The Impact of Patent Extensions on Access to Pharmaceuticals

By

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Table of Contents

Main Acronyms

CI/HAI	CONSUMERS INTERNATIONAL AND HEALTH ACTION INTERNATIONAL
CIPO	CANADIAN INTELLECTUAL PROPERTY OFFICE
CJEU	COURT OF JUSTICE OF THE EUROPEAN UNION
EC	EUROPEAN COMMISSION
ECHR	EUROPEAN CONVENTION ON HUMAN RIGHTS
EDR	EMERGENCY DRUG RELEASE
EML	ESSENTIAL MEDICINES LIST
EPC	EUROPEAN PATENT CONVENTION
EPO	EUROPEAN PATENT OFFICE
EU	EUROPEAN UNION
FDA	FOOD AND DRUG ADMINISTRATION
FTA	FREE TRADE AGREEMENT
IALS	INSTITUTE OF ADVANCED LEGAL STUDIES
ICESCR	INTERNATIONAL CONVENTION ON ECONOMIC, SOCIAL AND CULTURAL RIGHTS
IND	INVESTIGATIONAL NEW DRUGS
IP	INTELLECTUAL PROPERTY
IPR	INTELLECTUAL PROPERTY RIGHT
LDCS	LEAST DEVELOPMED COUNTRIES
LMICS	LOWER AND MIDDLE INCOME COUNTRIES

MA	MARKETING AUTHORISATION
NDS	NEW DRUG SUBMISSION
NOC	NOTICE OF COMPLIANCE
PCT	PATENT COOPERATION TREATY
PMRB	PATENTED MEDICINE PRICES REVIEW BOARD
PTE	PATENT TERM EXTENSIONS
SPC	SUPPLEMENTARY PROTECTION CERTIFICATE
TA	TRADE AGREEMENTS
TRIPS	TRADE RELATED AGREEMENT ON INTELLECTUAL PROPERTY
UKIPO	UNITED KINGDOM INTELLECTUAL PROPERTY OFFICE
UN	UNITED NATIONS
UNDP	UNITED NATIONS DEVELOPMENT PROGRAMME
USPTO	UNITED STATES PATENT AND TRADEMARK OFFICE
WHO	WORLD HEALTH ORGANISATION
WIPO	WORLD INTELLECTUAL PROPERTY ORGANISATION
WTO	WORLD TRADE ORGANISATION

Preface

This book is an adaptation of thesis submitted for the degree of Doctor of Philosophy by Theona R. Elizee, Brunel University London, titled: "The Extent of Extensions in Access to Pharmaceuticals".[1]

During the course of the research, patenting and pharmaceuticals have been under the radar including the SPC system, resulting in developments in three areas of patents where proposals for legislative changes are underway and which have already taken effect. Essentially, understanding the information presented requires consideration of the following:

Timeline – the relevant dates for the state of law covered is as of December 2020, as such, does not incorporate legislative changes but makes reference to updates in industry. These changes are incorporated throughout the text.

EC, EU, and Europe – These references do not denote specific political or geographical areas but are mainly based on the reporting styles and timelines of published data. For the purposes of the research, the references mainly apply to the jurisdiction of SPC Directive and Regulation.

COVID-19 – Such discussions, although relevant and despite invaluable issues of access raised during and post pandemic, the timeline did not allow for deeper research and or focused conclusions to be drawn based on inadequate or premature data. To do so would result in an injustice being done to its prominence. Nonetheless COVID-19 related responses are incorporated and appropriate references made where necessary.

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[1] Theona R. Elizee, *The Extent that Term Extensions, (SPCs), are Creating a Barrier to Access to Pharmaceuticals*, (2024)

Background

The problem which required investigation

It is well accepted in global health and pharmaceutical industries that adapting prices of pharmaceuticals to the purchasing power of patients and consumers in varying geographical or socio-economic contexts can improve access to and affordability of life-saving medication for the long term and immediate relief. Further, it can be effective as part of extensive attempts at ensuring that healthcare systems are sustainable. Access to pharmaceuticals, although mainly seen as a developing country issue, is relevant in the European context where the gaps between GDP and health-care spend per capita and access to the latest innovative medicines have been widening and are significant. Right to health is considered a human right and so access, for the purposes of this research, is defined using the four principles of the right to health: availability; accessibility, acceptability and quality. Patents and the SPC system appear to touch all four principles however, the focus will be on availability and accessibility.

Thus, the problem arises from the link between the cost and availability of pharmaceutical products and the impact that term extensions in EC legislation contributes to or hinders such access. With access being the pivotal focus, it became imperative to consider the delay of generics entering the market and the positive contribution of a vibrant generics industry on access.

The right to health is considered a human right and so access, for the purposes of this research, is defined using the four principles of the right to health: availability; accessibility, acceptability and quality, (CESR, General Comment No.14(2000),[2] focussing on availability and accessibility, which translates to time and cost.

