatives have been observed when individuals and researchers take inspiration from both the open source movement in the computer science context as well as experimental biomedical innovation activities that rely on openness, sharing and socially-determined governing norms.⁶²³ The return to open science, in this sense, has adopted an alternative form on the basis of voluntary and decentralised communities, thereby sidestepping patent and creating alternative norms.

The three key aspects reinforce the transformative approach to alternative conceptualisation, as they are largely related to the ideal, institutional and material forces that are interactional in the context of biomedical innovation. Each of the aspects make efforts to challenge and compete with the dominant order, simultaneously providing transformative political opportunities. The remainder of this chapter will look at the first

⁶²³ Janet Hope, *Biobazaar: The Open Source Revolution and Biotechnology* (Harvard University Press 2006); Eric von Hippel and G von Krogh, 'Open Source Software and a "Private-Collective" Innovation Model: Issues for Organisation Science' [2001] 14 (2) *Organisation Science* 209-223; Steven Levy, *Hackers: Heroes of the Computer Revolution* (Penguin 2001); RM Stallman, 'The GNU Operating System and the Free Software Movement' in C DiBona and others (eds), *Open Source: Voices from the Open Source Revolution* (CUP 1999) <<http://www.oreilly.com/openbook/opensources/book/>> accessed 20 May 2017; Y Benkler, "'Sharing Nicely": On Shareable Goods and the Emergence of Sharing as a Modality of Economic Production' (2004) *Yale Law Journal* 144, 273-358, 273-275; Eric von Hippel, 'Open Source Projects as Horizontal Innovation Networks—by and for Users' [2002] MIT Sloan Working Paper No. 4366-02, <<http://www.oecd.org/edu/innovation-education/32125887.pdf>> accessed 20 May 2017; Janet Hope, 'Open Source Genetics: Conceptual Framework' in Geertrui van Overwalle (ed), *Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open Source Models and Liability Regimes* (CUP 2009); Stephen Maurer, Arti Rai and Andrej Sali, 'Finding Cures for Tropical Diseases: Is Open Source the Answer?' (2004) 1(3) *Public Library of Science: Medicine* <<https://doi.org/10.1371/journal.pmed.0010056>> accessed 20 May 2017.

aspect, namely the approaches through which the ideas of medicines and biomedical knowledge can revisit and revise the normative context.

5.2 Revisiting the Concepts of Medicine, (Bio) Medical Knowledge and Health

5.2.1 Medicine and Its Divides

Conventionally the concept of medicine refers to both the material substance of medicines used for the treatment or prevention of disease⁶²⁴ as well as the science and practice of diagnostics and the treatment and prevention of diseases.⁶²⁵ Medicine means both the material products and its system of knowledge and practices. In Chapter 2, the product dimension of medicine was discussed, looking at how technological development has changed the way in which modern medicines are developed and produced. In this section, the broader conceptual dimensions of medicine will be examined. Firstly, the point of having science as a dividing line splitting medicine into modern and traditional systems is problematic. Modern medicines – mostly referring to the Western system of medicine – are considered as experimental, evidence-based and thus scientific.⁶²⁶ In contrast, traditional medicines are holistic, related to indigenous knowledge, beliefs and practices. However, the dichotomy of ‘traditional’ and ‘modern’ in medicines has been considered as politically constructed and artificial.⁶²⁷

⁶²⁴ ‘Medicine’ in *Oxford Concise Medical Dictionary* (8th edn, OUP 2014) online version <<http://www.oxfordreference.com/view/10.1093/acref/9780199557141.001.0001/acref-9780199557141-e-6016?rskey=KQ7QiP&result=6559>> accessed 20 March 2018.

⁶²⁵ *ibid.*

⁶²⁶ In the context of Western medicine, the literature on clinical practices and sociology of medicines has also discussed the conceptual and practical distinctions between evidence-based, science-based, and experimental medicines respectively. Debates on the overly relying on evidence and scientific statistics might come in conflict with clinical uncertainty are also ongoing. A detailed and substantive review of these issues are, however, outside the scope of this research.

⁶²⁷ Graham Dutfield, ‘TK Unlimited: The Emerging but Incoherent International Law of Traditional Knowledge Protection’ [2017] 20 *J World Intellect Prop* 144.

Many of the medicine systems that had been named as ‘traditional’ are continuing, actively practiced and developed in contemporary societies alongside Western medicines, such as Chinese, Tibetan, and Ayurveda medicines as well as others.⁶²⁸ Naming a particular medicine system as ‘traditional’, ‘complementary’ or ‘alternative’ can reflect a monolithic approach to science that is Western-centric while downplaying the value of other medicine systems. This is especially the case given the historical process of colonisation⁶²⁹ and modernization.⁶³⁰ Commentators have also critiqued the trend of ‘integrative medicines’, an attempt to fit traditional medicines into Western medicine in terms of both medical education and practices, as a cultural fit using neoliberal strategies.⁶³¹ They further challenge the ignorance of such an ‘integrative’

⁶²⁸ The literature on Chinese, Tibetan and Indian medicines including Ayurvede, Siddha and Unani have illuminated a variety of aspects including the medical philosophy, structure, practices, historical and political context of the origin, development and practices of these systems, with much of the literature reflecting views similar to those of Western medicine systems. Some of the recent literature discussing the relationships between Western medicine and active non-Western medicine systems include, for example: Zhang Qi, Zhu Liming and Wim van Lerberghe, ‘The Importance of Traditional Chinese Medicine Services in Healthcare System in China’ [2011] 2(2) *International Journal of Human Development and International Cooperation* <<http://universitasforum.org/index.php/ojs/article/view/63/242>> accessed 01 May 2018; Sienna Graig and Vincanne Adams, ‘Global Pharma in the Land of Snows: Tibetan Medicine, SARS and Identity Politics Across Nations’ [2008] 4(1) *Asian Medicines* 1; LiLi Lai, ‘Nationality Medicines in China: Institutional Rationality and Healing Charisma’ [2015] 57(2) *Studies in Society and History* 381; Yanchun Liu and others, ‘Medicinal Plants used by Tibetans in Shangri’la, Yunnan, China’ [2009] 5(15) *Journal of Ethnobiology and Ethnomedicine* <<https://ethnobiomed.biomedcentral.com/track/pdf/10.1186/1746-4269-5-15>> accessed 01 March 2018; World Health Organization, *Traditional Medicines in Asia* (2001) <<http://apps.who.int/medicinedocs/documents/s22292en/s22292en.pdf>> accessed 01 July 2018.

⁶²⁹ Abena Dove Osseo-Asare, ‘Bioprospecting and Resistance: Transforming Poisoned Arrows into Strophantin Pills in Colonial Gold Coast 1885-1922’ [2008] 21(2) *Social History of Medicine* 269; Maryidez Lyons, *The Colonial Disease: A Social History of Sleeping Sickness in Northern Zaire, 1900-1940* (CUP 2010); Daniel Hollenberg and Linda Muzzin, ‘Epistemic Epistemological Challenges to Integrative Medicine: An Anti-colonial Perspective on the Combination of Complementary/Alternative Medicine with Biomedicine’ [2010] 19(1) *Health Sociology Review* 34.

⁶³⁰ Dutfield, ‘TK Unlimited’ (n 627).

⁶³¹ Christopher J Fries, ‘Governing the Health of the Hybrid Self: Integrative Medicine, Neoliberalism, and the Shifting Biopolitics of Subjectivity’ [2008] 17(4) *Health Sociology Review* 353,

practice as the legacy of colonial history that politically segregates medical knowledge from other, different systems.⁶³²

The division of medicine into modern and traditional touches on a deeper epistemic and political question regarding the embedded knowledge system in medicine and medical practices and its associated innovations. As reviewed in the introduction chapter, in the context of biomedical innovation's patent law-centric model, there remains the issue of competing systems of law in which knowledge and innovation are presented differently.⁶³³ Alternative normative systems – especially as refracted through the Convention of Biological Diversity (CBD) – has revealed the possible mechanism of facilitating community-based and community-controlled knowledge production and dissemination. The distinctive CBD arrangement has a specific historical and political background and focuses primarily on the issues of biological and genetic resources and their associated traditional knowledge, including those resources with therapeutic applications. However, a question worth exploring is whether the CBD process provides an opportunity to re-examine how innovation in medicine as a whole can be redefined by involving non-commercially motivated entities, knowledge and resource holders, in order to push for greater accountability. Section 5.4 will further discuss this point.

The second level of division in medicine concerns its material and behavioural dimensions. As stated above, medicine is not only about medical products, but also an integral system of diagnostics, prevention and treatment that involves knowledge and practices developed, accumulated and shared between professional medical practitioners.

⁶³² Daniel Hollenberg and Linda Muzzin, 'Epistemic Epistemological Challenges to Integrative Medicine: An Anti-colonial Perspective on the Combination of Complementary/Alternative Medicine with Biomedicine' [2010] 19(1) Health Sociology Review 34.

⁶³³ Philippe Cullet, *Intellectual Property Protection and Sustainable Development* (LexisNexis Butterworths 2005) 288.

When it comes to the questions of saving life and quality of care, the availability of medicine as a material tool is as essential as the availability of medicine practised based on professional autonomy. These interlocking aspects of medicine have nonetheless been treated in a segmented manner under the current patent-centred framework. As discussed in Chapter 4, the issues and debates on patenting the methods of diagnosis and treatment, and patenting second medical indications touch on the central question of power between the innovators and patent holders, the commercial entities and medical practitioners, while leading to medical professional and public disquiet.⁶³⁴

Patent law's specificity and high level of technicality also enable the segmentation between product and use, and between the single elements of the same product when resorting to patent protections. This dynamic has deconstructed the integrity of medicine in the context of innovation discussion, forcing the debate to orbit around the criteria set forth by patent law. Accordingly, on the surface, multiple patentable elements of the same medicine⁶³⁵ could contribute to a decent-sized patent portfolio which can then be used as a key indicator of innovation capacity.⁶³⁶ The possibility of patenting the method of use independent of the related product enables the patent holder to control the use in a clinical context even though the product itself might be copied by competitors. At the

⁶³⁴ Literature on this line of contestation includes, for instance: Katerine Strandburg, 'Derogatory to Professional Character? The Evolution of Physician Anti-Patenting Norms' in Darling K and Perzanowski A (eds), *Creativity without Law: Challenging the Assumptions of Intellectual Property* (New York University Press 2017) 63; Katerine Strandburg, 'Legal but Unacceptable: Pallin v. Singer and Physician Patenting Norms' in Rochelle Cooper Dreyfuss and Jane C. Ginsburg (eds), *Intellectual Property at the Edge: The Contested Contours of Intellectual Property* (CUP 2014) 321.

⁶³⁵ This refers to the 'patent thicket' and 'patent evergreening' issues which have been common practices used by commercial entities in the biopharmaceutical field. See: Andrew Hitchings, Emma Baker and Teck Khong, 'Making Medicines Evergreen' [2012] 345 (e7941) BMJ <<https://doi.org/10.1136/bmj.e7941>> accessed 1 May 2018.

⁶³⁶ It is worth noting that, for instance, the Global Innovation Index published annually by WIPO uses multiple indicators to measure the innovation capacity of a country, in which the performance of patenting is one of the key indicators and defining factors in relation to the science and technology activities of a given country. WIPO, Global Innovation Index (2018) <http://www.wipo.int/edocs/pubdocs/en/wipo_pub_gii_2018.pdf> accessed 1 August 2018.

same time, the segmentation approach to medicine also enables a different form of patent bundling when the patent on a device can rescue an off-patent pharmaceutical compound by locking in the old compound as an indispensable part of a device and its use.⁶³⁷ For instance, research has observed that the company Boehringer has effectively secured at least 58 years market exclusivity by locking in its off-patent medicine ipratropium, for the treatment of bronchitis and emphysema, into its multiple patent-protected inhaler.⁶³⁸ Thus, the segmented presentation of medicine in the patent-centric framework plays a critical role in how biomedical innovation is reflected through the lens of patent law criteria, rather than through the real life experience of medical practices in their social, interactional and dynamic contexts.

The two divides in medicine, as discussed above, are both related to the conceptual dilemma when presenting patent's central role in biomedical innovation. In relation to the modern/traditional medicines divide, patent law specifically and intellectual property law in general privilege a certain type of medical tradition and culture over others. In terms of the material/practical medicines divide, patent law's segmented approach to medicine facilitates the misrepresentation of innovation, overshadowing the social cost of patent evergreening. On the other hand, the two sites of the splits discussed here can provide an opportunity to rethink their possible reunification in a normative context.

⁶³⁷ A notable example of the device/medicine combination patent and its impact on access to medicine is the re-patenting of the old asthma medicine through the patenting of asthma inhalers. Elisabeth Rosenthal, 'The Soaring Cost of a Simple Breath' (New York Times, 12 October 2013) <https://www.nytimes.com/2013/10/13/us/the-soaring-cost-of-a-simple-breath.html?pagewanted=all&_r=2> accessed 8 June 2018.

⁶³⁸ Reed Beall and others, 'Is Patent "Evergreening" Restricting Access to Medicine/Device Combination Products? PLOS One (24 February 2016), <<https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0148939>> accessed 6 June 2018.

This chapter's later sections will further examine how medicine and knowledge have been positioned in non-patent-centric normative discussions.

5.2.2 (Bio?)Medical Knowledge and the Health Perspective

As the above section has discussed, the division of medicines into modern science-based and traditional is political, reflecting an embedded hierarchy of knowledge and practices under different medical cultures and traditions. In addition, the construction of 'biomedical' out of the medical has also been observed as a process of moving towards a technoscientific worldview and as a result of 'the commodification of health'.⁶³⁹ Research has underlined that the trend to pursue 'biomedicalization' is a rather recent phenomenon.⁶⁴⁰ By integrating more highly complex techno-scientific elements into medicines, the biomedical turn has been facilitated by multiple technological developments such as molecular biology, biotechnology, genome technology and transplant medicines.⁶⁴¹ It is, at the same time, manifested as the societal expansion of medicalization.⁶⁴² Medicalization, on the other hand, has been studied from sociological perspectives as a process of altering and framing nonmedical problems in human society into medical problems that can be dealt with by medicine's technical and material means.⁶⁴³

Research has pointed out the multiple strands of enquiries that the biomedicalization scholarship can bring, including the impact of the highly technoscientific means of

⁶³⁹ Adele E Clarke and others, 'Biomedicalization: Technoscientific Transformation of Health, Illness and US Biomedicine' [2003] 68(2) *American Sociology Review* 161.

⁶⁴⁰ *ibid.*

⁶⁴¹ *ibid.*

⁶⁴² Peter Conrad, 'The Shifting Engine of Medicalization' [2005] 46(1) *Journal of Health and Social Behaviour* 3.

⁶⁴³ Peter Conrad, *The Medicalization of Society: On the Transformation of Human Conditions into Treatable Disorders* (John Hopkins University Press 2007) 4.

biomedical knowledge production, and the impact of genetics on individuals and communities' identities and autonomy.⁶⁴⁴ Although detailed discussion on biomedicalization is beyond the scope of this research, there are two relevant notions in the biomedicalization analyses. The first one concerns the dramatic changes in biomedical knowledge production and dissemination with the development of internet and computerised information.⁶⁴⁵ This aspect relates to the discussion on the possibility of pursuing the new type of open science in light of the open source concept that Chapter 6 will further discuss. The second line of biomedicalization analysis that is more relevant to this research is the discussion on the multifaceted use of the meaning of 'bio-' in the context of medicine, health, society and individual's identities.⁶⁴⁶ In contrast to revealing the prominent role of biotechnology and biological science in medicine, the meaning of *bio-* in biomedicalization enquiries also includes the power struggles and exercise 'at the level of life' itself.⁶⁴⁷ Section 5.2.3 will further discuss this aspect.

Biomedicalization's technoscientific focus informs a further specialised and segmented approach that imagines biomedical solutions to human problems.⁶⁴⁸ In addition, the biomedicalization turn is a commercially-driven phenomenon.⁶⁴⁹ Bio-medicalised knowledge, in this sense, serves a particular vision of the relationship between human society, medicine and health, one in which the specialised segments of technological and scientific solutions can be deployed through the consumption of newer medicines. The

⁶⁴⁴ A good review of the biomedicalization literature can be found in Adele E. Clarke and others, 'Biomedicalising Genetic Health, Disease and Identities' in Paul Atkinson and others (eds) *Handbook of Genetics and Society: Mapping the New Genetic Era* (Routledge 2009)21.

⁶⁴⁵ *ibid* 22.

⁶⁴⁶ *ibid* 22-23.

⁶⁴⁷ *ibid*. The 'level of life' itself in 'bio-' refers primarily to the Foucauldian notion of biopolitics, according to Clarke, which concerns the power situated and exercised by social groups and social movements concerning health and identities.

⁶⁴⁸ Clarke and others, 'Biomedicalization: Technoscientific Transformation' (n 639).

⁶⁴⁹ *ibid* 168-169. See also Peter Conrad and Valerie Leiter, 'Medicalization, Market and Consumers' [2004] 45 *Journal of Health and Social Behavior* 158.

advances in science and technology in medicine have undoubtedly brought about significant benefits such as saving of life, improved health and wellbeing. However, the approach to trickling down question of life and health in relation to the technoscientific dimension of biomedicine is rather contestable. As critics have pointed out, the background to the commodification of health – which spans from looking at the availability of healthcare as a public good to the view of healthcare as a consumable commodity – has contributed to this level of controversy.⁶⁵⁰

Pursuing better health, in the sense articulated by the biomedicalization narrative, means consuming and being able to consume newer and better medicines, including for prevention, diagnostics and treatment. The shift from a focus on public authorities' responsibility to providing healthcare to focusing on individuals' ability to consume health-related products and services⁶⁵¹ may contribute to avoiding asking hard questions in terms of social and political inequalities and the asymmetric powers in play in the field of medicine. More importantly, whether and how medicines are considered as 'newer' and 'better' remain controversial in a patent-centric and exclusivity-based model. In such a model, the construction of the meanings of 'new' and 'better' has taken place in a highly specialised and textualised process with a distinctive language system based on patent claims that may present a very different kind of reality on paper than prevails in real life. While bringing about and justifying newer medicines would inevitably mean going through the patenting process as the current predominant model necessitates, in which a newer patent may not mean any actual advance in medical knowledge, the presumed social benefit of this patent-centred model remains illusory.

⁶⁵⁰ Clarke and others, 'Biomedicalization: Technoscientific Transformation' (n 639)161.

⁶⁵¹ *ibid.*

While critiques of the medicalisation and biomedicalization of social problems are pertinent, lacking access to both medicines and benefits derived from the development of medical technology and science are equally negative in terms of the enjoyment of health. The meaning of health, therefore, is a site of contestation in itself and the former is defined by the World Health Organization (WHO) as ‘a state of complete physical, mental and social well-being and not merely the absence of disease or infirmity’.⁶⁵² Adopting a rights-based approach by defining health as a fundamental human right, the WHO affirms in its constitution that ‘the extension to all peoples of the benefits of medical, psychological and related knowledge is essential to the fullest attainment of health’⁶⁵³ while governments bear an obligation to ensure the ‘highest attainable level of health’⁶⁵⁴ as so defined. The meaning of health as defined by the WHO is incorporated in the following international human rights law instruments. For instance, the International Covenant on Economic, Social and Cultural Rights (ICESCR) recognises ‘the right of everyone to the enjoyment of the highest attainable standard of physical and mental health’.⁶⁵⁵ The extent to which the WHO-led approach to defining health alters the techno-scientific-focused discussion in law and policy context or rather reinforces the medicalisation of social issues, remains a subject of debate.⁶⁵⁶

The critiques of biomedicalization as outlined above underlines the necessity to re-examine at what we mean when we use the phrase ‘biomedical’, and alerts us to how

⁶⁵² Preamble, Constitution of World Health Organization, adopted on 22 July 1946, entered into force 7 April 1948.

⁶⁵³ *ibid.*

⁶⁵⁴ *ibid.*

⁶⁵⁵ Article 12.2, International Covenant on Economic, Social and Cultural Rights, adopted 16 December 1966, entered into force 3 January 1976.

⁶⁵⁶ For instance, some scholars consider that the WHO’s definition may reinforce the medicalisation of health. Machteld Huber, ‘How Should We Define Health?’ [2011] 343 *BMJ* <<https://doi.org/10.1136/bmj.d4163>> accessed 19 July 2018.

over-reliance on the techno-scientific dimension in medicine can displace the very objective of protecting health when innovation and access are discussed. The patent-centric framework, in this sense, reinforces a biomedicalized vision of medicine and health, and represents a seemingly technically-grounded solution to the rather complex social and political problem of innovation. These controversies, again, provide space for a possible reconsideration, especially in terms of the extent to which 'biomedical' can be understood differently compared to the dominant technoscientific approach.

5.2.3 Reinterpreting Life and Medicine in Terms of Building an Alternative Conceptual Framework

The above section has reviewed how definitions of and divisions within medicine have reflected the power asymmetry in different historical and political contexts, which reflect the supremacy of Western medical science and the establishment of a commercially-driven and technoscientific-centred view of medicine. The artificial construction of a 'traditional' versus 'modern' opposition ignores the co-existence of traditional and Western medicines throughout history and the cross-learning and cross-referencing that they have shared in both the past and the present. In addition to the social and political context in which medicine's meaning has become more monolithic, another level of contestation has emerged when human problems have been framed within biomedical problems so that they can be solved by specific techno-scientific means, without necessarily challenging the systemic order. Far from simply being a debate between sociologists and biomedical scientists, biomedicalization's underlying motives and contributing factors are closely related to the move toward the commodification of health and the extended specialisation of knowledge and expertise. This trend is also direct relevant to the central concern of this research.

When the benefits of medicine became entirely technoscientific, the reliance on consuming newer and better medicines becomes inevitable. Under a patent-centric model of stimulating and commercialising newer medicines, however, the meaning of ‘new’ and ‘better’ can be easily manipulated through the textual construction of patent documents rather than real advancements in the field of medicine. Informing alternative conceptual discussions, therefore, requires reengaging with the meaning of medicine and biomedical knowledge, especially the extent to which a monolithic view of science and technology in a narrow Western sense can be overridden.

In the context of the biomedicalization of medical knowledge, as noted in literature, the prefix *bio-* carries multiple implications including the preferences and undertones of the biological, biotechnological and genomic technologies’ application in medicines.⁶⁵⁷ Leading to a higher level of specification in medicine, the meaning of *bio-* in this context is technologically defined. However, the Greek origin of *bio-* does not refer to any particular scientific or technological dimension dissociated from human life. Enquiries in the social and political power relations concerning identities, health and biomedicines have also used the meaning of *bio-* to refer ‘the level of life’ itself.⁶⁵⁸ Therefore, can the meaning of ‘biomedical’ change from a technocratically-focused concept to a term that opens up the relationship between life, health and medicine? Should biomedical knowledge become a system of knowledge facilitating the enjoyment of the diversity of medical traditions and cultures, and the source of innovation that are developed, disseminated and used outside of the monoculture of patenting? These are questions to be further explored. To this end, the following sections examine three main conceptual discussions containing critical elements regarding how knowledge and innovation in

⁶⁵⁷ Clarke and others, ‘Biomedicalising Genetic Health’ (n 644).

⁶⁵⁸ *ibid.* See also n 647.

medicine can be understood differently when compared to the conventional patent-centric narrative.

5.3 Biomedical Knowledge in the Approach to Knowledge Commons

5.3.1 Studies on Knowledge Commons and Public Goods

The notion of commons traditionally referred to natural resources shared by a group of people, often involving social and economic dimensions regarding their use and preservation. Studies of traditional commons have analysed the tensions between human behaviours and the sustainability of the commons, as well as institutions and principles that govern their use and preservation.⁶⁵⁹ Key aspects in the studies of commons in the context of tangible resources include the principles of governance and uses that reflect the objectives of equity, efficiency and sustainability; the institutional arrangements that are related to boundaries' determination; the roles and rules concerning individuals and communities around the commons; and the nested enterprises and multiple layers of activities involved in their use and preservation.⁶⁶⁰ Commons can be bound or open as well as subject to either self-governing rules or property rights.⁶⁶¹ The studies on

⁶⁵⁹ A large body of literature has contributed to the discussion of commons in the context of natural resources, see: Elinor Ostrom, *Governing the Commons: The Evolution of Institutions for Collective Action* (Cambridge University Press 1990); Elinor Ostrom and others, 'Revisiting the Commons: Local Lessons, Global Challenges' [1999] 284(5412) *Science* 278-282; Elinor Ostrom and Charlotte Hess, 'A Framework for Analyzing the Knowledge Commons' in Charlotte Hess and Elinor Ostrom (eds), *Understanding Knowledge as a Commons: From Theory to Practice* (MIT Press 2006) 41-83; Daniel W Bromley and others (eds), *Making the Commons Work: Theory, Practice, and Policy* (ICS Press 1992); Siegfried V. Ciriacy-Wantrup and Richard C Bishop "'Common Property"' as a Concept in Natural Resource Policy' [1975] *Natural Resources Journal* 15/4 (October) 713-727; Thomas Dietz, Elinor Ostrom and Paul C Stern, 'The Struggle to Govern the Commons' [2003] 302(5652) *Science* 1907-1912.

