

How do the Jurisdictions of India, Canada and the United Kingdom
Interpret the Inventive Step Requirement for Follow-on Pharmaceutical
Innovation?

by
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Abstract

This paper looks at the three jurisdictions of the United Kingdom, Canada and India to determine how each interpret the inventive step, for follow-on pharmaceutical innovation. An analysis of domestic statutes and case law, allows the stringency of approach to the inventive step in each jurisdiction to be determined on a comparative basis. The paper provides the comparison by utilising two differing benchmarks as a means to establish a lenient, versus a stringent perspective. The stringent perspective is established from UN recommendations whilst the lenient perspective is provided by a critical analysis of the recommendations by Christopher Holman et al.

The first three chapters detail the approach taken by each jurisdiction respectively. This is achieved through extensive literature reviews and case law analysis. Through a comparison of a dosage patent, which was challenged before both the Federal Court of Appeal and the UK Supreme Court this paper reveals the similarity in approach between the UK and Canada's inventive step inquiries. The comparative nature of this paper further establishes the stringency of application in India, through a step by step, comparative analysis of the inventive step inquiries.

The potential consequences of the stringent approach in India and the comparatively lenient applications in Canada and the UK, are established through summaries of key debates in this area. This includes ethical debates such as the vital 'innovation v accessibility balance', the controversial 'lifecycle management plans' and Erooms law. In order for these key concerns to be adequately accounted for, unnecessarily strict standards for the inventive should not be applied. It is established that an emphasis on flexibility in approach to the inventive step inquiry, as is beginning to emerge in the United Kingdom, is an appropriate first step towards an inventive step inquiry which is capable of accounting for these crucial concerns.

Lay Summary

This paper comparatively examines the approach to the inventive step inquiry in three jurisdictions. The Jurisdictions of the United Kingdom, Canada and India offer different approaches to inventive step inquiries, concerning follow-on pharmaceutical patents. Through literature reviews and case law analysis, the stringency of each approach is established. The comparative process employed in the paper reveals the increasingly flexible approach adopted in the UK. The paper conclude that an inventive step inquiry of this nature is best equipped to account for the highly ethical and moral debates surrounding follow-on-pharmaceutical research and development.

Preface

The following thesis is the result of unpublished, independent and original work, by George Rainforth.

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Glossary

Active Ingredient: The ingredient in a drug which primarily responsible for the alleged therapeutic effect

Claim Date: The date from which patent protection, if approved, is retrospectively active

Closest Prior Art: the relevant disclosure on which the follow on pharmaceutical innovation has utilised in order to invent the subject claim matter

Dosage Patent: A patent on an entirely novel dosage regime, usually applied for using a 'swiss claim'

Evergreening: a form of patent abuse by which a drug approaching the patent cliff is modified in an insignificant, incremental way and a new patent is sought in an attempt to extend the length of patent protection.

Filing Date: The date at which a patent application is filed with a respective Patent Office

First Generation Drug: A drug which is the product of 1st generation innovation. A completely novel drug, patented and brought to market.

First Generation Innovation: the process which leads to a completely novel invention which does not rely on any previous patent.

Follow-on Drug: A drug which is the product of follow-on pharmaceutical activity

Follow-on Pharmaceutical Innovation: the process which yields an improvement on an existing drug, often considered to be a 2nd generation drug.

Generic Company: The companies such as TEVA which manufacture and sell previously branded medication which has come off patent.

Genus Patent: The patent which a subsequent patent claims priority. Discloses a large class of potential compounds, often in the hundreds of thousands.

Hygroscopicity: The ability to absorb moisture, a desirable characteristic for drugs as this aids shelf-life.

Improvement Patent: A patent which offers an improvement over the prior art. Must contain a further inventive step over genus patent¹

Inventive Step Requirement: for the purposes of this paper, the inventive step requirement is used synonymously with the term "obviousness"

IPO: Indian Patent Office

Me Too Drug: A drug which provides the same therapeutic effect as another drug on the market. Released by a competitor or often as second generation product

Obvious to Try: also known as the could/would assessment. Was it obvious for the person skilled in the art to try to reach the claimed invention, furthermore, did the prior art provide motivation to do this.

Originator Company: A pharmaceutical company which engages in “first of a kind” innovation. The big pharmaceutical companies which provide branded medication, such as Pfizer and Johnson & Johnson.

Patent Cliff: The date at which a high profit patented drug comes off-patent, causing the price to plummet due to generic entry.

R&D: Pharmaceutical research and development.

Second Generation Drug: A drug which is the product of follow-on pharmaceutical innovation. An improved version of a first generation drug.

Secondary Patents: the collective term used for; improvement patents, selection patents and dosage patents.

Selection Patent: A patent which covers a specific selection of compounds, previously disclosed in the respective genus patent

Watchdog Litigation: litigation used to challenge alleged evergreening patents.

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Chapter 1: Introduction

The patentability standards of ‘primary’ and ‘secondary’ pharmaceutical innovation, is the subject of much debate in both academic and legislative spheres.¹ Primary Innovation, also referred to as ‘originator innovation’ is the process of research and development (R&D), which yields a first generation drug.² Whereas secondary innovation (or follow-on pharmaceutical innovation) refers to the research and development process which yields a second generation drug.³ As the title suggests, this paper will focus on the patentability standards of the latter form of pharmaceutical R&D. The approach taken by the jurisdictions of the United Kingdom, Canada and India to assess the inventive step of follow-on pharmaceutical innovation will be compared. This paper will articulate an answer to the core research question “how do the jurisdictions of India, Canada and the United Kingdom apply the inventive step requirement to follow-on pharmaceutical innovation?” This paper therefore, aims to establish the stringency of the inventive step requirement for follow-on pharmaceutical innovation in each jurisdiction, on a comparative basis.

1.1 Methodology:

This paper takes a ‘functionalist comparative approach’ towards the assessment of the inventive step regarding follow-on pharmaceutical innovation.⁴ ‘A functionalist comparative approach’ is one which is “practically orientated” – the consequence of the rule is of greater concern than what the law specifically states.⁵ In other words, the effect of a rule (or law in this case) will be the point of comparison. This paper is largely concerned with the practical interpretation of the inventive step requirement. How the inventive step is being assessed is of greater importance than the iteration of the requirement. Thus a functionalist comparative approach is apt for such an analysis.

Alongside the comparative methodology, this paper also employs a doctrinal methodology, in order to review the key scholarly debates in this area. A doctrinal approach is primarily concerned with the assessment of legal rules; “which should be applied consistently and evolve organically

¹ Donald W Light & Joel R Lexchin, “Pharmaceutical research and development: what do we get for all that money?” (2012) 345:aug07 1 (BMJ : British Medical Journal) e4348, online: <<http://dx.doi.org/10.1136/bmj.e4348>> at e4348.

Sigrid Sterckx, “Can drug patents be morally justified?” (2005) 11:1 (Science and Engineering Ethics) 81–92, online: <<https://www.ncbi.nlm.nih.gov/pubmed/15727003>> at 81–92.

María José Abud Sittler, Bronwyn H Hall & Christian Helmers, An Empirical Analysis of Primary and Secondary Pharmaceutical Patents in Chile, Nber working paper series 20995 (Cambridge, Mass: National Bureau of Economic Research, 2015) vol 20995.

Guidelines for pharmaceutical patent examination : examining pharmaceutical patents from a public health perspective, by Carlos M Correa (United Nations Development Programme, 2016).

² A completely novel drug or a drug with a new medical use

³ Christopher M Holman, Timo Minssen & Eric M Solovy, “Patentability Standards for Follow-On Pharmaceutical Innovation” (2018) 37:3 (Biotechnology Law Report) 131–161, online: <<https://www.liebertpub.com/doi/abs/10.1089/blr.2018.29073.cmh>> at 131–161.

⁴ Oliver Brand, “Conceptual Comparisons: Towards a Coherent Methodology Of Comparative Legal Studies” (2007) 32 405 at 405–1227.

⁵ Oliver Brand, “Conceptual Comparisons: Towards a Coherent Methodology Of Comparative Legal Studies” (2007) 32 405 at 405–1227.

and slowly.”⁶ This enables the analysis and comparison of the relevant case law in this area - an imperative process in determining the interpretation of the inventive step requirement. The jurisdictions of India, Canada and the United Kingdom have been selected due to the varying thresholds of inventiveness applied in each; India being the most stringent and Canada the least.⁷ Furthermore, each jurisdiction is a common-wealth and common law nation, which provides an appropriate platform for a comparative approach.

1.2 Key Debates:

The issue of pharmaceutical patentability standards encompass not only legal and precedential issues, but also highly ethical and moral issues.⁸ Inevitably, when a new lifesaving drug –whether first or second generation – is afforded patent protection, it results in a high retail price.⁹ These high prices are unaffordable for many patients, especially in developing nations.¹⁰ Thus, the granting of patents for pharmaceutical innovation has a direct correlation to access to medicine.¹¹ Consequently, the ethics surrounding the patentability of pharmaceutical innovation is subject to much academic debate.¹² For example, the pharmaceutical industry can be described as “a lifeline industry”¹³ and as a result, it is imperative that the governing laws are appropriately equipped to deal with a wide array of ethical public health dilemmas. One of the ways which the law is equipped, is through compulsory licensing clauses. Compulsory licencing enables governments to authorize the production of patented medication, by companies other than the patent holder. This is justified in times of public health emergencies.¹⁴

Seemingly, the trickiest aspect of governance is ensuring that an appropriate balance between accessibility and innovation is struck.¹⁵ This refers to the balance between the availability of medical treatment, against the need to incentivise innovative research and development (R&D) in medical science.¹⁶ Incentivising R&D is the primary argument to support the patentability of

⁶ Terry Hutchinson; Nigel Duncan, *Defining and Describing What We Do: Doctrinal Legal Research*, 17 *Deakin L. Rev.* 83 (2012)

⁷ As will be established through-out this paper

⁸ Sigrd Sterckx, “Can drug patents be morally justified?” (2005) 11:1 (*Science and Engineering Ethics*) 81–92, online: <<https://www.ncbi.nlm.nih.gov/pubmed/15727003>> at 81–92.

⁹ *Ibid* 8

¹⁰ Donald W Light & Joel R Lexchin, “Pharmaceutical research and development: what do we get for all that money?” (2012) 345:aug07 1 (*BMJ : British Medical Journal*) e4348, online: <<http://dx.doi.org/10.1136/bmj.e4348>> at e4348.

¹¹ Roger Collier, “Drug patents: innovation v. accessibility” (2013) 185:9 (*CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne*) E379–E380, online: <<https://www.ncbi.nlm.nih.gov/pubmed/23630237>> at E379–E380.

¹² *Ibid* 8

¹³ Due to the dependency of patients’ well-being on the products of this industry

¹⁴Section 128A: EU Compulsory licences, Manual of Patent Practice UK

¹⁵*Ibid* 11

¹⁶ Sir Hugh Laddie, *Patents – what’s invention got to do with it?* Intellectual Property in the New Millennium (Cambridge University Press, 2004) at 91–95.

pharmaceutical innovation.^{17 18 19} The business models of the large originator pharmaceutical companies, such as Pfizer and Johnson & Johnson, are heavily reliant on intellectual property rights. It is for this reason that the top three originator companies²⁰ (according to the fiscal reports from the originator companies) collectively invested over 28.5 billion US dollars for R&D in 2018 alone.²¹ Unsurprisingly, originator companies are responsible for the lion's share of pharmaceutical R&D as noted by Chakravarthy et al.²²

Fundamentally, the foundational principles of patent law oppose those of competition law.²³ The government authorised monopoly, which is granted by a patent, is done so on the basis that society receives a benefit.²⁴ The benefit in this case is considered to be the requirement for disclosure. A new invention is rewarded with a monopoly as 'payment' for full public disclosure of the invention and its operation.²⁵ This enables society to benefit from new inventions, which are made widely available, at lower costs (due to market competition), upon expiry of the patent. Furthermore, the requirement for disclosure allows the public to access the invention, in its entirety, with a full description for its construction and operation.²⁶

Patents tend to be highly lucrative in the pharmaceutical industry. Originator companies can generate billions of dollars a year for a given 'blockbuster drug'. For example the Oncology drug Ibrance, which generated 4.9 billion US dollars of revenue in 2019 alone.²⁷ The low cost of

¹⁷ Donald W Light & Joel R Lexchin, "Pharmaceutical research and development: what do we get for all that money?" (2012) 345:aug07 1 (BMJ : British Medical Journal) e4348, online: <<http://dx.doi.org/10.1136/bmj.e4348>> at e4348.

¹⁸ Sigrid Sterckx, "Can drug patents be morally justified?" (2005) 11:1 (Science and Engineering Ethics) 81–92, online: <<https://www.ncbi.nlm.nih.gov/pubmed/15727003>> at 81–92.

¹⁹ Roger Collier, "Drug patents: the evergreening problem" (2013) 185:9 (CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne) E385–E386, online: <<https://www.ncbi.nlm.nih.gov/pubmed/23630239>> at E385–E386.

²⁰ According to Forbes 500

²¹ Pfizer Fourth Quarter and Full Year 2018 Results, by Pfizer (Pfizer, 2019). online: <<https://investors.pfizer.com/investor-news/press-release-details/2019/PFIZER-REPORTS-FOURTH-QUARTER-AND-FULL-YEAR-2018-RESULTS/default.aspx>>

Johnson & Johnson 2018 Investor Fact Sheet 4 (J&J, 2019) online: <http://www.investor.jnj.com/_document/2018-investor-fact-sheet-4-19?id=0000016a-5681-d475-a17f-d78db54a0000>

Merck & co UNITED STATES SECURITIES AND EXCHANGE COMMISSION Form 10-k Fourth Quarter 2018 Filing (2019) online: <[https://s21.q4cdn.com/488056881/files/doc_financials/2018/Q4/2018-Form-10-K-\(without-Exhibits\)_FINAL_022719.pdf](https://s21.q4cdn.com/488056881/files/doc_financials/2018/Q4/2018-Form-10-K-(without-Exhibits)_FINAL_022719.pdf)>

²² "our analysis indicates that industry's contributions to the R&D of innovative drugs go beyond development and marketing and include basic and applied science, discovery technologies, and manufacturing protocols, and that without private investment in the applied sciences there would be no return on public investment in basic science." Ranjana Chakravarthy et al, "Public- and Private-Sector Contributions to the Research and Development of the Most Transformational Drugs in the Past 25 Years" (2016) 50:6 (Therapeutic Innovation & Regulatory Science) 759–768, online: <<https://journals.sagepub.com/doi/full/10.1177/2168479016648730>> at 759–768.

²³ Intellectual Property Enforcement Guidelines "Chapter 2 Overview of IP Law and Competition law" (2019) <<https://www.ic.gc.ca/eic/site/cb-bc.nsf/eng/04421.html#sec02>>

²⁴ European Patent Convention Art.83 , Indian Patent Act 1970 s.8, Patent Act 1987 s.27

²⁵ Jason Rantanen, "Patent law's disclosure requirement" (2013) 45:2 (Loyola University of Chicago Law Journal) 369 at 369.