The effects of patent rules on access to affordable medication in LDCs, provides significant impetus and motivation to investigate and understand some of the underlying legislative and industry specific policy considera-

[2] Article 12 of the International Convention on Economic, Social and Cultural Rights, 22nd Session. E/C. 12/2000/4, 11 August 2000: Para 12.

tions that drive growth and development in innovation of pharmaceutical products. To that end, the ramifications for the generic trade business and the direct impact on public health affordability are of primary concern. The introduction and use of PTEs, including SPCs, can be regarded as potential circumvention machinery thus require studies to be undertaken on the actual use and impact on access to affordable medication. The importance of this cannot be overemphasized, mainly due to the EU, being considered an international driver of standards on the administration of IPRs and, in most cases, are considered the authors and engineers of the major international instruments, TRIPS, being a prime example. Nonetheless, it seems as soon as developing countries gain some ground on the international scene, the EU resorts to tactics geared at saving key industries.[3] These issues are not new per se, even the European Court has had certain questions referred to it from Member States. However, the validity of the sui generis right or its compliance with international obligations appear to be off limits. The literature suggests, and mostly accepts, that these sui generis rights are in fact legal extensions and do not question their validity or compliance with international obligations.[4]

This study sought to combine assessment of these issues in order to facilitate a clearer understanding of the actual impact that term extensions have on drug prices.[5]

Justification of the study

Consequently, studies on SPCs have largely been based on economic foundations connected with data exclusivity; which, for the most part, appear speculative and devoid of direct linkages between the use of SPCs and the cost to the generic medication trade.[6] Studies on generic medication have always been linked with the use of compulsory licences and border

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3 CLIP Report, *A Report by The Common Law Institute of IP*, (1991)

4 Duncan Curley, *Extending Rewards for Innovative Drug Development – A Report on Supplementary Protection Certificates for Pharmaceutical Products – Prepared for the Institute of Intellectual Property*, (2007)

5

6 Samuel A Oddi, 'Plagues, Pandemics, and Patents: Legality and Morality' (2011) 51 IDEA 1, 46

measures.[7] Following the 2009 codification Regulation, there have been some discussion on the way the courts have been interpreting the legislation. Slanted with a bias towards the pharmaceutical industry, there is an absence in the information or real data on linkages of intellectual property, competition law and access.[8] Even the new reports on studies offer divergent views on various aspects of the SPC system but do not specifically address access, particularly from the perspective of LDCs.

Partial justification[9] lies in the problems inherent in utilising the SPC system. Other justifications include; the need for a degree of discerning whether the SPC system is achieving its intended purpose and what changes can be made to enhance its usability and or functionality, from an access standpoint. Additionally, the impact of SPC's on access matters did not seem to feature much, if at all, in the literature. Previously, studies on SPCs were purely based on the effects of patent rules, generally, on access, but without any direct linkage or assessment of the various segments of patenting. This research breaks down the theory further to provide insight into an integral part of patenting which adds a divergent dimension to the discourse. Key recent developments in patenting and EU regulatory changes are indicative of the need to have the system revamped.

Majority of previous studies on SPCs are linked with the use of compulsory licences and pharma regulatory aspects as such the literature reveals a lack of real data on the actual workings of the SPC system. From a practical standpoint, it became essential to understand the intricate workings of the system and to investigate the extent of patent protection period and real impact for drugs becoming cheaper in terms of access: time and cost. Previously, most of the literature give a fleeting overview of the possible overlap with competition law with little discourse on the legal nature and its interplay with international obligations.

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7 Zita Lazzarini, 'Making Access to Pharmaceuticals a Reality: Legal Options under TRIPS and the Case of Brazil' (2003) 6 Yale Hum. Rts. & Dev. L.J. 103

8 Catherine Katzka, 'Interpretation of the Term 'Product' in EU Council Regulation 1768/92 and 1610/96 On Supplementary Protection Certificates, (2008) 3 Journal of Intellectual Property Law & Practice, 650.

9 Chatterjee Charles, *Methods of Research in Law*, (OUP 1997)

Post Brexit scenario presented yet another reason for examining the SPC system, albeit from a UK perspective (although the research does not address specific, individual EU countries, a special mention of the UK is warranted). However, the UK will have to make decisions on SPCs, from a regulatory standpoint, as part of the necessary overhaul of legislation on pharmaceutical issues, in particular, clinical trials, marketing authorisations, quality assurance and product safety, pharmacovigilance, regulatory authorities and parallel imports. From a patents viewpoint, the issue of unitary patent system, trademarks, designs and SPCs will definitely have to be reviewed. For SPCs the regulations enacted by the UK to bring the SPCs into effect will no longer apply, as such, it will be important to consider the fate of the SPCs in UK law, post BREXIT.

Notably, SPCs are currently granted and enforced at national levels, which can give rise to a lack of harmonisation as indicated through the decided cases. Herein lies one of the fundamental glitches with the system which was recognised by the European Commission. Thus a subsequent proposal, (among other things), a targeted SPC manufacturing waiver to allow the manufacture of generic and biosimilar medicines in the EU during the SPC period for export to non-EU countries where there is no SPC protection and stressed the need for coherence between the Unitary Patent System, (UPS), and the current SPC framework.[10]

The Unitary Patent System, when it becomes fully functional, will have consequences for SPCs as all SPCs protected by Unitary Patents will be subject to the exclusive competence of the UPS. The position may change once the UPS is operational which was originally scheduled for Early 2022.[11] Of course, concerns with the UPS System abound and how it will operate for patents and SPCs, in particular, a disconnect between the Unitary SPC and the MA. The EU's attempts to update the system is evident in its tenders for various commissioned studies intending to: "*be used by the Commission for an overall evaluation of the SPC system in the EU and to inform the decision on whether to come forward with a new SPC title at European level*

[10] *Commission Staff Working document – A Single Market Strategy for Europe-Analysis and Evidence-Accompanying the Document Upgrading the Single Market: More Opportunities for People and Business*, 28 Oct. 2015, SWD (2015) 202

[11] European Patent Office website publication, "When will the Unitary Patent system start?" <https://www.epo.org/law-practice/unitary/unitary-patent/start.html>

and whether to revise the existing SPC legislation…."[12] This is indicative of distrust with the way that SPCs have been subject to judicial scrutiny and an understanding of the major difficulties with using the system.