⁶⁶⁰ *ibid.*

⁶⁶¹ Charlotte Hess and Elinor Ostrom (eds), *Understanding Knowledge as a Commons: From Theory to Practice* (MIT Press 2006) 5. Common-pool resources refer to a type of economic good that depends on property rights in terms of its governance.

knowledge commons adopt the analogy of knowledge as a shared resource that can suffer from either underuse or overuse.⁶⁶²

It has been observed that intellectual enquiries on knowledge commons are a rather recent attempt following the increasing number of debates on governing the enormous amount of information generated, shared, used and commercialised in the digital age.⁶⁶³

In addition, the literature on knowledge commons has emerged from different disciplines, including legal and economic studies, and discusses the dual functions of knowledge in the information age, with data and information act as its carriers of production and dissemination, as both commodities and social forces.⁶⁶⁴ While the economic and utilitarian interpretation of knowledge as a commodity has not led to a structural arrangement facilitating easy access to knowledge, this has been made easy and quick in the digital age.⁶⁶⁵ As Ostrom has noted, the classic economic account of knowledge as a pure public good has overwhelmingly focused on discussing exclusion while treating the knowledge process as one dimensional.⁶⁶⁶ In contrast, Ostrom differentiates between two types of resources in the context of knowledge commons, namely the public good and common-resource pools.⁶⁶⁷ Public good in the form of

662 Elinor Ostrom, 'Introduction' in Charlotte Hess and Elinor Ostrom (eds), *Understanding Knowledge as a Commons: From Theory to Practice* (MIT Press 2006) 3-27; See also: Garrett Hardin, 'The Tragedy of the Commons' [1968] 162 *Science* 1243-1248; Michael A Heller, 'The Tragedy of the Anticommons: Property in the Transition from Marx to Markets' [1998] 111(3) *Harvard Law Review* 622-688; Michael A Heller and Rebecca S Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' [1998] 280(5364) *Science* 698-701.

⁶⁶³ *ibid.*

⁶⁶⁴ *ibid.* See also: Sandra Braman, 'Defining Information: An Approach for Policymakers' in DM Lamberton (ed), *The Economics of Communication and Information* (Edward Elgar 1989); Jerome H Reichman and Jonathan A Franklin, 'Privately Legislated Intellectual Property Rights: Reconciling Freedom of Contract with Public Good Uses of Information' [1999] 147(4) *University of Pennsylvania Law Review* 875-970.

⁶⁶⁵ Elinor Ostrom, 'Introduction' in in Charlotte Hess and Elinor Ostrom (eds), *Understanding Knowledge as a Commons: From Theory to Practice* (MIT Press 2006) 3-27.

⁶⁶⁶ *ibid.*

⁶⁶⁷ *ibid* 9-10.

general knowledge that is difficult to exclude anyone else from knowing and using, while common-resource pools are easier to enclose and a realm in which property, rules and governing institutions can be created.⁶⁶⁸ In the context of the digital age, disruptive technologies have contributed to moving subjects from a public good to becoming common-resource pools while the commons analytical approach can be applied in understanding the pools' institutions and governance.⁶⁶⁹ Returning to Hardin and Eisenberg's earlier accounts of commons and anti-commons in the context of biomedical research and intellectual property,⁶⁷⁰ the dilemmas facing the openness and enclosure of research data and information in the innovation process are pertinent here, especially in the face of exclusion through intellectual property rights. Therefore, it is important to further examine the process of how research data is generated, governed and used, and the manner in which institutional interactions have played a role in managing research data as commons, regardless of whether or not intellectual property will be used as a tool in its governance.

5.3.2 Emergence of Commons Studies in Biomedical Knowledge

The most profound technological changes in contemporary biomedical research and development have come in the wake of studies of DNA structure and genomic functions in humans, which have led to new technologies and the possibility to identify genomic causes of diseases and targeted diagnostics, intervention and treatments. The advance of genomic technologies has been seen as transformative in the biomedical field, as many actors are alert to the possibility of profoundly changing both the methodologies and

⁶⁶⁸ *ibid.*

⁶⁶⁹ *ibid.*

⁶⁷⁰ Garrett Hardin, 'The Tragedy of the Commons' [1968] 162 *Science* 1243-1248; Michael A Heller and Rebecca S Eisenberg, 'Can Patents Deter Innovation? The Anticommons in Biomedical Research' [1998] 280(5364) *Science* 698-701.

practices of medicine.⁶⁷¹ The changing technological landscape and the increasing use of genetic and genomic approaches involves generating, storing, using and sharing large amounts of data in the R&D and clinical application stages. The growing importance and concerns around the issues of ownership, management and government of data in the biomedical field are relevant to this research. The value of data as an essential research enabler, a presenter of medical identities of individuals and communities, and as an indicator and guide in medical practice have resulted in an emerging body of literature using the studies of knowledge commons framework to make sense of medical knowledge specifically.⁶⁷²

The recent literature on knowledge commons provides specific analysis of medical knowledge governance, especially in the context of genomic research and development projects, such as the well-known Human Genome Project (HGP) and others.⁶⁷³ The HGP, for instance, has been richly documented and discussed from medical, ethical, scientific, political and legal perspectives.⁶⁷⁴ In addition, HGP has ambitions that require global collaboration and mega data management in order to ensure its completion, comprehension and accuracy. With its completion, genomic data management at national levels have also become a subject for commons studies scholars, who intend to explore the establishment and limitations of a genomic data commons and its governance

⁶⁷¹ Literature of this kind could be mostly in the disciplines of medical research and science studies, for instance: GJB van Ommen and others, 'The Human Genome Project and the Future of Diagnostics, Treatment and Prevention' [1999] *The Lancet* 354 Special Issue, s5-10.

⁶⁷² For the recent leading literature see Katherine J Strandburg and others (eds), *Governing Medical Knowledge Commons* (CUP 2017), a volume containing case studies on emerging commons in the context of biomedical research and development.

⁶⁷³ *ibid.*

⁶⁷⁴ A rich multi-disciplinary body of literature has emerged concerning the implications and organisations of HGP. See: Brigitte Nirlich and others, 'The Book of Life: How the Completion of the Human Genome Project was Revealed to the Public' [2002] 6(4) *SAGE Journals of Health* 445-469; Charles Dilisi, 'The Human Genome Project: The Ambitious Proposal to Map and Decipher the Complete Sequence of Human DNA' [1988] 76(5) *American Scientists* 488-493; Francis S Collins, 'Medical and Societal Consequences of the Human Genome Project' [1999] 341 *N Engl J Med* 28.

framework.⁶⁷⁵ The resultant analysis has placed a central focus on the role of the state and government in the creation, management and sustaining of the emerging medical knowledge commons in the age of genomic data and technologies.⁶⁷⁶

There are some central features of this line of literature that are highly relevant to this research. Firstly, the approach used to discuss medical knowledge commons does not base its analytical foundation on the necessity of intellectual property rights as often seen in the conventional patent law literature. Rather, it looks at medical knowledge commons, typically in the context of genomic data knowledge as a shared resource that is somewhere in-between a nature resource and intellectual enquiry.⁶⁷⁷ Its interest is not limited to solving the perceived free-riding challenge, but rather to more broadly interrogate the interactive enterprise that key actors around the commons are adapting as their governing structure. This analytically driven approach⁶⁷⁸ has helped the scholars of commons to escape political polemic and to contribute to an alternative discussion starting point.

Secondly, one of the key focuses that scholars have used to approach medical knowledge commons governance is the framework of functions of the state in relation to medical data generation, management and dissemination. In contrast to the intellectual property law-based literature which looks at the state as more of an abstract actor regulating from afar, studies of medical knowledge commons have developed a rather novel approach

⁶⁷⁵ See, for example: Peter Lee, 'Centralization, Fragmentation and Replication in the Genomic Data Commons' in Katherine J Strandburg and others (eds), *Governing Medical Knowledge Commons* (CUP 2017) 46-73; Barbara J Evans, 'Genomic Data Commons' in Katherine J Strandburg and others (eds), *Governing Medical Knowledge Commons* (CUP 2017) 74-102.

⁶⁷⁶ *ibid.*

⁶⁷⁷ *ibid.*

⁶⁷⁸ As also acknowledge by the author in Katherine J Strandburg and others (eds), *Governing Medical Knowledge Commons* (CUP 2017).

that looks at the multiple roles that the state has been playing in a variety of medical and genomic data governance structures. In particular, researchers have argued that, instead of looking at the state as purely a regulator or occasional funder of medical knowledge production, there are nine different typical roles that the state can and has been playing in contemporary medical knowledge government practice.⁶⁷⁹ Across the process of biomedical data commons creation and governance, the state can be the creator itself in terms of generating the data, funding others to create such data, the convenor of research activities between the private sector and governmental agencies, a direct collaborator in specific research activities, the endorser of research proposals and plans, the curator of hosting biomedical data repositories, the regulator and enforcer of research ethics and practices, and also the consumer of the research outcomes.⁶⁸⁰ The analytical framework of multifaceted roles that the state could and has been playing in the context of biomedical research are helpful as each dimension can have a distinctive system of governance. Some of those rules may have a clear normative nature such as when the state acts as regulator and enforcer, and some may imply a rather flattened relationship between state and non-state actors, including industry, especially when the state's roles focus more on facilitating and consuming.

Research on the state's multiple roles has also applied this approach when analysing examples of genomic data commons governance structures including those arising during the HGP.⁶⁸¹ By looking at the different roles that the state has played in the HGP's research and data management contexts, commons scholars hope that the

679 Jorge L Contreras, 'Leviathan in the Commons: Biomedical Data and the State' in Katherine J Strandburg and others (eds), *Governing Medical Knowledge Commons* (CUP 2017) 19-46.

680 *ibid* 23-24.

681 *ibid*.

analytical framework can be used to assess the effectiveness of the state's engagement in biomedical research generally in the future.⁶⁸²

5.3.3 Merits and Limitations of the Biomedical Knowledge Commons Approach

The emergence of commons studies of biomedical knowledge is a welcome intellectual attempt that provides an alternative discussion starting point in contrast to the conventional patent-centric literature on biomedical innovation. The commons studies provide an opportunity to open up a space for alternative discussions. By looking at biomedical knowledge as a public good but can also be possibly transitioned into property-based common-resource pools, commons studies adopt a rather flexible approach and focus on analytical rather than normative implications. This is both an advantage and disadvantage in terms of developing a transformative conceptual framework from the perspective of this research.

For the purpose of this research, there are certain elements that the studies on biomedical knowledge commons offer when exploring the possibility of reimagining biomedical innovation's conceptual framework. In particular, unpacking the multiplicity of the state's roles is beneficial and reinforces the notion of communities and actors in the context of driving and shaping biomedical innovation norms. Multiplicity in this context could also be read as another manifestation of fragmentation. Analytically, it helps to demystify the belief that the state acts with an unquestionable authority in the context of regulating biomedical research and governance while its role has instead been much more fragmentary as revealed in commons studies. This is especially relevant when linking to the discussion of scientific communities' role, which has traditionally been

⁶⁸² *ibid.*

perceived as pure but have been contemplated in the course of the commodification of science and knowledge in public institutions. Reimagining an alternative conceptual framework also requires the need to reimagine the roles of key actors, especially the broader innovator community.

In addition, commons studies on biomedical knowledge and genomic data emphasise the importance of self-governing and complexity in governing systems in the context of using, creating and sustaining the commons. Self-governing, as claimed by commons scholars, has been proved to deliver effective innovations without private intellectual property.⁶⁸³ This is a rather high level requirement that goes beyond the remit of the discussion of proprietary boundary settings and rules. Bearing in mind the necessity of access and the benefits of growing and sustaining the commons for future research, commons studies on biomedical knowledge examine how different actors have constructed self-governing rules in contrast to traditional regulation and enforcement through intellectual property norms' formal settings. The complexity of the governing structures – another element closely related to the notion of self-government among actors – is critical because the creation and sustaining of biomedical commons often cannot rely on a single source of authority or one type of strong motivation.⁶⁸⁴ This approach reinforces the earlier discussion in this thesis in terms of co-production between key actors while norms are constantly rewritten and overwritten. In sustaining a co-production process that reimagines biomedical innovation concepts, the notion of self-government as one alternative normative approach is helpful.

⁶⁸³ 'Introduction' in Katherine J Strandburg and others (eds), *Governing Medical Knowledge Commons* (CUP 2017).

⁶⁸⁴ Katherine J Strandburg and others 'Governing Knowledge Commons: An Appeal' in Katherine J Strandburg and others (eds), *Governing Medical Knowledge Commons* (CUP 2017) 421, 426-427.

Nonetheless, commons studies on biomedical knowledge and research also have some limitations for the purpose of this research, some of which are derived from its own advantages, especially relating to its analytically-oriented approach. As mentioned above, the analytically -oriented approach helps commons researchers to focus on revealing the empirical evidence while contributing to a better understanding of knowledge governance. However, this approach is simultaneously short of political ambition and is non-critical in relation to the present entrenchment of the patent-centric paradigm in mainstream biomedical innovation discourse. Empirical and analytical evidence based on commons studies could be hugely beneficial in engaging with such a political process, but using commons studies itself is not sufficient to generate such a systemic transformation.

In addition, while the analytical framework relating to the state's multiple roles is helpful, the approach itself also risks indirectly legitimizing the trend to flattening the role of the state in relation to the private sector, including increasingly influencing private donors and industry-led research initiatives. Flattening the role of the state may undermine the public power to represent unrepresented individuals and communities that are often not visible in the discourse of biomedical knowledge generation, use, and sustainability. The political strength of the state, and its distinctive mandate in biomedical research might be degraded if the focus remains concentrated on the issue of efficiency among all actors in an undifferentiated and flat manner. The absence of a discussion regarding the role and rights of individuals, including those contributing personal data and materials to either genomic research projects or clinical trials, is a considerable shortcoming in commons studies which is also related to its rather apolitical discussion of the role of the state.

Enclosing biomedical research tools and outcomes has been a continual process as discussed above with a variety of legal tools deployed and multiple key actors and their communities involved. Political and economic motives – especially those related to reinforcing neoliberal ideologies – have been woven into the creation, debating and sustaining of new forms of proprietary arrangements for knowledge produced by scientific communities. The path of proprietary protection has presented a new norm, one that is very competitive while triumphing over non-proprietary norms. The phenomenon, however, once again reveals the dialectical potential for a paradigm shift if alternative norms come into play and compete with the prevailing norms. The emergence of commons studies has provided one alternative approach, thereby revealing the plays and interactions of key actors in creating, governing and sustaining key biomedical knowledge and data. While its approach is more analytically focused, it has a number of beneficial elements that could help in pursuing a possible re-imagination of biomedical innovation’s conceptual frameworks, especially in its revelation of the fragmentation of the state’s roles and its analysis of the effectiveness of self-governing in the innovation process.

5.4 Biomedical Knowledge in the Access and Benefit-sharing Framework

5.4.1 Normative Background and Development of the Access and Benefit-Sharing Mechanism

Entirely missing in the conceptualization of intellectual property’s normative impact on knowledge society and innovation, is its compatibility with the diverse cultural and knowledge systems outside of Western traditions.⁶⁸⁵ The specific historical and political

⁶⁸⁵ Philippe Cullet, *Intellectual Property Protection and Sustainable Development* (LexisNexis Butterworths 2005) 288.

conditions that prevailed in the context of the industrial revolution have contributed to the establishment and development of patent law as a highly technical and complex institution. Accordingly, an individualistic and commercially-oriented mode of knowledge production and dissemination through patenting has become the mainstream rationale. By contrast, systems operating in a communally-based mode of production, preservation and use of knowledge, and associated resources are considered as traditional.⁶⁸⁶ The binary construction of ‘traditional’ versus ‘modern’ has been considered as ahistorical and artificial.⁶⁸⁷ As research has observed, the modern pharmaceutical industry was a much more recent phenomenon that emerged in the late 19th century as a result of the systemic isolation of plant-derived therapeutic effects in that era.⁶⁸⁸ With decidedly political intentions, medical knowledge and practice outside of the realm of Western medicines were also labelled quite recently as ‘traditional’, taking the example of Chinese medicines.⁶⁸⁹ The constructed notions of ‘scientific’ versus ‘non-scientific’, ‘traditional’ versus ‘modern’ rather reflect the legacy of empire and colonialism⁶⁹⁰ when medicines from the West were reconfigured as a symbol of superiority. The evolutionary narrative assuming all that was traditional would eventually become modern is also problematic for its omission of ‘traditional’ medical knowledge and practices, such as Chinese medicines and Ayurveda medicines in India, which continue to be being actively used and developed in contemporary society.⁶⁹¹ The

⁶⁸⁶ For instance, ‘traditional knowledge’ as introduced by WIPO to refer to ‘knowledge that is created in a manner that reflects community traditions; it is often intergenerational and created and held collectively’. See the WIPO background note on ‘Intellectual Property and Traditional Medical Knowledge’ <http://www.wipo.int/export/sites/www/tk/en/documents/pdf/background_briefs-e-n6-web.pdf> accessed 1 June 2018.

⁶⁸⁷ Dutfeld, ‘TK Unlimited’ (n 627).

⁶⁸⁸ *ibid* 149.

⁶⁸⁹ *ibid* 148.

⁶⁹⁰ *ibid* 150. See also: Abena Dove Osseo-Asare, ‘Bioprospecting and Resistance: Transforming Poisoned Arrows into Strophanthin Pills in Colonial Gold Coast 1885-1922’ [2008] 21(2) *Social History of Medicine* 269.

⁶⁹¹ For instance, Chinese and Indian medicine systems remain active in healthcare systems in the two

interactional, rather than unidirectional, relation between different knowledge systems concerning medicines are not adequately captured and represented in the current legal framework at the international level.

In relation to the protection of traditional knowledge, the long-time practices of pharmaceutical companies in collecting and misappropriating traditional knowledge and the associated genetic resources from their community holders have triggered huge controversies around bio-prospecting and bio-piracy.⁶⁹² To obtain exclusivity while fitting traditional medicines into the existing patent system, a similar route in terms of the expert-led construction of the meaning of novelty out of traditional medicinal knowledge, the creation of new patent claims and patentability criteria on formulations, ingredient and combinations of traditional medicines have been observed.⁶⁹³ Taking the example of the patenting of Chinese medicines, when substituting for patent protection, it is necessary to segment the medical utilities from Chinese medicine's holistic medical philosophy in order to construct patentability elements recognizable by the existing legal framework.⁶⁹⁴

countries nowadays. Reference can be made to Dutfield, 'TK Unlimited' (n 627) 144, 148.

⁶⁹² Vandana Shiva, 'Bioprospecting as Sophisticated Biopiracy' (2007) 32(2) *Signs: Journal of Women in Culture and Society* 307. Daniel F Robinson, *Confronting Biopiracy: Challenges, Cases and International Debates* (Routledge 2011).

⁶⁹³ For instance, traditional Chinese medicines become patentable based on their formulations, extracted ingredients and combinations of substances in a number of jurisdictions including the US, China and Taiwan. Discussions on the patenting of traditional Chinese medicines can be found in a wide range of literature. See: Xinsheng Wang and Albert Wan-kit Chan, 'Challenges and Patenting Strategies on Chinese Herbal Medicines' [2010] 5(24) *Chin Me* <<https://cmjournal.biomedcentral.com/articles/10.1186/1749-8546-5-24>> accessed 3 May 2018; Yongzhong Qiao and Xuezhong Zhu, 'The Protection of Traditional Chinese Medicines and the Impact on Industry R&D in China' [2009] 6(3) *Journal of International Biotechnology Law* 99; Jerry IH Hsiao, 'Patent Protection on Chinese Herbal Medicine Product Invention in Taiwan' [2007] 10(1) *J World Intellect Prop* 1.

⁶⁹⁴ See the analysis in Xinsheng Wang and Albert Wan-kit Chan, 'Challenges and Patenting Strategies on Chinese Herbal Medicines' [2010] 5(24) *Chin Med* <<https://cmjournal.biomedcentral.com/articles/10.1186/1749-8546-5-24>> accessed 3 May 2018.

In contrast to the fitting-in approach, more systematic efforts to build alternative institutions have been made through the Convention on Biological Diversity (CBD),⁶⁹⁵ which entered into force in 1992. As noted by certain commentators, CBD was intended to provide a *sui generis* protection of traditional knowledge associated with genetic resources and practices significantly distinguishable from the intellectual property system.⁶⁹⁶ Initiated in order to protect biodiversity and genetic resources as the ‘common concern of mankind’,⁶⁹⁷ CBD is subtly framed as focusing on the ‘traditional knowledge’ associated with the use of genetic resources by indigenous and traditional communities and which are relevant to biodiversity protection.⁶⁹⁸

The political context of CBD negotiations have reflected the gaps between South-North interests and expectations, which have been in a state of constant competition.⁶⁹⁹ As a result, it has a strong focus on empowering less powerful entities and marginalized knowledge holders in its final text on traditional knowledge, practice and innovation.⁷⁰⁰ There are several places in CBD where knowledge and innovation are bound together as interdependent elements. The Preamble of CBD recognizes ‘the use of traditional knowledge, innovation and practice’⁷⁰¹ are the main desirable foundations for the equitable benefit sharing demand from the indigenous and local communities.

⁶⁹⁵ The Convention on Biological Diversity (adopted 5 June 1992, entered into force 29 December 1993).

⁶⁹⁶ Cullet, *Intellectual Property Protection and Sustainable Development* (n 633).

⁶⁹⁷ Preamble, Convention on Biological Diversity (Rio, 1992) para 3.

⁶⁹⁸ *ibid* para 9.

⁶⁹⁹ Kabir Bavikatte and Daniel F Robinson, ‘Towards a People’s History of the Law: Biocultural Jurisprudence and the Nagoya Protocol on Access and Benefit Sharing’ [2011] 7(1) *Law, Environment and Development Journal* 35 <<http://www.lead-journal.org/content/11035.pdf>> accessed 6 June 2018.

⁷⁰⁰ This is especially explicit in the CBD Preamble para 9 and Article 8(j) in which ‘the use of traditional knowledge and innovation and practices’ are legitimate basis for the equitable benefit sharing.

⁷⁰¹ Preamble, Convention on Biological Diversity (Rio, 1992) para 9.

Subsequently, Article 8(j) sets forth the explicit provision on in-situ conservation as part of the state obligation, requiring that

(j) Subject to its national legislation, respect, preserve and maintain **knowledge, innovations and practices** [*emphasis added*] of indigenous and local communities embodying traditional lifestyles relevant for the conservation and sustainable use of biological diversity and promote their wider application with the approval and involvement of the holders of such **knowledge, innovations and practices** [*emphasis added*] and encourage the equitable sharing of the benefits arising from the utilization of such **knowledge, innovations and practices** [*emphasis added*].⁷⁰²

Here, ‘knowledge, innovation and practices’ are going together as an integrated and interdependent state upon which the access and benefit sharing mechanism is established. This level of integrity also presents the dynamic relationship between holding knowledge, using and developing it in innovation practices as part of the lifestyle, including those related to medicines. The fundamental conceptual issue here lies in the notion that innovation driven by traditional knowledge locates and operates in a distinctive fashion and does not ‘fit in the western paradigm of science’.⁷⁰³ In contrast to the holistic recognition of the dynamic and interdependence between knowledge and innovation, the patent-centric logic adopts a highly specialised and segmented approach in which it is practically imperative to separate knowledge as intangible from the innovation outcomes as tangible. It is in this sense that the integrity presented in CBD

⁷⁰² Convention on Biological Diversity (Rio, 1992) art 8(j).

⁷⁰³ Philippe Cullet, *Intellectual Property Protection and Sustainable Development* (LexisNexis Butterworths 2005).

bears significant potential to inspire the alternative conceptual framework building idea in this research. Later section 5.4.3 will discuss this point further.

Under CBD, the intended objectives of protecting traditional knowledge are based both on defending such a system from misappropriation by using intellectual property means while providing an enabling legal framework for the knowledge production, diffusion and development by retaining its own features. Challenges remain in terms of achieving the full realization of such protection in law, especially when facing the patent-centric paradigm and ideology concerning innovations. For instance, one of the challenges involves accommodating sufficient disclosure doctrine under patent law while ensuring the access and benefit-sharing mechanisms enshrined in the CBD framework.⁷⁰⁴

5.4.2 Access and Benefit Sharing As a *Sui Generis* Knowledge and Innovation Framework⁷⁰⁵

Revisiting the negotiation history of CBD, the meaning, value and scope of traditional knowledge have been one of the key sticking points. During the Working Group 2009, the multidimensional nature of traditional knowledge and the explicit acknowledgement

⁷⁰⁴ A rich literature has contributed to this discussion, compounded with the normative discussions taking place in both the WIPO and WTO. For instance, under the WTO, a proposal has been made by members to amend TRIPS by incorporating a mandatory disclosure obligation of origin when patent application concerns the uses of genetic resources. Responses in this regard can also be found in national patent laws, such as in Brazil, India, China, Norway, Switzerland and others, where amendments have been introduced to make disclosure of origin a stricter obligation for patent applicants. Research, discussion and analyses on the issue of mandatory disclosure of origin can be found in, for example, WIPO *Technical Study on Patent Disclosure Requirement Related to Genetic Resources and Traditional Knowledge* (2004) <http://www.wipo.int/edocs/pubdocs/en/tk/786/wipo_pub_786.pdf> accessed 10 May 2015; Joshua D. Sarnoff and Carlos M Correa, *Analysis of Options for Implementing Disclosure of Origin Requirements in Intellectual Property Applications* (UNCTAD Report 2004) <http://unctad.org/en/Docs/ditcted200514_en.pdf> accessed 10 May 2015; Jonathan Carr, 'Agreements That Divide: TRIPS vs. CBD and Proposals for Mandatory Disclosure of Source and Origin of Genetic Resources in Patent Applications' (2008) 18(1) *J of Transnational Law & Policy* 131 <http://archive.law.fsu.edu/journals/transnational/vol18_1/carr.pdf> accessed 10 May 2015.