²⁶ *Ibid* 24, *Ibid* 25

²⁷ Pfizer Fourth Quarter and Full Year 2019 Results, by Pfizer (Pfizer, 2019). online:

manufacturing a drug versus the high price at which blockbuster drugs are sold, is enabled by the patent protection which they are afforded.^{28 29} The lucrative nature of patents serves as a huge incentive for companies to take the monumental inherent risk of investing in research and development.³⁰

As previously explained, an inevitable side effect of affording patent protection to pharmaceutical products, is it enables pharmaceutical companies to sell the drugs at artificially inflated prices.³¹ This ultimately leads to lifesaving medication becoming unaffordable for many individuals. However as explained above, unless the patented drugs generate high profit, then the incentive for pharmaceutical companies to continue to invest in R&D, is greatly diminished.³² This predicament of incentive to innovate and access to health is commonly referred to by academics as the innovation v accessibility balance.³³ Researching and developing a drug to the point at which it can enter the market, is largely accepted to be a multi-million dollar process. Often running in to the hundreds of millions of dollars.³⁴ Furthermore, the process of bringing a fully approved, efficacious drug to market, is exceedingly risky. It has been observed that drug development can be forced to a halt on several grounds (for example safety) even after years of development and substantial investment.³⁵ It is for these reasons that originator companies and governments, have recognised the need for pharmaceutical patents to be economically valuable enough to incentivise R&D investment, despite the significant monetary risks.³⁶ For example, Biogen abandoned two Alzheimer's drugs in early 2019, during clinical trials - resulting in an eighteen billion dollar loss of its company market value.³⁷

Debate exists around the 'true cost' of developing a drug. For the reasons stated above, there is an incentive for the cost of drug development to be embellished by pharmaceutical companies.³⁸ Originator companies, by definition focus on researching and developing new drugs to bring market. As stated above, the process of bringing drugs to market is a particularly expensive and risky, estimates place this cost in the billions of dollars.³⁹ Therefore, a drug which eventually

<https://s21.q4cdn.com/317678438/files/doc_financials/Quarterly/2019/q4/Q4-2019-PFE-Earnings-Release.pdf>

²⁸ Roger Collier, "Drug patents: innovation v. accessibility" (2013) 185:9 (CMAJ : Canadian Medical Association journal) online: <<https://www.ncbi.nlm.nih.gov/pubmed/23630237>>

²⁹ Intellectual Property Protection - Lifeline for the Pharmaceutical Industry CHIMIA International Journal for Chemistry 54(5):318-320 Thomas B. Cueni

³⁰ Roger Collier, "Drug patents: innovation v. accessibility" (2013) 185:9 (CMAJ : Canadian Medical Association journal), online: <<https://www.ncbi.nlm.nih.gov/pubmed/23630237>>

³¹ Robin Feldman & Evan Frondorf, *Drug wars* (New York, NY: Cambridge University Press, 2017)

³² John J Castellani, "Engineered in India — Patent Law 2.0" (2013) 369:22 (The New England Journal of Medicine) 2163, online: <<http://dx.doi.org/10.1056/NEJMc1311602>>

³³ *Ibid* 28

³⁴ *Ibid* 28

³⁵ Joseph A DiMasi, Henry G Grabowski & Ronald W Hansen, "Innovation in the pharmaceutical industry: New estimates of R&D costs" (2016) 47 (Journal of Health Economics) 20–33

³⁶ Amy Kapczynski, "Engineered in India — Patent Law 2.0" (2013) 369:6 (The New England Journal of Medicine) 497–499

³⁷ Steenhuyzen Julie & Takashi Umekawa, "Biogen scraps two Alzheimer drug trials wipes \$18 billion from market value", (21 March 2019), online: <<https://www.reuters.com/article/us-biogen-alzheimers/biogen-scraps-two-alzheimer-drug-trials-wipes-18-billion-from-market-value-idUSKCN1R213G>>.

³⁸ *Ibid* 36

³⁹ Joseph A DiMasi, Henry G Grabowski & Ronald W Hansen, "Innovation in the pharmaceutical industry: New estimates of R&D costs" (2016) 47 (Journal of Health Economics) 20–33

makes it to market, not only has to cover the usual overheads incurred with any business, but must pay for its own research and development costs as well. Furthermore it must help cover the additional cost of any other drugs which have expensively been abandoned (for any number of safety, clinical or economic viability reasons) along the way.⁴⁰ Clearly, the reason that novel drugs which eventually complete the arduous journey to market require patent protection, is to allow pharmaceutical companies to recoup their large expenditure, whilst also making enough profit to incentivise drug R&D in the first place. Without patent protection, this would not be allowed to happen, due to competition from generic manufacturers. The cost to manufacture a clinically approved, market ready drug are comparatively extremely low.⁴¹ Consequently, generic manufacturers have comparatively low overheads, compared to originator companies (as they provide little to no R&D expenditure).⁴² If originator companies could not protect their branded drugs with patents, it would be easy for competing pharmaceutical companies (usually generic manufacturers) to reverse engineer and sell the drug for a fraction of the price. This practice occurs despite the fact that generic companies have incurred none of the risk or expense, of bringing the drug to market.^{43 44} This business model has received criticism in the past, however it is essential to the global accessibility of medicines and provides further justification for the patentability of pharmaceutical products.^{45 46}

Since the beginning of the new millennium, the amount of first generation drugs receiving clinical approval from governing bodies (such as the European Medical Agency (EMA), the Indian Central Drugs Standard Control Organisation (ICDSCO) and Canada's Health Product and Food Branch (HPFB)), has been declining. This trend has become known as Eroom's law.⁴⁷ Erooms law states that while the number of new drugs is halving each year, the amount of money invested in pharmaceutical R&D is doubling.⁴⁸ In other words, first generation drugs are becoming twice as expensive to bring to market, yet half as successful at doing so.⁴⁹ Alternatively, it means that despite technological advances since the 1980s (when the trend was first seen), R&D has somehow become less efficient. This occurs despite advances in modern technology.⁵⁰ Academics have suggested that this is due to pharmaceutical research and development becoming "less-useful", something which 'section 3(d) type clauses' aim at rectifying.⁵¹ The 'less

⁴⁰Roger Collier, "Drug patents: innovation v. accessibility" (2013) 185:9 (CMAJ : Canadian Medical Association journal = journal de l'Association medicale canadienne) E379–E380, online: <<https://www.ncbi.nlm.nih.gov/pubmed/23630237>> at E379–E380.

⁴¹ Christoph Baumgartel, "Myths, questions, facts about generic drugs in the EU" (2012) 1:1 (Generics and Biosimilars Initiative Journal) 34–38

⁴² *Ibid* 41

⁴³ Thomas B Cueni, "Intellectual Property Protection Lifeline for the Pharmaceutical Industry" (2000) 54:5 (CHIMIA International Journal for Chemistry)

⁴⁴ Roger Collier, "Drug patents: innovation v. accessibility" (2013) 185:9 (CMAJ : Canadian Medical Association journal)

⁴⁵ Patrick Kierans in Roger Collier, "Drug patents: the evergreening problem" (2013) 185:9 (CMAJ : Canadian Medical Association journal) <<https://www.ncbi.nlm.nih.gov/pubmed/23630239>>

⁴⁶ *Ibid* 51, 52

⁴⁷ "Medicine adaptive pathways to patients (MAPPs): using regulatory innovation to defeat Eroom's law" (2014) 3:2 (Chinese clinical oncology) 21

⁴⁸ A figure which accounts for inflation.

⁴⁹ Jack W Scannell et al, "Diagnosing the decline in pharmaceutical R&D efficiency" (2012) 11:3 (Nature reviews. Drug discovery) 191–200, online: <<https://www.ncbi.nlm.nih.gov/pubmed/22378269>>

⁵⁰ *Ibid* 49

⁵¹ Amy Kapczynski, "Engineered in India — Patent Law 2.0" (2013) 369:6 (The New England Journal of Medicine) 497–499

useful' R&D argument, pertains to claims that originator companies spend large sums of their R&D budgets on 'product lifecycle management schemes' – which attempt to incrementally modify current drugs (nearing patent expiry), in order to acquire further Intellectual property protection.⁵² This process is known as evergreening.⁵³

1.3 Follow-on innovation:

Follow-on pharmaceutical innovation refers to a pharmaceutical product (usually a drug) which has been formed from the prior art.⁵⁴ Due to the highly lucrative nature of patented blockbuster drugs, follow-on pharmaceutical innovation is often faced with claims of evergreening, or invalidity due to lacking an inventive step.⁵⁵ Evergreening is a pejorative term utilised by critics of originator pharmaceutical companies, defined as extending periods of market exclusivity through unwarranted secondary protection.⁵⁶ ⁵⁷The secondary protection (for example an improvement patent, dosage patent or selection patent)⁵⁸ is obtained through the incremental modification of an existing drug, as explained by Robin Feldman:

“Commentators have written for some time on the phenomenon known as “evergreening,” in which a company tries to refresh its market monopoly by making slight modifications to a drug’s delivery mechanism, dosage, or other characteristics to make the drug eligible for additional exclusivity or patents.”⁵⁹

The new product, often a second generation of a previously patented drug, offers an improvement over the first generation drug. Often the improvement relates to therapeutic efficacy, safety or lower toxicity.⁶⁰ ⁶¹ ⁶²If the second generation drug receives patent protection, the first generation of that drug can still be manufactured and sold by competitors.⁶³ ⁶⁴Due to the nature of the claimed improvements, critics often allege that the improvements are too incremental in nature to meet the threshold of inventiveness required to obtain a patent.⁶⁵ This paper aims to look at how the

⁵² Robin Feldman & Evan Frondorf, *Drug wars* “Chapter 4: Generation 3.0” (New York, NY: Cambridge University Press, 2017) at 80

⁵³ *IP strategies and policies for and against evergreening*, by Ove Granstrand & Frank Tietze, Cambridge University (Cambridge University centre for technology management, 2015) at page 5

⁵⁴ Christopher M Holman, Timo Minssen & Eric M Solovy, “Patentability Standards for Follow-On Pharmaceutical Innovation” (2018) 37:3 (Biotechnology Law Report) 131–161, online: <<https://www.liebertpub.com/doi/abs/10.1089/blr.2018.29073.cmh>>

⁵⁵ *Ibid* 52

⁵⁶ Bhaven N Sampat & Kenneth C Shadlen, “Secondary pharmaceutical patenting: A global perspective” (2017) 46:3 (Research Policy) 693–707, online: <<http://dx.doi.org/10.1016/j.respol.2017.01.005>>

⁵⁷ *Ibid* 53

⁵⁸ Definitions provided in glossary

⁵⁹ *Ibid* 52

⁶⁰ *Ibid* 54

⁶¹ C Scott Hemphill & Bhaven N Sampat, “Evergreening, patent challenges, and effective market life in pharmaceuticals” (2012) 31:2 (Journal of Health Economics) 327–339, online: <<http://dx.doi.org/10.1016/j.jhealeco.2012.01.004>> at 327–339.

⁶² *Novartis v Union of India & Others AG*

⁶³ *Ibid* 54

⁶⁴ *Apotex Inc. v. Sanofi-Synthelabo Canada Inc*, 2008 SCC 61 at para 97 - 117

⁶⁵ *Ibid* 52

three jurisdictions of India, Canada and the UK interpret the inventive step requirement for follow-on pharmaceutical innovation. The importance of this task is discussed below.

The debates highlighted above are of particular importance when assessing the patentability of follow-on pharmaceutical innovation. The assessment of pharmaceutical patents is the pinnacle of legal ethics. The stringency of patent assessment has a direct correlation with R&D incentives and patients access to health.^{66 67 68} Not only are the laws complex in nature, but often the subject matter is highly specialised, with claims pertaining to complex, scientifically specific claims.⁶⁹ The rhetoric surrounding follow-on innovation is often highly critical, however follow-on pharmaceutical innovation has been instrumental in or resulted in the creation of revolutionary medical treatments.^{70 71} It is for this reason that the question this paper poses is an important one. The balance which is struck between innovation and accessibility effects everyone, yet this balance is primarily dictated by the interpretation of the inventive step requirement.⁷² The three jurisdictions have been selected due to the difference in approach which they take, India takes a stringent approach to follow-on innovation, whereas Canada has typically been lenient in this area.⁷³ Both of these jurisdictions have their roots in UK law, which allows for an apt comparison between the three jurisdictions in order to answer the question posed by this paper.⁷⁴ Incentivising research and development, ensuring access to medicine and driving forward medical science, are all influenced by the interpretation of the inventive step.⁷⁵ It is for this reason that the question posed by this paper is important.

1.4 Stance of the Paper:

This paper takes the stance that follow-on pharmaceutical innovation is worthy for patent protection, just as first instance pharmaceutical innovation is. The worth of follow-on innovation has been demonstrated numerous times, for example the revolutionary AZT drug.⁷⁶ A known drug, the development of which had been abandoned. However it was discovered at a later date to be a particularly effective anti-HIV drug, due to secondary patent protection, it could be developed and brought to market.⁷⁷

⁶⁶ *Ibid* 29

⁶⁷ *Ibid* 53

⁶⁸ *Ibid* 36

⁶⁹ Amy Kapczynski, Chan Park & Bhaven Sampat, "Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of 'Secondary' Pharmaceutical Patents" (2012) 7:12 (PloS one)

⁷⁰ E Ackiron, "Patents for critical pharmaceuticals: the AZT case" (1991) 17:1–2 (American journal of law & medicine) 145, online: <<https://www.ncbi.nlm.nih.gov/pubmed/1877607>>

⁷¹ *Ibid* 54

⁷² *Ibid* 54, 73

⁷³ Matthew B Stanbrook, "Limiting 'evergreening' for a better balance of drug innovation incentives" (2013) 185:11 (CMAJ : Canadian Medical Association journal) online: <<https://www.ncbi.nlm.nih.gov/pubmed/23877665>>

⁷⁴ PHILIP GIRARD, JIM PHILLIPS & R BLAKE BROWN, *A History of Law in Canada, Vol. 1*, Osgoode Society for Canadian Legal History 1 (University of Toronto Press, 2018)

⁷⁵ *Ibid* 41, 44, 52

⁷⁶ E Ackiron, "Patents for critical pharmaceuticals: the AZT case" (1991) 17:1–2 (American journal of law & medicine) 145, online: <<https://www.ncbi.nlm.nih.gov/pubmed/1877607>>

⁷⁷ *Ibid* 54

Furthermore, follow-on pharmaceutical innovation is a fundamentally routine practice of originator pharmaceutical companies.⁷⁸ Preventing or drastically discouraging the development of follow-on innovation through stringent patentability standards could prevent the creation of life-saving medications both today and generations from now.⁷⁹ The present cannot be prioritised over the future in such a way that Erooms law continues to prevail.

The goal of an effective medicine is to provide a cure to an ailment, with as few side effects as possible.⁸⁰ It is inevitable that high toxicity drugs will eventually be brought to market, for example cancer treatments currently involve the use of highly toxic drug - which encompass highly demonstrative side-effects. The primary way through which these side effects are to be reduced, is through follow-on pharmaceutical innovation. The demand for pharmaceutical drugs are not determined by freedom of choice, or disposable income⁸¹ but rather by necessity. In other words, the demand for a drug or treatment stems from the number of patients suffering from a particular illness. Drugs are an essential rather than a luxury commodity, indeed this distinction was brought in to statute in India.⁸² Without secondary patent protection, once a drug is brought to market, there is little to no monetary motivation for the drug to be improved upon (which encompasses the reduction of side-effects and increasing therapeutic efficacy).⁸³ It is for this reason that this paper takes the stance that follow-on innovation should be eligible for patent protection.

Importantly, this is not to advocate that clear instances of evergreening should be rewarded with patent protection, but to argue that follow on innovation should be held to the same standards of patentability (specifically regarding the inventive step) as first generation innovation. These views are largely in line with the arguments presented by Christopher Holman et al. Whom argue that the globally influential measures taken in India (and proposals by the UN) unfairly target follow-on pharmaceutical innovation as being less worthy for patent protection than other forms of innovation.⁸⁴ The most prominent example of heightened standards of the inventive step for follow-on innovation, can be observed in India's controversial implementation of section 3(d).⁸⁵

Although not the primary aim of the paper, this paper will suggest that many of the criticisms pertaining to the patentability of follow-on pharmaceutical innovation, could likely be solved through limiting pharmaceutical advertising rights. One of the criticisms in this area is the timing of second generation drugs being released; if a drug needed to be improved, this would be done towards the beginning of the product's lifecycle, rather than towards the end when patent expiry is imminent.⁸⁶ ⁸⁷This implies the second generation could be an attempt at evergreening. Policy reform could enable the patent system in the pharmaceutical industry to operate as it does in

⁷⁸ Evident in the huge increase second generation drug patents

⁷⁹ *Ibid* 54

⁸⁰ Stefan Leucht et al, "How effective are common medications: a perspective based on meta-analyses of major drugs" (2015) 13:1 (BMC medicine) 253, online: <<https://www.ncbi.nlm.nih.gov/pubmed/26431961>>

⁸¹ In nations with free healthcare

⁸² Essential Commodity Act 1955 s.2 (a) (iva)

⁸³ As previously established, patents provide the incentive for R&D investment

⁸⁴ Holman et al *Ibid* 54

⁸⁵ María José Abud Sittler, Bronwyn H Hall & Christian Helmers, "An Empirical Analysis of Primary and Secondary Pharmaceutical Patents in Chile, Nber" (Cambridge, Mass: National Bureau of Economic Research, 2015) vol 20995.