Methodological aspects of the study

Based on the subject-matter, the research adopted an inter-disciplinary approach as access to pharmaceuticals touches many subject areas including: IP and patents, regulatory, human rights issues, economic, public policy, politics and the international trading system which are all embedded in the study of access to medicines which fostered a practical approach to using a combination of methods.[13] Essentially, the SPC system was dissected through a positivist lens in the sense that it sought to understand the functionality of the system not just the intricate functioning but, with an access viewpoint. Additionally, further analysis of previously collected empirical data, mindful of Systems Theory[14], facilitated critical analysis which assisted in fostering a clearer understanding of how systems impose impractical in-built nuances that hinder efficient functioning of such systems.

Indeed, the human rights element in access informed the investigation and was explored to delve into the significance of highlighting the challenges posed by increased monopolies and protectionist regimes instituted by countries to safeguard certain industries. The aim was essentially to get a microscopic view of the real effect that term extensions, in particular, SPCs, have had on access with particular focus on the generic trade business and access in terms of time and cost implications. In this regard, a combination of research methods was employed.

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[12] Call for Tender 479/PP/GRO/IMA/15/15153, *Study on the legal aspects of the supplementary protection certificates in the EU*, European Commission, DG for Internal Market, Industry, Entrepreneurship and SMEs..., <https://etendering.ted.europa.eu/cft/cft-display.html?cftId=1206#caDetails>

[13] Peter Clinch, *Legal Research: A Practitioner's Handbook*, Second Edition, Wildy, Simmonds & Hill Publishing, (2013)

[14] Richard Nobles and David Schiff, *Observing Law Through Systems Theory*, Hart Publishing (2013)

Thus law and economics presented the most pragmatic approach to scrutinise the legal underpinnings raised in this project. Based on the philosophical justifications for IPRs, a law and economics dimension presented an avenue to make reasonable conclusions.[15] Using Posner's interdisciplinary perspective, it appears more plausible to use the methodology of law and economics to shed light on access matters. Further the research assumed the position that the economics of law are the set of economic studies that build on a detailed knowledge of some area of law; whether the study is done by a "lawyer", an "economist", someone with both degrees, and a lawyer-economist team has little significance. The application of economics to law is not new. What is new and controversial is the variety of problems in the field of law to which economics is now being applied.[16] In a nutshell, legal doctrine discipline is applied, mainly because studying law as a normative system, limits the data to legal texts and court decisions thus a systematic combination of legal reality, law as it is, through law and economics. This presented an opportune moment for a paradigm shift/ change in legal research methodologies.[17]

- Doctrinal research, or "black-letter law" was used to determine the law on SPCs are relevant to term extensions and pharmaceutical regulation. That involved locating and interpreting relevant primary and secondary sources of law and synthesising those sources to form a rule or rules of law. Further, it assisted in the evaluation and critique of competing or inconsistent sources and was indicative of ways in which the law on SPCs should develop. Black letter law encompassed looking at the relevant rules for coherency, departure and to identify possible gaps.

- Comparative as a method and methodology[18] was used to assess law or legal system pertaining to SPCs, its aims, goals, substance

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[15] Landes & Posner, *The Economic Structure of IP*, The Belknap Press of Harvard University Press (2003)

[16] Richard A Posner, 'The Economic Approach to Law' (May 1975) 53(4) Texas Law Review 757-82

[17] T Hutchinson, 'Developing legal research skills: Expanding the paradigm' (2008) 32 Melb. UL Rev. 1065

[18] Robert Cryer, et.al, *Research Methodologies in EU and International Law*, Hart Publishing (2011) pg. 28

or efficacy and attempted to identify common themes across different legal systems with the intention of showing how SPCs have a direct impact on the cost of pharmaceuticals in two contrasting systems. Here, the aim was not the harmonisation of laws, neither did it seek to determine whether a law reflects a consistent manner of dealing with behaviour across states or represents a local idiosyncrasy but simply to test the direct financial additions to the cost of pharmaceuticals as a result of legal transplantation of term extensions from the EC's SPC system compared with a system that previously did not, Canada. Further justification for this is that, Canada is regarded as a neutral country on the international trading system and has always adopted a pro generics stance in its administration of pharmaceuticals thus, has designed its legal system to support this. Comparing the EC's SPC system, a direct result of regulation with civil law origins with Canada's pluralistic system presented as idyllic for the purposes of this project.