⁷⁰⁵ Part of the analysis and text in this section are adapted from the author's earlier unpublished work.

of the incompatibility of traditional knowledge and the contemporary intellectual property regime were spelled out.⁷⁰⁶ With the intention of preventing biopiracy while returning traditional knowledge, genetic resources and practices to the centre of the debate, CBD proposed a *sui generis* system of knowledge production, sharing and practicing. Article 8(j) of CBD explicitly set out the obligation of the state to ‘respect, preserve and maintain knowledge, innovations and practices of indigenous and local communities embodying traditional lifestyles’.⁷⁰⁷ The holders of such knowledge and practice have to be involved and approve the use of these knowledge and resources, and receive equitable benefits derived from the use accordingly.⁷⁰⁸ Based on this framework, a more detailed instrument based on the framework of access and benefit sharing (ABS) was introduced and entered into force in 2014 as the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization (Nagoya protocol).⁷⁰⁹ Accordingly, it should be obliged of prospective users of traditional knowledge and genetic resources to enter into Prior Informed Consent (PIC) and Mutually Agreed Terms (MAT) with the relevant indigenous and traditional communities. The supposedly traceable and accountable process of access to the concerned knowledge and resources including their use and development, are intended to generate benefits which are then shared with the holders, have been considered as an innovative norm setting working towards building a bio-cultural jurisprudence for the people.⁷¹⁰

⁷⁰⁶ CBD, 2009. *Elements of Sui Generis Systems for The Protection of TK, Innovations and Practices*. Montreal, UNEP/CBD/WG8J/6/5.

⁷⁰⁷ Article 8(j) Convention of Biological Diversity.

⁷⁰⁸ *ibid.*

⁷⁰⁹ Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, Nagoya, 29 October 2010.

⁷¹⁰ Kabir Bavikatte and Daniel F Robinson, ‘Towards a People’s History of the Law: Biocultural Jurisprudence and the Nagoya Protocol on Access and Benefit Sharing’ [2011] 7(1) *Law, Environment*

ABS under the Nagoya protocol has been subject to heated commentaries and critiques. On the one hand, positive comments acknowledge a political opportunity to rebalance the power between traditional knowledge holders and the users while moving away from the realm of the conventional intellectual property regime to a framework governing the practice of knowledge use and innovation.⁷¹¹ Some have pointed out the outstanding limitations of ABS under the CBD and Nagoya protocols, especially its ambiguity in terms of the exact meaning and interpretation of traditional knowledge and the missing wording in Nagoya protocol compared with the complete ‘knowledge, innovation and practice’ phrasing in CBD Article 8(j).⁷¹² As noted, the Preamble of the Nagoya protocol recalled Article 8(j) of CBD only in relation to ‘traditional knowledge associated with genetic resources’,⁷¹³ while Article 8(j) of CBD takes a more holistic approach, including concerns regarding ‘knowledge, innovation and practices’. The missing words of ‘innovation and practices’ in the Nagoya protocol have been noted as ‘implicitly downplay[ing] the creativity and dynamism’ of indigenous people and traditional communities given that they are also active innovators.⁷¹⁴ Following this line, CBD’s political background as a North-South mode of bargaining might have also contributed to the rather static view of innovation in the Nagoya protocol. Its preamble refers to the recognition of the need to contribute to the development of innovation capacity in developing countries in the context of implementing ABS and might therefore imply an assumption of a lack of innovation capacities in the first place. It is true that while innovation capacity is understood and measured within the parameters of the current

and Development Journal 35 <<http://www.lead-journal.org/content/11035.pdf>> accessed 6 June 2018.

⁷¹¹ *ibid.*

⁷¹² Dutfield, ‘TK Unlimited’ (n 627).

⁷¹³ Preamble, Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization, Nagoya, 29 October 2010.

⁷¹⁴ Dutfield, ‘TK Unlimited’ (n 627).

existing world order, innovation and creativity that happens outside of the prevailing regime also needs to be recognised.

In addition, the success of ABS under CBD and the Nagoya protocol could, potentially, be limited and challenged when there are competing ABS norms proposed in a partial adaptation of the current intellectual property system under the World Intellectual Property Organization (WIPO) process.⁷¹⁵ The extent to which national level legislation and governing mechanisms will be able to compromise the CBD obligations is still to be observed.

Notably, ABS mechanism in CBD and its Nagoya protocol has triggered ongoing normative discussions in some international institutions such as WHO to promote research and development in a defined context of pathogen sharing at a global level.⁷¹⁶ Based on the Pandemic Influenza Preparedness Framework (PIP Framework) established in 2011, as part to support the Global Influenza Surveillance and Response System (GISRS), WHO acts as a reservoir and incubator to implement an *ad hoc* mechanism of access and benefit sharing concerning flu virus, vaccine and antiviral medicine development between the WHO member states, WHO and R&D institutions.⁷¹⁷ The PIP framework implements upon the Standards Material Transfer Agreements (SMTA) in which a number of benefit sharing options, including for

⁷¹⁵ Graham Dutfield, 'Traditional Knowledge, Intellectual Property and Pharmaceutical Innovation: What's Left to Discuss?' in Matthew David and Debora Halbert (eds), *The SAGE Handbook of Intellectual Property* (SAGE 2015) 649, 661.

⁷¹⁶ World Health Organization (WHO), 'Implementation of Nagoya Protocol and Pathogen Sharing: Public Health Implications' (WHO Secretariat, 2016) <http://www.who.int/influenza/pip/2016-review/NagoyaStudyAdvanceCopy_full.pdf> accessed 5 August 2018. See also WHO 'Fact Sheet: Nagoya Protocol and Public Health' (20 March 2018) <http://www.who.int/influenza/pip/NagoyaProtocolandPH_EN_20Mar2018.pdf> accessed 5 August 2018. The R&D institutions can be a company, a research institute or other types of entities.

⁷¹⁷ *ibid.*

instance technology transfer are proposed and become legally binding between WHO and the private R&D entities who have access to the virus that member states share and reserve via WHO.⁷¹⁸ SMTA approach, however, has not engaged more directly with the potential hindrance of intellectual property rights held by the private developers when they entered into an agreement with WHO. The adoption of a neutral position on whether pathogen and the associated technologies entering into PIP framework can be subject to patent protection may potentially limit the outreach of this approach beyond the defined area for the health emergency preparedness. The discussion on the future impact of Nagoya protocol on the global pathogen sharing mechanism also does not confront more specifically on the conceptual conflict between the patent centric business model and the global access and benefit sharing mechanism. In fact, the possibility of seeking joint ownership of intellectual property, including patent, under the current Nagoya protocol and the WHO discussion⁷¹⁹ may once again omit the opportunity to initiate a more fundamental debate challenging the prevailing order of patent centric paradigm. A patent neutral position allows the parties to leave aside the enquiries on the internal problems of how particular patents are produced via legal fictions and whether they represent and bring robust advancements in science and technology. In this sense, while ABS enshrined under CBD spirit may potentially open up the global framework building to sidestep patent centric ideology, further steps need to be taken by WHO to realise such potential, especially to link with its human rights mandate related to the right to health and the right to extend the benefit of medical knowledge to all. Section 5.5 will discuss

⁷¹⁸ SMAT2 and the benefit sharing options, WHO, < <http://www.who.int/influenza/pip/smta2/en/>> accessed 20 July 2018.

⁷¹⁹ WHO, Implementation of Nagoya Protocol and Pathogen Sharing (n 716).

this aspect further in the context of human rights framework related to biomedical knowledge.

5.4.3 Significance of the ABS Framework for the Building of an Alternative Conceptual Framework

Initiated against a particular historical and political background, the establishment of the ABS system under CBD and its Nagoya protocol could be seen as a direct challenge and intended departure from the intellectual property-centric narrative of knowledge, development and innovation. As an innovative design in itself, the success of ABS in altering the power asymmetry in innovation debates has faced certain challenges. In particular, while ABS under CBD created a new legal institution that does not rely on patent-defined property and obligations, the more direct role of rulemaking and governing by indigenous people themselves, rather than only their representatives, on knowledge, creativity and innovation has been much needed.⁷²⁰

In the context of this research, ABS under CBD and its Nagoya protocol has provided at least two levels of inspiration for the building of an alternative conceptual framework. Firstly, the CBD process has achieved the recognition of the integrity and connectedness between knowledge, genetic resources and the knowledge creators, users and innovators' way of life. CBD process has helped to return to the connectivity between the human and nature when discussing the value of biodiversity and the questions of why, how, and for whom knowledge is obtained and used. It is particularly helpful to use this recognition to address problems with the segregation of the technical aspects of medicine

⁷²⁰ Dutfield, 'Traditional Knowledge, Intellectual Property and Pharmaceutical Innovation' (n 715).

in terms of its broader social, behavioural and systematic contexts, as discussed in an earlier section 5.2 of this chapter.

Secondly, ABS under CBD demonstrated a possibility of establishing an alternative normative institution outside of the intellectual property-based model. Law is invited to guarantee the protection of the rights of the knowledge holders, in contrast to the mechanism invoked under the patent-centric regime in which the actual creators of knowledge are often silenced through licensing practices. The remaining moral rights of the individual inventors as existing in patent documents⁷²¹ do not translate into their political standing in terms of reclaiming the polity of creativity based on sharing. There are also notable challenges and limitations with ABS as has been established now and as noted above, especially in relation to the need to improve indigenous people's direct participation, rulemaking and decision making, in order to mitigate the political compromises that might take place in the process of negotiating PIC and MAT on behalf of the knowledge holders.⁷²² This is also relevant to the discussion of an alternative framework in this research. The problem with representation in the patent-making process is that it has effectively diluted the role and political spaces available to the broader innovation community. Exploring an alternative conceptual framework would thus require a reengagement with the public and creative community outside of patent holders, and the exploration of self-regulation and governance. These elements will be further discussed in the next chapter.

⁷²¹ For a historical review of the preservation of inventors' moral rights in patent documents, see Graham Dutfield, 'Collective Invention and Patent Law Individualism, 1877-2012; Or, the Curious Persistence of Inventor's Moral Right' in Stathis Arapostathis and Graham Dutfield (eds), *Knowledge Management and Intellectual Property: Concepts, Actors and Practices* (Edward Elgar 2013) 109.

⁷²² Dutfield, 'TK Unlimited' (n 627).

Third, it is worth noting that the concept of ABS and the normative link with Nagoya protocol have been adopted in the ongoing initiative of WHO in prompting global pathogen sharing mechanism for the purpose of emergency preparedness and the related R&D under its PIP framework. Conceptually, it opens up the possibility to seek a bold global framework that sidestep patent centric logic. Yet, there are noticeable limitations with discussion as noted above. This, however, requires further integration of the ABS concept with WHO's human rights mandate in a broader sense. The next section will discuss this point further.

5.5 Biomedical Knowledge under the Human Rights Lens

5.5.1 Right to Health and Access to Medicines

The concepts of both health and medicine are integrated in the international human rights law framework. The right to the highest attainable standards of health under Article 12 of the International Covenant on Economic, Social and Cultural Rights (ICESCR) sets out the core obligations for states to respect, protect and fulfil the rights to be enjoyed by everyone on a non-discriminatory basis.⁷²³ The Committee of Economic, Social and Cultural Rights (CESCR) who monitors the implementation of the treaty, interprets in

⁷²³ International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 03 January 1976) UN General Assembly Resolution 2200 A(XXI) (ICESCR) art 12. This states that:

1. The States Parties to the present Covenant recognize the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:
 - (a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;
 - (b) The improvement of all aspects of environmental and industrial hygiene;
 - (c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;
 - (d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

General Comment No. 14 on the right to health under ICESCR.⁷²⁴ As the authoritative interpretation of the Covenant, General Comment 14, however, contains some shortcomings from the perspective of this research. Firstly, it affirms that to provide ‘essential drugs’ is part of the core obligations of the state in regard to the right to health, but narrowly defines the scope of medicines as those under the WHO Action Programme on Essential Drugs only.⁷²⁵ This was later lifted. A Human Rights Council resolution adopted in 2009 stresses ‘the responsibility of States to ensure access to **all**, without discrimination, of medicines – in particular essential medicines – that are affordable, safe, effective and of good quality’.⁷²⁶ The confirmation of ‘all’ medicines, rather than only those under the WHO essential medicines list, are within the remit of the right to health discussion is a significant clarification. Secondly, General Comment 14 does not provide explicit discussions regarding the intersection between intellectual property and the realization of the right to health, nor does it analyse the elements of knowledge and innovation in the realisation of the human right to health. Knowledge is only footnoted under General Comment 14 in the context of discussing the right to health of indigenous people.⁷²⁷ The extent to which the availability, accessibility and dissemination of medical knowledge are essential to the realization of the right to health is not clearly addressed.

Nonetheless, following the expansion of the intellectual property regime through the TRIPS agreement, the human rights obligation of the state to ensure access to all

⁷²⁴ CESCR, General Comment No. 14, ‘The right to the highest attainable standard of health (article 12 of the International Covenant on Economic, Social and Cultural Rights)’ (2000) E/C.12/2000/4.

⁷²⁵ *ibid.* Para 12(a), 43(d).

⁷²⁶ Human Rights Council, Res 12/24, ‘Access to medicine in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health’ (12 October 2009) A/HRC/RES/12/24, Para 2.

⁷²⁷ CESCR General Comment 14, Note 19 concerns Indigenous People under Paragraph 27.

medicines on a non-discriminatory and equal basis has faced a dilemma when the status of availability and accessibility of medicines can be determined by private right of patents. The conceptual dilemma between human rights law and intellectual property law systems in this regard is a long-standing scholarly enquiry. As research has pointed out, the two systems have evolved separately and independently⁷²⁸ with distinctive foundational principles and legal cultures.⁷²⁹ Although a systemic comparison is not within the scope of this thesis, research on the relationship of the two systems has nonetheless provided a valuable framework of discussion.

The tension between the two systems on the issue of the right to health has been presented typically as embodying a developing and developed country divide.⁷³⁰ In this context, the United Nations' human rights bodies have issued a number of instruments, analysing and advising the intersection between human rights and intellectual property, especially in the context of trade agreements such as TRIPS.⁷³¹ The UN Sub-Commission on the Promotion and Protection of Human Rights specifically pointed out in its 2000 resolution the conflicts between the two systems, and criticised the TRIPS agreement as 'not adequately reflect[ing] the fundamental nature and indivisibility of all human rights, including the right of everyone to enjoy the benefits of scientific progress and its applications, the right to health, the right to food, and the right to self-determination'.⁷³² Subsequently, the Committee on Economic, Social and Cultural

⁷²⁸ Philippe Cullet, 'Human Rights and Intellectual Property Protection in the TRIPS Era' [2007] 29(2) *Human Rights Quarterly* 403,404, 412-413.

⁷²⁹ Aurora Plomer, 'The Human Rights Paradox: Rights of Access to Science and Intellectual Property Rights' [2013] 35(1) *Human Rights Quarterly* 143 143, 156-160.

⁷³⁰ *ibid* 146.

⁷³¹ Philippe Cullet, 'Human Rights and Intellectual Property Protection in the TRIPS Era' [2007] 29(2) *Human Rights Quarterly* 403, 413-414. David Weissbrodt and Kell Schoff, 'Human Rights Approach to Intellectual Property Protection: The Genesis and Application of Sub-Commission Resolution 2000/7' [2003] 5 *Minn Intell Prop Rev* 1; Plomer, 'The Human Rights Paradox' (n 729) 146.

⁷³² UNCHR Res. 2000/7, Sub-Comm'n on the Hum Rts, 'Intellectual Property Rights and Human Rights' (2000) UN Doc E/CN.4/Sub.2/Res/2000/7.

Rights (ESCR Committee) in a statement in 2001 argued that intellectual property rights that undermine the state's ability to comply with its core human rights obligations concerning the right to health would be inconsistent with the binding obligation of the state.⁷³³ In a further report in 2001, the ESCR Committee and the Sub-Commission pointed out the inequality in knowledge between developing and developed countries, and the lack of guidance and clarity under the TRIPS framework in terms of balancing the rights and interests of all actors concerned.⁷³⁴

At the height of the debates on the impact of the expansion of the global intellectual property regime on human rights – especially the right to health – normative developments under the WTO were also happening simultaneously. In 2001, WTO members adopted the Doha Declaration on the TRIPS Agreement and Public Health (Doha Declaration) affirming that the implementation of intellectual property should not hinder the right to access to medicines for all.⁷³⁵ It also affirms the right of WTO members to freely determine the grounds of using compulsory licenses in response to their needs.⁷³⁶ As a follow up implementation, a permanent amendment of the TRIPS Agreement was decided in 2005 and entered into force in 2017, establishing a special compulsory license mechanism for the export of generic medicines.⁷³⁷

⁷³³ UNESCOR Comm on Econ, Soc & Cult Rts, 'Report on the Twenty-Fifth, Twenty-Sixth and Twenty-Seventh Sessions: Statement by the Committee on Economic, Social and Cultural Rights on Human Rights and Intellectual Property' (2001) UN Doc E/2002/22-E/C.12/2001/17.

⁷³⁴ Cullet, *Human Rights and Intellectual Property Protection in the TRIPS Era* (n 731) 415; Plomer, 'The Human Rights Paradox' (n 729) 146; UN ESCOR, Comm'n on Hum Rts, 'The Impact of the Agreement on Trade Related Aspects of Intellectual Property Rights on Human Rights' (2001) UN Doc E/CN.4/Sub.2/2001/13.

⁷³⁵ Declaration on TRIPS Agreement and Public Health (adopted 14 November 2001) WT/MIN(01)/DEC/2, Para 4.

⁷³⁶ *ibid.* Para 5.b.

⁷³⁷ WTO General Council, Amendment of the TRIPS Agreement (Article 31.bis) (decided on 6 December 2005) WT/L/641.

As a result of a hard fought battle involving developing countries, civil society organizations, and public health advocates, the Doha Declaration has been considered as a ‘turning point in political and legal relations at WTO’.⁷³⁸ It is, however, worth noting a few issues and limitations with the Doha Declaration and its follow-up implementation under the WTO framework for the purpose of this research. Firstly, although the intersection of intellectual property and access to medicines is acknowledged, the Doha Declaration does not explicitly use human rights language in its text. Instead of engaging the right to health directly, it refers to governments’ right to protect ‘public health’ and promote ‘access to medicines for all’.⁷³⁹ Certainly, from the point of interpretation, the meaning of ‘access to medicines for all’ under the Doha Declaration is commensurate with the content of the right to health in the human rights framework. In fact, a number of human rights instruments issued by UN human rights bodies have quoted explicitly the Doha Declaration in the context of the realization of access to medicines as an integral and fundamental human right.⁷⁴⁰ However, lacking an explicit rights-based approach leaves an open question regarding the extent to which TRIPS has adopted a human rights perspective more substantively or whether it has merely used the Doha process as a public engagement showcase.

Secondly, the legal mechanism derived from the Doha Declaration under the TRIPS framework is limited. The amendment to TRIPS introduces a waiver to Article 31 of

⁷³⁸ Frederick M Abbott, ‘The Doha Declaration on the TRIPS Agreement and Public Health: Lighting a Dark Corner at the WTO’ [2002]5 *International Journal of Economic Law* 469; Ellen t’ Hoen, ‘TRIPS, Pharmaceutical Patents and Access to Essential Medicines: A Long Way from Seattle to Doha’ [2002]3(1) *Chicago Journal of International Law* 27 <<https://chicagounbound.uchicago.edu/cjil/vol3/iss1/6/>> accessed 1 November 2017.

⁷³⁹ Doha Declaration.

⁷⁴⁰ For instance, Human Rights Council. Resolution 12/24, ‘Access to medicine in the context of the right of everyone to the enjoyment of the highest attainable standard of physical and mental health’ (2009) A/HRC/RES/12/24. Para 4 and 5.

TRIPS concerning a special type of compulsory license allowing countries to export medicines produced under a compulsory license on request from another country, subject to a notification procedure.⁷⁴¹ However, the effectiveness of the mechanism established by this amendment has been critiqued and questioned.⁷⁴² Thirdly, the missing explicit use of the rights-based approach in the Doha Declaration has limited its reach in terms of reconceptualising biomedical innovation more directly. In particular, its unsuspecting recognition that ‘intellectual property protection is important for the development of new medicines’⁷⁴³ might have fenced in the parameters of the discussion regarding the issue of price without challenging the underlying scenario of TRIPS. The less critical tone regarding the role of intellectual property in drug development under the Doha Declaration leaves it an uncertain tool in the context of discussing an alternative non-patent-centric biomedical innovation framework. Nonetheless, using the Doha Declaration as a trigger to discuss TRIPS flexibilities as a whole still allows the inclusion of issues such as research and experimental use exceptions and reforms to the existing patent system.

Following the invoking of the Doha Declaration to support the legitimacy of prioritizing the right to health in the face of intellectual property, efforts at the UN level have continued primarily via non-binding instruments. Following the report of the UN Special

⁷⁴¹ Products produced under compulsory license issued according to Article 31 of TRIPS need to be used in a predominately domestic market, which is challenging for countries who do not have the manufacturing capacity to make a concerned medicine and thereby meaningfully use a compulsory license to facilitate access to medicines. Article 31 *bis* of TRIPS as amended enables countries to produce solely for export after fulfilling a number of conditions.

⁷⁴² Duncan Matthews, ‘WTO Decision on Implementation of Paragraph 6 of the Doha Declaration on the TRIPS Agreement and Public Health: A Solution to the Access to Essential Medicines Problem?’ [2004] 7(1) *Journal of International Economic Law* 73; Graham Dutfield, ‘Delivering Drugs to the Poor: Will the TRIPS Amendment Help?’ [2008] 34 *American Journal of Law and Medicine* 107 <<http://journals.sagepub.com/doi/pdf/10.1177/009885880803400202>> accessed 20 June 2018.

⁷⁴³ Doha Declaration, para 3.

Rapporteur on the right to health,⁷⁴⁴ the Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines was published in 2008.⁷⁴⁵ The Guidelines call for pharmaceutical companies to adopt non-exclusive licensing practices and refrain from applying for patent on trivial changes of old medicines in low-middle-income countries as key measures to promote access to medicines.⁷⁴⁶ On research and development, the Guidelines stress that ‘the right to the highest attainable standard of health not only requires that existing medicines are accessible, but also that much-needed new medicines are developed as soon as possible.’⁷⁴⁷ It ascribes further priority to neglected diseases, and calls for companies to fulfil certain public commitments and contribute to the improvement of research and development on neglected diseases which market-based mechanisms may not deliver.⁷⁴⁸ The Guidelines, however, remain ambiguous on the possible alternatives to the intellectual property-based framework in the context of research and development. In 2009, the Human Rights Council adopted a resolution further illustrating the role of access to medicines in the context of the right to health.⁷⁴⁹ The resolution has rightly clarified the scope of access to medicines as inclusive of all medicines.⁷⁵⁰ It also explicitly referred to the Doha Declaration in terms of the use of TRIPS flexibilities.⁷⁵¹ However, it simultaneously states ‘that intellectual property protection is important for the development of new medicines, as well as the concerns about its effects on prices.’⁷⁵² Taking an identical line as the Doha Declaration

⁷⁴⁴ UNGA, ‘Report of the Special Rapporteur on the right of everyone to the enjoyment of the highest attainable standard of physical and mental health’ (11 August 2008) A/63/263. Para 3 of the report affirms that the provision of essential medicines is the state’s immediate core obligation.

⁷⁴⁵ *ibid.* Annex: Human Rights Guidelines for Pharmaceutical Companies in Relation to Access to Medicines.

⁷⁴⁶ *ibid.*

⁷⁴⁷ *ibid.*

⁷⁴⁸ *ibid.*

⁷⁴⁹ Human Rights Council, (2009) A/HRC/RES/12/24.

⁷⁵⁰ *ibid.* Para 2.

⁷⁵¹ *ibid.* Para 4.

⁷⁵² *ibid.* Para 5. It is identical to the wording used by the Doha Declaration paragraph 3.

in this regard, the Human Rights Council resolution here missed an opportunity to provide an alternative framework of discussion on innovation beyond what the TRIPS framework had previously defined.

A recent effort is evident in the process of the UN Secretary General's High Level Panel on Access to Medicines (the High Level Panel), and its final report published in 2016.⁷⁵³ As a result of a global consultation process, the final report of the High Level Panel reiterated the view of the conflict and the incoherence between the intellectual property system and the human right to health.⁷⁵⁴ In addition to analysis and recommendations concerning barriers to access, the report contains lengthy discussions concerning innovation. It explicitly recalled the mismatch between the intellectual property-based and profit-driven model of innovation, and the need to look for alternatives. The report discusses possible alternative approaches to innovation in three main ways including 1) open model of innovation for drug development (including licensing model),⁷⁵⁵ 2) alternative financing mechanisms for innovation,⁷⁵⁶ and 3) ensuring patent is only granted to 'genuine innovation'.⁷⁵⁷ The report notes that patent is often sidestepped in open models of innovation,⁷⁵⁸ but does not go deeper to discuss how an alternative conceptual framework might be established accordingly. Being a policy report with no binding force, the report serves a primarily political function and has been used by public

⁷⁵³ UN Secretary General's High Level Panel on Access to Medicines, Final Report 'Promoting Innovation and Access to Health Technologies' (14 September 2016) <<http://www.unsgaccessmeds.org/final-report/>> accessed 8 July 2018.