⁸⁶ *Ibid* 52

⁸⁷ *Ibid* 36

other industries - on a basis of popularity.⁸⁸ Currently direct to doctor advertising practices damage the effectiveness of the patent system within the pharmaceutical industry, this particularly concerns follow-on pharmaceutical innovation.⁸⁹

Alternatively, it will be proposed that incorporating a greater degree of flexibility, as is beginning to emerge the United Kingdom and Canada, the key debates as discussed above can provide further influence within the assessment of the inventive step for follow-on pharmaceutical patent applications.^{90 91}

1.5 Structure:

This paper consists of four main chapters, each of which are divided into sub-headings. The first three chapters will provide a robust overview of the inventive step requirement in the United Kingdom, Canada and finally India. The fourth chapter will provide a comparative analysis of the previously discussed jurisdictions under the following sub-headings: the Inventive step test, Dosage patents, person skilled in the art and inventive capacity, routine nature and predictability, and finally grace period and disclosure. This will allow for a conclusion to be drawn on the stringency of the inventive step requirement in each jurisdiction.

⁸⁸ Holman et al *Ibid* 49

⁸⁹ This will be addressed later in the paper

⁹⁰ *Teva Canada Limited v Pfizer Canada Inc*, 2019 FCA 15 at para 1

⁹¹ *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15

Chapter 2: United Kingdom

2.1 Introduction:

This chapter will first explain the current laws in the United Kingdom by which the inventive step is governed. Next the relationship between UK and EU patent law will be clarified. Following this, a large section of this chapter will be dedicated to explaining the recent Supreme Court Case *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* which specifically addresses the inventive step requirement. The chapter will then discuss the requirements of the inventive step test under the following sub headings: person skilled in the art, the routine nature and predictability of clinical trials, the inventive concept of the claim and a penultimate heading discussing grace period & disclosure provisions. Finally a conclusion will be drawn as to the perceived stringency of the inventive step requirement in the UK with regard to follow-on innovation.

2.2 Relevant Statutes:

There are two types of patent which offer valid protection within the United Kingdom; a patent which is filed with the UK patent office, or a European patent which is filed with the European Patent Office (EPO).⁹² In the United Kingdom, both of these patents offer the same protection and are fundamentally equivalent when viewed within the boundaries of the UK's jurisdiction.⁹³ This will be further explained under the pursuant subheading.

In the United Kingdom, the inventive step requirement is a codified, statutory requirement found in Section 3 of The Patents Act 1977 which reads:

“An invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art.”⁹⁴

2.3 The UK and EU Patent Law Relationship:

A patent which is granted by the EPO is valid in all of the European Union member states and is considered to be the closest example of a unitary international patent system. However, this must not be confused with a 'unitary patent law' – although the European patent office can grant or refuse a patent application through its own criteria for patentability⁹⁵ – any granted patent will only have rights in each of the respective nations so long as the patented material meets the patentability requirements at a national level.⁹⁶ This results in a unique situation; a European patent could be challenged in two different jurisdictions, which could yield two differing verdicts

⁹² United Kingdom Parliament, *Apply for a Patent*, online: <<https://www.gov.uk/apply-for-a-patent>>

⁹³ *The Patents Act 1977* s 77

⁹⁴ *The Patents Act 1977* s 3

⁹⁵ European Patent Convention art. 52

⁹⁶ *The Patents Act 1977* s 77

on the patent's validity. Herein lies the distinction between a 'unitary patent system' and 'unitary patent law.'⁹⁷ Unitary patent law would provide any divergence in judgements of this nature.

One of the important aspects stemming from the European Patent Office is the approach towards the inventive step requirement, known as the "*problem/solution approach*".⁹⁸ This is as opposed to the *Windsurfing/Pozzoli* test, which has been the favoured approach within the UK.⁹⁹ The *Windsurfing/Pozzoli* test is a common law test which stems from the UK case *Windsurfing International Inc. v Tabur Marine (GB) Ltd.* [1985] and was refined in *Pozzoli SPA v BDMO SA* [2007]¹⁰⁰ in which the following four questions were posed:

"(1)(a) Identify the notional "person skilled in the art"

(1)(b) Identify the relevant common general knowledge of that person;

(2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it;

(3) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed;

(4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?"¹⁰¹

These questions appear in the UK patent guidelines and were recently acknowledged by the Supreme Court in *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr (ICOS)* as being the favoured common law test for assessing the inventive step requirement.^{102 103}

2.4 ICOS and the Inventive Step Test:

In March 2019, Lord Hodge of the United Kingdom Supreme Court passed down a judgement in *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr*.¹⁰⁴ (ICOS) This case concerns the validity of a dosage patent lack of inventive step grounds. This is important to this paper as it provides a reiteration of the inventive step requirement for follow-on pharmaceutical innovation, from the UK's highest court.

⁹⁷ European Patent Office, *Unitary patent*, online: < <https://www.epo.org/law-practice/unitary/unitary-patent/start.html>>

⁹⁸ European Patent Office "Guidelines for Examination in the European Patent Office" *Chapter 7 Part 5 Problem Solution Approach* (2019), online: < https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_vii_5.htm.

⁹⁹ *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15

¹⁰⁰ *Pozzoli SPA v BDMO SA* [2007] EWCA Civ 588

¹⁰¹ *Pozzoli SpA v BDMO SA* [2007] EWCA Civ 588 para 23

¹⁰² Manual of Patent Practice UK S 3.13 Online: <<https://www.gov.uk/guidance/manual-of-patent-practice-mopp/section-3-inventive-step>>

¹⁰³ *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15 at para 60

¹⁰⁴ *Ibid* 97

2.4.1 Background:

ICOS “concerns the application of the test of obviousness under section 3.”¹⁰⁵ The issue at hand concerns the validity of a new “dosage patent”¹⁰⁶ for the drug ‘Tadalafil’. This particular drug, which is sold by Eli Lilly Pharmaceutical Company under the brand name “ADCIRCA” was made available from generic manufacturers in 2018. The 181 patent relies on a genus patent known as the ‘Daugan patent.’ It is in this patent that the potential usefulness of Tadalafil to treat erectile dysfunction, was initially disclosed.¹⁰⁷ The Supreme Court identifies the Daugan patent as the closest prior art, on which the claims of the 181 patent are based.¹⁰⁸ The Daugan patent therefore constitutes the starting point for the inventive step assessment in this case. The Daugan patent disclosed a potential dosage range for oral use of Tadalafil – “0.5mg – 800mg daily.”¹⁰⁹

The dosage patent (patent 181) was filed on April 26th 2000, claiming Tadalafil as an effective treatment for erectile dysfunction at the low, novel dose of up to 5mg. Furthermore, it claimed to minimize side effects associated with other PDE5 inhibitors.^{110 111} The dosage patent also refers to the fact that, unlike other brands, the drug can be taken daily, rather than on demand.¹¹²

Initially Justice Colin Birss held that it was not obvious for the person skilled in the art to trial a dosage as small as 5mg, concluding that the claimant’s motion should be dismissed. This decision was overturned by the Court of Appeal in 2017.¹¹³ Consequently in 2019, the case was heard before the Supreme Court. The unanimous judgement being provided by Lord Hodge.

Lord Hodge clarifies the relationship between UK and European patent law stating that it is common practice (although not mandatory) for UK courts to follow “*the settled jurisprudence of the EPO.*”¹¹⁴ Nonetheless, there remains a distinction between the approaches taken by the UK and EPO towards the assessment of the inventive step. Therefore, the United Kingdom Supreme Court (UKSC) applied the UK based ‘*Windsurfing/Pozzoli*’ test, rather than the EPO ‘*problem/solution*’ approach. The former was expressed as follows:

“(a) Identify the notional “person skilled in the art”(b) Identify the relevant common general knowledge of that person; (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it; (3) Identify what, if any, differences exist between the matter cited as forming part of the “state of the art” and the inventive concept of the claim or the claim as construed; (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute

¹⁰⁵ *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15 at para 1

¹⁰⁶ European patent 1173181

¹⁰⁷ *Ibid* 94

¹⁰⁸ ICOS at para 96

¹⁰⁹ Daugan patent

¹¹⁰ European patent 1173181

¹¹¹ Such as those associated with sildenafil – marketed as VIAGRA.

¹¹² *Ibid* 97

¹¹³ *ICOS Corporation & Anr v Actavis Group PTC EHF* [2017] EWCA Civ 1671

¹¹⁴ *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15 at para 56

steps which would have been obvious to the person skilled in the art or do they require any degree of invention.”^{115 116}

As previously stated, the EPO employs the “*problem and solution approach*” to decide whether or not a patent meets the inventive step requirement as per article 56 of the European Patent Convention. Article 56 provides that “*An invention shall be considered as involving an inventive step if, having regard to the state of the art, it is not obvious to a person skilled in the art.*”¹¹⁷

The problem/solution test for an inventive step inquiry is expressed as follows:

*“there are three main stages: determining the ‘closest prior art’, establishing the ‘objective technical problem’ to be solved, and considering whether or not the claimed invention, starting from the closest prior art and the objective technical problem, would have been obvious to the skilled person.”*¹¹⁸

In the resolution of *ICOS*, Lord Hodge paid close attention to the fact that both of these approaches rely on the person skilled in the art and the actions which this person would take:

*“the task which the notional skilled team would undertake was that of implementing daugan. The target of the skilled team would be to ascertain the appropriate dose, which would usually be the lowest effective dose”*¹¹⁹

The obiter dictum offered by Lord Hodge with regards to follow-on pharmaceutical innovation and “invention patents” is brief. It primarily reaffirms the 2004 House of Lords case of *Buchanan v Alba Diagnostics*.¹²⁰ This case stated that a patentable improvement is where the primary invention¹²¹ “*comes within the claims of an earlier patent but contains a further inventive step.*”¹²² Lord Hodge importantly goes on to add that “*use of well-known research tests of itself does not render such selections and improvements obvious.*”¹²³ Arguably, the 181 patent itself is indeed ‘follow-on pharmaceutical innovation’ as it pertains to the drug Tadalafil which has already been established to have been disclosed by the daugan patent. Critics often use dosage patents as an example for patentable follow-on innovation.¹²⁴ Thus the interpretation and the application of the inventive step in this case remains particularly relevant to this paper.

Lord Hodge presented a non-exhaustive, ten factor list at paragraphs 65 through 74. These factors provided the basis for the decision of this case.¹²⁵ These factors are helpfully summarised in a point by point form by European Patent Attorney Rose Hughes:

“Whether something is “obvious to try”

¹¹⁵ *Windsurfing International Inc. v Tabur Marine (GB) Ltd.* [1985] RPC 59

¹¹⁶ *Pozzoli SPA v BDMO SA* [2007] EWCA Civ 588

¹¹⁷ *European Patent Convention* Art 56, EU 1977

¹¹⁸ Paul England, “Inventive step in Europe and the UPC” (2018) 13:7 (Journal of Intellectual Property Law & Practice) 534–541

¹¹⁹ *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15 para at 105

¹²⁰ *Buchanan v Alba Diagnostics* [2004] RPC 34

¹²¹ Primary invention: the base invention which has subsequently been improved

¹²² *Buchanan v Alba Diagnostics* [2004] RPC 34

¹²³ *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15 at para 104

¹²⁴ Guidelines for pharmaceutical patent examination : examining pharmaceutical patents from a public health perspective, by Carlos M Correa (United Nations Development Programme, 2016) at page 11

¹²⁵ *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15 at para 64

Whether something is "routine"

The burden and the cost of the research program

Necessity for and nature of value judgments

Existence of alternative or multiple paths of research

Motivation of the skilled person

Unexpected or surprising results of research

Caution against hindsight and step-by-step (i.e. salami slicing) analysis

*Bonus effects*¹²⁶

There has been some academic speculation that these ten factors may form the basis for future evaluations of the inventive step requirement in UK courts.¹²⁷ Arguably, the practicality of such an exercise would be limited. Lord Hodge provides no criteria to weigh these factors and further emphasised the non-exhaustive nature of this list.¹²⁸ Furthermore, Lord Hodge strongly reiterates that the inventive step requirement lies within statute and both the *Windsurfing/Pozzoli* test and the aforementioned problem solution approach are but “*glosses on the text of section 3 of the 1977 Act and article 56 of the EPC.*”¹²⁹ In other words, the Supreme Court highlighted that although there is a favoured common law test in the United Kingdom,¹³⁰ there are alternative common law tests (or approaches) which may be used. For example the *problem/solution approach* as set out by the EPO was considered within this judgement. Nonetheless, “*The glosses on the text*” statement serves to emphasise that section 3 of the patent Act (the inventive step) should not be read as a requirement to pass a given common law test. Rather, the various common law tests should be considered as tools to aid the court’s assessment of the inventive step.¹³¹

2.4.2 The Importance of ICOS:

As previously discussed, a dosage patent shares similarities with that of an ‘improvement patent.’ Both ‘dosage patents’ and ‘improvement patents’ are forms of protection for follow-on pharmaceutical innovation. The Supreme Court draws a distinction between these two types of patents, whilst leaving the reasoning behind this distinction (in terms of the inventive step) unclear. A dosage patent is defined as a “novel dosage regime”¹³² which contains an inventive step. As previously mentioned, Lord Hodge utilises Lord Hoffmann’s 2004 judgement in *Buchanan v Alba Diagnostics Ltd* to define the subject matter of an improvement patent:

¹²⁶ Rose Hughes, *Supreme Court confirms no hard line on inventive step test in finding Cialis dosage patent obvious*, Online: <<http://ipkitten.blogspot.com/2019/03/breaking-supreme-court-confirms-no-hard.html>>

¹²⁷ *Ibid* 126

¹²⁸ *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15 at para 63

¹²⁹ *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15 at para 62

¹³⁰ *Windsurfing/Pozzoli* *Ibid* 102, *Ibid* 103

¹³¹ *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15 para at 60

¹³² *Ibid* 97

“[an improvement is] an invention which comes within the claims of an earlier patent but contains a further inventive step.”¹³³

If this case does become the starting point for assessing the inventive step requirement, then presumably it must also be used for assessing whether “a further inventive step” is present.¹³⁴ Nonetheless, at this stage it is worth reiterating that ICOS also reaffirms the case by case basis on which an inventive step inquiry should operate:

“that obviousness be approached by a fact specific assessment on a case by case basis, an approach which is consistent with my approach in this judgment, and resisted recognition of any one factor as being of overriding importance, whether it be the cost and effort which pre-clinical and clinical trials entail, or the standardised but sometimes routine nature of such tests.”¹³⁵

The implications of this for follow-on pharmaceutical innovation, is a reinforcement of the unpredictable nature of the inventive step criteria. This case does not offer any advice on how each of the 10 factors should be weighted, consequently there has been little done to remedy this issue. This case therefore, has re-affirmed the unpredictable nature of patent law in this area of pharmaceutical innovation.¹³⁶ This comes as a consequence of the non-exhaustive ‘10 factor approach’ adopted by the Supreme Court, which has potentially emphasised flexibility over certainty of application, as explored below.