– Interpretation of Published Material – Following the EC's tenders, economic studies, a dimension not previously tackled, have been conducted on SPCs[19] and have been utilised in re-analysis. These studies were timely in that until recently, 2018-2019, studies on SPCs appeared unchartered territory however, from 2017 to 2019, new published reports surfaced on studies undertaken during the course of this research project. The findings presented in these reports reveal much timely and required data and appear to tremendous value to the literature gap on the topic. However, these reports are either academic or industry specific as they were commissioned for specific purposes, and they do not, in a strict sense undermine the contribution or originality of this research. Data from these studies form part of the information utilised in re-analysis in this research project. Simultaneously, a view through the lens of the cost factor analysis of the SPC legal system is imperative. The value of economic analysis of law is that it produces normative conclusions of vastly greater certainty than other methods. The methodological rigor of law and economics produces norma-

[19] Kyle (2017), Meijer (2017), Max Planck Institute (2018) and Charles Rivers Associates (2018)

tive conclusions that approach the certainty of positive scientific conclusions.[20] According to Oliver Wendell Holmes "for the rational study of the law the black letter man may be the man of the present, but the man of the future is the man of statistics and the Master of Economics.[21]

Sources

The main sources included databases containing legislative material, cases, reports and commentary. Where information was taken directly from various databases and reports, such are clearly stated and the appropriate permissions were sought and granted. This following does not by far represent an exhaustive list and sources are referenced appropriately:

National Prescription Drug Utilization Information System (NPDUIS) Database, Canadian Institute for Health Information – provides pan-Canadian information on public drug programs, including anonymous claims-level data collected from the plans participating in the NPDUIS initiative from all Regions as well as Health Canada's Non-Insured Health Benefits (NIHB) drug plan.[22]

PMPRB Human Drug Advisory Panel (HDAP), (PMRB/HDAP) – evaluates data from patented pharmaceuticals at the market introductory stage and proposes enhancements to therapeutic material used in patented products. This informs the process of PMPRB price regulation and facilitates comparison between Canada and EU.[23]

Canadian Generic Pharmaceutical Association (CGPA) – to inform the savings from the use of generic prescription medicines from 2013 to 2017.[24]

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[20] Richard A Posner, "The Law and Economics Movement" (May 1987) 7(2) American Economic Review Papers and Proceedings 12

[21] Holmes (1897, 469), *Lee Epstein & Andrew D. Martin, An Introduction to Empirical Legal Research*, Preface, OUP (2014)

[22] More detailed information available at, https://publications.gc.ca/site/eng/9.512490/publication.html

[23] See further, PMRB Website, http://www.pmprb-cepmb.gc.ca/en/regulating-prices/scientific-review

[24] The Canadian Generic Pharmaceutical Association Website, <https\\:www.canadiangenerics.ca>

The DrugBank Database – This is publicly available data on pharmaceutical targets in Canada which has enabled the discovery and repurposing of a number of existing drugs to treat rare and newly identified illnesses.[25]

Credit is also given to: Association for Accessible Medicines: Generics & Biosimilars; Canada Pharma Regulators; EFPIA, Intellectual Property and Pharmacy; EMA Reports; EU Canada pharmaceutical Industries; Government Studies on pharmaceutical access; Health Canada's Drug Product Database; International Generic and Biosimilar Medicines Association – IGBA; New reports from EU Studies: Meijer, Marx Planck; OECD Reports; The Canadian Agency for Drugs and Technologies in Health (CADTH) Common Drug Review (CDR) reports, and The Canadian Generic Pharmaceutical Association (CGPA); The European Medicines Agency's orphan drug database; The United Nations' world population statistics; WHO Reports; Lloyds List; SCRIP; OHE; Pharma Intelligence.

[25] See further, https://go.drugbank.com/about

Introduction

Almost inevitably, most, if not all, conversations on pharmaceuticals, whether it is production, administration, marketing, selling or deciding which one to choose, includes some discourse on patents. It is surely not by accident that this occurs as without patents, the pharmaceutical industry would not exist in that they provide the means for the innovators of pharmaceuticals to recoup their investment into drug discovery through the grant of market monopolies, for a fixed term.

In the simplest form, a bout of research and development being performed to discover a new chemical entity, usually, the first step, which has become almost a reflex action, is to make an application for a patent to protect the new molecule. Despite being costly and time-consuming, this represents just one step. There will be pre-clinical and later clinical studies to demonstrate safety and efficacy. Another step involves getting a marketing authorisation to enable the new drug to be sold. Marketing and sales follow which adds to the total cost of bringing the drug to the market. It means that the cost of the patented product at the start is normally substantial but would drop at the end of the 20-year period,[26] after which the original product falls into the public domain and generic companies can make use of the information.

The advantage to generic companies in using data in the public domain is that they have not invested in neither the research and development process, the clinical process nor the marketing of the product but are now able to produce the very product from that information. It is not to say that generic companies are totally without costs as the product they produce must be bio-equivalent to the original patent to rightfully be called a generic.[27] Nonetheless, whatever costs incurred by the generic companies appear

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[26] This is the maximum term of protection countries should offer patent holders as mandated by The Agreement on Trade Related Aspects of Intellectual Property Rights, 1994, (TRIPS Agreement). The TRIPS Agreement is Annex 1C of the Marrakesh Agreement Establishing the World Trade Organization, signed in Marrakesh, Morocco on 15 April 1994 and is enshrined in all major patent systems including the Patent Cooperation Treaty. That 20-year rule represents the general principles and standards in patents administration.

[27] Council Directive (EC) 2004/27 of 31 March 2004 amending Council Directive (EC) 2001/83 on the Community code relating to medicinal products for human

minimal as they are able to offer for sale the same product at approximately 1/10th of the original cost.