⁷⁵⁴ *ibid* 16, 20, 21.

⁷⁵⁵ *ibid* 26, 9-10, 27.

⁷⁵⁶ *ibid* 29-32.

⁷⁵⁷ *ibid* 8, 9, 27.

⁷⁵⁸ UN High Level Panel report (n 753).

health advocates and developing countries to push for further policy processes at the WHO, the Human Rights Council and the WTO.⁷⁵⁹

In 2017, in light of the Sustainable Development Goals 2030 (SDG), the Human Rights Council adopted another resolution on the right to health in the context of SDG,⁷⁶⁰ calling on states to fully implement SDG as a step towards the full realization of the right to health. It cited Target 3.d of SDG Goal 3⁷⁶¹ relating directly to intellectual property:

3.b Support the research and development of vaccines and medicines for the communicable and non-communicable diseases that primarily affect developing countries, provide access to affordable essential medicines and vaccines, in accordance with the Doha Declaration on the TRIPS Agreement and Public Health, which affirms the right of developing countries to use to the full the provisions in the Agreement on Trade-Related Aspects of Intellectual Property Rights regarding flexibilities to protect public health, and, in particular, provide access to medicines for all.⁷⁶²

The significance of the Doha Declaration is again highlighted, particularly in the context of access to medicines for all and the use of TRIPS flexibilities. The point of research and development is included but qualified as ‘in accordance with’ the Doha Declaration,

⁷⁵⁹ Catherine Saez, ‘UN High-Level Panel on Access to Medicines Issues “Landmark” Report’ (IP-Watch, 14 September 2016) <<http://www.ip-watch.org/2016/09/14/un-high-level-panel-on-access-to-medicines-issues-landmark-report/>> accessed 8 August 2017.

⁷⁶⁰ UN General Assembly, Human Rights Council, Res. 35/ ‘The right of everyone to the enjoyment of the highest attainable standard of physical and mental health in the implementation of the 2030 Agenda for Sustainable Development’ (21 June 2017) A/HRC/35/L.18/Rev.1.

⁷⁶¹ UN General Assembly, Resolution 70/1 ‘Transforming our world: the 2030 Agenda for Sustainable Development’ (21 October 2015) A/RES/70/1.

⁷⁶² WHO, SDG 3: Ensure healthy lives and promote wellbeing for all at all age <<http://www.who.int/sdg/targets/en/>> accessed 9 November 2017.

making it unclear whether an alternative approach is possible beyond a TRIPS-defined arena.

The above-mentioned non-binding instruments adopted by the human rights bodies have taken general note of the inadequacy of using the current intellectual property system to generate the innovation needed in the context of the realization of the right to health for all. However, there are noticeable limitations to their approach. Although general terms have been proposed such as ‘open models of innovation’, it remains unclear how substantively these might directly confront the patent-centric ideological and operational paradigm, re-examine the meaning of medical knowledge, and redefine the core obligations of states and other actors. Arguably, using the political power of TRIPS flexibilities might ironically and indirectly lock the debate into the intellectual property-defined framework when it comes to innovation. On the other hand, the forum of human rights law provides an important opportunity to rethink innovation and knowledge more systematically, thereby moving beyond the TRIPS-defined framework. It is in this sense that the discussions in the context of the right to health need to be related to other rights under the human rights framework.

5.5.2 The Right to Biomedical Science and Knowledge

The nature of indivisibility and interdependency between substantive human rights makes it possible to link the right to health with the other rights enshrined under the human rights law framework. This section examines whether the right to participate in and access to the benefits of scientific progress and their application under the international human rights law framework, and the WHO’s notion of access to medical knowledge in realising the right to health have provided further inspiration for building an alternative conceptual framework for biomedical innovation.

5.5.2.1 International Human Rights Law

The key provisions related to science and knowledge often cite Article 27 of the Universal Declaration on Human Rights (UDHR),⁷⁶³ and the subsequent provisions under Article 15 of ICESCR.⁷⁶⁴ Both articles contain the positive rights of ‘everyone’ to participate in cultural life, enjoy and share in the benefits of scientific progress and its applications, and enjoy the protection of the moral and material interests resulting from intellectual contributions.⁷⁶⁵ Scholars consider that Article 27 of the UDHR could be the first to introduce the concept of benefit ‘sharing’ in the context of the right to science and culture.⁷⁶⁶ Article 15 of ICESCR also sets forth the state’s obligation to respect freedom in research and creative activities,⁷⁶⁷ and the obligation to ensure the conservation, development and diffusion of science and culture.⁷⁶⁸

Article 15.1(c) of ICESCR, and Article 27.2 of UDHR in particular, have led to the question of the extent to which there is a human right to intellectual property.⁷⁶⁹ However, research tracing the drafting history have observed the diverse motivations and rationales of negotiating countries,⁷⁷⁰ and that the current provisions are rather the result of a process of political compromise between different philosophical and

⁷⁶³ Universal Declaration of Human Rights (adopted 10 December 1948 UNGA Res 217 A (III) (UDHR) art 27.

⁷⁶⁴ International Covenant on Economic, Social and Cultural Rights (adopted 16 December 1966, entered into force 3 January 1976) UN General Assembly Resolution 2200A (XXI) (ICESCR) art 15.

⁷⁶⁵ *ibid* art 15.1 (a) (b) (c).

⁷⁶⁶ Elisa Morgera, ‘Fair and Equitable Benefit-sharing at the Cross-Roads of the Human Rights to Science and International Biodiversity Law’ [2015]4 *Laws* 803, 804 <doi:10.3390/laws4040803> accessed 9 July 2018. The author noted that Article 27 of UDHR is worded as the right of everyone to ‘share in scientific advancement and its benefits’, different from the wording of Article 15.1(b) of ICESCR which stresses the sharing of the ‘benefit’ of scientific progress.

⁷⁶⁷ *ibid* art 15.3.

⁷⁶⁸ *ibid* art 15.2.

⁷⁶⁹ Some of the literature argues that there is a human right to intellectual property because of Article 15.1(c) of ICESCR. See, for instance, Robert L. Ostergard Jr, ‘Intellectual Property: A Universal Human Rights?’ [1999] 21 *HRQ* 156.

⁷⁷⁰ Plomer, ‘The Human Rights Paradox’ (n 729) 175.

ideological standpoints.⁷⁷¹ The drafting history and the intention of the provisions provide no support to the view that intellectual property is a fundamental human right under the ICESCR and UDHR.⁷⁷²

Unlike the right to health on which CESCR has issued one General Comment covering the whole of Article 12, the treaty interpretation of Article 15 has yet to be completed. Two General Comments have been issued on Article 15.1(a) and (c) respectively,⁷⁷³ with the third one on Article 15.1 (b) is in preparation.⁷⁷⁴ Scholars have also been discussing whether the right to science under the human rights legal framework exists,⁷⁷⁵ and the concept and meaning of the right to science at large.⁷⁷⁶ From 2011 onwards, a number of initiatives have emerged that aspire to clarify the outstanding conceptual issues with the right to science and knowledge in the context of the discussion on cultural rights. In particular, the UN Special Rapporteur in the field of cultural rights in her report proposed four primary dimensions concerning the right to science and knowledge under Article 15 of ICESCR:⁷⁷⁷

- 1) The right to access the benefits of science by everyone without discrimination,

⁷⁷¹ Aurora Plomer, *Patent, Human Rights and Access to Science* (Edward Elgar 2015) 53.

⁷⁷² Plomer, 'The Human Rights Paradox' (n 729) 175; Cullet, *Human Rights and Intellectual Property Protection in the TRIPS Era* (n731) 409.

⁷⁷³ CESCR, General Comment No. 17, 'The right of everyone to benefit from the protection of the moral and material interests resulting from any scientific, literary or artistic production of which he or she is the author' (2006) E/C.12/GC/17; CESCR, General Comment No. 21, 'Right of everyone to take part in cultural life' (2009) E/C.12/GC/21.

⁷⁷⁴ At the time when this thesis was being completed, CESCR was in preparation for a draft general comment on the right to enjoy the benefit from scientific progress and its application under Article 15.1 (b) and other provisions of Article 15. A general discussion is to be organized on 9 October 2018.

⁷⁷⁵ Mikel Mancisidor, 'Is There Such a Thing as a Human Rights to Science in International Law?' [2015] 4 *European Society of International Law* 1 <<http://www.esil-sedi.eu/node/896>> accessed 15 August 2018.

⁷⁷⁶ Audrey R. Chapman, 'Towards an Understanding of the Right to Enjoy the Benefits of Scientific Progress and its Application' [2009] 8 *Journal of Human Rights* 1.

⁷⁷⁷ Report of the Special Rapporteur in the Field of Cultural Rights: The right to enjoy the benefits of scientific progress and its application (2012) UN Doc A/HRC/20/26.

- 2) The opportunity for all to contribute to scientific research,
- 3) The obligation to protect all persons against negative consequences of scientific research or its application on their food, health, security and environment,
- 4) The obligation to ensure that priorities for scientific research focus on key issues for the most vulnerable.⁷⁷⁸

The Special Rapporteur recommended the CESCR work out a new general comment to add clarity to the pertinent questions regarding the meaning, scope and value of Article 15.1(b), the overall meaning of Article 15 and, more generally, the relationship between science and human rights.⁷⁷⁹ CESCR agreed and started working toward a general comment from 2013 onwards,⁷⁸⁰ which is still ongoing.

Despite the ongoing process of developing a more authoritative interpretation of Article 15, research has already pointed out a number of conceptual issues with the current ICESCR language. Research has underlined that there has been inconsistencies concerning the use of certain terms in the Special Rapporteur's report as well as differences between the UDHR and ICESCR.⁷⁸¹ For instance, Article 27 states that everyone has the right to 'share in scientific advancement and its benefit',⁷⁸² while Article 15 suggests that the right is to 'enjoy the benefit of the scientific progress and its application'.⁷⁸³ The Special Rapporteur's report also used different words to express the meaning of 'right' in this context.⁷⁸⁴ Research has also criticised the lack of a unified

⁷⁷⁸ *ibid.*, para 1, 25, 30-43. See also Elisa Morgera, 'Fair and Equitable Benefit-sharing at the Cross-Roads of the Human Rights to Science and International Biodiversity Law' [2015]4 *Laws* 803, 804 <doi:10.3390/laws4040803> accessed 9 July 2018.

⁷⁷⁹ Special Rapporteur in cultural rights report.

⁷⁸⁰ Elisa Morgera, 'Fair and Equitable Benefit-sharing at the Cross-Roads of the Human Rights to Science and International Biodiversity Law' [2015]4 *Laws* 803, 804, 807 <doi:10.3390/laws4040803> accessed 9 July 2018.

⁷⁸¹ *ibid.*

⁷⁸² UDHR Article 27.1.

⁷⁸³ ICESCR Article 15.1(b).

⁷⁸⁴ Morgera (n 780) 811.

theory or ideology regarding the rights herein and the lack of a clear normative guidance provided by CESCR.⁷⁸⁵ In this regard, scholars propose adopting the human capabilities conceptual framework, in contrast to the concept of well-being, noting the essential role and contribution that sharing in and benefiting from science and knowledge have made in promoting overall human capabilities.⁷⁸⁶

Given the ongoing normative development under ICESCR, the right to science and knowledge is loosely embedded in the category of cultural rights. The two existing and one forthcoming General Comments only deal with section 1 of Article 15, while the other sections 2-4 have not been interpreted in full. These three subsections, however, explicitly refer to the state parties' obligations regarding realising the rights contained in Article 15. Although General Comments 17 and 21 have respectively illustrated state parties' obligations in their own contexts, it is unclear how these can be more organically linked to the obligations stipulated under Article 15.2-15.4. In particular, Article 15.2 asks the state to take steps for 'the conservation, the development and the diffusion of science and culture',⁷⁸⁷ indicating the importance of open knowledge and science as an integral part of the realization of the rights contained in Article 15. It remains ambiguous regarding what this obligation exactly entails, especially in terms of ensuring the diffusion of science and knowledge. The fact that the CESCR spent three General Comments to interpret three coherent and interdependent sub-sections of one section of Article 15 has also triggered criticism as they should be treated systematically rather than separately.⁷⁸⁸

⁷⁸⁵ Plomer, *Patent, Human Rights and Access to Science* (n 771) 164.

⁷⁸⁶ *ibid* 36-42.

⁷⁸⁷ ICESCR Article 15.2.

⁷⁸⁸ Cullet (n 731) 424.

It is also questionable whether the normative development of Article 15 has provided a clear pathway out of the intellectual property- defined framework of thinking. Indeed, scholars have critiqued the CESCR's U-turn on General Comment 17 in relation to the protection of traditional knowledge.⁷⁸⁹ It has been pointed out that with the entire first part of General Comment 17 makes a great effort to distinguish intellectual property from human rights under Article 15, while CESCR surprisingly turned to intellectual property when it came to the protection of traditional knowledge.⁷⁹⁰ To the contrary, the debate on the protection of traditional knowledge in the context of CBD negotiations, as Section 5.4 has mentioned, argues precisely that the current intellectual property regime does not fit the purpose of the protection and development of traditional knowledge.

Interestingly, the notion of 'benefit' from and 'share' in of science and knowledge under Article 15 has inspired scholarly analysis of the potential to link Article 15 to the ABS mechanism set forth in the CBD framework.⁷⁹¹ Though the current discussion on this level of cross-learning does not analyse the issue of intellectual property in detail, this line of thinking has nonetheless provided an alternative angle when looking at Article 15 and the ABS mechanism under CBD, together with a vision regarding the promotion of a fair and equitable governance structure concerned with knowledge production and diffusion.

5.5.2.2 Contribution of UNESCO

In addition to the normative role that CESCR has been playing in the process of clarifying the meaning and content of the right to share in and benefit from science and

⁷⁸⁹ Cullet (n 731)423-424.

⁷⁹⁰ *ibid.*

⁷⁹¹ Morgera (n 778).

knowledge under ICESCR, the other UN body that has played an important role is the United Nations Educational, Cultural and Scientific Organization (UNESCO).⁷⁹²

Research has traced UNESCO's historical contribution to the drafting of Article 15 of ICESCR.⁷⁹³ A standpoint of envisaging the right to science, education and culture as being interlinked with the contribution to peace and security, and with the notion of the preservation of cultural and scientific heritage is particularly relevant to UNESCO's later involvement in biomedical innovation debate.⁷⁹⁴ For the purpose of this research, two lines of commentaries on UNESCO's involvement are worth noting. First, the approach of recognizing human genome as common heritage of humankind is especially relevant when UNESCO escalated its leadership in the normative discussions primarily regarding the ethics on biomedicines amidst the conclusion of the human genome project and the global level of controversies around the race to gene patenting from late 1990s.⁷⁹⁵ For instance, under the Universal Declaration on the Human Genome and Human Rights, it explicitly states that

[T]he human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity.⁷⁹⁶

⁷⁹² Plomer, *Patent, Human Rights and Access to Science* (n 771) ch 6.

⁷⁹³ *ibid* ch 4.

⁷⁹⁴ *ibid*.

⁷⁹⁵ *ibid* 146-150. See also Melisa L Surges, 'Who Should Hold Property Rights to the Human Genome?: An Application of the Common Heritage of Mankind' [1997] 13(1) *Am U Int'l* 219; Christina Byk, 'A Map to a New Treasure Island: The Human Genome and the Concept of Common Heritage' [1998] 23(3) *Journal of Medical Philosophy* 234; David B Rusnik, 'The Human Genome: Common Resource But Not Common Heritage' in Michiel Korthals and Robert J Bogers (eds), *Ethics for Life Scientists* (Springer 2004) 197; Pilar N Ossario, 'The Human Genome as Common Heritage: Common Sense or Legal Nonsense?' [2007] 35(3) *Journal of Law, Medicine and Ethics* 425.

⁷⁹⁶ Universal Declaration on the Human Genome and Human Rights (11 November 1997) art 1.

Accordingly, it considers that ‘the human genome in its natural state shall not give rise to financial gains’.⁷⁹⁷ Perhaps it was aspirational to have the common heritage approach as a strategy to counter the controversy over gene patenting at the time. However, it is noticeably limited to its discussion on genome in its natural state while keeping it vague on genomic subject obtained through gene engineering technologies. Research has pointed out the theoretical difficulties of using such as doctrine especially in the sense that proprietary protection is not necessarily precluded by a common heritage property approach.⁷⁹⁸ Rather, common heritage duties approach, as a proviso of the common heritage doctrine, might be more relevant.⁷⁹⁹ In addition, it is also interesting to note that the Declaration was launched in the same period of time when TRIPS agreement took ground in its global outreach under WTO in which a technology neutral principle was established. Therefore, even though the traditional doctrine of the common heritage of humankind might have equipped UNESCO to engage further normative discussion in international law related to biomedical innovation involving human genome materials, it was historically and politically difficult to achieve.

The second line of commentary that is relevant to this research concerns the interpretative efforts that UNESCO has made in its normative discussions related to biomedical innovation. Research has pointed out that the main normative instruments issued by UNESCO in this context, however, have been focusing on bioscience, research involving human genetics and bioethics.⁸⁰⁰ These focuses are much concerned the application of science in the field of health, and contributed to the provisions interpreting

⁷⁹⁷ *ibid* art 4.

⁷⁹⁸ Pilar N Ossario, ‘The Human Genome as Common Heritage: Common Sense or Legal Nonsense?’ [2007] 35(3) *Journal of Law, Medicine and Ethics* 425.

⁷⁹⁹ *ibid*.

⁸⁰⁰ Plomer, *Patent, Human Rights and Access to Science* (n 771) 148-149.

the meaning of sharing in the benefit of science under the Universal Declaration on Bioethics and Human Rights

Article 15 – Sharing of benefits

1. Benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries. In giving effect to this principle, benefits may take any of the following forms:

- (a) special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research;
- (b) access to quality health care;
- (c) provision of new diagnostic and therapeutic modalities or products stemming from research;
- (d) support for health services;
- (e) access to scientific and technological knowledge;
- (f) capacity-building facilities for research purposes;
- (g) other forms of benefit consistent with the principles set out in this Declaration.

2. Benefits should not constitute improper inducements to participate in research.⁸⁰¹

This set of interpretation on what it means in sharing in the benefit of science is helpful in contributing to the clarity of Article 15 of ICESCR. Nonetheless, scholar has pointed out that while UNESCO's efforts are valuable, it has been overly focused on the areas of health, which should have been taken up more by WHO as its core mandate.⁸⁰² The next section will follow this critique discussing the role of WHO in the context of the right related to biomedical knowledge and innovation.

⁸⁰¹ Universal Declaration on Bioethics and Human Rights (19 October 2005) art 15. See also Plomer, *Patent, Human Rights and Access to Science* (n 771)155-159.

⁸⁰² Plomer, *Patent, Human Rights and Access to Science* (n 771) 161.

5.5.2.3 Constitution of the World Health Organization (WHO)

A much less discussed normative instrument in the context of biomedical innovation and the right to science and knowledge discourse is the WHO Constitution. Adopting a human rights-based approach, the WHO Constitution explicitly states in its preamble that ‘the extension to *all peoples of the benefits of medical, psychological and related knowledge* [emphasis added] is essential to the fullest attainment of health’.⁸⁰³ In contrast to ICESCR’s Article 15 which uses ‘scientific progress’ as the subject to benefit from, the WHO Constitution highlights ‘medical, psychological and related knowledge’ instead. When the WHO Constitution was endorsed in 1946 as the outcome of the International Health Conference, the aspiration of extending the benefit of medical knowledge to everyone was indisputably supported by the members.⁸⁰⁴ The Conference discussed the meaning of the Preamble in the sense that ‘[N]ot only would the Organization help in disseminating and applying all the scientific knowledge now possessed to prevent disease and promote health; it would also encourage and conduct scientific research to forge more effective tools’.⁸⁰⁵ By the time this aspiration was framed, the intellectual property regime had not gained the global outreach as it does today. As a result, it was hard to say that the WHO Constitution was drafted with keeping the political tension between the right to health and intellectual property in mind. Instead, the educational mandate of WHO was more of the relevant foundation when the topic of generating, extending and disseminating medical knowledge was envisaged. The educational dimension in the topic of disseminating medical knowledge to all has also

⁸⁰³ WHO Constitution.

⁸⁰⁴ WHO, ‘Official Records of the World Health Organization: Summary Report on Proceedings Minutes and Final Acts of the International Health Conference’ (New York, 19 June-22 July 1946) III.I Constitution of the World Health Organization <<http://apps.who.int/iris/handle/10665/85573>>, accessed 9 August 2018.

⁸⁰⁵ *ibid* 95.

been further reinforced in recent years' discussion on the institutional reform of WHO.⁸⁰⁶

This notion of access to the benefit of medical knowledge by all as an integral part of the realization of the right to health is not reflected clearly in the current CESCR General Comments, neither in No. 14 on the right to health, nor in Nos. 17 and 21 concerning the right to science in the broad sense of cultural rights. General Comment 14, for instance, does not explicitly discuss the role of medical knowledge but focuses on medical services and scientifically-proven medicines in its interpretation. In addition, General Comments 17 and 21, together with the wording of Article 15 of ICESCR, focus on the discussion of 'science' and 'scientific progress and its application' instead of 'knowledge'. Research on the right enshrined under Article 15 of ICESCR has referred to the definition of 'science' as what has been used by the sociology of science.⁸⁰⁷ Accordingly, science is applied, verifiable and universally valid, associated with accumulated knowledge and the activities governed by a set of shared cultural values and norms.⁸⁰⁸ The norms of science, especially in terms of its communal ethos, imply that 'the fruit of scientific investigation belong to everyone'.⁸⁰⁹ On this note, the notion of 'everyone' implies having the right to share in science, as noted in Article 15 of ICESCR, while 'all people' have the right to benefit from medical knowledge, as noted by the WHO Constitution, are therefore correlated and commensurate. This correlation

⁸⁰⁶ Charles Clift, 'The Role of the World Health Organization in the International System' (Chatham House Working Group on Governance, 2013)

<<https://www.chathamhouse.org/sites/default/files/publications/research/2013-02-01-role-world-health-organization-international-system-clift.pdf>> accessed 1 August 2018.

⁸⁰⁷ Robert Merton, *The Sociology of Science: Theoretical and Empirical Investigations* (University of Chicago Press, 1973) 268-278.

⁸⁰⁸ *ibid.*

⁸⁰⁹ *ibid.*

also provides a signpost indicating the possibility of detecting further undertones in the WHO Constitution.

Literature interrogating the underlying rationale of this part of the preamble of the WHO Constitution is rare. From limited observations, this researcher considers that the principle set forth in the preamble concerning medical knowledge aims to serve ‘as a reminder that the availability of essential knowledge and medicines must not be stopped at any national border, and that such interference must not be tolerated for any political or economic reasons.’⁸¹⁰ Reading this interpretation together with the preamble text could potentially clarify two levels of undertone. First, it provides an opportunity to reunite the material and practical aspects of medicine which are often segregated, as mentioned in the earlier section of this chapter. This unification is important to redefining and re-examining the holistic meaning of medicine when the question of innovation is addressed. Medicine as an integral system of medication and practice is dynamic and evolving with innovations derived from both the typical new drug development process and, more importantly, the clinical experiences of medical practitioners and patients. The two aspects commonly exist in different medical and knowledge systems, be it Western modern medicine or traditional medicines. In the normative debates, which we have observed in the context of CBD, the focus is on the dynamic and experience-based nature of traditional knowledge, including medical knowledge, in contrast to more scientific and experimentally-based modern Western medicine, with the objective being to redress historical wrongdoings and pursue equity. However, the dynamic and experience-based aspect of medicine has also never died out

⁸¹⁰ Frank P Grad, ‘The Preamble of the Constitution of the World Health Organization’ [2002] 80(12) Bulletin of the World Health Organization 981, 982, <[http://www.who.int/bulletin/archives/80\(12\)981.pdf](http://www.who.int/bulletin/archives/80(12)981.pdf)> accessed 8 August 2018.

in the Western medicine system. Medical literature in the context of discussing scientific medicine and evidence-based medicine has long been cautious about the marginalization of tacit knowledge in medical practices.⁸¹¹ In contrast to the belief that medical practices ought to be based primarily on scientifically verifiable evidence and statistics, critics have argued that this understanding has overlooked the important aspect of tacit knowledge, including medical practitioners' accumulative clinical experience and judgment made based on individual cases over the course of medicine's development.⁸¹² Unification of medicine's practical and materials aspects can therefore be seen as a theme common to both Western and non-Western medicine and knowledge systems.

Secondly, the preamble's wording suggests an openness and accessibility on the part of medical knowledge at a global level, without being restricted by national borders or for 'political or economic reasons'.⁸¹³ This will not be easy to achieve when medicines and the associated medical knowledge can be restricted by the type and scope of patent protections. The segregation of medical practice from medicine as a product, as discussed earlier, also hinders different aspects of medicine with patents permissible on respective aspects of medicine. In contrast to the status quo, the preamble of the WHO Constitution rather suggests the possibility of fostering a global framework for medical

⁸¹¹ There have been long debates on the relationship between the science and the art of medicines in the context of discussions concerning scientific and evidence-based medicines. Evidence-based medicine, being mainstream, suggests that clinical practices are to be based primarily on scientific evidence, while critics consider it is equally important to not lose vision of the interactive and individually-focused clinical practice and experience of physicians in the context of medicine. There is rich literature in medical writings discussing this issue. See, for instance: Mark R Tonelli, 'The Philosophical Limits of Evidence-based Medicine' [1998] 73(12) *Academic Medicines* 1234; Stephen G Henry, 'Recognizing Tacit Knowledge in Medical Epistemology' [2006] 27 (3) *Theoretical Medicine and Bioethics* 187; Vimal L Patel and Jose F Arocha, 'Expertise and Tacit Knowledge in Medicine' in Robert J Sternberg and Joseph A Horvath (eds), *Tacit Knowledge in Professional Practice* 75; Tim Thornton, 'Tacit Knowledge as the Unifying Factor in Evidence-based Medicine and Clinical Judgment' [2006] 1(2) *Philosophy, Ethics and Humanities in Medicine* <<https://doi.org/10.1186/1747-5341-1-2>> accessed 19 August 2018.