This case highlights that the effort and cost of “pre-clinical and clinical trials” are to be included in the search for an inventive step.¹³⁷ However, it also further re-established the role of predictability in the inventive step assessment. If the results of ‘standardised preclinical and clinical trials’ could have been reasonably expected at the moment of the inventions conception, then it is likely that the presence of an inventive step will not be found.¹³⁸

Consequently, if the predictability of clinical trial results and obviousness (lacking an inventive step) are found to have a positive correlation, then it can be inferred that the ‘riskier’ the nature of pharmaceutical R&D the more likely it is that an inventive step will be found. This issue was summarised by Professor Benjamin N Roin commenting on US patent law in 2009:

“This rule means that a drug is unpatentable if its relevant properties were reasonably expected at the time of its invention, regardless of whether it has yet to be proven safe and effective in clinical trials.”¹³⁹

From a public health perspective, the correlation highlighted by Roin is not desirable. Academics have already established that besides from providing an incentive to innovate, secondary patents

¹³³ *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15 para at 104

¹³⁴ *Buchanan v Alba Diagnostics* [2004] RPC 34

¹³⁵ *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15 para at 102

¹³⁶ Ben Benjamin N Roin, “Unpatentable drugs and the standards of patentability” (2009) 87:3 (Texas Law Review) 503, online: <<https://search.proquest.com/docview/203704797>>

¹³⁷ *Ibid* 97

¹³⁸ *Ibid* 137

¹³⁹ *Ibid* 137

also provide an incentive to develop.¹⁴⁰ This is especially prevalent in the field of follow-on innovation, as summarised by Holmen et al who highlight:

*“If selection patents were not allowed, then under such a scenario there might be no patent incentive for the development of the compound into an approved drug.”*¹⁴¹ (Selection patents are a common form of follow-on innovation protection)

Ultimately this may lead to effective drugs being left undeveloped, never being brought to market. This in turn leads to potentially lifesaving medication never being made available. The interpretation of *ICOS* therefore, is clearly important. The Supreme Court took the opportunity to reiterate the inventive step requirement for dosage patents and refined how follow-on pharmaceutical innovation is likely to be assessed.¹⁴² However, this refinement seemingly encompasses the somewhat undesirable correlation between unpredictability and patentability as observed in the US by Roin.¹⁴³

2.5 Person Skilled in the Art:

The inventive step requirement specifies the need for a person skilled in the art:

*“An invention shall be taken to involve an inventive step if it is not obvious to a person skilled in the art, having regard to any matter which forms part of the state of the art”*¹⁴⁴

The statute does not provide a definition for this term and thus the courts rely on common law interpretations, which the Supreme Court has since reiterated:

*“The notional skilled person, while having the compendious knowledge of the state of the art which section 2(2) requires, has no inventive capacity. But that does not mean that the skilled person has no skill to take forward in an uninventive way the teaching of the prior art.”*¹⁴⁵

Lord Hodge reinforced the notion that the person skilled in the art, is only capable of carrying forward information from the prior art *“in an uninventive way.”*¹⁴⁶ This is a fundamental principle of patent law in the United Kingdom. The *ICOS* case has served to reiterate its continued relevance to the inventive step. A further corner stone principle which was reinforced, is the ability for the person skilled in the art to become the ‘team’ skilled in the art, which in this case includes a clinical pharmacologist and a urology specialist.¹⁴⁷

¹⁴⁰ Christopher M Holman, Timo Minssen & Eric M Solovy, “Patentability Standards for Follow-On Pharmaceutical Innovation” (2018) 37:3 (Biotechnology Law Report) 131–161, online: <<https://www.liebertpub.com/doi/abs/10.1089/blr.2018.29073.cmh>> at 131–161.

¹⁴¹ *Ibid* 141

¹⁴² *Ibid* 126

¹⁴³ *Ibid* 137

¹⁴⁴ Patent Act 1977 s3

¹⁴⁵ *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15 at para 59

¹⁴⁶ *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15

¹⁴⁷ *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15 at para 17

The person skilled in the art receives further attention from the Supreme Court in the form of the sixth factor; “*motive of the person skilled in the art.*”¹⁴⁸ This resembles the Could/Would test encompassed in the EPO’s *problem/solution* approach which provides that:

*“the point is not whether the skilled person could have arrived at the invention by adapting or modifying the closest prior art, but whether he **would have done** so because the prior art incited him to do so in the expectation of some improvement or advantage.”*¹⁴⁹

In terms of UK jurisprudence, the UK put forward their own reiteration as follows:

*“It is not sufficient that a skilled person could undertake a particular trial; one may wish to ask whether in the circumstances he or she would be motivated to do so. The absence of a motive to take the allegedly inventive step makes an argument of obviousness more difficult.”*¹⁵⁰

The role of the person skilled in the art has been left largely unaffected by the *ICOS* case and thus remains of fundamental importance to the assessment of the inventive step.

2.6 Routine Nature and Predictability of Clinical Trials:

Lord Hodge partly comments on the effect of routine clinical trials stating that “*A fortiori, efficacious drugs discovered by research involving standard pre-clinical and clinical trials should be rewarded with a patent if they meet the statutory tests.*”¹⁵¹ (Emphasis added)

In this context, the statutory test refers to section 3 of the Patent Act (the person skilled in the art). Although this may be representative of the things that a patent system should reward, in practice it has been observed that searching for an inventive step, by assessing the predictability of clinical trials in this way, may actually prevent certain efficacious drugs from reaching the market.¹⁵² As previously stated, this is primarily a result of riskier R&D being indicative of a finding of non-obviousness. Furthermore, it has already been established that pharmaceutical patents offer just as much incentive to develop (likely through routine, predictable means) as they do to innovate.¹⁵³ Hence, an assessment in this manner discourages follow-on pharmaceutical innovation.

¹⁴⁸ *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15 at para 70

¹⁴⁹ “Guidelines for Examination in the European Patent Office, *Chapter 7 Part 5.3 Could – Would Approach*” (2019), online: <https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_vii_5_3.htm>

¹⁵⁰ *Ibid* 148

¹⁵¹ *Ibid* 146

¹⁵² Benjamin N Roin, “Unpatentable drugs and the standards of patentability” (2009) 87:3 (Texas Law Review) 503, online: <<https://search.proquest.com/docview/203704797>> at 503.

¹⁵³ At page 15

2.7 Inventive Concept of the Claim:

Another important principle which was reiterated in *ICOS* pertains to the precise wording of the patent claims. The appellants argued that obviousness should be assessed on the “*precise wording of the claim and not a loose paraphrase.*”¹⁵⁴ The *Medimmune* judgement was relied upon in order to substantiate this argument.¹⁵⁵ However Lord Hodge emphasised that the courts are not bound to the precise wording of a claim, but rather that the court “*must answer a relatively simple question of fact: was it obvious to the skilled but unimaginative addressee to make a product or carry out a process falling within the claim.*”¹⁵⁶ (Emphasis added by Lord Hodge).

Thus it is clear that the courts should seek to establish the inventive concept of a claim and subsequently establish the obviousness of the concept by reference to the claim. Lord Hodge further explains that this requirements, termed the *Medimmune* requirement, is met:

*“if the step by step approach, without the benefit of hindsight, demonstrates that the skilled team would be very likely to pursue the tests to the point at which they would ascertain the product or process falling within the claims.”*¹⁵⁷

The ‘step by step approach’ refers to common law tests such as the *Windsurfing/Pozzoli* test and the *problem/solution* approach.^{158 159} Thus the inventive concept in the United Kingdom, although undefined, is construed from the “*precise wording of the claim*”¹⁶⁰ and not from “*a vague paraphrase based upon the extent of his [the appellants] disclosure.*”¹⁶¹

2.8 Grace Period & Disclosure:

The United Kingdom offers a very limited grace period. Any form of disclosure, unless under the very specific circumstances in render a patent application invalid. This remains the outcome even if the invention was disclosed outside of the United Kingdom’s jurisdiction. Consequently, it has been observed that jurisdictions which provide stringent standards, such as those provided by the United Kingdom effect the behaviour of pharmaceutical companies in other jurisdictions.¹⁶² Pharmaceutical companies will attempt to adhere to the most stringent requirements for patentability in their target markets.¹⁶³

This inadvertently makes the UK’s grace period requirements one which the vast majority of pharmaceutical companies conform to, due to the developed status and comparatively lucrative nature of the United Kingdom’s market.¹⁶⁴

¹⁵⁴ *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15 at para 89

¹⁵⁵ *MedImmune Ltd v Novartis Pharmaceuticals UK Ltd* [2012] EWCA Civ 1234

¹⁵⁶ *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15 para 90

¹⁵⁷ *MedImmune Ltd v Novartis Pharmaceuticals UK Ltd* [2012] EWCA Civ 1234

¹⁵⁸ *Ibid* 114, 115

¹⁵⁹ *Ibid* 96

¹⁶⁰ *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15 at para

¹⁶¹ *Ibid* 156

¹⁶² *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15 at para 92

¹⁶³ *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15 at para 90

¹⁶⁴ UN Country classification

2.9 Conclusion:

ICOS highlights that the UK will continue to adopt common law tests in order to assess the inventive step of a disputed patent claim. However, these common law tests such as the *windsurfing/pozzoli* test are to be considered as *approaches* towards the assessment of the inventive step. Lord Hodge put forwards the notion that the common law tests should be used as tools to help the courts avoid the various pitfalls, namely that of avoiding hindsight bias, when assessing the inventive step. This case serves to reiterate the overriding importance of the statutory requirement of the inventive step and thus it is imperative that this requirement is not read as being a requirement to pass the *Windsurfing/Pozzoli* test.^{165 166}

It appears evident through the presentation of the 10 factors, that *ICOS* advocates for a flexible approach to the inventive step inquiry in order to adequately assess all the relevant case specific facts.¹⁶⁷

¹⁶⁵ *Ibid* 129

¹⁶⁶ *Ibid* 115, 116

¹⁶⁷ *Ibid* 126

Chapter 3: Canada

3.1 Introduction

The discussion within this chapter will first focus on an explanation of the inventive step in Canada (referred to as the non-obviousness requirement in Canada and this chapter) and how this rule came in to being. Following this, a discussion regarding the issues this requirement has faced in its evolution will take place. This will largely be achieved through an analysis of the Canadian Supreme Court in the Case of *Apotex v Sanofi*.¹⁶⁸ Following this, the importance of the *Sanofi* case will be highlighted through the use of two Federal Court of Appeal proceedings; *Teva Canada Limited v. Pfizer Canada Inc*¹⁶⁹ and *Apotex Inc. v. Pfizer Canada Inc*.¹⁷⁰ This chapter will then discuss elements which are important to the inventive step (obviousness) inquiry under the following subheadings: The routine nature of clinical trials & predictability, the inventive concept, person skilled in the art and finally grace periods and disclosure. These headings are chosen to enable comparison in a later chapter of this paper.¹⁷¹ Finally a conclusion will be drawn to provide a summary of how the law of obviousness in Canada is perceived by academics and why some critics believe Canada to be “friendly towards to evergreening.”¹⁷²

3.1.2 A Brief History of the Inventive Step Requirement in Canada:

The inventive step requirement in Canadian patent law is a codified requirement, referred to within Canada as the requirement of non-obviousness.¹⁷³ The requirement itself is found in the 1985 Patent Act, section 28.3 which reads:

“The subject-matter defined by a claim in an application for a patent in Canada must be subject-matter that would not have been obvious on the claim date to a person skilled in the art or science”¹⁷⁴

Professor David Vaver highlights that the requirement for obviousness was not always a codified requirement in Canadian law. It was not until 1989 that the requirement for a patent to be ‘non-obvious’ was codified in statute. Nonetheless, as Vaver notes, the requirement for obviousness was still “part of most countries’ law, including Canada’s, well before then.”¹⁷⁵ Justice Rothstein further explains that prior to 1989, the requirement was considered to be “*implied in the definition*

¹⁶⁸ *Apotex Inc. v. Sanofi-Synthelabo Canada Inc*, 2008 SCC 61

¹⁶⁹ *Teva Canada Limited v. Pfizer Canada Inc.*, 2019 FCA 15

¹⁷⁰ *Apotex Inc. v. Pfizer Canada Inc.*, 2019 FCA 16

¹⁷¹ Chapter 4

¹⁷² Matthew B Stanbrook, “Limiting ‘evergreening’ for a better balance of drug innovation incentives” (2013) 185:11 (CMAJ : Canadian Medical Association journal) 939, online: <<https://www.ncbi.nlm.nih.gov/pubmed/23877665>>

¹⁷³ Patent Act 1985

¹⁷⁴ Patent act 1985 s 28.3

¹⁷⁵ David Vaver, “Being Old and Obvious: *Apotex v. Sanofi* SCC” (2010) 3:1 (OHRLP: Osgoode Hall Review of Law and Policy) online: <<https://digitalcommons.osgoode.yorku.ca/cgi/viewcontent.cgi?article=1016&context=ohrlp>>

of an invention in the Patent Act: an invention that invented nothing was obvious and so no invention at all.”¹⁷⁶

As with many commonwealth nations, in Canada the inventive step requirement is one which is codified in nature. However the test and its interpretation is found at common law. The *Beloit* case¹⁷⁷ highlighted that the Canadian test for obviousness should be objective. Whereby ‘a mere scintilla’ of inventiveness is sufficient for the requirement to be met.¹⁷⁸ A notion which is still referred to by Canadian courts to establish the capabilities of the person skilled in the art.^{179 180}

Currently, Canadian courts follow a four-step approach, which was first utilised in the UK *Windsurfing/Pozzoli*¹⁸¹ cases. The application and refinement of this test by Canadian courts is seen in the 2008 Supreme Court case of *Apotex v Sanofi*.¹⁸² This particular case deals with the test for non-obviousness as applied to selection patents. It has since become the leading precedent for Canadian courts pursuing an obviousness inquiry.¹⁸³ Selection patents are a familiar subject of non-obvious claims, with critics citing concerns that selection patents are utilised for the purpose of evergreening and should therefore be invalidated.¹⁸⁴ A selection patent is a patent which covers a small number of previously disclosed compounds. The previous disclosure occurs in the ‘genus patent.’ The genus patent discloses an entire “class of compounds” which are often in the hundreds of thousands, these disclosed compounds will often share similar therapeutic characteristics. However, they will vary in therapeutic efficacy and toxicity. It is only through further research, development and ingenuity that the most effective compounds can be identified. It is these compounds which form the subject of the selection patent, usually several years later.^{185 186 187}

Justice Rothstein of the Supreme Court dismisses the concern of evergreening in this field by expressly stating that “a generalized concern about evergreening is not a justification for an attack on the doctrine of selection patents.”¹⁸⁸ This statement consequently reaffirmed the doctrine of selection patents as good law. The Supreme Court case of *Apotex v Sanofi* is currently the leading precedential authority on the application of the *windsurfing/Pozzoli* test in instances where the obviousness requirement is in issue.¹⁸⁹ However, this reiteration referred to as the *Apotex* or *Sanofi* test within Canada. Nonetheless, for the purposes of this paper, the tests are one and the same.

¹⁷⁶ Marshall Rothstein, “Intellectual property and the generalist judge” (2015) 27:2 (Intellectual Property Journal (Carswell)) 135, online: <<https://search.proquest.com/docview/1674664872>> at 135.

¹⁷⁷ *Ernest Scragg & Sons Ltd. v Leeson Corp.*, 1964 ExCR 649, 45 CPR 1

¹⁷⁸ *Ibid* 177

¹⁷⁹ *Apotex Inc. v. Sanofi-Synthelabo Canada Inc* 2008 SCC 61 at para 52

¹⁸⁰ *Beloit Canada Ltd. v. Valmet Oy*, (1986) 64 N.R. 287 at para 294

¹⁸¹ *Ibid* 115, 116

¹⁸² *Apotex Inc. v. Sanofi-Synthelabo Canada Inc* 2008 SCC 61

¹⁸³ *Frac Shack Inc. v. AFD Petroleum Ltd*, 2018 FC 1047 at para 53

¹⁸⁴ Roger Collier, “Drug patents: the evergreening problem” (2013) 185:9 (CMAJ : Canadian Medical Association journal)

¹⁸⁵ Christopher M Holman, “In Defense of Secondary Pharmaceutical Patents: A Response to the UN’s Guidelines for Pharmaceutical Patent Examination” (2017) 50:3 (Indiana Law Review) 759 at 759.

¹⁸⁶ *Teva Canada Limited v. Pfizer Canada Inc.*, 2019 FCA 15

¹⁸⁷ *I. G. Farbenindustrie A. G.’s Patents* (1930), 47 R.P.C. 289 at para 321 - 323

¹⁸⁸ *Apotex Inc. v. Sanofi-Synthelabo Canada Inc*, 2008 SCC 61 at para 98

¹⁸⁹ *Windsurfing International Inc. v Trilantic Corp.*, 1985 FCJ No 1147, 8 CPR (3d) 241 (FCA)

3.2 Apotex V Sanofi:

This section of the chapter will focus on the *Apotex v Sanofi* case which was eventually heard before the Canadian Supreme Court.¹⁹⁰ It will first give a brief summary of relevant case facts and the subsequent claims being made. Following this, the chapter will look to subsequent case law to offer an explanation on how the *Sanofi* test is being applied.

The case heard before the Supreme Court in 2008, focuses on a selection patent referred to as patent '777 which is reliant on the genus patent '875. The defendants in this case, Sanofi, are the owners of both of these patents.¹⁹¹ Patent '875 disclosed an entire class of compounds in excess 250,000 back in 1982.¹⁹³ The '777 selection patent protects a much smaller number of compounds. The primary purpose of the '777 patent was to afford protection to the anti-coagulant drug, branded as Plavix in 1995.¹⁹⁴ This was done so on the basis that the compound Clopidogrel Bisulfate (Plavix) was found to exhibit unique characteristics in relation to the '875 class of compounds – primarily; a “*greater therapeutic effect*” whilst maintaining “*lower toxicity than the other compounds of the '875 patent.*”¹⁹⁵

The '777 patent was disputed by the claimants, Apotex, on the grounds of “*anticipation, obviousness and double patenting.*”¹⁹⁶ For the purposes of this paper, the grounds of double patenting and obviousness are of particular importance.