Whereas the factors that contribute to the cost of the product is not definite, innovators claim that the maximum 20-year period of patent protection is insufficient to recoup those costs incurred during the life of the product, from research and development to the end of the 20-year period. The use of term extensions became a tool to assist in that regard and has been adopted in different formats in developed countries, including European Community (EC), United States of America (USA), Japan and Australia. In most instances the protection offered by the basic patent is extended to up to five years, beyond the 20 years and in some cases more. In the EU, the system of term extensions is enshrined in the patents legislation and effectively adds additional time or delay to generic companies using data pertaining to such drugs.

From an access standpoint, countries around the world rely on research and development and innovation in pharmaceuticals but must firmly consider the cost of medication to its citizens, particularly when there is an outbreak of infectious disease or in cases of a national emergency, as evidenced by steps taken during the COVID-19 pandemic season. The use of generic versions presents a welcome alternative to the costly innovator drugs especially in low-income countries where manufacturing is non-existent. The availability of essential medicine to a country is not considered a privilege but more of a basic right.[28] It means that all drugs must come from somewhere and must be made available when it is required.[29] The use of term extensions is seen to not only give extra time to the innovators but less time to the generics, which presumes that it may take more time for the drugs to become cheaper and readily available.

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use, OJ L136/34 (Medicines Directive).

[28] General Comment No. 14 (2000) and Article 12 of the International Covenant Economic, Social and Cultural Rights. 22nd Session, E/C.12/2004, 11 August 2000 and subsequent reports of the UN General Assembly, Report of the Special Rapporteur of the Commission on Human Rights

[29] UN General Assembly. Report of the Special Rapporteur of the Commission on Human Rights. 61st Session, 13th September 2006, A/61/338.

This becomes more of an issue as one-third of the world's population lacks access to the most essential medicines.[30] Similarly, most of the world's population lacks access to safe and appropriate medical devices, according to the World Trade Organisation (WTO) Fact sheet.[31] Developing and least developed countries are the most affected by limited access to medicines and medical devices. Most countries rely on the World Health Organisation (WHO), Model List of Essential Medicines[32] (EML), to provide guidance on various active ingredients suitable for diseases and ailments, which ultimately results in policy considerations on cost-effective drugs for their populaces. That list allows for customization to each country's needs but ultimately must be considered in conjunction with the pharmaceuticals that are actually available or more affordable.

Access to more affordable medication has been an issue at the forefront of the international scene and although it is most often considered a developing country issue, more recently it has become a talking point for all countries as all countries are mandated to make available pharmaceuticals at minimal cost to citizens or governments, particularly in the circumstances and advent of the COVID-19 pandemic.

Thus, investigations into term extensions appears justified. The study aimed at dissecting the European SPC system with a view to determining its effect on the real cost of pharmaceuticals in the EC, particularly, on whether it in fact contributes to delayed access in terms of cost and time for generics to enter the market. To this end a quasi-comparative analysis of what obtains in Canada became the focus purely due to the fact that Canada is one of the countries in the Organisation for Economic Cooperation and Development (OECD), which before 2017, (the start of the research), unlike other developed countries, did not have a provision that extends the patent

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[30] Hans V. Hogerzeil & Zafar Mirza, 'The World Medicines Situation 2011, Access to Essential Medicines as part of the Right to Health' (2011) WHO/EMP/MIE/2011.2.10

[31] Hembadoon Iyortyer Oguanobi, 'Broadening the Conversation of the TRIPS Agreement: Access to Medicines Includes Addressing Access to Medical Devices' (2018) 21 JWIP 70-87

[32] WHO Model List of Essential Medicines 20th List (March 2017) (Amended August 2017), <https://apps.who.int/iris/bitstream/handle/10665/273826/EML-20-eng.pdf?ua=1-> WHO Model List of Essential Medicines for Children 6th List (March 2017) (Amended August 2017), <https://www.who.int/medicines/publications/essentialmedicines/6th_EMLc2017_FINAL_amendedAug2017.pdf ->

protection period to compensate for delays in the marketing approval process.[33] Consequential to the Comprehensive Economic and Trade Agreement (CETA), between Europe and Canada, Canada introduced a patent term restoration system much similar to the European SPC system, with a maximum period of 2 years. Although CETA allows for the possibility of exceptions during the term for purposes of export to third countries, it has effectively resulted in transplanting a system of extension into Canada's patent administration which, no doubt, is directly attributed to its bilateral arrangements with the EU. [34]

Based on literature review and utilizing a combination of doctrinal desk research and analysis of published data the following claims and conclusions are made:

1. Availability –Time added – SPCs have added years to the effective protection period for those innovator products where the SPC is the last measure of protection to expire. The data reveals that 45% of the medicinal products have obtained an SPC in at least one of the European countries. While the protection for medicinal products in the EU is amongst the strongest in the world, the average effective protection period has decreased by approximately two years from 15 to 13 years since 1996. Companies choose to launch more medicinal products faster in larger and wealthier countries. Hence, not all new products are made available in all European countries and not at the same time, (Chapter Three);

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[33] Charles Rivers Associates, *Assessing the Economic Impacts of Changing Exemption Provisions During Patent and SPC Protection in Europe,* (2017) pg.67, EUROPEAN COMMISSION, Directorate-General for Internal Market, Industry, Entrepreneurship and SME, February – 2016, Luxembourg: Publications Office of the European Union, 2017 ISBN: 978-92-79-73301-7, doi: 10.2873/673124, (herein referred to as Charles Rivers Associates 2017).