⁸¹² Mark R Tonelli, 'The Philosophical Limits of Evidence-based Medicine' [1998] 73(12) *Academic Medicines* 1234, 1237-1238.

⁸¹³ Grad (n 810).

knowledge diffusion and enrichment, which would act as an integral part of the realization of the human right to health. This notion indicates state parties' extraterritorial obligations in terms of collaborating on and ensuring that the medical knowledge diffusion and enrichment framework is not interrupted by other forces.

These two possible undertones of the preamble suggest a further reinterpretation of the right to both health and biomedical knowledge. Recalling the interdependence of human rights, the realization of the right to health will be hindered if the right to biomedical knowledge is restricted.

5.5.3 Significance of Human Rights in an Alternative Conceptual Framework

The current human rights framework offers another angle to look at the role of biomedical knowledge in the context of redefining medicines and health in the context of innovation. Two major group of rights are of relevance here, namely the right to health and the right to science and knowledge. Looking at the former, normative development has acknowledged the conflict between the human right to health and the expansive and dominant protection of medical technology intellectual property. A considerable number of non-binding instruments have been produced outlining the objectives, obligations and measures needed to overcome such a conflict whereby the realization of the right to health – with access to medicines as an integral part – can be ensured. However, as discussed above, this line of critique and normative development have some visible limitations. It does not address innovation and the role of knowledge explicitly, despite general mentions of the importance of fostering innovation and the need to develop models as an alternative to the patent-centric mode. Facing an intellectual property law regime which has been developed with more concrete and substantive rules, especially under WTO auspices, the overall conciliation between the two systems is rather limited.

This conciliation has been focused primarily on the implementation of TRIPS flexibilities, which are constrained in terms of promoting innovation openness. The TRIPS system has also never used an explicitly human rights-based approach.

The merits and limits of the right to health framing leads to this research underlining the necessity of consolidating the right to science and knowledge. The existing human rights framework and normative text, however, offers a valuable and yet limited inspiration. On the one hand, the treaty interpretation of Article 15 of ICESCR is in development. With its previous rather segmented approach to interpretation, a new General Comment is underway, which is intended to offer a more thorough interpretation of the article as a whole. On the other hand, while making an effort to distinguish intellectual property rights from the cultural rights enshrined under the human rights framework – especially in ICESCR’s Article 15 – the U-turn towards the intellectual property system for traditional knowledge protection under General Comment 17 is rather disappointing. Although the normative development of Article 15 bears enormous potential in terms of redefining the discussion of the role of knowledge in innovation in the context of the realization of human rights, further development is still needed.

In the context of medical knowledge and for the purpose of this research, the importance of access to the benefits of medical knowledge is explicitly invoked by the WHO Constitution. Without being thoroughly interpreted or researched, the notion that the availability and accessibility of medical knowledge is an integral part of realising the right to health is important. It provides two potential opportunities in terms of redefining the meaning of medicine for innovation under an alternative transformative framework. First, it illuminates on the reunification of the material and practical aspects of medicine, which have long been segregated, especially under the proprietary-based regime. It also

provides an opportunity to reconcile the role of the accumulative clinical knowledge of physicians in terms of their systematic contribution to the development of medicine, which an alternative innovation discussion should be based upon. Secondly, that the benefit of medical knowledge should be accessed by all people indicates a global level of action is required to ensure the diffusion, exchange and development of medical knowledge. This further signals an extraterritorial obligation for states to collaborate and ensure the realization of such actions, which may be at odds with the status quo, which is the exclusivity-based logic of medical innovation.

5.6 Ideal Options for the Critical Transformation of the Conceptual Framework

Based on critiques of the conceptual and practical distortions in the patent-centric biomedical innovation narrative, the chapter started by discussing possible approaches to the building of an alternative conceptual framework. A critical and transformative framework is possible by consolidating the triangulation approach borrowed from critical political economy scholars as well as STS scholars' co-production critiques. Accordingly, the transformative forces might be found in the constant interplay and readjustment between ideals, materials and the institutional dimensions of a world order, while reinforcing and weakening each dimension could support the move toward an overall transformation. As such, the critical intention seeks to override the prevailing order rather than continue with problem solving. In light of this, the key elements for exploring the building of an alternative conceptual framework include revisiting and redefining the meaning of medicine and knowledge as the underlying ideal forces for transformation, reengaging with innovators outside of patent holders in biomedical fields, and exploring the plurality of norms and self-governed innovation.

The first element of the ideal space for alternative conceptualisation has been explored in this chapter by discussing contested meaning of medicine and biomedical knowledge first. It recalls medicine's politically-constructed hierarchy and preferences, while the connectiveness of traditions and cultures have been divided into 'modern' and 'traditional' to prioritise a specific understanding of medicine. The trend toward the biomedicalisation of social issues as motivated by the commodification of health has deepened the techno-scientific perspective on life and health. Instead, this chapter suggest that the dimensions and meaning of bio- should be reinterpreted in order to reflect its original meaning, namely 'life'. The cultural implication of this would help to redefine the relationship between biomedical innovation and the lost social connection with the cultural context of life.

In addition, three conceptual approaches which challenge individualistic and exclusivity-based knowledge systems have been reviewed, namely the approach to knowledge commons, the mechanism of access and benefit-sharing established in the context of CBD and the human rights framework concerning the right to health and science and knowledge respectively. The chapter argues that these approaches have advantages and disadvantages but shed lights in terms of defining biomedical innovation by re-examining the meaning of knowledge, medicine, and innovation in their broader contexts.

Chapter 6: Democratizing Biomedical Science and Research: Openness in Biomedical Innovation and the Sidestepping of Patent

In previous chapters, the effects of co-production in the context of biomedical innovation and patent law have been discussed from three main perspectives. The first of these includes the mechanics of how patent law professionals – especially patent attorneys – have presented the epistemic construction of the notion of innovation through a closed system of patent specialisations while the boundary of ‘newness’ in biomedical science and technologies has been constantly reshaped. Second, the legal construction of innovation has been examined through the doctrinal development of patentability. This has resulted in a contentious relationship with the main actors involved in biomedical innovation including, for instance, medical practitioners. Third, the new technological fronts in biomedical innovation – especially given the development of genetic technologies – have involved further controversies whereby the established spaces of the law concerning nature and non-nature, human and non-human, have been challenged, investigated and redefined. As discussed in earlier chapters, these processes have particular ideological underpinnings. The proprietary-based model and commercialisation of biomedical knowledge has triumphed via the use of the patent law regime. These aspects of co-production have also rewritten the governing rules while redrawing biomedical innovation’s normative landscape. The question remains open regarding whether a different conceptual framework would act as an alternative to the prevailing patent regime in the biomedical innovation context.

Building on these critiques, Chapter 5 introduced a critical approach to the transformative conceptual framework building through a combination of a co-production approach from science and technology studies and triangulation frameworks

derived from critical political economy. Accordingly, the key elements of an alternative conceptual framework might be explored from below and outside of the prevailing order. Three key aspects are identified that might support the ideal, institutional and material forces in altering the patent-centric approach to biomedical innovation.

Firstly, in terms of the ideal dimension, the nature and normative implications of medicine and biomedical knowledge are to be redefined in contrast to the patent-centric model's construction of rivalry and exclusivity. Studies of knowledge commons in a biomedical context and research on access and benefit-sharing mechanisms in the context of the protection of traditional knowledge and genetic resources have illuminated the relocation of knowledge production's collectiveness and responsibilities. The human rights framework provides two further normative lines, namely the right to health and the right to science and knowledge through which the role of knowledge, science and medicine can be re-examined. Reading the right to health and the right to science and knowledge alongside each other offers the possibility to unify the material and behavioural aspects of medicine while recognising the value of medical knowledge as an integral part of the realisation of the right to health. The right for everyone to participate in and benefit from science, as well as to benefit from medical knowledge underlines the necessity to have a national and international framework of medical knowledge creation and diffusion, a framework that moves beyond the private property-based conceptualization.

Secondly, the broader innovation community beyond corporate patent holders (holding the majority of the patents on biomedical inventions), should be reengaged. The politically formed and hegemonic view of patent's indispensable role in biomedical innovation is largely driven by a particular neoliberal ideology and corporate

commercial interests. The sources of innovation and the broader communities of innovators – especially medical practitioners and scientists – have been marginalised in the relevant debates. Yet, discontent with these innovators regarding biomedical innovation and patenting has continued throughout the entirety of the history of patent law development. An alternative conceptual framework should thus reposition innovators in relation to patent holders by re-examining the role of the professions including the medical and legal professions. This would also inform the third aspect of the discussion – democratizing biomedical innovation by looking at the diversity and plurality of norms in the face of disruptive technological developments and public initiatives in innovation.

Chapter 5 discussed the normative possibilities of reimagining the role of biomedical knowledge, while this chapter looks at two other aspects relating to the construction of an alternative conceptual framework. It first examines the role of the broader innovator community and innovation users, especially medical professions and patients, in the production, preservation and diffusion of biomedical knowledge and innovation. It then discusses the approach to openness as a means to democratize biomedical innovation. The role of innovators and users beyond patent holders is an integral part of the path to democratizing innovation. In contrast to the exclusivity-based rationale in the patent-centric conceptual framework, openness brings with it the political possibility of forming new transformative forces. It is worth noting that openness has been used within the patent-centric model with rather different connotations. The idea of openness has also been used in the context of innovation management without necessarily changing the underlying conceptual framework. Both contexts, however, are far from being transformative as other aspects of more fundamental critiques have not been incorporated. Instead, this chapter discusses socially constructed and voluntarily-formed

innovation consciousness and initiatives in the biomedical field, inspired by the computer science open source movement. It suggests further decentralised participation from the public is essential in reimagining a future democratically-centred biomedical innovation conceptual framework.

6.1 Innovators in the Biomedical Context

Discussing the normative possibility of empowering innovators and users other than patent holders in the context of biomedical innovation serves the second main element of building an alternative conceptual framework. This element focuses on the active actors in innovation and is closely aligned with the institution of openness as will be discussed in the following sections. The institution of openness, in the context of discussing democratizing biomedical innovation, forms the third main element when building an alternative conceptual framework.

6.1.1 Innovators, Inventors and Patent Holders

The biomedical innovation's patent-centric model attributes the contribution to the advancement of medical technologies and science primarily to patent holders. However, innovation as a collective enterprise involves broader contributors. At the basic level, there are legal and normative distinctions and an overlap between innovators, inventors and patent holders, in turn affecting how they organise, obtain rights and bear obligations. These distinctions and overlaps are helpful for the following section's discussion on openness and democracy.

Patent holder as a legal status is not necessarily related to actual innovative or inventive activities, rather it is a status confirming one's ownership and exclusive rights under patent law. A patent holder can be any person who obtains this status through legally

recognised ways. Accordingly, the patent holder can be the same person as the inventor named in the patent, or a completely different person from the inventor and who has obtained ownership through licensing or other agreements made with the inventors. Inventors – be they an individual or a team – are also different from innovators. Innovators, although not legally defined, involve broader actors and communities than inventors recognized by patent law. In the context of biomedical innovation, the patent-centric paradigm concentrates on the rationale of rewarding the investment in inventions by acknowledging the exclusivity rights enjoyed by the patent holders, who are often pharmaceutical corporations. However, looking at innovation in medicine as a whole as including both material and behavioural aspects, innovators in the biomedical context involve multiple actors including – but not limited to – physicians, pharmacists and patients (see Fig. 4)

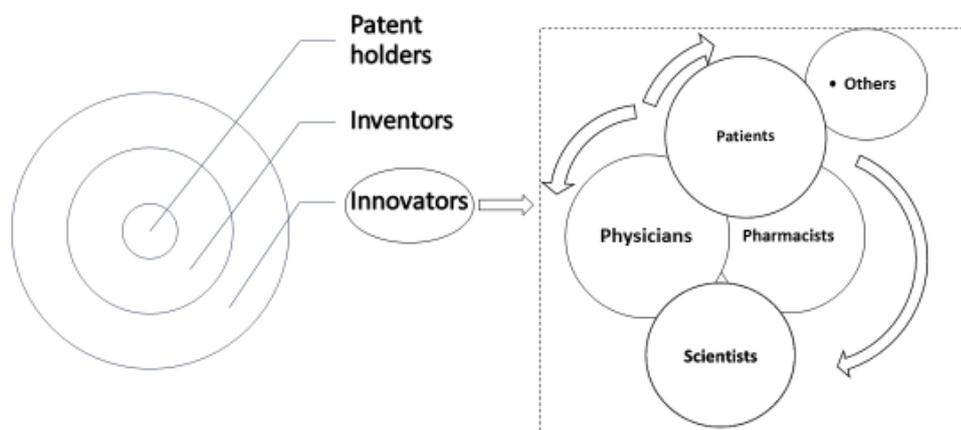


Figure 4: Innovators in the Biomedical Context

In the current patent law system, the relationship between patent holders and inventors is worth examining. Research has observed the systematic shift from individual inventor-centred patent ownership toward the increasing business ownership of patents

in the aftermath of the late nineteenth century.⁸¹⁴ This shift is closely associated with the increased collectiveness evident in inventive activities driven by a number of factors ranging from the development of firms' in-house R&D capacity as well as the professionalization of science and the new relationship between industry and employee scientists.⁸¹⁵ Although the names of individual inventors remain visible in patent documents and they still enjoy some moral rights,⁸¹⁶ the financial, material and legal privileges generated by inventions are enjoyed mostly by the patent-holding business entities.⁸¹⁷ Some research argues that academic institutions also benefit financially from holding patents, but this is also largely related to the changing research scenarios in academic settings, particularly given the influence of commercialisation.⁸¹⁸

Some innovator communities, such as physicians and patients, also have long term disagreements with the interruptions brought about by the current patent-centric paradigm. These phenomena provide the opportunity to look at physicians and patients' contributions from outside of the patent system as well as from the bottom up.

6.1.2 Contributions by Broader Innovators

The innovation studies literature has documented the contributions of innovators other than those located in the vertical context of innovations, and named them 'user

⁸¹⁴ Graham Dutfield, 'Collective Invention and Patent Law Individualism, 1877-2012 – or, the Curious Persistence of Inventor's Moral Right' in Stashis Arapostathis and Graham Dutfield (eds), *Knowledge Management and Intellectual Property: Concept, Actors and Practices from the Past to the Present* (Edward Elgar 2013) 109.

⁸¹⁵ *ibid.*

⁸¹⁶ *ibid.*

⁸¹⁷ *ibid.* Despite the asymmetry, this research also points out that keeping the attribution to individual inventors in patent documents does not contradict the interests of the industry and is, in fact, good for business.

⁸¹⁸ Reference can be made to works such as Philip Mirowski, *Science-Mart: Privatizing American Science* (Harvard University Press 2011).

innovators'.⁸¹⁹ In the context of biomedical innovation, at least three lines of discussion can be identified while the overall literature on this issue remains limited. The first cluster of academic studies examine the role of physicians in resisting patent's impact on treatment methods and diagnostics.⁸²⁰ The second strand in the literature looks at the contribution made by physicians through off-label use of medicines,⁸²¹ while the third discusses the self-initiatives adopted by patients or hobby scientists.⁸²²

In terms of both the patenting of medical treatment and diagnostic methods, the academic literature has analysed the individual legal battles and collective resistance by physicians and their professional bodies.⁸²³ While such resistance was based on the perspective of professional ethics research,⁸²⁴ it has noted that

...the physician community relies on an internally governed system of publication credit and other reputational mechanisms for allocating rewards for procedure inventions and thus sees medical procedure patents as unnecessary, cumbersome, and threatening to the sharing norm. Formal IP rights can threaten such a norm-based governance regime.⁸²⁵

⁸¹⁹ Katherine Strandburg, 'Legal but Unacceptable: Pallin v. Singer and Physician Patenting Norms' in Rochelle Cooper Dreyfuss and Jane C Ginsburg (eds), *Intellectual Property at the Edge* (CUP 2014) 321; Katherine Strandburg, 'User Innovators Community Norms at the Boundary between Academic and Industrial Research' [2009] 77 *Fordham L. Rev.* 2237.

⁸²⁰ Strandburg, 'Legal but Unacceptable' (n 819).

⁸²¹ Eric Hippel, Harold DeMonaco and Jeroen de Jong, 'Market Failure in the Diffusion of Clinician-developed Innovations: The Case of Off-label Drug Discoveries' [2017] 44(1) *Science and Public Policy* 121; Harold De Monaco, Ayfer Ali and Eric Hippel, 'The Major Role of Clinicians in the Discovery of Off-label Drug Therapies' [2006] 26(3) *Pharmacotherapy* 323.

⁸²² Stephen Flowers, 'Chronic Disease, New Thinking and Outlaw Innovation: Patients on the Edge in the Knowledge Commons' in Katherine Strandburg and others (eds), *Governing Medical Knowledge Commons* (CUP 2017) 328.

⁸²³ Strandburg, 'Legal but Unacceptable' (n 819).

⁸²⁴ *ibid.* 340.

⁸²⁵ *ibid.*

Similar observations have also been made in relation to defining physicians as user innovators more generally against the backdrop of patentability exceptions regarding medical treatment in a European context.⁸²⁶ In this context, the scenario of patent being indispensable for the development of medical treatment innovation is apparently not compatible, as the physician community has developed a rather stable system of sharing both explicit and tacit knowledge of medical treatment practices without resorting to patent as an incentive.⁸²⁷

The system of knowledge sharing as the key means of advancing clinical practices also takes place in the context of the off-label use of medications⁸²⁸ and the initiatives launched by patients themselves in testing and treating through self-learning and sharing of experiential knowledge.⁸²⁹ These observations are important. Although the sharing norms in these user innovators communities do not necessarily and ideologically preclude the notion and possibility to pursue patent, however patenting is not by any means the default form of reward. Norm-based systems of sharing, rather than the formal law-based patent system, act as the primary governing mechanism. This alternative mechanism also embraces the objective of openness in the like-minded community and offers an opportunity to democratise biomedical innovation as Section 6.3 discusses.

6.2 Institutions of Openness? The Reformist Approach and Its Limitations

Recapping the main changes in the context of the norms of science following the increased integration of patent law influences, especially in academic and publicly-

⁸²⁶ Stephen Bechtold, 'Physicians as User Innovators' in Rochelle Cooper Dreyfuss and Jane C Ginsburg (eds), *Intellectual Property at the Edge* (CUP 2014) 343.

⁸²⁷ *ibid.*

⁸²⁸ Hippel and others (n 821).

⁸²⁹ Flowers (n 822).

funded research settings, informs at least two conceptual levels that are relevant to the current research. Firstly, the notion of publicity remains desirable in the scientific community, either in its traditional form (i.e. publication) or in the context of disclosure and publication in patent terms. Secondly, the notion that the contemporary development and expansion of the intellectual property system, especially patent, has resulted in conflicting values in terms of scientific norms has been discussed. This provides a critical backdrop to the following examination of ideas of openness in the context of biomedical R&D.

The main idea of openness, interpreted and understood from different perspectives, could be understood in terms of three distinct dimensions. The first concerns openness in the structural arrangement of the innovation process, which is reflected mostly in discussions on open innovation in the product development sectors. The second dimension involves openness in the context of the management of intellectual property, such as those discussions and initiatives related to patent pooling and licensing. The third openness dimension relates to radically reversing the monopoly-based model thereby opening up the entire process of innovation with alternative governing rules and behaviours, such as those that affect access and benefit sharing. The existing paradigm with strong proprietary protection remains in the background when openness is approached under each of the above dimensions, either in the sense of seeking a middle ground regarding management or in an attempt to promote a more radical departure.

6.2.1 Open Innovation in the Biomedical Context and the Limitations

One trend and practice concerning openness involves the concept of open innovation. ‘Open innovation’ was initially invoked by large corporations in presenting a business model in which individual company-based innovation is compared to a model where

internal and external factors work complementarily in an attempt to advance innovative output.⁸³⁰ It has also been considered to be where ‘a wide network of developers participate in building on a shared technological base that is freely available to all.’⁸³¹ Furthermore, OECD-supported research has considered pharmaceuticals as an industry with a high level of open innovation practices.⁸³² However, open innovation is also very vaguely defined with the potential to accommodate any form of collaboration and collective activities,⁸³³ without necessarily touching on the core question of its potential departure from the proprietary-based model.

In the context of biomedical R&D, the loose remit of open innovation has incorporated two interrelated and yet frictional wish lists from public health policy and economic perspectives. From the standpoint of the World Health Organisation (WHO), which intends to pursue an alternative approach in health-related innovation in contrast to the current patent-centric model, has adopted a broad policy approach to qualifying open innovation initiatives as long as an innovation initiative involves a less dependent approach to patent in the innovation process, such that the adverse impact of patent monopoly on innovation might be minimized.⁸³⁴ While the notion of the adverse impact of patent might be a peculiar assessment from the perspective of the pharmaceutical industry, the latter nonetheless embraces the concept of open innovation mostly from an economic outlook whereby a more collaborative approach would potentially help to

⁸³⁰ Henry William Chesbrough, *Open Innovation: The New Imperative for Creating and Profiting from Technology* (Harvard Business School Press 2003).

⁸³¹ James Boyle, ‘Open Source Innovation, Patent Injunction and the Public Interest’ [2012] 11 *Duke Law & Technology Review* 31.

⁸³² *ibid* 14.

⁸³³ WHO, *Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination*, Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination (Geneva, April 2012) 30.

⁸³⁴ *ibid*.

reduce the overall cost and time involved in R&D and commercialisation.⁸³⁵ These two wish lists, appreciate the notion of open innovation at the same time exposing ongoing ideological conflicts when the meaning of ‘openness’ might bear different interpretations. The public health policy perspective understands the meaning of openness as reflecting a tendency to depart from the proprietary rights-dependent business model. Industries, on the other hand, appreciate the benefits brought by openness in business management which might potentially optimise commercial performance; openness in this sense is related to ‘a set of practices for profiting from innovation, and also a cognitive model for creating, interpreting and researching those practices’.⁸³⁶ It therefore has little to do with departing from proprietary-based operational models or, at the most, any revision of intellectual property’s management. I will discuss the point of management of intellectual property later.

The differences between the two wish lists in the context of open innovation have also influenced the research and pragmatic agendas representing the two stand points. Mainstream literature on open innovation from corporate perspectives has suggested that retaining a strong proprietary mechanism could be preferred by firms in parallel with opening up resources to external actors.⁸³⁷ The desire and ability to keep the possibility of the appropriation of research outcomes in open innovation practices are generally chosen and preferred in firm-level approaches to open innovation.⁸³⁸

⁸³⁵ Chesbrough (n 830)

⁸³⁶ *ibid.*

⁸³⁷ For a comprehensive literature review on open innovation at firm level, see Linus Dahlander and David M Gann, ‘How Open is Innovation?’ [2010] 39(6) *Research Policy* 699, available at: <<https://doi.org/10.1016/j.respol.2010.01.013>>.

⁸³⁸ *ibid.*

These may well be at odds with public perspectives when open innovation is reviewed and tested. In the context of having an open innovation approach to health R&D, preferences have been indicated in terms of the effects of the ‘open sharing of information between multiple partners, including the principle that research results should be in the public domain.’⁸³⁹ This line of thought on openness focuses on the level of publicity involved. With the preference for the public domain potentially limiting the use of the proprietary approach on the research results, there are also challenges in clearly defining the actual boundaries of the public domain in the context of biomedical research. For instance, the meaning of the public domain could imply the possibility of only making publically available the research outcome after a patent has expired. This could not only limit the ambitions to pursue a total non-proprietary-based model, but could also involve practical difficulties. Research has suggested that the dynamic and complex patent situation concerning biotechnologies could make uncertainty a pertinent issue when identifying the freedom to operate.⁸⁴⁰ Although we have discussed the global expansion of the intellectual property regime, especially in the aftermath of the TRIPS agreement and as furthered through FTAs, intellectual property law at large and patent law more specifically, are still territorial. Mechanisms such as PCT under the WIPO is only able to achieve procedural harmonisation based mostly on mutual recognition and consensus, but there is no such thing as international patent or a harmonised global pace whereby one patent can be prosecuted at the same time across territories and spaces. The temporal aspect of this territorial feature of patent prosecution is significant in the context of uncertainty regarding the boundary of exclusivity and the extent of the public

⁸³⁹ WHO, *Research and Development to Meet Health Needs in Developing Countries: Strengthening Global Financing and Coordination. Report of the Consultative Expert Working Group on Research and Development: Financing and Coordination* (Geneva, April 2012) 31.