As previously discussed, the Supreme Court used this case as means of re-affirming the presence of the UK founded *Windsurfing/Pozzoli*¹⁹⁷ test for the assessment of obviousness in Canadian Law.¹⁹⁸ At this stage it is worth reiterating the four steps of the *windsurfing* test as applied by the Canadian Supreme Court;

“In the result I would restate the Windsurfing questions thus:

(1) (a) Identify the notional “person skilled in the art” (b) Identify the relevant common general knowledge of that person; (2) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it. (3) Identify what, if any, differences exist between the matter cited as forming part of the “state of the art” and the inventive concept of the claim or the claim as construed. (4) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of invention?”¹⁹⁹

¹⁹⁰ *Ibid* 182

¹⁹¹ “PROCESS FOR PREPARING THIENO [3,2-C] PYRIDINE DERIVATIVES AND DERIVATIVES THUS OBTAINED” 1985 patent number CA1194875A

¹⁹² DEXTRO-ROTATORY ENANTIOMER OF METHYL ALPHA-5 (4,5,6,7-TETRAHYDRO (3,2-C) THIENO PYRIDYL) (2-CHLOROPHENYL)-ACETATE, A PROCESS FOR ITS PREPARATION AND THE PHARMACEUTICAL COMPOSITIONS CONTAINING IT, Patent number CA 1336777

¹⁹³ *Ibid* 192

¹⁹⁴ *Ibid* 192

¹⁹⁵ Joshua Sealy-Harrington, “The inventive concept in patent law: not so obvious” (2015) 27:3 (Intellectual Property Journal) 385, online: <<https://search.proquest.com/docview/1716260615>> at 385

¹⁹⁶ *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61 at para 2

¹⁹⁷ *Ibid* 115, 116

¹⁹⁸ *Ibid* 196

¹⁹⁹ *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, 2008 SCC 61 at para 67

It was highlighted that the element of ‘obvious to try’ falls under the fourth step in this test.²⁰⁰ The courts further clarified the final stage of the test, by setting out five factors to consider when deciding whether a particular invention was obvious;

*“Is it more or less self-evident that what is being tried ought to work? ... What is the extent, nature and amount of effort required to achieve the invention? ... Is There a Motive From the Prior Art to Find the Solution That the ‘777 Patent Addresses? ... What Is the Course of Conduct Which Was Followed Which Culminated in the Making of the Invention? ... Was the Invention of the ‘777 Patent ‘Obvious to Try’?”*²⁰¹

The Supreme Court went through the process of answering the five questions, which lead to the ultimate determination that “*there was a significant difference between the ‘875 genus patent and the ‘777 selection patent.*”²⁰² It was further clarified that this difference was deemed to be not obvious.²⁰³

3.2.1 Interpretation of Sanofi:

As previously established, the leading precedential authority for determining obviousness in Canada, is the Supreme Court case of *Apotex v Sanofi*.²⁰⁴ The importance of this case and how the *Sanofi* reiteration of the *Windsurfing/Pozzoli* test has come to be interpreted, can be identified through the analysis of how the lower courts have applied this test. The Federal Court of Appeal cases of *Teva Canada Limited v. Pfizer Canada Inc*²⁰⁵ and *Apotex Inc. v. Pfizer Canada Inc*²⁰⁶ highlight how the *Sanofi* test is being applied. The judgement in these two cases, also provide clarification on the effect that the routine nature of clinical trials have on obviousness. The dual proceedings before the Federal Court of Appeal concerned patent ‘668, which covered a crystalline form of a particular salt. The salt in question, Desvenlafaxine, constitutes a drug sold by Pfizer for the treatment of depression. It was sold under the brand name PRISTIQ.²⁰⁷ The motion before the Federal Court of Appeal (FCA) was a determination on whether patent 668 was obvious.

The subject matter of patent 668 is the salt Desvenlafaxine succinate in crystalline form. As previously stated, this makes constitutes Pfizer’s drug PRISTIQ and is referred to as “form I.”²⁰⁸ The main question before the trial judge and subsequently Justice Boivin of the FCA is whether the discovery of “form I” was obvious.²⁰⁹

‘Form I’ of the drug was established through a screening study. A screen study is a process utilised by pharmaceutical companies, to establish characteristics of a compound in various salt

²⁰⁰ *Ibid* 179

²⁰¹ *Apotex Inc. v. Sanofi-Synthelabo Canada Inc*, 2008 SCC 61 at para 84 - 92

²⁰² *Apotex Inc. v. Sanofi-Synthelabo Canada Inc*, 2008 SCC 61 at para 93

²⁰³ *Ibid* 169

²⁰⁴ *Ibid* 169

²⁰⁵ *Teva Canada Limited v. Pfizer Canada Inc.*, 2019 FCA 15

²⁰⁶ *Apotex Inc. v. Pfizer Canada Inc.*, 2019 FCA 16

²⁰⁷ FDA, *Approved Drug List December 2019* online: <<https://www.fda.gov/media/71494/download>>

²⁰⁸ *Ibid* 205

²⁰⁹ *Ibid* 205

or crystalline forms. This is done in order to establish candidates for further research and development.²¹⁰ It was at this stage that ‘form I’ of PRISTIQ was established. Consequently, Teva and Apotex argued that ‘form I’ (which constitutes the subject matter of patent 668) arose from a routine clinical trial and was therefore obvious on this basis.²¹¹

The trial judge implements the Sanofi test at paragraphs 223 through to 329 and pays particular attention to the ‘obvious to try’ test, under the fourth step.²¹² It was reiterated that this step should be applied with caution and does not provide the final answer on the issue of obviousness.²¹³ Rather that the *Sanofi* test as a whole must be utilised to establish a finding of obviousness. There was no indication of weight to be given to the conclusion made at each step.

Ultimately it was decided that the obvious to try test had not been met and after a thorough application of the *Sanofi* questions (which has already been established to be the same as the *Windsurfing/Pozzoli* test.) patent 668 was found to not be obvious. Subsequently, Teva pursued further judicial action and the case was heard before Justice Boivin of the Federal Court of Appeal.

The basis for the appeal is stated at paragraph 3:

“In essence, Teva argues that the Federal Court Judge misconstrued and misapplied the test for obviousness as set out in Apotex Inc. v. Sanofi-Synthelabo Canada Inc., 2008 SCC 61, [2008] 3 S.C.R. 265 [Sanofi] and that his obviousness analysis is directly contrary to two judgments rendered by our Court: Bristol-Myers Squibb Canada Co. v. Teva Canada Limited, 2017 FCA 76, 146 C.P.R. (4th) 216 [Atazanavir]; and Pfizer Limited v. Ratiopharm Inc., 2010 FCA 204, 87 C.P.R. (4th) 185 [Amlodipine].”

The Federal Court of Appeal dismissed the appeal and reiterated that obviousness must be decided on a case by case basis and that there are no “hard and fast rules”²¹⁴ which mitigate this fact:

“contrary to what Teva appears to urge, past cases cannot be used to force a given conclusion on obviousness based on broad factual similarities to the detriment of otherwise significant differences in a given case. However trite, each case is decided on the basis of the specific evidentiary record put before a judge.”²¹⁵

This reinforces the notion that the weight given to each step of the test should be determined on a case by case, fact specific basis.

²¹⁰ *Pfizer Canada Inc. v. Apotex Inc.*, FC 774 at para 29

²¹¹ *Pfizer Canada Inc. v. Apotex Inc.*, FC 774 at para 29

²¹² *Pfizer Canada Inc. v. Apotex Inc.*, FC 774 at para 287

²¹³ *Pfizer Canada Inc. v. Apotex Inc.*, FC 774 at para 285

²¹⁴ *Teva Canada Limited v Pfizer Canada Inc*, 2019 FCA 15 at para 38

²¹⁵ *Teva Canada Limited v Pfizer Canada Inc*, 2019 FCA 15 at para 39

3.3 Routine Nature of Clinical Trials & Predictability:

As previously stated, one of the issue before the trial judge in *Teva v Pfizer* was whether ‘form I’ (which was formed out of a non-novel, routine trial) was obvious.²¹⁶ Specifically, whether this was obvious to try. The federal court of appeal maintained that this was not obvious to try. The foreseeability of form I being both successfully formed and medically effective, was deemed to be unpredictable. This was heavily weighted in the assessment of whether it was obvious to person skilled in the art and whether it was obvious to try. (ODV in the following quote refers to the drug of which ‘form I’ is a derivative)²¹⁷

“there is no evidence that at the relevant time a skilled person would know which salt, or which crystalline form, would work to achieve the invention i.e., the crystalline Form I ODV succinate. In fact, in this case the evidence is stronger than that in Sanofi against obviousness to try, because here there is evidence which I accept on a balance of probabilities that the salt ODV succinate in fact would not work. This evidence was based on the fact that ODV fumarate, another salt of ODV, had not worked... If one did not work it was logical the other would now (sic) work...”²¹⁸

Justice Boivin concluded that this was consistent with both the test set out in *Sanofi* and the subsequent clarification provided in the *Bristol-Myer Squibb* case.²¹⁹ Therefore it is evident that in Canada, un-predictability of results from routine tests are positively correlated with a finding of non-obvious. Subject matter of this nature can pass the obvious to try test if the result of the test was unexpected. However, this will be decided on the facts of each case and should not be interpreted as providing a ‘correctness standard’ or “hard and fast rules” to obviousness. The Federal Court of Appeal concurred that un-expected results of a clinical trial, do not guarantee a finding of non-obviousness.²²⁰

3.4 The Inventive Concept:

Apotex v Sanofi systematically reiterates the test to assess the obviousness of a claimed invention. Academics such as Joshua Sealy Harrington, argued that the non-obviousness requirement and the test implemented to assess its presence, substantially lacked clarity. Harrington questions the role of “the concept of inventiveness” in the criteria set out to test for obviousness;

“Step 3 of the court’s four-step test in Apotex Plavix is similarly ambiguous with respect to whether the inventive concept is a necessary part of the obviousness test.”²²¹

²¹⁶ *Ibid* 205

²¹⁷ *Teva Canada Limited v Pfizer Canada Inc*, 2019 FCA 15 at para 1

²¹⁸ *Pfizer Canada Inc v Apotex Inc* 2017 FC 774 at para 306

²¹⁹ *Ibid* 217

²²⁰ *Apotex Inc. v. Pfizer Canada Inc.*, 2019 FCA 16

²²¹ Joshua Sealy-Harrington, “The inventive concept in patent law: not so obvious” (2015) 27:3 (Intellectual Property Journal) 385, online: <<https://search.proquest.com/docview/1716260615>> at 385.

Harrington articulates an argument which poses the question; 'is the "*concept of inventiveness*" a mandatory or optional pre-requisite for a judicial finding of non-obviousness?'²²² Harrington suggests that through a decisive definition from the appellate courts, many of these concerns could be addressed.²²³

To an extent, the inventive concept was clarified in the case of *Bristol-Myers Squibb Canada Co v Teva Canada Limited*²²⁴ where it was held that the inventive concept should be considered as synonymous with "*the solution taught by the patent.*"^{225 226} This can subsequently be utilised to address the concerns presented by Harrington. The clarification that the inventive concept is "*the solution taught by the patent*" results in the assessment of obviousness, simultaneously being an identification and assessment of the inventive concept. Essentially, this case teaches that an enquiry in to obviousness is one which determines whether the gap between the prior art and the inventive concept, can be "bridged" by the person skilled in the art.²²⁷

The implementation of the obviousness inquiry (since the Supreme Court reiteration of the *Windsurfing/Pozzoli* questions in *Sanofi*) had arguably been somewhat rigid in the lower courts' application. The courts would tend to state the *Beloit/Scragg* definition of the person skilled in the art²²⁸ and then recite the four questions as per *Sanofi*.²²⁹ However, the Federal Court of Appeal cases of *Teva v Pfizer*²³⁰ and *Apotex v Pfizer*²³¹ (as discussed above) have helped to dispel the regimented nature in their approach. Indeed Justice Boivin stated that obviousness is a "*Flexible, Contextual, Expansive, and Fact-driven Inquiry.*"²³²

The questions of obviousness pertain to the inventive concept as construed by the courts. Absent a "*palpable and overriding error by the Federal Court judge*" the obviousness inquiry should not be held to a "correctness standard."²³³ This highlights that judges should be entitled to their own "*appreciation of the evidence, including the weight given to competing evidentiary submissions.*"²³⁴ Which arguably grants the obviousness inquiry a greater degree of flexibility than previously observed. This was further reinforced by stating: "*However trite, each case is decided on the basis of the specific evidentiary record put before a judge.*"²³⁵

²²² *Ibid* 221

²²³ *Ibid* 221

²²⁴ *Bristol-Myers Squibb Canada Co. v. Teva Canada Limited*, 2017 FCA 76

²²⁵ *Bristol-Myers Squibb Canada Co. v. Teva Canada Limited*, 2017 FCA 76 at Para 75

²²⁶ *Hospira Healthcare Corporation V The Kennedy Trust For Rheumatology Research*, 2018 FC 259 at para 209

²²⁷ *Bristol-Myers Squibb Canada Co. v. Teva Canada Limited*, 2017 FCA 76 at para 82

²²⁸ *Ibid* 177

²²⁹ *Ibid* 169

²³⁰ *Ibid* 210

²³¹ *Ibid* 196

²³² *Teva Canada Limited v Pfizer Canada Inc*, 2019 FCA 15 at 35

²³³ *Ibid* 232 at para 31

²³⁴ *Ibid* 233

²³⁵ *Ibid* 233 at 39

3.5 Person Skilled in the Art:

The requirement for the person skilled in the art is contained in the Patents Act under section 28.3. As previously established, this is a requirement which is of fundamental importance to the *Windsurfing/Pozzoli* reiteration in *Sanofi*.²³⁶ Nonetheless, the definition for the person skilled in the art is not provided for in the Act.

The often used definition for the person skilled is the one provided in the case of *Beloit Canada Ltd. v. Valmet Oy (1986)*:

“The test for obviousness is not to ask what competent inventors did or would have done to solve the problem. Inventors are by definition inventive. The classical touchstone for obviousness is the technician skilled in the art but having no scintilla of inventiveness or imagination; a paragon of deduction and dexterity, wholly devoid of intuition; a triumph of the left hemisphere over the right.”²³⁷

Judges will identify the person skilled in the art pertaining to a given industry. Following this, the ‘general common knowledge’ of this fictitious person will be identified. Once this has been done, the lens of the person (or team) skilled in the art, will be utilised to assess the obviousness of the inventive concept.²³⁸ Obviousness therefore is determined in light of their specific general knowledge and the prior art combined.²³⁹

3.6 Disclosure & Grace Period:

The date at which a patent applicant is filed with the patent office, is known as the filing date. The claim date refers to *“the date of a claim in an application for a patent in Canada.”²⁴⁰* This is often the same as the filing date, however in accordance with the Paris convention, this may refer to a previously filed patent, to which the current patent application claims priority.²⁴¹

Canada operates a grace period for disclosure which is contained within section 28.3(a) of the Patents act 1985:

“information disclosed before the one-year period immediately preceding the filing date or, if the claim date is before that period, before the claim date by the applicant, or by a person who obtained knowledge, directly or indirectly, from the applicant in such a manner that the information became available to the public in Canada or elsewhere;”²⁴²

This clause is the only way in which disclosure of an invention does not harm its eligibility for patent protection. It is a fundamental premise of patent law, that disclosure of an invention denies patentability. Indeed the definition of an invention contained in section 2 states:

²³⁶ *Ibid* 169

²³⁷ *Beloit Canada Ltd. v. Valmet Oy*, (1986) 64 N.R. 287

²³⁸ *Ibid* 169

²³⁹ *Packers Plus Energy Services Inc. v. Essential Energy Services Ltd.*, 2019 FCA 96 at para 37

²⁴⁰ Canada Patent Act 1985 RSC s 2

²⁴¹ Paris convention 1883 art 4(a)

²⁴² Patent act 1985 28.3 (a)

“any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter;”²⁴³ (emphasis added)

Thus any prior disclosure of an invention prevents the novelty requirement from being met. Unless disclosure occurs within the 12 months prior to the filing or priority date, whichever is earlier, disclosure can be used against a patent application.²⁴⁴ Any disclosure which occurs within the 12 month grace period should not be used in the assessment of the novelty or the inventive step requirement as per section 28.3 of the Patents Act 1985.