[34] Literature Review revealed that little work or studies have been conducted in this area and most references to term extensions are mainly centred on comparisons made between USA/Canada, USA/Japan and other jurisdictions utilising extensions.
See further, Mary Atkinson, 'Patent Protection for Pharmaceuticals: A Comparative Study of the Law in the United States and Canada' (2002) 11 Pac. Rim L. & Pol'y J., 181

2. Accessibility– Cost and Generic entry – Pharmaceutical spending has increased in some therapeutic areas including oncology and care for certain rare diseases where many new medicines target small population groups and command higher prices. SPCs can cause delays resulting in an average price drop of approximately 50% following the entry of generics. Sudden large price increases for off-patent medicines have made important treatments unaffordable for patients, (Data and discussion at Chapter Three);

3. Massive increases in cost for pharmaceuticals is envisaged in Canada based on post CSP projections. The Canadian experience offers a divergent workable system however there is no confidence that it will yield cost savings, (Chapter Four);

4. A balanced system of protection and access requires a collaboration of key stakeholders and reorganisation of IP systems, (Chapter Five);

5. Optimisation of legal systems for increased access based on a system of fostering resilience, (Chapter Six).

The foregoing claims/conclusions are structured based on a chronology dissecting the system from an access standpoint: Background chapters discussing legal theory, historical analysis of patents, global and regulatory concerns linked to Term Extensions; Interpretation and re-analysis of published data; Optimisation of legal infrastructures for improved access and Conclusions.

Chapter 1

Patents and access

This chapter breaks down the patent system and introduces discourse on prices and public policy which are often considered in managing local access to pharmaceuticals. Key theoretical and philosophical approaches to patenting are scrutinised which demonstrates major difficulties in the intricate workings of the system that give rise to the problem of monopolies, nationally and regionally. This highlights the significant dilemma faced by countries in attempting to navigate what seems to be a tightly woven web of legal hurdles in balancing patents and access.

The chapter fosters a deeper understanding of the ramifications of patent systems and how they have impacted and or give rise to the problem of lack of access. The main arguments here are concerned with problems associated with overall access to health discourse that relates to patents and demonstrates the inequalities enshrined in utilising international systems for protection. The case is made for a requirement to adopt a holistic approach to public policy on spending where pharmaceuticals are concerned based on the difficulties associated with the global patent monopolistic climate.

Theories on these issues are endless and in order to navigate them, the chapter focuses on the specific IPR and patents related jurisprudential theories and introduces the relevant legal theory, in particular, patent theory and the link to monopolies. Some practicalities of patent systems are considered, highlighting international, EU and Canadian structures to understand the genesis of extra layers of protection justified by industry which, consequently, distorts access efforts. An introduction to SPC's, the European version of term extensions, is also given.

Legal Theory Relating to Intellectual Property Rights, (IPRs) and Access

Understanding the nature of Term Extensions, (TEs), (Supplementary Protection Certificates), (SPCs), requires some familiarity and or elab-

oration of the philosophical justifications of IPRs and the patent system in a way that uncovers the theoretical jurisprudential standing of SPCs.[1] Importantly this provides an overview on the ontological principles as well as an understanding of the metaphysical construction attributed to the patent system and IPRs.

Prima Facie, Intellectual Property,(IP), Law, covers a diverse range of transferable territorial rights which are not normally easily defined. Intangible rights can prove extremely valuable and although there may be some overlap, generally IP law normally seek to protect: ideas and inventions (patents and designs); information and data (confidential information, copyright and database); brand and trade names (trademarks and GIs). As with other property rights, the value of these rights is not necessarily ownership but the ability to exploit them to generate revenue and to enforce them against third parties.

The general principles of IP law, in particular patents,[2] are commonly seen as part of an interdependent mix of incentives and restraints that bestow benefits and impose costs on society and individuals alike. Some principles adopt the view that patents can be employed in facilitating innovation, access and competition while others rationalise patents as frustrating these important interests. On the contrary, patent law is not a one size fits all regime, thus a nuanced approach to understanding the costs and benefits of patent law is needed to appreciate its effect on economic and social welfare, which, in this case, access to medicine.

Patent law is said to bestow negative rights in the sense that it does not give the inventor a positive right to make, use, or sell the invention but merely the right to exclude others from so doing. Dating back to ancient Greece, the idea behind granting of a patent was meant to be an incentive-based mechanism wherein a potential inventor is encouraged to disclose something new and useful to society.[3] Each school of thought places emphasis on varying aspects of IPRS and patent law and navigating the plethora of theories unearths no clear guidance.

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1 Michael Freeman and Ross Harrison, (eds) *Law and Philosophy, Current Legal Issues* , Volume 10, OUP (2007)

2 Newman Kieff, Schwartz & Smith, *Principles Of Patent Law: Cases And Materials*, 4th Edition, Foundation Press, (2008)

3 Laura A Underkuffler, *The Idea of Property: Its meaning and Power*, OUP (2003)

Economic theorists take the quasi-monopoly stance however Posner[4] makes the case for a merger of law and economics and contends than an area of legal regulation of explicit markets is just beginning to ripen for economics is intellectual property, with special reference to copyrights and trademarks and that patents have long been an object of economic study. The relevant legal theories offer some guidance on how such balance can be achieved.

An important finding in the law and economics literature is that economic analysis can be helpful in designing reforms of the legal system. Another finding in the literature is that the quantitative study of the legal system is fruitful. The economic approach to law has enormous potential for increasing knowledge about the legal system.