⁸⁴⁰ Janet Hope, *Biobazaar: The Open Source Revolution and Biotechnology* (Harvard University Press 2006) 44.

domain. Within a given period of time, applications on the same patent could be pending, granted, rejected, opposed or revoked in multiple jurisdictions simultaneously, and other patents covering the same technology could start expiring, lapsing or be withdrawn.⁸⁴¹ The actual scope and depth of the public domain concerning a particular technology is changing dynamically. The resultant fluidity and uncertainty remains a normative situation when the model is perpetrated by a proprietary-centred model, as the exclusivity and enforceability of the proprietary rights would make it a constantly changing task to identify the public domain.

6.2.2 Alternative Management of IP to Promote Openness and the Constraints

Other ideas on openness in the context of biomedical innovation relate to alternative means of managing IP, instead of moving away from a proprietary approach entirely. This line of thought is closely linked with the above section on open innovation, especially given its focus at the corporate level but also related to other non-profit players.

Instead of looking at traditional firms only, this line of interpretation on openness also looks at public-private-partnerships, some of which can be loosely designated as open innovation in biomedical research and development contexts. One approach to handling patent in open innovation initiatives is to clarify at the institutional policy level the move away from patent application as a default strategy, but rather seeking the flexible management of patent in a case-by-case manner, especially by making patent protection an exception.⁸⁴² For instance, in the institutional Intellectual Property policies of both

⁸⁴¹ *ibid.*

⁸⁴² Part of the analysis in this section are referred to the previous unpublished work of the author especially.

the Drug for Neglected Diseases Initiative (DNDi)⁸⁴³ and the Medicines for Malaria Venture (MMV),⁸⁴⁴ decisions on patent acquisition and IP management could be done on a case-by-case basis under the aspiration of making patent ‘an exception rather than the rule’.⁸⁴⁵ However, it remains unclear how policies have been implemented in the routine partnership agreements as most of the text of the agreements are not publically available.

Adjusted management of IP has also been discussed and tried in the terms of pooling and licensing. On patent pooling in the context of biomedical innovation, one typical example is the Pool for Open Innovation against Neglected Tropical Diseases established in 2009 by GSK and Alnylam Pharmaceuticals, and managed by Bio Venture for Global Health.⁸⁴⁶ The Pool comes under GSK’s open innovation strategy, in which the concept of open innovation has been used to refer loosely to any collaborative R&D with actors outside of GSK.⁸⁴⁷ Openness in this sense implies only the opening up to R&D actors external to GSK as defined by the Pool, but does not reflect any intention of altering the patenting practice. Rather, the Pool concentrates its policies on licensing from contributors to the Pool’s qualified participants.⁸⁴⁸

⁸⁴³ DNDi, <<http://www.dndi.org/>> accessed 20 June 2016.

⁸⁴⁴ MMV, <<http://www.mmv.org/>> accessed 20 June 2016.

⁸⁴⁵ DNDi’s Intellectual Property Policies, III. Basic Principles, available at: <<https://www.dndi.org/partnership/ip-a-licensing-policies/>> accessed 01 May 2018.

⁸⁴⁶ GSK, Sharing our Research, < <http://us.gsk.com/en-us/research/sharing-our-research/researchopen-innovation/> > accessed 01 May 2018.

⁸⁴⁷ *ibid.*

⁸⁴⁸ *ibid.*

Discussions on openness-framed adjusted licensing practices have also been made, for instance the idea of the open license approach,⁸⁴⁹ including an equitable access license⁸⁵⁰ for biomedical R&D in universities, with the intention of amending the distortions of the current paradigm. The proposal on the equitable access license includes adapting copy-left clauses similar to open sources licenses in order to support a ‘self-enforcing open licensing regime that minimizes transaction costs and is insulated from the vicissitudes of internal university politics and market relationships’.⁸⁵¹ However, it is also noted that an equitable access license is not truly a ‘open source’ license in that while an open source license makes the source code freely available for all those starting from the very beginning of the innovation process, an equitable access license focuses on the downstream and ensures the licensed technology and follow-on development are freely available only within the defined scope of low and middle income countries (LMIC).⁸⁵² Open source licenses are discussed further in the next section. Another open license proposal put forward in parallel to the equitable access license focuses on neglected diseases specifically.⁸⁵³ Both proposals are referenced in the literature on commons,⁸⁵⁴ aiming to allow researchers to freely market any innovations without hindrance from exclusive rights held by a university in defined countries. However, the

⁸⁴⁹ The literature discussing open license for health innovation includes: Amy Kapczynski and others, ‘Addressing Global Health Inequities: An Open Licensing Approach for University Innovations’ [2005] 20 Berkeley Tech LJ 1031; Kevin Outterson, ‘Pharmaceutical Arbitrage: Balancing Access and Innovation in International Prescription Drug Markets’ [2005] 5 Yale J Health Pol’y L & Ethics 193, 255-58.

⁸⁵⁰ Amy Kapczynski and others, ‘Addressing Global Health Inequities: An Open Licensing Approach for University Innovations’ [2005] 20 Berkeley Tech LJ 1031.

⁸⁵¹ *ibid* 1037.

⁸⁵² *ibid*.

⁸⁵³ *ibid* 1037.

⁸⁵⁴ Elinor Ostrom, *Governing the Commons: The Evolution of Institutions for Collective Action* (CUP 1990); Carol Rose, ‘The Comedy of the Commons: Custom, Commerce, and Inherently Public Property’ [1986] 53 U Chi L Rev 711.

proposals do not intend to shift the entire business model and thus will not redefine the product development and distribution industry structure.⁸⁵⁵

Before moving on the open source model, initiatives promoting information transparency, such as open databases, are worth mentioning. Instead of conducting R&D directly, the main function of open database initiatives is to provide sourcing information for innovation practices.

One example is the WIPO's Re:Search initiative. Essentially, Re:Search is a public database containing intellectual property information submitted by contributors – normally research-based pharmaceutical companies – information which is necessary for conducting research on neglected tropical diseases (NTDs).⁸⁵⁶ The major difference of such a database compared to the patent database is that it was created around identified neglected tropical diseases and includes information of patents on chemical compounds, relevant technologies, and know-how.⁸⁵⁷ It is founded by the WIPO together with BVGH (Bio Venture for Global Health), the latter an industry-led organisation focusing on biotechnology research in the medical field and funded by both pharmaceutical companies and other private funding bodies such as the Bill and Melinda Gates Foundation and the Rockefeller Foundation.⁸⁵⁸ The Re:Search website lists 120 collaborations including research institutions, universities and industries as of January 2018.⁸⁵⁹ In its guiding principles, terms have been suggested for the users and providers of the consortium in their licensing negotiations to pursue granting royalty-free and non-

⁸⁵⁵ Kapczynski and others, 'Addressing Global Health Inequities' (n 850).

⁸⁵⁶ WIPO, Re: Search, <<http://www.wipo.int/research/en/about/>> accessed 09 June 2016.

⁸⁵⁷ *ibid.*

⁸⁵⁸ See BVGH History, <<http://www.bvgh.org/Who-We-Are/History.aspx>> accessed 09 June 2016.

⁸⁵⁹ See WIPO Re:Search, List of Collaboration Agreements, available at: <http://www.wipo.int/export/sites/www/research/docs/collaboration_agreements.pdf> accessed 09 June 2018.

exclusive licenses to least-developed country (LDC) partners on research projects concerning NTDs.⁸⁶⁰

However, apart from making the search process easier for research entities, the above guiding principles in IP management and licensing also have considerable limitations. Firstly, despite a certain level of flexibility in IP management outlined in the guiding principles, such as a limited scope of royalty-free and nonexclusive licensing, the WIPO-supported platform does not engage in the actual licensing negotiation nor does it publish the details of the agreements reached between the users and providers. It is therefore difficult to track the actual implementation and consequential impacts. Secondly, the restrictions on both the types of diseases together with the countries who can benefit make the actual beneficiaries very limited. The royalty-free and non-exclusive licenses are only encouraged and available for LDCs, and on NTDs only. According to the WHO,

⁸⁶⁰ WIPO Re:Search, Guiding Principles, available at:

<http://www.wipo.int/export/sites/www/research/docs/guiding_principles.pdf> accessed 09 June 2016,

3. It recommended that the users and providers of the platform should commit to conduct agreement and licensing negotiation to achieve the goals outlined here:

Providers agree to grant Users royalty-free licenses to this Intellectual Property for research and development, anywhere in the world, of products, technologies or services, for the sole purpose of addressing public health needs for any or all NTDs in LDCs.

Providers agree to grant Users royalty-free licenses to this Intellectual Property anywhere in the world to make or have made such products, technologies or services, and to import and export, for the sole purpose, to sell or have sold, these products in LDCs.

Users shall be allowed to retain ownership of and apply for registration of intellectual property rights generated as they deem fit, but shall be encouraged to license to third parties through WIPO Re:Search new intellectual property rights generated under an agreement made pursuant to membership in the Consortium under terms consistent with these Guiding Principles.

For the avoidance of doubt, Providers will not make any claims to rights in new intellectual property, materials or derivatives of materials generated by a User under a license agreement made pursuant to membership in this Consortium but may require such User not to assert such new intellectual property rights against the Provider.

The provision of physical supplies of active pharmaceutical ingredients (API) is encouraged subject to resource availability, but such provision is not required.

In the event of the need for arbitration and/or dispute resolution, Users and Providers are encouraged, but not required, to use the services of WIPO's Arbitration and Mediation Center which shall develop mediation procedures specific to the needs of WIPO Re:Search.

there are 18 NTDs recognised that primarily affect 149 countries worldwide.⁸⁶¹ The distributions NTDs' disease burdens are based in tropical and subtropical countries that have different GNI per capita levels. While the NTDs were neglected not because of the type of country involved, but the type of market which has an economically poor population in a given context, the limiting of the scope of application only to LDCs who suffer from NTDs has significantly reduced the initiative's impact. Many countries affected by NTDs are not within the LDC category, and would therefore not receive any benefit from Re:Search's claimed open approach. In particular, the entire continent of Latin America and most South and Southeast Asian countries who appear to be NTD-prone, are excluded from any licensing benefits defined under the Re:Search project.

The above ideas relating to open innovation and adjusted management of IP in biomedical field in terms of patent pooling for research and alternative licensing share some common features. None of these approaches is intended to explore the possibility of a non-proprietary or non-market-based model, and all would operate only within a defined community, either among the defined partners in the pooling initiative or benefitting only the countries defined. Compared to the total monopolistic model, there are merits within the approaches related to a certain level of opening up, allowing improved freedom to link research activities with final access to biomedical products. However, the limitations of such approaches might still restrict the further achievement of openness in two senses. Firstly, the boundaries defined based on participating parties in the pooling and licensing beneficiaries would exclude developers with niche expertise and start-up enterprises in commercial settings in the pooling as well as patients with

⁸⁶¹ See the WHO's full list of recognized NTDs which are a series of communicable diseases affecting primarily tropical and sub-tropical regions:
<http://www.who.int/neglected_diseases/diseases/summary/en/> accessed 20 July 2018.

limited purchasing power living in rich countries in the licensing. Openness in this sense is specific and targeted and unilaterally defined by one or a couple of leading entities in a given field without the broader participation of other actors. Secondly, it is still yet to be seen the extent to which the approaches would have an impact on altering the systemic issues with patenting behaviours and the changing culture in science and knowledge production. As discussed in previous chapters, the evolution of patent law in relation to biomedical science represents a relatively enclosed system of legal practices. These technically-formed practices underline various technological aspects to be considered as patentable during the overall R&D process. Therefore, adjustments to the overall practices from inside of the system might only achieve limited effects.

6.3 Towards Democratizing Biomedical Innovation: Open Source, Self-Governance and the Plurality of Norms Required For Transformation

6.3.1 The Open Source Movement and Its Success

Experiments in terms of improving openness in the context of biomedical innovation have been pursued in the shadow of the proprietary market model as discussed above, but there has also been research that examines more radical alternatives including open source approaches. The comparison has been made between the open source movement in software development and the context of biotechnology innovation, including open sourcing for pharmaceutical use.⁸⁶² The transformative success of the open source movement as a response to the increasing intellectual property protection of software has been widely documented and analysed with two main bodies of literature providing accounts of the reverse use of the concept and practice of intellectual property, and open

⁸⁶² Hope (n 840) Chapter 1.

source actors' governing structure.⁸⁶³ Open source, as initiated by the hacker community under the leadership of Richard Stallman, who firmly held the belief that proprietary exclusion on source code would not only cut off a critical source of innovation that the hacker community had relied upon, but would also significantly destroy hackers' sharing ethic.⁸⁶⁴

The success of the model is built upon a number of key elements. Firstly, there is the integration of the copyleft idea of open source licensing which, instead of emphasizing the software owner's rights, reverts all rights to software users.⁸⁶⁵ Under a copyleft license – also known as a 'General Public License' – the copyright owner grants the user the right to freely use, adapt, modify and distribute to others the source code without payment of royalties on the basis that any modified source code needs to be licensed out under the same terms and conditions as the original copyleft license.⁸⁶⁶ This is a genius twist on the IP system making free-revealing and free-riding normal in the interest of

⁸⁶³ There is a large body of literature documenting the success of the open source movement in software development. The typical literature provides appraisals of the radical use of IP and non-traditional governance in the open source movement including, but not limited to: Steven Weber, *The Success of Open Source* (Harvard University Press 2004); Georg von Krogh and Eric von Hippel, 'Special Issues on Open Source Software Development' [2003] 32(7) *Research Policy* 1149; Georg von Krogh and others, 'Community, Joining, and Specialisation in Open Source Software Innovation: A Case Study' [2003] 32(7) *Research Policy* 1217; Eric von Hippel and Georg von Krogh, 'Open Source Software and a "Private-Collective" Innovation Model: Issues for Organisation Science' [2001] 14 (2) *Organisation Science* 209; Greg R Vetter, 'Exit and Voice in Free and Open Source Software Licensing: Moderating the Rein over Software Users' University of Houston Law Centre No.2005-W-02; Richard M Stallman, 'The GNU Operating System and the Free Software Movement' in C DiBona and others (eds), *Open Source: Voices from the Open Source Revolution* (O'Reilly Media 1999), available at: <<http://www.oreilly.com/openbook/opensources/book/>>; Lawrence Rosen (ed), *Open Source Licensing: Software Freedom and Intellectual Property Law* (Upper Saddle River 2005); Eric Raymond, *The Cathedral and the Bazaar* (2000) available at: <<http://www.catb.org/esr/writings/cathedral-bazaar/cathedral-bazaar/>> accessed 30 June 2015; Tim O'Reilly, 'The Open Source Paradigm Shift' in J Feller and others (eds), *Perspectives on Free and Open Source Software* (MIT Press 2005).

⁸⁶⁴ Steven Levy, *Hackers: Heroes of the Computer Revolution* (Penguin 2001); Richard M Stallman, 'The GNU Operating System and the Free Software Movement' in C DiBona and others (eds) *Open Source: Voices from the Open Source Revolution* (O'Reilly Media 1999), <<http://www.oreilly.com/openbook/opensources/book/>> accessed 30 June 2015.

⁸⁶⁵ Hope (n 840) 11.

⁸⁶⁶ *ibid.*

constructing a dynamic commons self-regulated by members' reciprocal contributions from which people cannot withdraw.⁸⁶⁷ The use of copyleft licensing also had the objective of resisting the re-appropriation of free software developed under open source conditions for proprietary use.⁸⁶⁸

Secondly, innovation management scholars have attributed the success of the open source movement to new methods of governance and production. In contrast to traditional software development's centralised and hierarchical governance, open source projects are decentralised and quasi-anarchical.⁸⁶⁹ This has been metaphorically termed 'bazaar governance' while the conduct of members is influenced neither by legal nor social controls while free-revealing with non-proprietary exploitation is the prevailing incentive.⁸⁷⁰ Ordering and controlling transaction conducts are at weak or minimum levels, which has become a strength of the bazaar.⁸⁷¹ Open source development also fits within the studies of user innovation and has been seen as a type of horizontal user innovation network⁸⁷² breaking down sheer barriers and distinctions between users, developers and producers in the innovation process, making production more efficient.⁸⁷³ Users, instead of being passive, are simultaneously innovators.

⁸⁶⁷ *ibid.*

⁸⁶⁸ *ibid.*

⁸⁶⁹ Eric Raymond, *The Cathedral and the Bazaar* (2000) available at:

<<http://www.catb.org/esr/writings/cathedral-bazaar/cathedral-bazaar/>> accessed 30 June 2015.

⁸⁷⁰ Benoit Demil and Xavier Lecocq, 'Neither Market nor Hierarchy nor Network: The Emergence of Bazaar Governance' [2006] 27(10) *Organization Studies* 1447, 1452.

⁸⁷¹ *ibid.* See also Yochai Benkler, "'Sharing Nicely": On Shareable Goods and the Emergence of Sharing as a Modality of Economic Production' [2004] 144 *Yale Law Journal* 273, 273-275.

⁸⁷² Eric von Hippel, 'Open Source Projects as Horizontal Innovation Networks—by and for Users' (2002) MIT Sloan Working Paper No. 4366-02 <<http://www.oecd.org/edu/innovation-education/32125887.pdf>> accessed 10 May 2017. See also: Eric von Hippel and Ralph Katz, 'Shifting Innovation to Users via Toolkits' [2002] 48(7) *Management Science* 821-834.

⁸⁷³ *ibid.* See also Hope (n 840)114.

Thirdly, the value of usefulness is an essential motivation to pursue non-proprietary exploitation of the innovation outcome.⁸⁷⁴ In an open source context where the identities of users, developers and producers are blurred, everybody can play each of these roles in a dynamic transaction process. Under open source licensing, the more freely-revealed contributions are used, the more innovation is generated and shared. The use value will therefore encourage further free-revealing, discouraging a return to a proprietary-based collaborative model. It has also been observed that free-revealing promotes interoperability as open source code effectively develops open technical standards⁸⁷⁵ which, alongside peer review and certified signals from the community, in turn ensures the product's improved quality and reliability.⁸⁷⁶

6.3.2 Open Source Innovation for Health: Building an Epistemic Community for Transformation

Taking the key elements driving the open source movement into account, the attempts to transplant the success of the open source movement in software development into biomedical innovation was not a pure coincidence. The time when the intellectual property protection on software source code triggered the open source movement in the 1980s onward, was also the same moment when the patent system was undertaking its own transformation in the context of biomedical research,⁸⁷⁷ especially given landmark cases such as *Diamond v Chakrabarty*⁸⁷⁸ and the major law reforms which started in the

⁸⁷⁴ *ibid* 120-121.

⁸⁷⁵ *ibid*.

⁸⁷⁶ Peter B Meyer, 'Episode of Collective Inventions' [2003] BLS Working Paper No. 368, Washington DC Bureau of Labor Statistics, US Department of Labor.

⁸⁷⁷ Janet Hope, 'Open Source Genetics: Conceptual Framework' in Geertrui van Overwalle (ed), *Gene Patents and Collaborative Licensing Models: Patent Pools, Clearinghouses, Open Source Models and Liability Regimes* (CUP 2009).

⁸⁷⁸ *Diamond v Chakrabarty* 447 US 303 (1980).

US with the introduction of laws such as the Bayh-Dole Act.⁸⁷⁹ These changes have had a profound impact on the scope and boundary of patent protection on life science and the way in which science and technology are produced, shared, presented to and used by the public. As discussed in previous chapters, these changes are derived from a multifaceted co-production process touching on the norms and behaviours of key actors such as scientists, medical practitioners and patent professionals; conceptual and legal understandings of innovation; and the continued appropriation process within the spaces of new health-based technologies. Open source software demonstrated the possibilities of reversing the trend while promoting a democratized model of innovation that can promote society's welfare without relying on proprietary monopoly. It has been remarked that the establishment of an open source model for biomedical research and development is not impossible.⁸⁸⁰

Research on biotechnology – especially the development and application of genomic technology – has observed that, following the breakthrough of the Human Genome Project, the science of genomics have moved pharmaceutical innovation into a new era, one in which when biological research for medicines is driven by the vast volume and availability of data.⁸⁸¹ The practical implications of this shift is that research will rely more on computerised analysis of data related to genes, proteins and biomedical pathways causing diseases, thereby making the development of medicines more efficient, streamlined and targeted.⁸⁸² This digitalised R&D environment lowers the cost and time needed on average and significantly improves innovation efficiency. The dilemma in

⁸⁷⁹ Hope, 'Open Source Genetics' (n 877).

⁸⁸⁰ Arti K Rai, 'Open and Collaborative Research: A New Model for Biomedicine' in Robert Hahn (ed), *Intellectual Property in Frontier Industries* (AEI Press 2005) 131.

⁸⁸¹ Arti K Rai, 'The Information Revolution Reaches Pharmaceuticals: Balancing Innovation Incentives, Cost and Access in the Post-genomic Era' [2001] 1 *University of Illinois Law Review* 173-210.

⁸⁸² *ibid.*

this context recalls the discussions in previous chapters, namely that the patenting paradigm can effectively enclose necessary data and research tools, thereby lowering the overall efficiency and outcome of innovation. Preserving data and research tools as commons and in the public domain is desirable.

Secondly, the increasingly digitalized research environment, now connected through the internet, enhances the potential of a considerable biomedical innovation user-based community worldwide. This of particular appeal to research based in public non-profit research institutions. At firm level, research has observed that the biotechnology and pharmaceutical industries are characterised by intensive relational contracting between firms leading to considerable networks.⁸⁸³ However, digitalised access does not come without limitations as a proprietary approach can easily enclose and limit sharing through either IP exclusivity or contractual obligations of secrecy.

As mentioned above, more amiable licensing approaches have been proposed and experimented with in a biomedical innovation context, with mixed outcomes and limited impact due to the conventional use of IP licensing where the owner's right takes ultimate priority. Moving from the proprietary model could potentially contribute to alternative ways of using the license mechanism as has happened in the open source context.

To further examine the possibilities of transformation in a biomedical context, the triangulation approach, which considers that transformation occurs as a reciprocal process in the context of ideas, institutions and material conditions, with the integrated notion of co-production will be further discussed below. As noted in the previous chapter,

⁸⁸³ Walter W Powell, 'Network of Learning in Biotechnology: Opportunities and Constraints Associated with Relational Contracting in a Knowledge-intensive Field' in Rochelle Cooper Dreyfuss and others (eds.) *Expanding the Boundaries of Intellectual Property: Innovation Policy for the Knowledge Society* (OUP 2001) 251-266.

the reinforcing or weakening of each of the three dimensions – namely ideas, institutions and material conditions – would lead to the progressive transformation of the total regime.⁸⁸⁴

Modelling the triangular framework by first using the open source software movement, the key elements related to the ideas, material conditions and institutional forces involved are presented in Figure 3’s triangulation dynamic.

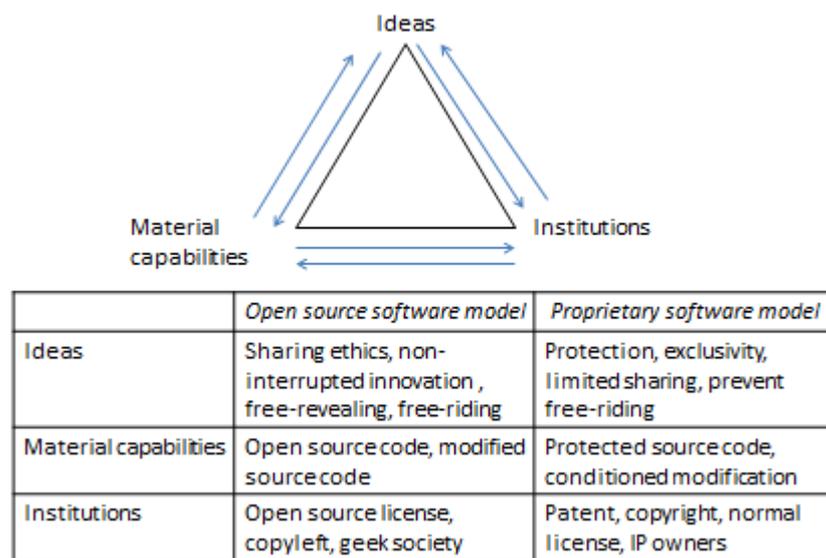


Figure 5: Transformative Dynamics in the Open Source Software Movement⁸⁸⁵

⁸⁸⁴ Robert W Cox, ‘Social Forces, States, and World Orders: Beyond International Relations Theory (1981)’ in Robert W Cox and TJ Sinclair (eds), *Approaches to World Order* (CUP 1996).

⁸⁸⁵ The triangular model adapted from Cox, ‘Social Forces, States, and World Orders’ (n 884)98.

As discussed earlier, the open source software movement conducted a systematic reversal of the traditional proprietary model in order to achieve a radical departure from market logic in software research. Enhancing each element of the forces under the open source category would weaken the corresponding forces at play in the proprietary model. It is also a reciprocal and dialectic process rather than unidirectional. The triangulation metaphor also indicates that this dialectical process is pertinent, as to date the two models co-exist in computer software development and distribution.

To experiment with an open source model for biomedical R&D would also involve considering similar effects with key elements under each force in the triangulation dynamic. A few more examinations are also needed before remodelling. Firstly, one aspect in the open source software movement is the existence of an active ‘geek society’ composed of largely diversified members, namely traditional hackers, institutional and university researchers, or individual hobbyists. In the context of biomedical innovation, the question to explore is whether scientists in traditional contexts have the potential to grow a new biomedical geek society. Secondly, the success of the open source movement was built on a novel type of user innovation with the lead users of software programmes also being the lead inventors and contributors. The question for biomedical innovation is whether a similar actor dynamic exist such that the barriers to actors in the innovation process could be traversed and free. Thirdly, the open source movement does not depend on any existing and structured legal or social order in any given jurisdiction, but rather uses the function of IP laws in a self-regulating manner. In the context of biomedical research which has a heavy regulatory framework, the question is if it would be possible to achieve a certain level of self-regulation in a biomedical geek society.