3.7 Canada and Evergreening:

Canada’s patent laws have been described as *“among the friendliest toward evergreening in the world.”*^{245 246} Indeed critics such as Stanbrook and Lexchin rely on statistics such as ‘90 percent of newly approved medical products are ‘me too’ drugs.’²⁴⁷

“Me-too drugs can be broadly defined as chemically related to the prototype, or other chemical compounds which have an identical mechanism of action.”²⁴⁸

In this instance, “the prototype” refers to the initially disclosed chemical compound of a particular drug. Often these me-too drugs can be patented under claims of an improvement over the prior art. An option which critics argue Canadian patent law is friendly towards. For the purpose of this paper it is important to highlight that me-too drugs are often treated as being synonymous with ‘follow-on’ drugs. Follow-on drugs (or second generation drugs) are subject to claims that they offer no therapeutic advantage over their predecessor and exist to transfer sales of brand drugs nearing patent expiry, to the recently patented ‘me-too’ follow-on drug.^{249 250 251} This concept will be further explored in the comparison chapter of this paper.²⁵²

The current system in Canada used to contest the validity of pharmaceutical patents, is largely reliant on generic litigation. Grootendorst et al explain:

²⁴³ Patents Act ,RSC 1952

²⁴⁴ Patent Act, RSC 1985, s 28.3(a)

²⁴⁵ *Ibid* 172

²⁴⁶ Barbara Sibbald, “Rules that extend drug patents face challenge” (2003) 169:9 (Canadian Medical Association. Journal) 950, online: <<https://search.proquest.com/docview/204788293>> at 950.

²⁴⁷ *Ibid* 172

²⁴⁸ S Garattini, “Are me-too drugs justified?” (1997) 10:6 (Journal of nephrology) 283, online: <<https://www.ncbi.nlm.nih.gov/pubmed/9442441>> at 283.

²⁴⁹ P Toll’s-Hertogenbosch & T van Gelder, “The truth about drug companies: how they deceive us and what to do about it” (2006) 44:3 (MFM)

²⁵⁰ Merrill Goozner, *The \$800 Million Pill*, 1st ed (US: University Of California Press, 2004).

²⁵¹ David A Kessler et al, “Therapeutic-Class Wars -- Drug Promotion in a Competitive Marketplace” (1994) 331:20 (The New England Journal of Medicine) 1350–1353

²⁵² Chapter 4

*“these legal challenges ensure that brand drug firms are unable to extend exclusivity — and high prices — based on patent claims that fail the test of novelty, utility or nonobviousness. Generic firms perform this role, not as a public service, but in the pursuit of profits.”*²⁵³ (Collier terms this form of litigation “watchdog litigation.”)

However as previously noted by Collier, pharmaceutical patent litigation is notoriously complex and risky.²⁵⁴ Nonetheless, many academics consider this form of litigation to be vital to the identification of evergreening and should thus be encouraged.²⁵⁵ Grootendorst et al further explain

*“this [litigation] exposes the [generic] firm to financial risk: generic drugs sell at a fraction of the cost of brand drugs, but damages are calculated based on the full price of the brand drug. The financial risk is thus greater the lower the price of the generic drug.”*²⁵⁶

The high damages at stake strongly discourages generic litigation, which consequently portrays Canada as being friendly to evergreening as the current system arguably favours originator pharmaceutical companies. Therefore the predictability and clarity of the threshold of inventiveness, as applied in an obviousness inquiry, is a vital step towards minimise the risk involved in generic ‘watchdog’ litigation.²⁵⁷ The clearer and more predictable this process is made, the safe this type of litigation becomes for generic companies.

3.8 Conclusion:

The reasons that the laws in Canada are considered to be so ‘friendly’ towards evergreening²⁵⁸ are enhanced by lenient disclosure grace period compared to many other WIPO members.²⁵⁹ Correa seemingly advises that such provisions excluding certain prior art from examination as bad practice.²⁶⁰

Patentability standards regarding the inventive step in Canada are seemingly of a low threshold. The standard for the person skilled in the art is one which offers no creative or inventive capacity beyond following simple, predictable steps. The application of the *Sanofi* test has recently been refined by the Federal Court of Appeal, alleging in dual proceedings that an obviousness inquiry

²⁵³ Paul Grootendorst, Ron Bouchard & Aidan Hollis, “Canada’s laws on pharmaceutical intellectual property: the case for fundamental reform” (2012) 184:5 (CMAJ : Canadian Medical Association journal) 543–549, online: <<https://www.ncbi.nlm.nih.gov/pubmed/22065362>> at 543–549.

²⁵⁴ Roger Collier, “Drug patents: the high price of watchdog litigation” (2013) 185:9 (CMAJ : Canadian Medical Association journal)

²⁵⁵ Ibid 254

²⁵⁶ Ibid 227

²⁵⁷ Especially pertaining to follow-on innovation which, is the subject to the majority of evergreening claims.

²⁵⁸ As discussed above

²⁵⁹ *WIPO Certain Aspects Of National/Regional Patent Laws* “Sufficiency of Disclosure” (2019) Online: <https://www.wipo.int/export/sites/www/scp/en/national_laws/disclosure.pdf>

²⁶⁰ *Guidelines for pharmaceutical patent examination : examining pharmaceutical patents from a public health perspective*, by Carlos M Correa (United Nations Development Programme, 2016) at page 16

is “*Flexible, Contextual, Expansive, and Fact-driven*”. This has created a debate on whether this increases or decreases the standard of obviousness in patent litigation.²⁶¹ The threshold of inventiveness within Canada will become more obvious in terms of its stringency (or lack thereof) when comparison are drawn later in this paper. However, it has been established that the consistency and clarity of this requirement is particularly important in Canada, due to the “watchdog nature” of patent litigation.²⁶²

²⁶¹ *Ibid* 185

²⁶² *Ibid* 228

Chapter 4: India

4.1 Introduction:

This chapter will first briefly explain how Indian patent law looked prior to the Patent amendment act 2005. The effect of the pre-amendment patent act on the pharmaceutical market will be established, to show how the patent regime within India has evolved. After an explanation of the World trade Organisations' TRIPs agreement, the issues which the 2005 patent amendments attempted to address can be scrutinised. Once the above has been established, the current approach taken by the Indian judiciary towards interpreting the inventive step requirement will be explained. This will be achieved through the case study of *Novartis v Union of India & others* - the leading precedent to date.²⁶³ The case in question has a heavy reliance on section 3(d) of the Indian Patent Act. This particular section was one of the additions made in the 2005 amendments. It's important to note at this stage that there is a wealth of academic opinion on this relatively recent "landmark" case, with many commentators correctly predicting the judgements influence in other jurisdictions.²⁶⁴ ²⁶⁵ The chapter will then proceed to discuss relevant areas of patent law under the same subheadings of the previous two chapters, paying particular attention to *Novartis'* relevance to this paper.²⁶⁶

As previously stated, in 2005 India's patent law underwent amendments. The primary purpose of the act was to make India's patent legislation TRIPs compliant. Prior to the 2005 amendment act, it was not possible for pharmaceutical products to receive patent protection unlike Europe and North America. Academics have attributed the difference in the patent regime to various things. For example it is widely documented that India's pharmaceutical sector is dominated by generic drug manufacturing and supplies not only themselves with cheap 'off-brand' drugs – but is the largest exporter of generic drugs in the world.²⁶⁷ Janice Mueller and many academics alike, attribute this generic boom to the 1972 Indian Patent Act which prevented the acquisition of patents on pharmaceutical products.²⁶⁸

This enabled generic companies to acquire branded drugs which were patented in other markets and with the aid of the patents disclosure, reverse engineer them.²⁶⁹ This strategy allows the generic company to create low cost, affordable generic drugs to sell in India and other lesser developed nations, where patent protection for the branded originator drug is not available. In an effort for global patent law harmonisation, the TRIPs agreement forced World Trade Organisation

²⁶³ *Novartis v Union of India & Others*, AIR 2013 SC, App. No. 2706-2716 of 2013

²⁶⁴ Such as south Africa, Argentina and Brazil

²⁶⁵ Kevin Tarsa, "NOVARTIS AG v. UNION OF INDIA: WHY THE COURT'S NARROW INTERPRETATION OF ENHANCED EFFICACY THREATENS DOMESTIC AND FOREIGN DRUG DEVELOPMENT" (2016) 39:3 (Boston College International and Comparative Law Review) 40, online: <<https://search.proquest.com/docview/1865506805>> at 40.

²⁶⁶ *Ibid* 263

²⁶⁷ Varun Mahajan, "Structural changes and trade competitiveness in the Indian pharmaceutical industry in product patent regime" (2019) 13:1 (International Journal of Pharmaceutical and Healthcare Marketing) 21–39, online: <<https://www.emerald.com/insight/content/doi/10.1108/IJPHM-12-2016-0066/full/html>> at 21–39

²⁶⁸ Janice M Mueller, "The Tiger Awakens: The Tumultuous Transformation of India's Patent System and the Rise of Indian Pharmaceutical Innovation" (2007) 68:3 (University of Pittsburgh Law Review)

²⁶⁹ Arvind K Bansal & Vishal Koradia, *The Role of Reverse Engineering in the Development of Generic Formulations* (Monmouth Junction: MultiMedia Healthcare Inc, 2005) at 50.

signatory states to provide patent protection for pharmaceutical products. A change which was encompassed in the 2005 amendments.

4.1.1 TRIPs Legislation:

The World Trade Organisation released the Trade Related Intellectual Property agreement at the beginning of 1995. In essence, this agreement set out a criteria that WTO member states' patent law have to adhere to in order to remain a member of the WTO. Intellectual Property Protection offered between any two given jurisdictions has the potential to differ in its perceivable strength. As previously discussed, one of the purposes of the TRIPs agreement was to begin to harmonise intellectual property law across international borders. However it should be noted, that this agreement did not strive to create a unitary patent system²⁷⁰ but to further align the levels of intellectual property protection offered by signatory states, by setting the minimum standards of patent protection.²⁷¹

4.2 Section 3(d) and the Road to Novartis:

As previously discussed, the Patent Amendment Act (2005), was passed in response to the TRIPs criteria released by the WTO. In light of this, section 3(d) of the Indian patent act has become the basis for much debate. Section 3(d) sets out a requirement as follows:

*"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."*²⁷² (Emphasis added)

For the purposes of this paper, the importance of this section is that in order for a drug to be eligible for patent protection, it must be shown that its efficacy has been improved.²⁷³ This section was of paramount importance in the *Novartis v Union of India & others* case where judicial interpretation of this clause was considered at India's highest court.²⁷⁴

The eventuality of the Novartis case being heard before the two judge bench of the Indian Supreme Court, starts prior to the 2005 amendments in 1998. As previously discussed, at this time the Indian Patent statute did not allow for pharmaceutical products to be patented.²⁷⁵

²⁷⁰ an example being the European Patent Office (EPO), where one patent can be obtained which is valid across multiple EU jurisdictions. This is explained in chapter 2 of this paper.

²⁷¹ As stated by the World trade Organisation

²⁷² Indian Patent Act 1970 S 3 (d)

²⁷³ *Novartis v Union of India & Others*, AIR 2013 SC, App. No. 2706-2716 of 2013

²⁷⁴ *Ibid* 273

²⁷⁵ Kung-Chung Liu & Uday S (eds) Racherla, *Innovation, economic development, and intellectual property in India and China : comparing six economic sectors*, ARCIALA series on intellectual assets and law in Asia (Springer Nature, 2019) at 271–298.

However a patent application for the drug 'Glivec' was permissible, as it came after India had agreed to the TRIPs agreement of the World Trade Organisation.²⁷⁶

The patent application filed by Novartis was for a branded anti-cancer drug – specifically used for blood cancers such as Leukemia. Novartis sells the drug, Imatinib, under the brand name of 'Gleevec' or 'Glivec' dependant on the particular market.²⁷⁷

The first patent obtained for Imatinib by Novartis was actually a selection patent. This means that Imatinib already formed part of a previously known 'class of compounds' which had been disclosed in the genus patent.²⁷⁸ As discussed in the previous chapter, these patents include several different compounds, the usefulness of each (medical or otherwise) is often unknown until some form of testing or experimenting has been performed.²⁷⁹ In this case, the genus patent was termed the Zimmerman patent.²⁸⁰ The information disclosed in the Zimmermann patent of 1996,²⁸¹ included the 'freebase' form of Imatinib which the "beta crystalline salt form" is derived from. The latter of which, is the active ingredient in Glivec which Novartis was attempting to patent in India. As previously mentioned this patent application was for a selection patent claiming the Zimmermann patent as the genus patent but is otherwise a distinct patent application in its own right.²⁸²

Importantly, the beta crystalline form of Imatinib Mesylate was granted patent protection in Switzerland in 1997. Novartis then strove to obtain patent protection in India – filing with the Indian Patent Office in 1998 utilising the Swiss '97 patent as the priority date. As previously discussed, it was not until 2005 that pharmaceutical patents were allowed in India, and the case heard before the Supreme Court concerning this particular patent application was not resolved until April 2013.²⁸³

India had until 2005 to implement a regime which was TRIPs compliant, which meant that patent applications on pharmaceutical products filed after the TRIPs agreement of 1990 but before 2005 were held in a "mailbox." In other words, the patent applications on pharmaceutical products were not to be reviewed until the transitional period for developing countries (in the case of India) had expired. This is summarised by V. K. Unni:

"India was required to set up a "mailbox" facility for accepting pharmaceutical product patent applications filed during the TRIPS transition period and to assign them a filing date, a practice generally known as "pipeline protection". Apart from this requirement, TRIPS also mandated the grant of

²⁷⁶ *The World Intellectual Property Organization and the World Trade Organization "Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)" (1994)*

²⁷⁷ Juan Carlos Hernández-Boluda & Francisco Cervantes, "Imatinib mesylate (Gleevec, Glivec): a new therapy for chronic myeloid leukemia and other malignancies" (2002) 38:9 (Drugs of today (Barcelona, Spain : 1998)) 601

²⁷⁸ Zimmerman Patent US396796A

²⁷⁹ *Chapter 3*

²⁸⁰ Zimmerman patent number US396796A

²⁸¹ Although filed in '96 in the US, this received patent protection as early as April 1992 in Switzerland

²⁸² G. Nair "Landmark Pharma Patent Jurisprudence in India" (2014) 19 (Landmark Pharma Patent Jurisprudence in India) 79-88

²⁸³ *Ibid* 272, 244

*exclusive marketing rights (EMRs), with respect to certain mailbox applications that met additional conditions.*²⁸⁴

4.2.1 Novartis v Union of India & Others:

The *Novartis* case eventually fell to the Supreme Court to resolve the issue of patentability and importantly, whether section 3(d) was constitutional. It is also noted in the opening paragraphs of the judgement that the court was reminded:

*“an error of judgment by it will put life-saving drugs beyond the reach of the multitude of ailing humanity not only in this country but in many developing and under-developed countries, dependent on generic drugs from India.”*²⁸⁵

The Supreme Court had to decide whether Glivec could meet the inventive step requirement, as set out in section 2 of the India Patent Act, but fail the criteria for being an invention as specified in section 3(d). Furthermore, the courts would have to demonstrate the threshold by which “therapeutic efficacy” is to be interpreted and measured.²⁸⁶ In other words, how much of an improvement in drug efficacy is required in order for section 3(d) to be satisfied and which characteristics of a drug are to be considered as indicative of therapeutic efficacy in this regard.²⁸⁷ Through this analysis, the effect of section 3(d) on the threshold of inventiveness can be determined.