Even more important is that Positivist[5] approach introduces the fact/value dichotomy – Logical Positivism suggests that a proposition is factual if it can be reduced to propositions of physics, which in turn are verifiable through observation or sensory experience. It is the empirical part that changes prudentia to Scientia. Positivists seek to distance the existence of legal rights and duties from moral judgements although they do not deny the importance of morality or that moral views influence the content of law.[6]

Nicola Searle and Martin Brassell[7] make more clear-cut theoretical assumptions and contend that there exist three main schools of thought in the economic justification of IPRs: incentives to innovate, labour desert theory; a rejection of IP rights. These issues will be given more attention in future sections.

Simultaneously, Natural law jurists argue that IPRs are confined to personality rights theory and natural justice/rights. Those who advocate for the

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4 Richard A Posner, 'The Law and Economics Movement' (May 1987) 7(2) American Economic Review Papers and Proceedings 1-13

5 Tom Campbell, *Prescriptive Legal Positivism: Law, Rights and Democracy*, UCL Press (2004)

6 Nigel E. Simmons, *Central Issues in Jurisprudence*, 3rd Edition, Sweet & Maxwell, (2008) pg. 147

7 Nicole Searle and Martin Brassell, *Economic Approaches to Intellectual Property*, OUP (2016)

property theory contend that IPRs can be given protection of property rights as human rights. The reasoning behind this is that "things" bring into the play the whole discourse on the nature of the right in property law which may or may not include *Rights in a thing,* dominion in the form of ownership of a particular item of property or, *Rights against other people in that there is an inherent* right to use/exploit, right to revenue/profit and a right to receive payment in money if some right in property is contravened by a third person.

More modern understanding of property law suggests that property law represents a particular way of creating legal relationships around the possession and use of an object or resource that enables a novel legal analysis. Jesse Wall[8] asserts that categorising rights in things ultimately results in a focus beyond the thingness of the item to the content of the legally enforceable right which right includes the legal relationship between the rights-holder, the thing and the duty bearer. Thus, property rights focus on the exclusion of all other persons from an object or a thing.

Others challenge that IPRs better serve their purpose by acknowledging their importance in imparting knowledge and that ultimately, the effective way to achieve this is through making it accessible to most people, in particular, those who appear to need it most, at minimal cost, but preferably, free of cost.[9] This culture of sharing is more synonymous with copyright through the medium of the Creative Commons but recently, it is argued that this may be applied to other forms if IP.

Theoretically, examination of rights and obligations as it relates to property seem clear when talking about patents because usually, patents acts clearly indicate what patents holders' rights and obligations are. Applying the property, knowledge or even sharing concepts to TEs is problematic as TEs exist under none of these categories. It begs the question of why protection under the patent system, thus the 'sui generis' status. It is this sui generis status that sets the TEs and the European SPC system apart and affords it the flexibility to be creative with its organisation and operation, which may contain advantages and pitfalls.

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[8] Jesse Wall, *Being and Owning*, OUP (2015) pg. 112

[9] Olga Gurgula, 'Monopoly v. Openness: Two Sides of the IP coin in the Pharmaceutical Industry' (2017) 20 (5-6) Journal of World Intellectual Property 206-217

The Influence of Patent Theory and Practice in Creating Monopolies

Patent theory and practice is important to understand the theoretical underpinnings giving rise to global Intellectual Property, (IP) systems. Discussions on theoretical perspectives on patenting are paramount since such influences directly impact the manner in which the pharmaceutical industry structures itself which in turn informs the overall impact on what obtains globally.

As seen in the previous section, the jurisprudential/theoretical discourse on IPRs yields no strict formula for assessing such IPRs and varying perspectives abound. Patenting seems to be at the forefront of such tirade since various theories are at play. Understanding the modern system requires some background on the plethora of theories.

Economic/Incentive based explanations

An important starting point is that although patent laws are generally seen as part of an interdependent mix of incentives and restraints that bestow benefits and impose costs on society and individuals alike, it does not give the inventor a positive right to make, use, or sell the invention but merely the right to exclude others from so doing.

Early theorists believed in the incentive-based mechanism wherein a potential inventor is encouraged to disclose something new and useful to society, While Lockean Labour Theory and Natural Rights[10] favoured the inventor in patent law, utilitarianism,[11] injects the principle of utility. Bentham suggests that natural rights are simply nonsense: natural and imprescriptible rights, rhetorical nonsense-nonsense on stilts – the state should adopt policies that would maximise the happiness of members of its community. Bentham's theory goes deeper to explain that "by utility is meant that property in any object, whereby it tends to produce benefit, advantage, pleasure, good, or happiness or to prevent the happening of mischief, pain, evil or unhappiness to the party whose interest is considered: if the party be the community in

[10] Scott F Kieff, Pauline Newman, Herbert Schwartz Smith, *Principles of Patent Law, University Casebook Series,* 4th Edition, Foundation Press, (2008) pg. 39

[11] Kieff et al, (2008), pg. 49

general, then the happiness of the community: if the particular individual, then the happiness of that individual."[12] This is significant in comprehension of patents however, Robert Ostergard[13] argues that traditional theories (such as labour theory of property and inferences drawn from the utilitarian theory) fail to offer a rational and adequate theoretical justification for IPR, therefore consideration of IPR as human rights is indefensible.