Regarding the first question, the attempts to pursue open source is a not completely new idea in the context of biotechnology and biomedical innovation, which dates back as far as the initiation of open source software movement when the debates on the tragedy of anti-commons in biomedical research⁸⁸⁶ stimulated ideas and projects trying out some elements of open source approaches. For instance, a rather non-biomedical-related biotechnology initiative was documented in the late 1990s with the ‘General Public License for Plant Germplasm’(GPLPG) proposal, later modified as General Public License (GPL), in response to concerns over plant-breeding dependent on the freely-available plant germplasm, while genetically-modified organisms (GMO) could appropriate germplasm by inserting patented GMO genes.⁸⁸⁷ The GPL takes its inspiration from open source software licensing and aims to achieve standard cross-breeding, natural variation and distribution.⁸⁸⁸ Direct experiments have also been undertaken in the biomedical research field. For instance, the Tropical Diseases Initiative (TDI) was proposed as an open source drug discovery scheme by a team of lawyers and biologists.⁸⁸⁹ TDI adapts a research model that relies heavily on computational methods with high-skilled volunteer researchers, in order to reduce the need to work in physical labs, thereby reducing the overall cost.⁸⁹⁰ TDI was incubated

⁸⁸⁶ Michael A Heller and Rebecca S Eisenberg, ‘Can Patent Deter Innovation? The Anticommons in Biomedical Research’ [1998] 280 *Science* 698-701. This landmark piece inspired rich debates concerning anti-commons in biomedical research. Accordingly, granting too many patents or other intellectual property rights upstream can stifle socially-valuable innovation. See also: Hope, ‘Open Source Genetics’ (n 877).

⁸⁸⁷ Jack Kloppenburg, ‘Impeding Dispossession, Enabling Repossession: Biological Open Source and the Recovery of Seed Sovereignty’ [2010] 10(3) *Journal of Agrarian Change* 367-388.

⁸⁸⁸ *ibid.*

⁸⁸⁹ Stephen Maurer, Arti Rai and Andrej Sali, ‘Finding Cures for Tropical Diseases: Is Open Source the Answer?’ (2004) 1(3) *Public Library of Science: Medicine*
<<https://doi.org/10.1371/journal.pmed.0010056>> accessed 05 May 2017.

⁸⁹⁰ *ibid.*

by Synaptic Leap, a non-profit organisation that attempts to support online biomedical research communities who collaborate using an open source approach.⁸⁹¹

The Synaptic Leap platform currently hosts biomedical research projects focusing on drug discoveries for malaria, schistosomiasis, tuberculosis, toxoplasma and other general biomedical research projects.⁸⁹² The group's Chairman, Matthew Todd, an active advocate for open source drug discovery, works at the University of Sydney on organic chemistry. In a recent publication, he illustrated the high level of adaptation of the open source model in the initiative and suggested that '[A]n area in which OS (open source) could be particularly productive is drug repurposing, whereby existing drugs or candidates are found to have potential for the treatment of another disease and for which there exists a significant amount of preclinical and possibly clinical data'.⁸⁹³ This would be significant, if implemented, in effectively reversing the patent evergreening strategy discussed in Chapter 4 while repurposed drugs with new medical indications could be subject to second medical use patent protection, not only prolonging the monopoly of pharmaceutical companies, but also interrupting medical practices.

Another initiative directly naming open source is Open Source Drug Discovery (OSDD) based in India and launched by the Council for Scientific and Industrial Research which has committed USD 120 million for its development.⁸⁹⁴ It has been considered as a model with the potential to transform the current patent-centric paradigm by offering a strategy through commons-based rather than patent-based research.⁸⁹⁵ The initiative

⁸⁹¹ See the Synaptic Leap website:<<http://www.thesynapticleap.org/>> accessed 20 July 2018.

⁸⁹² *ibid.*

⁸⁹³ Manica Balasegaram and others, 'An open source pharma roadmap' [2017] 14(4) PLoS Med <<https://doi.org/10.1371/journal.pmed.1002276>> accessed 05 May 2017.

⁸⁹⁴ Aziz Rehman, 'Equitable Licensing and Publicly Funded Research: A Working Model for India?' (2010) 16 Southwestern Journal of International Law 75.

⁸⁹⁵ *ibid.*

started with the building of a database, and has collaborated with other initiatives, for instance TDI, who adopted an open licensing strategy to obtain information on a tropical disease through a kernel.⁸⁹⁶ Another example is the Biological Innovation for Open Society (BIOS) initiative launched in 2005 by the Centre for Application of Molecular Biology in International Agriculture (CAMBIA).⁸⁹⁷ BIOS runs a public patent search database titled Patent Lens and has developed model licenses named after the Biological Open Source idea.⁸⁹⁸ It has, however, been observed that BIOS licenses are quite different from the open source software license in that they ask for grants back to CAMBIA with any improvement and the availability of the seed technology subject to a fee.⁸⁹⁹ Open source licenses, by contrast, do not involve royalty payment and do not imply an exclusive grant paid back to a specific institution. The above examples can be seen as reflecting the existence of a geek society for biological and biomedical research. They might provide the foundation for a potential scaled open source approach to biomedical innovation.

The second question concerns the issue of the user innovation model and whether the biomedical innovation context might develop a similar active user-based dynamic. It has been pointed out that, according to the user-innovation approach, ‘users’ are defined as those who benefit primarily from using the innovation.⁹⁰⁰ Other actors may benefit from or contribute to the same innovation for different purposes.⁹⁰¹ In the context of biomedical innovation, scholars have suggested one more category of ‘consumer’ or ‘end user’ to be added in order to include those who benefit from the end products such

⁸⁹⁶ *ibid.*

⁸⁹⁷ CAMBIA, <<https://cambia.org/cambias-mission-ethos/>> accessed 20 July 2018.

⁸⁹⁸ *ibid.*

⁸⁹⁹ Hope (n 840)317.

⁹⁰⁰ *ibid* 115.

⁹⁰¹ *ibid.*

as medicines, vaccines and diagnostics.⁹⁰² Some of the key actors – including biomedical scientists, medical practitioners (such as doctors and pharmacists), patent attorneys and patients – have been discussed in previous chapters in the context of their roles and constraints in the proprietary-based paradigm. In an open source model, whether their roles could be potentially transformed is a question worth exploring. In an open source biomedical innovation model, scientists and medical practitioners plays a critical role in user-based innovation. At the upstream level of drug discovery, the scientific community uses and at the same time creates and modifies existing data and sources generated by other scientists. Scientists in this sense are innovators and users simultaneously, to use an analogy based on the open source community. In relation to medical practitioners, it is interesting to note that the current proprietary model has largely not recognised them while constant innovation has happened on a daily basis via the practices of drug prescription, diagnostics and treatment. Typically, and as discussed in Chapter 4, it is medical practitioners and pharmacists’ common practice to use off-label medicines.⁹⁰³ The capacity to make professional judgements on off-label use could be easily disrupted under a proprietary model while second medical use patent could be enforced up to the level of medical practice. Yet, this is also a typical user-based innovation context, while off-label use in an open source model could contribute to medicines’ improvement and repurposing without being constrained by constructed proprietary protection which does not add use value but only prolongs a firm’s market monopoly. The question of whether the patients could be viewed in the user-innovation framework in the biomedical context is also worth exploring. Patients come into the

⁹⁰² *ibid* 116.

⁹⁰³ Eric von Hippel, ‘Market Failure in the Diffusion of Clinician-developed Innovations: The Case of Off-label Drug Discoveries’ [2017] 44(1) *Science and Public Policy* 121, <<https://doi.org/10.1093/scipol/scw042>> accessed 20 June 2018.

picture through the compassionate use of new medicines, individuals from the general public who are participating in clinical trials, or individuals whose genomic materials have been used specifically in biomedical research, are simultaneously active users and contributors. User innovations under open source conditions remain applicable provided that adequate protection on personal data, genetic data and biological materials are in place.

On the third question regarding the possibility of self-regulation in the biomedical R&D context, a high level of self-regulating dynamic is possible. The novel ways of governing in the open source software movement have been discussed earlier. Instead of resorting to a formal structure of ordering and regulation, the open source model is run in a so-called bazaar governance model which is entirely inclusive and flexible.⁹⁰⁴ Without a proprietary-based monopoly to facilitate profitability, the incentive for joining the open source model with loose ties between members has been considered as based on rational self-interest.⁹⁰⁵ The self-interest in the context of open source is different from interests attached to profitability and exclusivity but are also related to the predictable benefits that the open source model could guarantee, i.e. once committed to open source license when contributing, others will do the same and the contributor will be benefited in turn without any financial burden being incurred. The free revealing and constant improvement of the product's quality are positively reinforced, making open source an attractive option for self-interested participants. This is also applicable to biomedical innovation. There might be some nuances in the downstream context when it comes to biomedical products because a totally different body of regulation would apply to ensure safety, efficacy and pre-determined quality standards for its use on humans. This is

⁹⁰⁴ Hope (n 840).

⁹⁰⁵ *ibid.*

different from the proprietary or non-proprietary discussions. The key issue at this stage would be to ensure the end products' affordability and accessibility to patients in need. In this – and although the regulatory issue is different – the open source model could bring significant advantages because the overall reduction of the R&D cost could help to pressing for more affordable prices at a global level because the development resources and expense have been openly shared.

Unpacking the above questions returns us to the possible framework necessary for a transformative open source biomedical innovation system. Figure 4 presents a preliminary triangulation dynamic using the analogy of open source software.

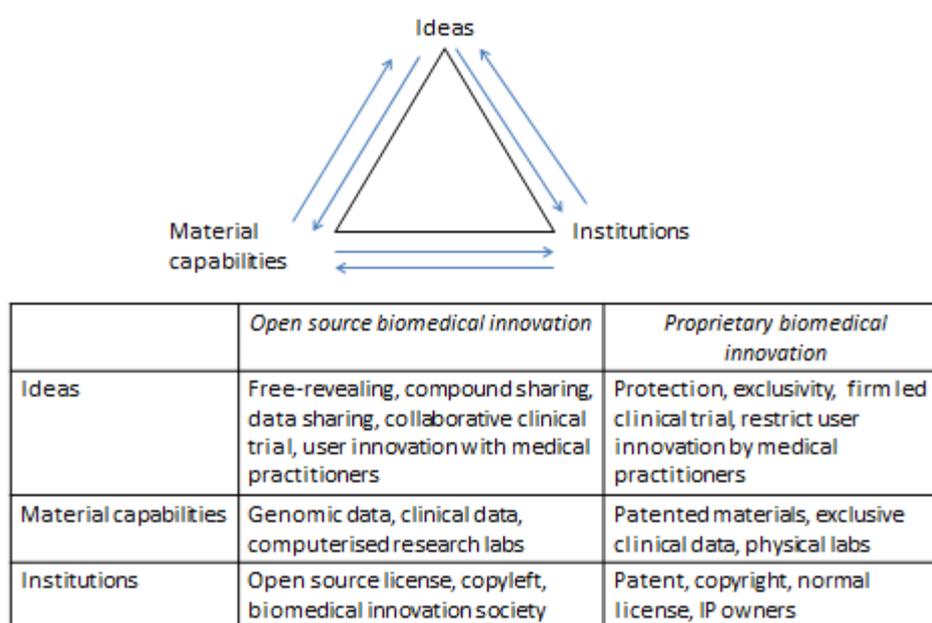


Figure 6: Transformative Dynamics in Open Source Biomedical Innovation

Similar to the systematic reversal of the proprietary model in the open source software movement, open source biomedical innovation, when pursuing transformative dynamic in the triangulation framework, also needs to utilize the enhancement of each element under each respective force of ideas, materials and institutions. For instance, the more

users innovate with medical practitioners' participation, the more can be achieved regarding repurposed drugs, the weaker the incentive to pursue evergreening patents on additional medical indications. The stronger publishing clinical data is pursued collectively, the weaker the exclusivity on clinical data under the proprietary model becomes. The better the open source license terms are able to promote wider beneficiaries from the open source model of innovation, the weaker proprietary-based licensing with controlled beneficiaries is as a result. The legal professions can play an important role in constantly improving open source licenses while facilitating the reversal of the use of intellectual property concept with the aim of departing from intellectual property.

As mentioned above, open source biomedical innovation remains a new model in which preliminary social and experiments have been conducted. There are also some small-scale success stories as a response to the extreme distortion of the current proprietary paradigm. One such story relates to a group of high school students from Sydney who reproduced a life-saving medicine which had increased price in the US from \$13.50 to \$750 overnight.⁹⁰⁶ The students achieved this 'generic' production in their school lab with using an open source approach, after which they opened their work to the internet, therefore 'scientists anywhere in the world were able to view all the data generated and mentor the students to accelerate their progress.'⁹⁰⁷

⁹⁰⁶ Melissa Davey, 'Australian Students Recreate Martin Shkreli Price-hike Drug in School Lab' *The Guardian* (01 December 2016)

<<https://www.theguardian.com/science/2016/dec/01/australian-students-recreate-martin-shkreli-price-hike-drug-in-school-lab>> accessed 15 August 2017

⁹⁰⁷ *ibid.*

6.4 Redesigning normative institutions for biomedical innovation

This chapter reviewed two aspects of the construction of an alternative conceptual framework, namely reengaging the broader community of innovators and users and the path to democratising innovation's governance. Sidestepping the patent-centric understanding of biomedical innovation requires a systemic re-imagination of how knowledge of disease and medicines is formed, as discussed in Chapter 5. In addition, two other aspects of building an alternative conceptual framework include re-examining the role and norms relating to the broader innovator communities, and the political possibility of pursuing publicly-accountable innovation without being bound by a monoculture of exclusive property. First, instead of focusing only on patent holders designing the reward mechanism, realigning the broader innovators in the biomedical context recognises the significant contribution of physicians and patients, who are defined as user innovators in the innovation studies literature. The norms-based rather than formal law-based community model is governed by the standard of sharing and publication. This phenomenon provides an important pathway to engage the last aspect of the building of an alternative conceptual framework. In contrast to exclusivity, the concept of openness involves debating the democratization of innovation in the biomedical field. Openness, however, has been used differently in the context of either the patent-based model or the discussion of open innovation in biomedical fields. Both contain limitations as openness is either conditioned with exclusivity or only meaningful for specific interest groups. Instead, the open source movement has experimented with making openness the norm for socially-constructed innovations in the context of computer science. Resorting to an alternative definition of relationships on the part of users who are at the same time also innovators, the open source model provides the institutional possibility to accommodate initiatives in the biomedical field. Accordingly,

biomedicines potential return to an open science culture takes up the analogy of open source and reflects a diverse community of innovators, making openness and sharing the norm. This, together with the other aspects discussed in Chapter 5, are critical in developing an alternative conceptual framework for biomedical innovation. Democratizing the space of biomedical knowledge production and sharing offers the possibility of restructuring the power relations between individuals and professionals in law and medical science, government and commercial entities. With innovation being socially constructed, demanded, conducted and managed, the role of law can therefore be repositioned beyond the boundary of patent and intellectual property.

CONCLUSION

I. Rethinking Innovation: Expertise and Openness

The thesis thus far has called on rethinking of two primary modes that I consider as critical for building an alternative conceptual framework concerning biomedical innovation.

Firstly, and taking a step back to look at the relationship between individuals, be they patients or trial participants alike, and biomedical researchers, it is important to rethink biomedical innovation as an interactional practice rather than just as an expert-led and technoscientific-oriented enterprise. This relationship between biomedical researchers and individuals has been traditionally covered by those laws and regulations concerning research ethics, but has not been explicitly related to the context of proprietary protection in terms of research activities, their outcomes and application. It is in this sense that expertise as a discursive and pervasive concept is largely relevant. Expertise refers not only to the characteristics of a specifically-trained expert group, but can be determined and manifested in everyone depending on the given circumstances. Expertise held by different participants in a collective action conveys a pluralistic knowledge and sense of authority. Exercising expertise held by different actors in a plural and mixed context implies the need for a normative ordering in order to accommodate diverse types of knowledge, authority, ownership and interests. This is, however, not to say that a non-differential treatment is applied without taking into account an inherent power asymmetry. Rather, recognizing the value of the expertise of non-expert entities and claiming such expertise to gain authority in decision making would open up the enquiry to a normative ordering different from the predominant order.

In the context of biomedical innovation discourse, the patent-centric model remains the predominant order in which industrial interests and legal expertise are at central to stabilising internal and external conflicts while retaining the regime's specifically-defined authority and legitimacy. The diverse expertise of non-experts can transform in the process of turning intellectual works into inventions and seeking patent protections. For instance, for the patent law professions, all the other entities can be considered as 'lay' persons given their lack of knowledge and skills that are recognised by the patent law system. Those knowledge and skills, on the other hand, are themselves the products of the work of patent law professions through the use of legal reasoning and imaginaries collectively. Examples of how imaginaries work in patent law practices in areas such as determining patentability and patent claim drafting, have been discussed in Chapters 2-4. Therefore, with the mission of producing more patents and justifying 'newness' using specialised techniques, patent attorneys' professional conduct has contributed substantively to the epistemic dimension of taking patent as the indispensable institution for biomedical innovation. Even though the patent law system claims to be operated on the basis of technical neutrality and objectivity, the understanding of its function in global level biomedical innovation nowadays has been justified by reference to commercial motivations and a particular neoliberal worldview. Patent provides a route to turning intellectual works and outcomes into commodities. The outcome of this route is also presented in the form of patent statistics, which, in turn, can be portrayed politically as indicating innovation. Achieving this requires collective work based on the expertise of the patent law professions, especially patent attorneys, a certain branch of economists, the biomedical industries and politicians.

While the patent law system primarily protects the rights of the patent holders – who are not necessarily inventors or innovators – the joint exercise of law and economic

expertise gains legitimacy and authority that could be used in sustaining the monolithic vision of biomedical innovation. Other biomedical innovation actors, including medical practitioners, patients and individual trial participants, are ‘lay’ entities. The segregation of innovation contributors from patent holders artificially establishes a hierarchy in the current patent law-centred model. Overcoming this segregation requires the normative infrastructure to be built from the below, whereby marginalised innovators and knowledge holders can exercise authority, ownership and define the rules of sharing and using intellectual works beyond patent law-defined boundaries. The discussions in Chapters 5 and 6 on approaches adopted alongside the biomedical context have illuminated the possibilities of empowering the innovator communities beyond patent. It is therefore critical to reclaim the knowledge bases of biomedical innovation in order to pursue a systemic transformation outside of discussions on reforming the R&D biomedical industry financing model as the means for change.

The knowledge bases of biomedical innovation start with the authority of individuals who contribute to biomedical research and science advances based on their own biological and genetic data, materials or disease experiences. This contribution then goes into biomedical research and clinical practices, forming a further layer of knowledge in the biomedical innovation infrastructure. Knowledge generated by biomedical researchers and clinicians involve experimental data, trial outcomes, the material development of chemical or biological entities with therapeutic value, diagnostic materials and techniques, and, importantly, medical practitioners’ accumulative and exchangeable clinical experiences and knowledge. It is also important to note that these individuals, researchers and clinicians are collaborators, functioning as co-existing and interactional entities in this context, rather than segregated, hierarchical and isolated players. In a non-Western medical context, the knowledge base can have a different

presentation. Traditional medical knowledge can be held by traditional healers, communities and individuals, whereby researchers can involve both those who adopt a Western science-based approach or those follow traditional medical methodologies. Therefore, there are commonalities between medical cultures and traditions in terms of the interconnectiveness between individuals and communities who are not medically trained, with medical practitioners including the traditional healers and researchers who form a disease, prevention and treatment knowledge base. Research-based knowledge can also be held by hobby scientists and non-institutional researchers especially in the emerging context of genetic technologies' use. The knowledge bases also include further systematic clinical trials for the purpose of gaining regulatory approval and commercialisation, which are often supported by commercial entities. Each layer of the knowledge bases function in terms of its own normative preference but these inevitably interact and influence each other. The patent-centric model concentrates on the last aspect of commercial entities' contribution and sometimes on the middle aspect in terms of academic researchers and institutions. However, this provides limited recognition and protection for the origin of the knowledge base held by individuals, communities, non-institutional researchers and medical practitioners' clinical experiences and practices in the middle, who also interact constantly with each other while contributing to the totality of biomedical innovation.

The access and benefit sharing (ABS) mechanism as enshrined under the CBD provides a route to rethink the implications of ABS beyond biodiversity protection. The application of ABS in the context of public health research has been recognized by the WHO in terms of the discussion of the global ABS mechanism for the flu virus and non-

flu pathogen sharing mechanism.⁹⁰⁸ The discussion now focuses on inter-state parties sharing mechanisms, and concerns ABS in relation to pathogens and their associated data.⁹⁰⁹ However, it should be possible to develop the ABS discussion further and look at its implications for biomedical innovation practices in general. Can individuals – patients and trial participants alike – invoke an ABS framework as a means of controlling how the biological and genetic data and materials derived from it are used to ensure innovation is publically accountable and enters an accessible domain? The traditional approach to ensuring ethical conduct in research uses prior-informed consent (PIC) as the primary tool to guarantee the protection of individuals from harmful practices in biomedical research. Prior-informed consent remains at the centre of the ABS framework enshrined under CBD, especially in terms of its Nagoya protocol. It is therefore plausible to propose the reinterpretation of PIC under CBD to include individuals who can potentially open up the space of discussion regarding accountability, particularly in terms of ensuring that any downstream use of biological and genetic data is accessible and open without being enclosed by commercial interests.

The clinical experiences and expertise of physicians have played a critical role in the development of medicine. Yet, as discussed in Chapters 5 and 6, biomedical innovation's patent-centric paradigm may pose a conflict rather than compromising physicians' professional norms in relation to innovation. The longstanding professional culture of sharing and physicians' professional norm-based operations may come into

⁹⁰⁸ World Health Organization, 'Implementation of Nagoya Protocol and Pathogen Sharing: Public Health Implications' (WHO Secretariat, 2016) <http://www.who.int/influenza/pip/2016-review/NagoyaStudyAdvanceCopy_full.pdf> accessed 5 August 2018. See also WHO 'Fact Sheet: Nagoya Protocol and Public Health' (20 March 2018) <http://www.who.int/influenza/pip/NagoyaProtocolandPH_EN_20Mar2018.pdf> accessed 5 August 2018.

⁹⁰⁹ *ibid.*

confrontation with the segmented approach to medicine in patent law, as discussed in Chapter 5. Reclaiming the expertise of physicians in biomedical innovation requires a re-examination of the nature of medicine and the role of medical knowledge. In this context, approaches using the human rights framework suggest certain possibilities. Jointly approaching the right to health and the right to share in and benefit from scientific progress and knowledge leads to the notion of everyone's right to access and benefit from medical knowledge, as stated in the WHO Constitution, as an integral aspect of enjoying the right to health. This level of reinterpretation has not been captured in the current human rights law framework and requires further normative discussions.

The second level of rethinking biomedical innovation as suggested in the thesis concerns the notion of openness, which recalls the relationship between the open source movement and its implications in the biomedical field, as discussed in Chapter 6. The idea of open source realigns actors, relations and polities, moving away from a centralised and institutionalised structure, instead becoming closer to a decentralised, democratic and oftentimes loosely structured framework. Consensus on values and social norms on the part of the participants as well as a peer-based sharing structure and award system are the necessary building blocks, which can be backed by another type of alternative legal instrument, namely open source licensing. The recognition of a given level of control is conditioned by the commitment and accountability in terms of sharing and returning back to the community. It is in this sense that the open source concept and institution offers an invaluable inspiration to the building of an alternative conceptual framework. Researchers and scientists interact as innovator citizens and community members, in contrast to commercially motivated entrepreneurs. Innovation, in this sense, can be both disruptive and incremental, but will not be valued in terms of the exclusivity and monopoly rationale.

The idea of altering the biomedical innovation patent-centric narrative also inevitably encounters the very meaning of medicine, biomedicine and their relation to the meaning of life and society. As discussed in Chapter 5, the trend towards the biomedicalisation of society has further moved away from the origin of the word ‘bio’ as the meaning of life. Medicine, on the other hand, has profound social, cultural and historical values, which are also subject to political reframing, reflecting the supremacy of a specific type of knowledge and technology while devaluing other meanings and interpretations. Creating an alternative biomedical innovation conceptual framework would thus begin by redefining the meaning and value of medicine and medical knowledge, revisiting the meaning of life in relation to the concept of biomedical knowledge, and move away from a technoscientific-centred worldview.

II. Towards a Transformative Conceptual Framework

The above review outlines the conclusion of the research, which attempts to explore an alternative biomedical innovation conceptual framework by adopting a critical and transformative perspective. The backdrop of the research is the complex picture facing the biomedical innovation field today. On the one hand, the industry-led and patent-centric mode remains the default narrative in innovation policy discourse. On the other hand, discontent with a lack of innovation, insufficient participation and the complicated framing and interpretation of life, society and wellbeing are all pertinent issues.

Accordingly, the research has taken a critical legal studies perspective, in which the role of law is considered as being politically constructed while exhibiting inherent uncertainties and indeterminacies. It takes an interdisciplinary approach by borrowing theoretical concepts from science and technology studies, particularly the co-production

approach, critical political economy studies, innovation studies and the sociology of medicine. The contextual, rather than doctrinal, approach to law has been used.