When interpreting section 3(d), the first challenge the courts faced was interpreting exactly what is meant by the term efficacy. The judges partly rely upon the definition given in the Oxford English Dictionary; “The ability to produce a desired or intended result.”²⁸⁸ The judges conclude that in the case of section 3(d) efficacy can only mean “therapeutic efficacy.”²⁸⁹ Here it can be inferred that for the courts, therapeutic efficacy refers to the ‘effect that the drug claims to have.’²⁹⁰ By this logic, the courts proceed to establish that it was intended for section 3(d) to be interpreted both strictly and narrowly.²⁹¹

Novartis argued that Glivec should be eligible for patent protection on the grounds that the 2nd generation drug (beta-Imatinib) had:

“has (i) more beneficial flow properties; (ii) better thermodynamic stability; and (iii) lower hygroscopicity than the alpha crystal form of Imatinib Mesylate. It further claimed that the aforesaid properties makes the invented product “new” (and superior!) as it “stores better and is easier to process”; has “better processability

²⁸⁴ V Unni, “India’s TRIPS-Compliant Patent Decade – The Tumultuous Journey in Search of a Pragmatic Equilibrium” (2019) 50:2 (IIC - International Review of Intellectual Property and Competition Law) 161–195

²⁸⁵ *Ibid* 272 at para 4

²⁸⁶ The Patents Act 1970, s 3(d)

²⁸⁷ *Ibid* 285, 286

²⁸⁸ The New Oxford Dictionary of English, Edition 1998.

²⁸⁹ *Novartis v Union of India & Others*, AIR 2013 SC, App. No. 2706-2716 of 2013 at para 170 - 181

²⁹⁰ *Novartis v Union of India & Others*, AIR 2013 SC, App. No. 2706-2716 of 2013 at para 180

²⁹¹ *Ibid* 289

of the methanesulfonic acid addition salt of a compound of formula I”, and has a “further advantage for processing and storing”²⁹²

It was argued that these qualities improved the efficacy of the drug. However it was held that none of these qualities aid *therapeutic* efficacy and therefore did not satisfy the section 3(d) requirement. The exclusion of the advantageous properties stated above highlights the strict manner by which the courts interpret section 3(d).^{293 294}

It was argued that Section 3(d) was codified in to Indian patent law, not as an attempt to preserve the generic company stronghold in the Indian (and global) pharmaceutical market, but rather as a counter-measure to prevent the unfair anti-competition practice of evergreening.²⁹⁵ Indeed this is referred to by the Supreme Court.²⁹⁶

4.3 Section 3(d) Controversy:

Undoubtedly this case is one of great importance, the strict stance taken by the courts in their interpretation of section 3(d) was largely met with open arms. Amy Kapczynski argues that this strict interpretation was a step towards creating a “patent law 2.0.” Kapczynski articulates the argument that unless steps (such as the section 3(d) implementation in India) are taken, the research and development (R&D) carried out by originator pharmaceutical companies will continue to be ‘non-useful’.²⁹⁷ Instead of focusing on the research and development of novel drugs and treatments, pharmaceutical research and development budgets are being plunged in to product ‘lifecycle management’ schemes, aimed at creating incremental ‘upgrades’ to warrant further exclusivity periods. Kaczynski therefore argues that restrictions such as section 3(d) will help prevent pharmaceutical evergreening practices.²⁹⁸

It is well established that pharmaceutical companies research and develop drugs at great risk and cost to themselves. North Fulbright CEO described the chance of new drugs making it to market as having “Vegas like odds.”²⁹⁹ It is not uncommon for drugs to be abandoned even after hundreds of millions of dollars have been invested.³⁰⁰

However, when a drug does make it to market – the annual returns have the potential to be in the billions of dollars. Drugs which produce this quantity of profit are known as ‘blockbuster drugs.’ The huge profit is generated by the drug being sold at an artificially inflated price, which is enabled by patent protection. The high price of the drug is justified only by the high risk and extensive cost of its research of development. Due to the considerable degree of difficulty involved with bringing

²⁹² *Novartis v Union of India & Others*, AIR 2013 SC, App. No. 2706-2716 of 2013 at para 8

²⁹³ *Ibid* 289

²⁹⁴ *Astrazeneca Ab & Ors vs P Kumar & Anr*, 2019 IAs.3986/2018 & 5096/2018 in CS(COMM) 749/2018 at Para 39 - 62

²⁹⁵ As discussed in the introductory chapter

²⁹⁶ *Novartis v Union of India & Others*, AIR 2013 SC, App. No. 2706-2716 of 2013 at para 100

²⁹⁷ Amy Kapczynski, “Engineered in India — Patent Law 2.0” (2013) 369:6 (The New England Journal of Medicine) 497–499, online: <<http://dx.doi.org/10.1056/NEJMp1304400>>

²⁹⁸ *Ibid* 297

²⁹⁹ Roger Collier, “Drug patents: the evergreening problem” (2013) 185:9 (CMAJ : Canadian Medical Association journal)

³⁰⁰ *Ibid* 37

a drug to market, it is conceivable therefore, that a pharmaceutical company may attempt to protect their profits by extending a drugs lifecycle. Kapczynski highlights these ‘lifecycle management schemes’ as “*non-useful*” originator research and development.^{301 302 303 304 305}

Pharmaceutical companies pour billions of dollars in to research and development each year. Johnson and Johnson spent 10.7 Billion dollars on research and development last year alone. Pfizer spent a further 8 Billion and Novartis over 7 billion.³⁰⁶ Other than the originator companies’ word, there is little way to establish exactly what kind of research and development is being undertaken. It is conceivable that pharmaceutical companies would attempt to modify a drugs composition in an attempt to call the drug new and receive patent protection. This practice, known as evergreening, is considered to be a danger by many academics.³⁰⁷

It has been further predicted that the decision in *Novartis* has not just effected India. The world pharmacy status of India has already been established, as has the number of less economically developed nations that are dependent on India’s production of cheap, generic medication.³⁰⁸ However, academic predictions regarding the potential global effect of *Novartis* are holding true.³⁰⁹ Nations such as Argentina appear to have implemented similar ‘section 3(d)’ type resolutions.³¹⁰

4.4 Person Skilled in the Art:

Presently, the leading Indian interpretation of the person skilled in the art is found in the Indian Supreme Court case of *Biswanath Prasad Radhey Shyam vs Hindustan Metal Industries*.³¹¹ The interpretation laid down in this case has since been expressed in the Indian pharmaceutical patent guidelines:

“This hypothetical person is presumed to know all the prior arts as on that date, even non-patent prior art available to public. He has knowledge of the technical

³⁰¹ Amy Kapczynski, “Engineered in India — Patent Law 2.0” (2013) 369:6 (The New England Journal of Medicine) 497–499, online: <<http://dx.doi.org/10.1056/NEJMp1304400>> at 497–499.

³⁰² Sigrid Sterckx, “Can drug patents be morally justified?” (2005) 11:1 (Science and Engineering Ethics) 81–92, online: <<https://www.ncbi.nlm.nih.gov/pubmed/15727003>> at 81–92.

³⁰³ Donald W Light & Joel R Lexchin, “Pharmaceutical research and development: what do we get for all that money?” (2012) 345:aug07 1 (BMJ : British Medical Journal) e4348, online: <<http://dx.doi.org/10.1136/bmj.e4348>> at e4348.

³⁰⁴ Merrill Goozner, *The \$800 Million Pill*, 1st ed (US: University Of California Press, 2004).

³⁰⁵ Joseph A DiMasi, Henry G Grabowski & Ronald W Hansen, “Innovation in the pharmaceutical industry: New estimates of R&D costs” (2016) 47 (Journal of Health Economics) 20–33, online: <<http://dx.doi.org/10.1016/j.jhealeco.2016.01.012>> at 20–33.

³⁰⁶ Johnson & Johnson 4th Quarter filings 2019

³⁰⁷ Pfizer 4th Quarter Filings 2019

³⁰⁸ Novartis 4th quarter filings 2019

³⁰⁹ *Ibid* 301

³¹⁰ *Guidelines for pharmaceutical patent examination : examining pharmaceutical patents from a public health perspective*, by Carlos M Correa (United Nations Development Programme, 2016) at 11

³¹¹ *Biswanath Prasad Radhey Shyam vs Hindustan Metal Industries* AIR 1982 SC 1444

*advancement as on that date, and the skill to perform experiments with the knowledge of state of the art.*³¹²

The case of *Enercon v Wobbens* provides the touchstone for the inventive capacity of the person skilled in the art, clarifying:

*“We do not intend to visualize a person who has super skills, but we do not think we should make this person skilled in the art to be incapable of carrying out anything but basic instructions”*³¹³

The guidelines further clarify that there are two standards used for the person skilled in the art.³¹⁴ The differences primarily pertain to the creative or inventive capacity of this notional person. The duality of skill is between the “*obviousness person*”, and the “*person of ordinary skill in the art*.”³¹⁵ It has been argued that the distinction between these two terms alters the standard of patentability; “*a person having ‘Ordinary skill in the art’ will obviously be lower than a ‘person skilled in the art’*”³¹⁶

Gulati argues that a person who has ordinary skill in the art, is much more useful in assessing whether something is novel or anticipated.³¹⁷ However the inventive step requires “*an additional layer that needs to be passed after novelty. Therefore here, the level of skill has to be somewhat higher than ordinary.*”³¹⁸ Gulati goes on to argue that the Indian Patent Appellate Board (IPAB) has achieved the correct balance in this regard.³¹⁹ IPAB have established two types of ‘person skilled in the art’. The first is the so called ‘obviousness person’ which is equivalent to (and substantially imported from) the European interpretation of the person skilled in the art.³²⁰ This person should be considered to be the higher standard of the two as they have “*a certain modicum of creativity*”³²¹ and is utilised in assessing the inventive step. The second person is that of “*ordinary skill in the art*” and is referred to as the “enablement man”. The person of ordinary skill is utilised in the assessment of novelty for any given application.³²²

The distinction between the two standards lies in the respective inventive capacity. Through having two differing thresholds of “skill” for the person skilled in the art, it enables for this perspective to be utilised during both the novelty and inventive step assessment. However, despite this addition, Thambisetty argues that the perspective of the person skilled in the art

³¹² Designs and Trademarks Office of the Controller General of Patents, *Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals*, Library Catalogue (India: Indian Patent Office, 2014).

³¹³ *Enercons v Wobben* 2013 order no.123/2013 at para 30

³¹⁴ *Ibid* 312

³¹⁵ N Naina & Jasmeet Gulati, “Knowledge / skill standards of a ‘person skilled in art’: A concern less visited” (2018) 17:4 (The John Marshall Review of Intellectual Property Law) 588–607, online: <<https://www.narcis.nl/publication/RecordID/oai:cris.maastrichtuniversity.nl:publications%2F4f9a1f30-be98-46bd-a1f9-bc5c97dc758a>> at 605

³¹⁶ N Naina & Jasmeet Gulati, “Knowledge / skill standards of a ‘person skilled in art’: A concern less visited” (2018) 17:4 (The John Marshall Review of Intellectual Property Law) 588–607

³¹⁷ *Ibid* 316

³¹⁸ *Ibid* 316

³¹⁹ *Ibid* 316

³²⁰ *Ibid* 311 at 19

³²¹ *Sankalp Rehabilitation Trust vs Hoffman–Roche*, 2012 IPAB [OA/8/2009/PT/CH]Oder No. 250/2012]

³²² *Enercon India Ltd. v. Aloys Wobben*, ORA 08 of 2009/PT/CH, 30 (IPAB 2013)

should have also been encompassed into section 3(d) assessments.³²³ The argument presented by Thambisetty will be further explored under the following subheading.

4.5 Inventive Step Test & Inventive Concept:

Currently there does not exist a step by step common law test for the determination of the inventive step.³²⁴ Nonetheless, the *Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals* provides “a method for objectively analysing the inventive step”:³²⁵

- a) Identify the inventive concept of the claim in question
- b) Identify the "person skilled in the art",
- c) Identify the relevant common general knowledge of the person skilled in the art at the priority date;
- d) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim;
- e) Viewed without any knowledge of the alleged invention as claimed, do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of inventive ingenuity?³²⁶

As of the 30th of January 2020, this step by step test has not been reproduced by the courts. Nonetheless, the three elements which constitute the test can be established from the Supreme Court judgement in *Novartis*

*“[the invention] must come into being as a result of an invention which has a feature that: (a) entails technical advance over existing knowledge; Or (b) has an economic significance And (c) makes the invention not obvious to a person skilled in the art.”*³²⁷

Unfortunately, the Supreme Court dismissed the appeal before proceeding to apply the above reiteration of the test. It remains further unseen how the inventive concept of a claim would be identified and construed in the process of identifying the inventive step. Thambisetty highlights that section 3(d) is of importance here when follow-on innovation is concerned:

³²³ Sivaramjani Thambisetty, “Novartis v Union of India and the person skilled in the art: a missed opportunity” (2014) 4:1 (Queen Mary Journal of Intellectual Property)

³²⁴ “Determination Of Obviousness/Inventive Step - Indian Approach”, (10 October 2014) Mondaq

³²⁵ Designs and Trademarks Office of the Controller General of Patents, *Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals*, Library Catalogue (India: Indian Patent Office, 2014)

³²⁶ Designs and Trademarks Office of the Controller General of Patents, *Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals*, Library Catalogue (India: Indian Patent Office, 2014) at 20

³²⁷ *Ibid* 292 at 90

“Thus to obtain a pharmaceutical patent in India, not only do applicants have to satisfy traditional criteria that are common across all countries, e.g. novelty and inventive step, but also meet Section 3(d) requirements.”³²⁸

4.6 Section 3(d) and the Inventive Step:

As previously established in this chapter, section 3(d) was introduced as a counter-measure to evergreening.³²⁹ Therefore, section 3(d) uniquely applies to follow-on pharmaceutical innovation, first generation innovation cannot be guilty of evergreening by definition.^{330 331}

Consequently, the Supreme Court accepted and re-asserted the notion put forward by the Intellectual Property Appellate Board, that section 3(d) is effectively a heightening of the inventive step requirement;

“Since India is having a requirement of higher standard of inventive step by introducing the amended section 3(d) of the Act, what is patentable in other countries will not be patentable in India. As we see, the object of amended section 3(d) of the Act is nothing but a requirement of higher standard of inventive step in the law particularly for the drug/pharmaceutical substances.”³³²

Notably, despite section 3(d) constituting a heightening of the inventive step requirement, the perspective of the person skilled in the art is not being utilised.³³³ Thambisetty argues that because the newly implemented section 3(d) requirement is not being read from the perspective of the person skilled in the art, it has begun to serve as a blanket ban on secondary pharmaceutical products.³³⁴ Holman et al suggest that a ban of this nature prevents the value of a patent from being determined by the public, which in their opinion would allow for “the needs of the patients to be better served.”³³⁵

Bhaven N. Sampat goes in to detail, regarding the effectiveness of section 3(d). As previously discussed, the section 3(d) provision was initially intended to target secondary patents, as a means of eradicating ‘evergreening’ type applications. However, through empirical research, Sampat establish that a disproportionately large number of primary patent applications are being

³²⁸ Bhaven N Sampat & Kenneth C Shadlen, “Indian pharmaceutical patent prosecution: The changing role of Section 3(d)” (2018) 13:4 (PloS one) e0194714, online: <<https://www.ncbi.nlm.nih.gov/pubmed/29608604>>

³²⁹ *Novartis v Union of India & Others*, AIR 2013 SC, App. No. 2706-2716 of 2013 at para 18

³³⁰ Bhaven N Sampat & Kenneth C Shadlen, “Secondary pharmaceutical patenting: A global perspective” (2017) 46:3 (Research Policy) 693–707, online: <<http://dx.doi.org/10.1016/j.respol.2017.01.005>> at 693–707.