A divergent view is taken in Economics of Patent Law which has demonstrated the causal link between intellectual property and the growth of national economies, contributing to technology transfer, foreign trade and promoting innovation and national economic development. The economics concept of monopolies is directly applicable to patent laws as patents are often branded as somewhat, value-laden. Some argue this may not really be correct. For instance, Giles S. Rich, offers a definition of the term monopoly which is of some significance:

> "A monopoly is an institution…. For the sole buying, selling, making, working, or using, of anything, whereby any person or persons……. Are sought to be restrained of any freedom or liberty that they had before or hindered in their lawful trade…. Letters patents are not to be regarded as monopolies, but as public franchise, granted… for the purpose of securing…. As tending to promote the progress of……. The useful arts." [14]

The above definition suggests that patents, give the potential for market, or even, monopoly power but inherently rarely lead to monopoly power. In fact, the average patent confers too little monopoly power on the patentee in a meaningful economic sense…. And sometimes it confers no monopoly power at all. Considerations on how monopolies work sheds more light on the interplay of patents and monopolies.

A monopoly is generally, described as an entire market. Markets tend to order themselves around consumer demand. Producers tend to sell what

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[12] Jeremy Bentham, *An Introduction to the Principles of Morals and Legislation*, in J.H. Burns and H.L. Hart (eds) Clarendon Press (1996) pg. 12

[13] Robert L Ostergard, 'Intellectual Property: An International Human Right?', (1991) 21(1) Human Rights Quarterly 156-178

[14] Giles S Rich, 'The Relation between Patent Practices and the Anti-Monopoly Laws' (1942) 24 J. Pat. Off. Soc'y 85-106

consumers will buy. In some instances, monopolies are confused with competition, in that new non-infringing products are invented around the original, which may supply the same market, giving rise to competitive products and prices.

On the other hand, patents share some aspects of monopolies and the case of pharmaceuticals offer a prime example where the patent may provide an effective barrier to entry to the market in sales to at least a certain class of patients having an acute illness that they are unable to wait for the development of alternative non-infringing solutions or for patent expiration. In this case the limited market at this time and for these patients is a monopoly. In the longer term however, and for less acute patients, the market may be entirely competitive. In assessing patent and monopoly microeconomics, the important lesson is that no monopoly exists if there is a substitute available to sate consumer's demand. The more substitutes there are for the patented product, the higher the elasticity of demand, the more horizontal will be the patentee's demand curve.[15] Thus, the economic theories underlying patents suggests four incentives that have been postulated to justify the patent system: The incentive to invent; the incentive to disclose; the incentive to commercialize; the incentive to design around. These incentives form the basis of modern patenting systems and has meandered its way into the pharmaceutical sector.

Economic theories operate under the illusion that the patent system will deliver the protection and the information it is supposed to deliver. Costs associated with such are likely to be heaviest for those who are new to the system or lightest for those with more experience. This also encompasses the costs society incurs in frustrated expectations of innovation. In an attempt to further unpack this thought it appears that "The Costs of Distortion" theory emerges. The system is supposed to help meet society's requirements for innovation, but it seems to happen the other way around. Discouraged innovation is seen by the empirical data from small and large firms. Nonetheless, proponents of a structured approach to innovation appear to suggest that patenting is averse to innovation.[16]

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[15] Giles S Rich, 'Principles of Patentability' (January 1960) 28 George Washington Law Review 2,

[16] Stuart Macdonald, in Peter Drahos and Ruth Mayne, (EDS), *Global Intellectual Property Rights: Knowledge, Access and Development,* Basingstoke: Palgrave Mac-

Sir Hugh Laddie[17] puts forward a different approach to looking at intellectual property: and contends that there is a significant difference between the civil law and common law approach to intellectual property rights. For civil law, the justification for creation and enforcement of such rights is the belief that the author has a moral right to retain control over his intellectual creations. In the latter, it appears that economic policies drive the justification.

Access based explanations

Although the language of fairness may be used as an additional tool to sell intellectual property rights to politicians and the public, both the existence of intellectual property rights and the scope of protection has to be justified on the basis that the commercial benefits to society outweigh the disadvantages of restrictions on competition.

Jim Lahore and Anne Duffy[18] argue that a legal system which offers protection to the creator of confidential information, while at the same time granting patent protection to suitably qualified inventors, must accept that there may be hard cases when the two very different protection regimes come into conflict.This is the type of conflict that has raised inquiry into the patent system and to investigate how a balance can be achieved in protection Vis a Vis access. The case is made even more significant for basic commodities which have been given special attention through the international rights system. Applying this concept to the health system requires in-depth analysis of the quadrants and no doubt incorporates access and cost considerations. Such considerations are significant in addressing public health requirements for cheaper medication which would assist in alleviating poverty.

Dissecting the figures reveal that poverty appears to be the reason why over two billion people have no regular access to even the basic list of a few essential drugs. It was suggested that when TRIPS is fully implemented, it would have effectively denied access to essential drugs to many more

millan, (2002), Drahos and Mayne (2002), pg. 35

[17] Vaver and Bentley, (eds) *Intellectual Property in the New Millennium: Essays in Honour of William R. Cornish*, Cambridge University Press (2004) pg. 91

[18] Vaver and Bentley, (eds) *Intellectual Property in the New Millennium: Essays in Honour of William R. Cornish*, Cambridge University Press (2004) pg. 202