Part I of the research presents a critical review of the prevailing justifications of patent's role in stimulating biomedical innovation. Chapter 1 reviews controversies concerning the mainstream economic justification of patent's role as an innovation incentive. As noted, even though the utilitarian justification remains dominant, the oft-cited economic value of patent in regard to innovation have not achieved a consensus in classic economic studies. The emergence of the Schumpeterian notion of innovation and evolutionary economics, on the other hand, have been used as the major policy framework in innovation debates. However, the fact that Schumpeter was not part of the support for strong patent is often omitted. This shaky theoretical foundation, however, did not hinder patent law's evolution into a highly specialised field of law, one which expanded dramatically in the context of the neoliberal approach to development and globalization. In the context of biomedical innovation, the above controversies are pertinent.

Building on this review, Chapter 2 centred its discussion on the contentious relationship between science, technology and law in the context of constructing the notion of innovation in pharmaceuticals. As observed by scholars, 'science and property' – formerly independent and even opposing concepts referring to distinct activities and social spheres – have been made contingent upon each other through the concept of intellectual property rights.⁹¹⁰ This kind of relationship has become routine in co-production processes while each of the intertwined aspects – science, property, law and

⁹¹⁰ Henry Etzkowitz and Andrew Webster, 'Science as Intellectual Property' in Sheila Jasanoff and others (eds), *Handbook of Science and Technology Studies* (SAGE 1995) 480.

medicine – started rewriting and underwriting each other’s pre-existing normative orders. The indeterminate features of such processes revealed the clash of linear explanations of the commonality and differences between the disciplinary cultures that are now melting in the field of patenting. On the other hand, the process also revealed a deep conflict regarding boundaries, one which would place the public interest in danger. Despite these co-produced rules and institutions, the overall functions of expertise play a vital role in the co-production exercise. In this regard, questions concerning the extent to which the patent paradigm has changed the scientific communities and research in medicines as well as how patent law practitioners have contributed to the construction in actions, were discussed further in Part II.

Keeping the co-production approach in its critique, Part II of the research moved into the discussion of the active role of legal professions in producing the text, meaning and system of patent documents, and examined how co-production occurs and manifests itself in the patenting of biomedical innovations. In addition, Chapter 3 introduced an area of inquiry insufficiently represented in the literature, namely the professional conduct and epistemic and cultural formation of patent law practitioners, especially patent attorneys. The highly skilled work of patent attorneys and other patent law practitioners are constitutive in terms of building the specific language system used in representing inventions. As noted in this chapter, critiques of the deficiency of the justification of patent as an indispensable institution stimulating biomedical innovation have focusing on two primary threads, namely debunking the economic rationale and revealing empirical incomprehension. Yet, the enquiry on the actual making and transmitting of the meaning of newness and innovation are often overlooked in the political and policy context.

Legal historians have traced back the evolution of modern patent law in the Western context, particularly in Europe and the US, and demonstrated the transformative traits whereby patent law shifted from a privilege-based system to becoming a system of rights and entitlement. This transformation took place in the context of systemic technological changes, especially during the industrial revolution. It also brought about significant changes in the regulatory and institutional infrastructure of patent administration with the introduction of patent specification and substantive examination processes. These changes have been considered as triggering the emergence of the specialised patent agent vocation, which later developed into a unique branch of the legal profession. Having concurrent knowledge and skills relating to biomedical science, technology and law, patent attorneys perform day-to-day production of the texts and meaning of inventions, mostly through patent claim drafting and prosecutions. In addition, the globalization of legal services and the increasing level of corporate-focused legal services have enabled professional skills and knowledge to be exchanged in transnational contexts. Indeed, patent attorneys' networks and associations in the transnational context have contributed to and formed an integral part of the discourse of biomedical innovation and patent.

Both the institutional establishment and political engagement of patent attorneys, as discussed in Chapter 3, present a co-production trait, in which legal knowledge is constitutive of and interacts with the foregrounded knowledge of biomedical science and technology. Transitioning from a scientist or engineer to a patent attorney has been bound by shared professional norms and client-centred ethics. This becomes prominent when specialised services have become substantively more accessible for corporate clients, raising the question of the decline of the legal profession as distinct from and independent of the impact of political, commercial and other interests. At the same time, studies on patent law practitioners have presented a non-linear picture with subversive

members of patent attorneys and legal practitioners joining forces to challenge the technical grounds and boundaries from within the patent law realm. The mainstream homogeneity evident in the narrative of patent's indispensable role in biomedical innovation alongside the questioning of the impact of expansive patent on the public interest have provided a site of conflict and segmentation within both the legal profession as well as the patent law-centred debate. This tension from inside may provide a critical point for an alternative conceptualisation and re-imagination, as Part III of this research discussed. Building on Chapter 3's critique, Chapter 4 further examined the work of law in the context of making meanings in the context of biomedical innovation and its impact on non-corporate innovators.

Building on observations of the role of active professions in producing the innovation epistemic within patent law, Chapter 4 further investigated the conduct of co-production and its underlying incoherence in the context of making of biomedical innovation patent. In this regard, the chapter outlined a concern that the lost social contact in the process of textualising patent claims has been manifested in its temporal and spatial dimensions while technological and legal imaginaries come together to co-produce the identity of patent proliferation, representing only a particular type of language shared by a particular community. The outcome of such a co-production exercise has sought political settlements through energetic commercial endorsements and legal recognition, simultaneously leaving social implications in several contexts unaddressed, especially those concerning medical practices.

For example, in the case of second medical use patents, it is a common practice for physicians in different countries to prescribe medicines for unapproved medical indications, which is also termed the 'off-label' use of medicines. Off-label prescriptions

have been found in every medical speciality in practice.⁹¹¹ Studies found that a high percentage of children (78.9%) discharged from paediatric hospitals were taking at least one off-label medication in the US.⁹¹² In the UK, the General Medical Council, the regulator for medical doctors, have issued guidance on off-label prescriptions, allowing such practices to be conducted with adequate guidance.⁹¹³

In addition, in many countries, it is the given medical professional's duty to prescribe medicines using their generic names rather than brand names⁹¹⁴ and the high professional standards vis-à-vis safeguarding patients' confidentiality in some countries has also lead to the separation of doctors' prescriptions from dispatching pharmacists while prescriptions often come without specific indications.⁹¹⁵ The patent status of indications outside of the licensed scope of a known medicine is not of concern to medical practitioners when they perform their medical duties within the long established

⁹¹¹ Christopher M Wittich and others, 'Ten Common Questions (and Their Answers) About Off-label Drug Use' [2012] 87(10) *Mayo Clinic Proceedings* <<https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3538391/#bib11>> accessed 20 July 2016.

⁹¹² Samir S Shah, Matthew Hall, Denis M Goodman, 'Off-label Drug Use in Hospitalized Children' [2007] 161(3) *Arch Pediatr Adolesc Med* 282.

⁹¹³ UK General Medical Council, 'Prescribing Unlicensed Medicines', *Good Practices of Prescribing and Managing Medicines and Devices* (2013), available at: <http://www.gmc-uk.org/guidance/ethical_guidance/14316.asp>. Accordingly, a doctor can issue off-label prescriptions under the following conditions:

d. be satisfied that there is sufficient evidence or experience of using the medicine to demonstrate its safety and efficacy;

e. take responsibility for prescribing the medicine and for overseeing the patient's care, monitoring, and any follow up treatment, or ensure that arrangements are made for another suitable doctor to do so;

f. make a clear, accurate and legible record of all medicines prescribed and, where you are not following common practice, your reasons for prescribing an unlicensed medicine.

⁹¹⁴ For instance, in France, it is a legal requirement for medical doctors to prescribe using medicines' International Non-proprietary Names (INN). Article L.5121-1-2 of the French Public Health Code

⁹¹⁵ For instance, doctors in the UK are trained to prescribe medicines in their generic names, and no specific indications are normally written in a description for the dispensing pharmacists. See: Richard Croker and others, 'The Clinician Impact and Financial Cost to the NHS of Litigation over Pregabalin: A Cohort Study in English Primary Care' [2018] *BMJ Open* < <http://dx.doi.org/10.1136/bmjopen-2018-022416>> accessed 05 August 2018.

discretion supported by their professional expertise. The ‘unlicensed’ new indication, in this context, is known to the medical professions as both an obvious knowledge and a practice. Thus, the existence and enforcement of second medical use patent can, however, interrupt the longstanding normative context of physicians’ professional conduct with a legally constructed binary patent infringement test. In the context of European patent regime, four decades after the heated debates on the exclusion and adaptation of second medical use patent, there are headlines concerning a series of patent disputes between the company Pfizer and its generic competitors. In *Warner-Lambert Company LLC v Generics (UK) Ltd (t/a Mylan) & Ors*,⁹¹⁶ the UK Court of Appeal upheld the decision made by Justice Arnold on the insufficient disclosure in the Swiss-type claim, hence the rejection of the Pfizer request for an interim injunction.⁹¹⁷ However, the process of how this case unfolded has revealed Pfizer requesting that the entire UK public health system – including the NHS and national pharmacy network – change its medical guidelines and prescription practices.⁹¹⁸

One might start questioning the possibility of reinterpreting patent laws as social thickness has been long lost in patent’s regime building through underwriting and rewriting science and technological norms through the manipulation of expertise and the textual reorientation of patent’s meaning. Yet, the system’s rather unsuccessful attempt to self-correct as shown, for instance, in the revisions of examination guideline on Markush claims in the US, has not suggested a promising pathway. Instead, a more thorough re-imagination of an alternative framework is needed while biomedical

⁹¹⁶ *Warner-Lambert Company LLC v Generics (UK) Ltd (t/a Mylan) & Ors* [2016] EWCA Civ 1006 (13 October 2016). The full text of the judgment is available at:

<<http://www.bailii.org/ew/cases/EWCA/Civ/2016/1006.html>> accessed 09 June 2017.

⁹¹⁷ *ibid.*

⁹¹⁸ *ibid.*

innovation's lost social aspects and broader innovators could reclaim certain boundaries. Among other issues, the concept of community remains critical whereby alternative expertise and norms might be explored. Alongside the re-imagining of the role and function of the legal community as such, it is equally important to look at the community of innovators beyond the patent holder-centric logic as defined by patent law, as discussed in Chapters 5 and 6.

The multiple layers and processes of co-production occur in material and conceptual spheres, where the knowledge and practices of scientists, clinicians, lawyers, hybrid-disciplined patent attorneys, patent examiners, judiciaries, civil society actors, the public and policymakers act upon each other. In the current biomedical innovation field, the supremacy of legal techniques plays a critical role in alienating the social from the technical in the creation of patent proliferation. There are also marginalised layers of expert knowledge that are either not yet entering the formal law realm or which might have been reinterpreted in order to fit in. Some of that knowledge might have been once dominant, but at a later stage has been subordinated as a result of reinterpretation and relocation. The hyper-interconnection and constant modification that takes place between the actors, norms and practices have presented a complex and antagonistic network and process that one might view as unsettled. However, this fluidity as such should not be overlooked because its historical, ideological and political underpinnings are critical in making sense of the process and inspiring a possible re-imagination.

Building on the critiques developed in Parts I and II, in Part III the research discussed the key elements and possible approaches whereby the alternative biomedical innovation conceptual framework could be reimagined. Chapter 5 discussed the possible approaches to alternative conceptual framework building. A critical and transformative

framework was adopted by consolidating critical political economy scholars' triangulation approach and STS scholars' co-production critiques. Accordingly, transformative forces might be found in the constant interplay and readjustment between a world order's ideals, materials and institutional dimensions, while reinforcing and weakening each dimension could support moving towards an overall transformation. The critical intention as such seeks to override the prevailing order rather than continuing with problem solving. Transformation, in this sense, requires working from the bottom up and outside of where conflicts arise. In light of this, the key elements in explorations of alternative conceptual framework building include revisiting and redefining the meaning of medicine and knowledge as transformation's underlying ideal forces when reengaging with innovators outside of biomedical patent holders alongside the exploration of the plurality of norms and self-governing innovation.

The first element of an alternative conceptualisation's ideal space was explored in Chapter 5 by first discussing the contested meaning of medicine and biomedical knowledge, recalling medicine's politically constructed hierarchies and preferences, while the connectiveness of traditions and cultures have been divided into 'modern' and 'traditional' in order to prioritise a specific understanding of medicine. The trend towards a biomedicalised society as motivated by commodified healthcare's narrative has depended on a techno-scientific view of life and health. Rather, the chapter suggests that the dimension and meaning of 'bio-' should be reinterpreted in order to reflect its original meaning of 'life'. The cultural implications of this would help to redefine the relationship between biomedical innovation and the lost social connection with the cultural context of 'life'.

In addition, three conceptual approaches challenging the individualistic and exclusivity-based knowledge system were reviewed, namely the approach to knowledge commons, the access and benefit-sharing mechanisms established in the Convention on Biological Diversity and the human rights framework concerning the right to both health and to share in (and benefit from) scientific progress and medical knowledge. The chapter suggests that these approaches bear advantages and disadvantages but have a benefit in defining biomedical innovation by re-examining the meaning of knowledge, medicine, and innovation in a broader context.

Continuing the discussion on the key elements for building an alternative conceptual framework, Chapter 6 looked at the broader biomedical innovator community, including the notion and practice of openness in relation to democratising innovation in the biomedical field. In this discussion, sidestepping patent-centric understanding of biomedical innovation requires a systemic re-imagination of the way in which knowledge of disease and medicines are formed, including the question of who constitutes an innovator, and the political possibilities of pursuing innovation without being restricted by a monoculture of exclusive property. In contrast to exclusivity, the concept of openness introduced debates on democratising innovation in the biomedical field. Openness, however, has been used differently in the context of the patent-based model and in the discussion of open innovation in biomedicine. Both have limitations as openness is either conditioned by exclusivity or only meaningful for specific interest groups. Instead, making openness the norm for the socially-constructed innovation movement has been experimented with in the open source movement in the context of computer science. Resorting to an alternative definition of relationships between users – who are at the same time also innovators – the open source model offers an institutional possibility to accommodate initiative in biomedicine. Accordingly, the return to a

biomedical open science culture can access the example of open source and constitutes the diverse community of innovators, making openness and sharing as the norm. This, alongside the other aspects discussed in Chapter 5, is critical in building an alternative biomedical innovation conceptual framework. A potentially democratized space for biomedical knowledge production and sharing offers a restructuring of the power relations between individuals, government, commercial entities, and law and medical science professionals.

If innovation were to be socially constructed, demanded, conducted and managed, the role of law could thus be repositioned beyond the boundary of patent and intellectual property. In addition to formal law as the normative order, the self-governing model and norm-based practice have also emerged as alternatives in biomedicine's innovation discourse. These alternatives present a plurality of norms when moving towards an alternative conceptual framework building as developed in this thesis. Plurality implies flexibilities and the co-existence of ordering systems, with the possibility of operating outside of the patent-based and exclusive property-based logic.

The plurality of norms was revisited in relation to three aspects discussed in this thesis. Returning the discussions in Chapter 5, the ABS mechanism's normative pathways and the engagement with human rights implied by looking at access, sharing in and benefitting from science and medical knowledge, an essential element of the realisation of health-related human rights, offers critical ideas for any reconceptualization. In addition to the state-focused discussion of ABS, the notion of PIC should be extended to include the broader biomedical innovation context. Although ABS as developed under CBD and its Nagoya Protocol focuses on access to genetic resources and the traditional knowledge associated with biodiversity protection, the conceptual intention behind

realigning accountability between knowledge and resource holders, researchers, commercial prospectors and governments in producing new knowledge and material benefits at a global level provides a means to rethink the conventional biomedical innovation context. Demanding an alternative accountability mechanism implies the empowerment of diverse expertise and calling on the authority of broader innovation contributors.

Instead of fitting empowerment into a commercially-defined logic as prevails under the current patent system, conceptualising science, culture and medical knowledge in the context of human rights provides an alternative intellectual framework. Although Chapter 5's analysis has revealed the visible limitations of the current conceptual apparatus in relation to the human rights law framework, this line of debate is still emerging, thus it provides an opportunity for further exploration. In the context of the right to health, the innovation-related discussion remains ambiguous and restricted by general reference to TRIPS flexibilities. A rare interconnection has been made in terms of integrating the right to share in and benefit from scientific progress. However, the right to share in and benefit from scientific progress itself remains vaguely interpreted under international human rights law, despite the potential of altering the focus of innovation-related discussions. In the context of biomedical innovation, the undisputed value of extending the benefit of medical knowledge to everyone as an integral part of the realisation of the fundamental right to health has been recognized by the WHO Constitution, thereby mandating WHO to ensure the diffusion of medical knowledge at the global level. This normative concept largely omitted under WHO auspices provides an additional critical dimension when reframing the debates on biomedical innovation through the lens of human rights.

In addition to the possibilities under the formal law settings, the innovation front has provided additional normative options when individuals and non-institutional-oriented researchers started forming transnational research initiatives using the analogy of the open source movement's self-governing model. Openness and sharing are bound by civic agreements and norms-based communities that go beyond state law, regional and international law-defined boundaries. Self-governing norms and practices challenge the orthodoxy of the centralised ordering system of innovation and opens up a truly disruptive transformation in contrast to the formal law-based approach.

III. Contribution and Implications for Future Research

As noted at the beginning of the research, the discontent with biomedical innovation's patent-centric paradigm remains pertinent, especially regarding areas where the commercial prospects of the conventional product development approach are low. Efforts that have been made to redress such challenges remain focused on alternative R&D economic models and financing mechanisms. Indeed, this is the main justification used by the biopharmaceutical industry in its attempt to retain the current monopoly-based mechanism so that they can recoup such R&D expenditure. In the law context, discussions on alternative approaches to biomedical innovation have looked primarily at the further use of TRIPS flexibilities including general exceptions, research exceptions, alternative licensing practices and changes to the management of intellectual property. Given the undeniable merits and political importance of these efforts, a more fundamental enquiry into the inherent inconsistencies of the existing order is also critical. This thesis opens up a number of avenues for further theoretical and conceptual debates in this regard.

Firstly, this dissertation provides an additional angle to this critique by referencing the STS scholarship's notion of co-production while discussing the role of the key actors, especially patent attorneys. This contributes to the discussion of the role of patent attorneys in textualising the materiality of patent and the meaning of newness while highlighting the dilemma of inter-professional and cross-disciplinary co-production evident in the production of the epistemic dimension of the role of patent in biomedical innovation.

This line of analysis opens up the possibility of further enquiries and debates on alternative professional norms for patent law practitioners. Patent attorneys in the transnational context also function as engineers generating the internal evolution of patent law, which remains relatively enclosed within a specifically designed linguistic system and an increasingly complex, segmented and textualised approach towards science and technologies. In medicine, the segmented approach adopted in patent law allows the splitting of medical and therapeutic properties of medicines into multiple types of patents and claims, facilitating the evergreening strategy commonly used by biopharmaceutical companies to extend market monopolies. Historically, patent attorneys came into legal profession with a very different (and somewhat controversial) background. In some jurisdictions, patent attorneys are still not considered as part of the legal profession, while in others they have obtained the same treatment as other branches of lawyers. The somewhat armature status of this group within the profession, in the sense that most patent attorneys acquire legal training in an abbreviated fashion during their employment, suggesting the need to further examine how the disciplinary influences of science, technology and law can be better aligned while adequately integrating the notion of law's function in a social context. As discussed in the thesis, it is also worth noting that looking at patent attorneys as a totality is problematic given

that a considerable number of this group of professionals also work actively with public health advocates and civil society organisations to challenge the patent law system's internal status quo.

However, to realise an alternative biomedical innovation conceptual framework in practice, it is essential to have more active and innovative professionals who adopt an alternative approach to norms and legal orders. Studies of legal professionals have included research on cause-lawyering and the function of lawyers in social movements in contexts other than patent law and innovation. It is, therefore, possible to consider the possibilities of interrogating the role of patent law practitioners in the context of social justice and social change, especially in relation to access to and benefit from biomedical knowledge and its applications while realising the human right to health.

Secondly, the thesis initiates a discussion on the reunification of the meaning of medicine, empowering the role of medical practitioners and highlighting the value of tacit medical knowledge in the context of biomedical innovation. Analysing this against the backdrop of the patent law-centric biomedical innovation narrative, the predominant debates have focused on how patents should be granted, interpreted and managed differently to allow future development and access to medicines. Medicine, in this discussion, only represents the material aspects in contrast to its original holistic meaning which also includes its system of practices. Patenting medical practices, such as treatment and diagnostic methods and procedures, have long triggered resistance on the part of medical professionals. Some of this resistance has entered into legal and political processes with other objections dissolving as internal discourse. Unifying the meaning of medicine as a holistic system within which active medical practitioners are the main innovators offers an additional lens. This suggests the need to adopt an

interdisciplinary approach which incorporates medical professionals' communal norms of sharing and producing knowledge based on experiences, medicines' social determinants, and studies on user innovations, thereby contributing to the normative discussion of biomedical innovation beyond the patent law-defined framework.

Thirdly, the thesis suggests a consolidated use STS's co-production idiom and critical political economy's triangulation framework to inform the critical approach to law's construction of an alternative conceptual framework. As discussed in the thesis, these two approaches have strong transformative intentions given their deployment of different and complementary critiques. In addition, a triangular framework has been used by critical scholars in the context of discussing the systemic and political tensions of the current intellectual property law regime in relation to access to knowledge. Co-production in STS scholarship has gaining ground given its analytical value in revealing the interaction of asymmetrical powers at the micro and macro levels of knowledge production and institutions related to science, technology and law. The complementary nature of these two approaches provides a viable analytical framework in which both micro and macro level critiques and reconstructions can be discussed. This has the potential to provide a reference point for other critical legal studies intending to reconstruct normative orders.

Lastly, the thesis is motivated by the real world problems derived from the tension between patent law-centric biomedical innovation paradigm and the challenge of a lack of health-related innovation, ending with a call for a more systematic and critical appraisal beyond the problem-solving logic. An alternative conceptual framework as discussed in this thesis suggests a strong reproach to institutions as one dimension of change. In the context of the right to science and the patent law system, the recent

literature has provided invaluable recommendations in relation to the systematic reform of the main governing international institutions including the WIPO, UNESCO and human rights treaty bodies, especially CESCR.⁹¹⁹ In addition, the role of the WHO in generating and diffusing medical knowledge to everyone as a part of the realisation of the right to health as mandated by its Constitution can also be examined further. The historical normative framing of this WHO mandate level is ambiguous⁹²⁰ and the later interpretation by the WHO has limited this aspect only to the organization's educational function.⁹²¹ However, going beyond the WHO's position as an educational or 'knowledge broker,'⁹²² its human rights mandate to respect, fulfil and protect the extension of the benefit of medical knowledge for all suggests two normative-level breakthroughs that go beyond the patent law-defined arena's specific problem-solving logic. First, in addition to the defensive framing of TRIPS-flexibilities to promote health (while the latter framework has never adopted a human rights perspective), the WHO's human rights mandate in regard to medical knowledge diffusion suggests the possibility for the WHO to further clarify and define the human rights implications of medical knowledge and its applications. The current normative interpretations of the right to health and the right to share in and benefit from science have not made any explicit connection to this notion under the auspices of the WHO. Secondly, access to and benefit from medical knowledge for all indicates the possibility of pursuing a global framework of medical knowledge preservation, development and diffusion, as discussed in Chapter

⁹¹⁹ Aurora Plomer, *Patents, Human Rights and Access to Science* (Edward Elgar 2015) 175-178.

⁹²⁰ WHO, 'Official Records of the World Health Organization: Summary Report on Proceedings Minutes and Final Acts of the International Health Conference' (New York, 19 June-22 July 1946) III.I Constitution of the World Health Organization <<http://apps.who.int/iris/handle/10665/85573>> accessed 9 August 2018.

⁹²¹ Charles Clift, 'The Role of the World Health Organization in the International System' (Chatham House Working Group on Governance, 2013)

<<https://www.chathamhouse.org/sites/default/files/publications/research/2013-02-01-role-world-health-organization-international-system-clift.pdf>> accessed 1 August 2018.

⁹²² *ibid.*

5. Citing the above mentioned discussions on biomedical innovation's multiple knowledge bases, the aspiration for a global framework for medical knowledge sharing could potentially establish a cosmopolitan forum that incentivises innovation while not relying exclusively on a defined group of industry and leading research institutions. Some pre-existing ideas and examples can be referred to in this regard in order to explore the potential and plural normative orders that can govern such a framework. For instance, the WHO itself has been hosting and promoting the further development of a global ABS mechanism on pathogens in order to support medical research and development.⁹²³ Looking beyond the sharing of pathogens, extending the normative discussion of the global biomedical innovation ABS mechanism, and realising the right to health, could possibly lead to the inclusion of all types of medical knowledge under different cultures and systems of medicine with their associated applications. Perhaps this level of unification and holistic reconceptualization is what is ultimately needed in order to achieve global transformative progress.

⁹²³ World Health Organization, 'Implementation of Nagoya Protocol and Pathogen Sharing: Public Health Implications' (WHO Secretariat, 2016) <http://www.who.int/influenza/pip/2016-review/NagoyaStudyAdvanceCopy_full.pdf> accessed 5 August 2018. See also WHO 'Fact Sheet: Nagoya Protocol and Public Health' (20 March 2018) <http://www.who.int/influenza/pip/NagoyaProtocolandPH_EN_20Mar2018.pdf> accessed 5 August 2018.

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