³³¹ *Novartis v Union of India & Others*, AIR 2013 SC, App. No. 2706-2716 of 2013 at para 100

³³² *Novartis v Union of India & Others*, AIR 2013 SC, App. No. 2706-2716 of 2013 at para 17

³³³ *Ibid* 321

³³⁴ Sivaramjani Thambisetty, “Novartis v Union of India and the person skilled in the art: a missed opportunity” (2014) 4:1 (Queen Mary Journal of Intellectual Property)

³³⁵ Christopher M Holman, Timo Minssen & Eric M Solovy, “Patentability Standards for Follow-On Pharmaceutical Innovation” (2018) 37:3 (Biotechnology Law Report) 131–161, online: <<https://www.liebertpub.com/doi/abs/10.1089/blr.2018.29073.cmh>>

challenged under section 3(d). Sampat suggests this is somewhat of an anomaly provided the justification for its introduction was to prevent the evergreening of pharmaceutical patents.³³⁶

Sampat further highlights that section 3(d) is being addressed as a standalone requirement, which is subsequently causing it to be applied to primary pharmaceutical innovation, rather than just secondary innovation.³³⁷ A solution can be found in the concerns raised by Thambisetty, whom argues that section 3(d) should be assessed from the perspective of the person skilled in the art.³³⁸ Consequently causing the requirement to be incorporated in to the inventive step inquiry, as initially intended at the time of the provision's introduction.³³⁹

The danger of having section 3(d) as a standalone requirement is further highlighted by Sampat. Drug research and development is accepted to be an area of great risk, thus the predictability of pharmaceutical patents is particularly important.³⁴⁰ The independence with which section 3(d) seemingly operates is having a detrimental effect on predictability. For example, Sampat notes that in January 2010, there was an attempt by the Indian Patent Office to apply section 3(d) to a compound patent pertaining to a Hepatitis C treatment.³⁴¹ This treatment (a drug called 'Solvadi') was deemed to be a "close derivative of an existing molecule"³⁴² by the Indian Patent Office (IPO). Nonetheless, on appeal it was shown that section 3(d) should not apply as the drug in question. Solvadi was not the result of secondary innovation and therefore section 3(d) was not an applicable requirement.³⁴³ Ultimately, if section 3(d) was to be included as a part of the inventive step requirement, it would make the provision's application and assessment more predictable for pharmaceutical companies.

The 2019 case of *Astrazeneca Ab & Ors vs P Kumar & Anr (Astrazeneca)* which concerns an inhibitor drug TICAGRELOR, highlights an inventive step inquiry post *Novartis*.³⁴⁴ ³⁴⁵The drug in question is administered after having a heart attack.³⁴⁶ It was argued in this case that TICAGRELOR was disclosed in patent 'IN 229', the patent which TICAGRELOR claims priority.³⁴⁷ Therefore, section 3(d) and inventive step were both in issue before the Delhi High Court. In their judgement, The New Delhi High Court looked to *Novartis* in order establish the criteria required for a section 3(d) claim and an inventive step inquiry.³⁴⁸ ³⁴⁹ ³⁵⁰

³³⁶ Bhaven N Sampat & Kenneth C Shadlen, "Indian pharmaceutical patent prosecution: The changing role of Section 3(d)" (2018) 13:4 (PloS one)

³³⁷ *Ibid* 336

³³⁸ *Ibid* 334

³³⁹ *Novartis v Union of India & Others*, AIR 2013 SC, App. No. 2706-2716 of 2013

³⁴⁰ John J Castellani, "Engineered in India — Patent Law 2.0" (2013) 369:22 (The New England Journal of Medicine) 2163, online: <<http://dx.doi.org/10.1056/NEJMc1311602>>

³⁴¹ *Ibid* 336

³⁴² *Ibid* 336

³⁴³ *Ibid* 336

³⁴⁴ *Astrazeneca Ab & Ors vs P Kumar & Anr*, 2019 IAs.3986/2018 & 5096/2018 in CS(COMM) 749/2018

³⁴⁵ *Novartis v Union of India & Others*, AIR 2013 SC, App. No. 2706-2716 of 2013

³⁴⁶ *Ibid* 344

³⁴⁷ Expired in 2018

³⁴⁸ *Astrazeneca Ab & Ors vs P Kumar & Anr*, 2019 IAs.3986/2018 & 5096/2018 in CS(COMM) 749/2018 at Para 39 - 62

³⁴⁹ Section 64 (1) (f)

³⁵⁰ *Ibid* 346

The court relied on the *Novartis* judgement to establish that “*not all advantageous or beneficial properties are relevant [to section 3(d)] but only such properties that directly relate to therapeutic efficacy.*”³⁵¹ It was ultimately held that TICAGRELOR did not meet the section 3(d) requirements. Furthermore, based on the *Novartis* interpretation of the statute, an inventive step was not found.³⁵² Seemingly, these two inquiries were carried out in parallel with one another, providing justification for the concerns raised by Thambisetty that section 3(d) is operating distinctly from the inventive step inquiry.³⁵³

4.7 Routine Nature of Clinical trials & Predictability:

The issue of the routine nature of clinical trials and the effect this may have on obviousness in India, has received little judicial or academic attention. *Novartis* focuses almost entirely on the implementation of section 3(d). As previously established, section 3(d) requires that follow-on pharmaceutical innovation, must show an increase in therapeutic efficacy over the prior art.³⁵⁴ It follows that in any given case; a routine clinical trial which irrefutably details the increased therapeutic efficacy of a product, would be enough to surpass the section 3(d) restrictions. However, in lieu of judicial or academic guidance on the effect of routine clinical trials on inventive step inquiries, this paper will instead rely on the IPO guidelines and judicial application of ‘the person skilled in the art’ to assess this factor.

The guidelines reiterate the following principle from the Intellectual Property Appellate Board (IPAB) case of *Ajanta Pharma Limited vs Allergan Inc*³⁵⁵:

*Obviousness cannot be avoided simply by showing of some degree of unpredictability in the art so long as there was a reasonable probability of success. Obviousness does not require absolute predictability of success. All that is required is a reasonable expectation of success*³⁵⁶

It therefore appears that the product of a routine clinical trial, may yield an un-patentable invention on the grounds of obviousness, even if the outcome is surprising. A World Intellectual Property Office (WIPO) report details various scenarios which would result in a patentable versus un-patentable pharmaceutical invention, according to the Indian guidelines.^{357 358} It can be inferred from the guidelines and WIPO report that a routine clinical trial in itself will not create an un-patentable product every time. There are two routes which point towards a higher chance of

³⁵¹ *Ibid* 345 at para 72

³⁵² *Ibid* 345 at para 33

³⁵³ Sivaramjani Thambisetty, “Novartis v Union of India and the person skilled in the art: a missed opportunity” (2014) 4:1 (Queen Mary Journal of Intellectual Property)

³⁵⁴ *Ibid* 345

³⁵⁵ *Ajanta Pharma Limited vs Allergan Inc.*, ORA/20/2011/PT/KOL,ORDER (No.172 of 2013)

³⁵⁶ Designs and Trademarks Office of the Controller General of Patents, *Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals*, Library Catalogue (India: Indian Patent Office, 2014) at s 8.9

³⁵⁷ Standing Committee on the Law of Patents, Thirtieth session *Further Study on Inventive step (Part III)* 2019 WIPO

³⁵⁸ *Ibid* 356

patentability: if the prior art teaches away from the claimed invention and second, if “*there is no coherent thread [in the prior art] leading to the invention.*”³⁵⁹

The latter example concerns the person skilled in the art making a change which would be obvious to perform. However, it would not be obvious that the ‘obvious change’ would lead to the creation of a desirable pharmaceutical property and is therefore not obvious.³⁶⁰

The ‘obvious change’ in this scenario is akin to a routine clinical trial. The assessment of obviousness when a routine clinical trial is concerned is permissible provided the prior art does not teach claimed invention and that there was not a “*reasonable expectation of success.*”³⁶¹

4.8 Grace Periods & Disclosure:

The grace period in India is particularly limited. All disclosure made by the inventor will be considered unless strict circumstances contained in sections 29 – 33 of the Indian Patents Act apply. There are no circumstances by which disclosure prior to a year of filing will not anticipate the invention.³⁶² The ‘limited grace-period’ provided by the Indian statute, is close to the recommendation of Correa in the UN guidelines.³⁶³

³⁵⁹ *Ibid* 357 at page 15

³⁶⁰ *Ibid* 356

³⁶¹ *Ibid* 356 at 23

³⁶² Indian Patent Act 1970 s.31

³⁶³ *Guidelines for pharmaceutical patent examination : examining pharmaceutical patents from a public health perspective*, by Carlos M Correa (United Nations Development Programme, 2016).

Chapter 5: Comparison

5.1 Introduction:

This chapter will highlight the similarities and differences between the three discussed jurisdictions' interpretation of the inventive step requirement. It will begin by establishing the similarities and differences of the inventive step test. Following this is a section dedicated to a comparison of UK and Canadian cases concerning the same dosage patent.³⁶⁴ ³⁶⁵ Each jurisdiction's standard of the person skilled in the art will then be compared. The penultimate section is dedicated to the effect routine clinical trials have on the inventive step assessment. Finally an analysis of grace periods for disclosure will be discussed. Each section will contain a concluding subsection where a determination will be made on which jurisdiction provides the most stringent provisions. It is the position of this paper that the guidelines advocate an unfairly stringent approach to assessing the inventive step of follow-on pharmaceutical innovation. Therefore, the guidelines will be utilised to determine the benchmark for a stringent approach, whilst the critical analysis of the guidelines provided by Holman et al, will be utilise to provide a perspective on a lenient approach to the inventive step requirement.³⁶⁶ ³⁶⁷ ³⁶⁸

Importantly the three jurisdictions are all part of the commonwealth, predictably causing there to be a large element of similarity between the nations' patent laws. For example all three nations are common law jurisdictions. Both the jurisdictions of Canada and India have their roots in UK jurisprudence, from which the foundational patent law principles have been "borrowed."³⁶⁹ Furthermore, all three nations are part of the World Trade Organisation, therefore each jurisdiction must adhere to the TRIPs agreement. As previously established, the TRIPs agreement is an attempt to create a minimum standard of intellectual property protection internationally.³⁷⁰ WTO members maintain discretion in the levels of protection given, so long as these levels do not drop below the minimum standards set out in TRIPs.³⁷¹

5.2 Inventive Step Test:

This sub heading will explore the tests utilised to assess the inventive step in each jurisdiction. First, the stringency of the United Kingdom and Canadian approaches, where a greater element

³⁶⁴ *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15

³⁶⁵ *Mylan Pharmaceuticals ULC v. Eli Lilly Canada Inc* 2016 FCA 119

³⁶⁶ Designs and Trademarks Office of the Controller General of Patents, *Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals*, Library Catalogue (India: Indian Patent Office) 2014

³⁶⁷ *Guidelines for pharmaceutical patent examination : examining pharmaceutical patents from a public health perspective*, by Carlos M Correa (United Nations Development Programme, 2016

³⁶⁸ Christopher M Holman, Timo Minssen & Eric M Solovy, "Patentability Standards for Follow-On Pharmaceutical Innovation" (2018) 37:3 (Biotechnology Law Report) 131–161, online: <<https://www.liebertpub.com/doi/abs/10.1089/blr.2018.29073.cmh>> at 131–161.

³⁶⁹ Department of Justice "Where our legal systems come from" 2019 online: <<https://www.justice.gc.ca/eng/csj-sjc/just/03.html>>

³⁷⁰ *The World Intellectual Property Organization and the World Trade Organization "Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)"* (1994)

³⁷¹ *Ibid* 370

of flexibility is beginning to emerge, will be explored.^{372 373} This is in opposition with the Indian approach which seemingly applies the most stringent test; focusing on the statutory questions rather than on common law approaches.³⁷⁴ Therefore this subheading will first compare the tests utilised in each jurisdiction, following this will be a comparison of relevant case law and respective patent office guidelines. Finally, the stringency of each approach will be concluded.

In Canada and the United Kingdom, the *Windsurfing/Pozzoli/Sanofi* test has been the preferred method (over other tests such as the EPO problem solution approach) to assess the statutory requirement of the inventive step.³⁷⁵ Compared to Canada, the Indian courts' assessment of the inventive step is done so in a much less regimented way. In Canada, the Supreme Court adopted the *Windsurfing/Pozzoli* test, however, as evident from *Novartis*, this has not been mirrored in India. Thus the word for word structure of the *Sanofi/Pozzoli* questions, as implemented in Canada and the UK, does not take place in India. Consequently, the Indian courts' approach in any given case lacks a definitive judicial approach, relying on the statutory questions instead.³⁷⁶ The structural difference therefore, pertains to the judicial guidance implicit in common law approaches.

This difference has arisen despite the fact that many Indian and Canadian laws, hold their roots in UK jurisprudence. In lieu of a structured, step by step common law approach, the Indian Courts utilise the statute's guidance in their assessment of the inventive step. This has been made possible due to section 2(j)(a) of the Indian patent act where the inventive step is defined as:

"a feature of an invention that involves technical advance as compared to the existing knowledge or having economic significance or both and that makes the invention not obvious to a person skilled in the art;"³⁷⁷

Neither The Patents Act 1977 (UK) or the Patent Act 1985 (Canada) provide a provision with this degree of detail, therefore there is a greater reliance upon common law interpretations to provide the relevant definitions and interpretation guidance.³⁷⁸

While the *Windsurfing/Pozzoli* test has not been adopted in to Indian common law, a version of the *Windsurfing/Pozzoli* test has seemingly been reiterated by the Indian Patent Office (IPO). The Manual of Patent Office Practice & Procedure set out the following questions, which bare a stark resemblance to the *Windsurfing/Pozzoli* test;

"1) Identify the "person skilled in the art", i.e competent craftsman or engineer as distinguished from a mere artisan; 2) Identify the relevant common general knowledge of that person at the priority date; 3) Identify the inventive concept of the claim in question or if that cannot readily be done, construe it; 4) Identify what, if any, differences exist between the matter cited as forming part of the "state of the art" and the inventive concept of the claim or the claim as construed; 5) Viewed without any knowledge of the alleged invention as claimed,

³⁷² *Ibid* 364

³⁷³ *Teva Canada Limited v Pfizer Canada Inc*, 2019 FCA 15 at para 1

³⁷⁴ *Novartis v Union of India & Others*, AIR 2013 SC, App. No. 2706-2716 of 2013

³⁷⁵ *Ibid* 115, 116

³⁷⁶ *Ibid* 374

³⁷⁷ Indian patents act s2 (j) (a)

³⁷⁸ As evident from *Astrazeneca Ab & Ors vs P Kumar & Anr*, 2019 IAs.3986/2018 & 5096/2018 in CS(COMM) 749/2018

*do those differences constitute steps which would have been obvious to the person skilled in the art or do they require any degree of inventive ingenuity?*³⁷⁹

Importantly, the questions set out above are seemingly only utilised by the Indian Patent Office and have not yet been referred to by the Indian Courts – where the statutory questions remain the focus of their attention.³⁸⁰ Consequently, the *Windsurfing/Pozzoli* test as set out in the IPO guidelines above, has yet to receive attention or refinement from the Supreme Court of India. An occurrence despite seemingly being accepted by the quasi-judicial Intellectual Property Appellate board.³⁸¹ (IPAB)

As established in the Canadian chapter of this paper, the leading Canadian precedent for the inventive step requirement is the 2008 Supreme Court case *Sanofi v Apotex*.³⁸² The reiteration of the *Windsurfing/Pozzoli* test in this case led to a difference in approach between the Canadian and UK approach to the inventive step. Arguably, the recent ICOS case will grant UK courts a greater degree of flexibility in their assessment of the inventive step, whereas the Sanofi case seemingly led to a rigid, step by step approach being adopted by the lower courts in Canada. This has since been partly dispelled by the Federal Court of Appeal's refusal to hold the obviousness inquiry to a correctness standard.³⁸³ Although the standard of review and inventive step test are two separate inquiries, the FCA's decision in this regard reiterates the judicial discretion granted judges. By allowing the judge to provide their own weight to any factors identified in a given case, provides the inventive step inquiry with a flexible, case specific structure.³⁸⁴

The flexibility in the UK can be derived from *ICOS* at paragraph 62 where Lord Hodge describes the *Windsurfing/Pozzoli* test and EPO problem solution/approach as

*“glosses on the text of section 3 of the 1977 Act and article 56 of the EPC and neither require a literalist approach to the wording of the claim in identifying the inventive concept.”*³⁸⁵

Furthermore, Lord Hodge reaffirms the notion first put forward by Lord Justice Jacob in 2009;

*“Like the Windsurfing/Pozzoli approach, it [the problem solution approach] provides a structured approach which may assist in avoiding the dangers of hindsight and may be more helpful in some cases than in others. No formula should distract the court from the statutory question”*³⁸⁶

³⁷⁹ Indian Patent Office *Manual of patent office practice & procedure* IPO, 2019 at 97 – 98, online: <http://www.ipindia.nic.in/writereaddata/Portal/News/505_1_Draft_MANUAL_OF_PATENT_OFFICE_PRACTICE_AND_PROCEDURE_01-03-2019.pdf>

³⁸⁰ *Novartis v Union of India & Others*, AIR 2013 SC, App. No. 2706-2716 of 2013

³⁸¹ Designs and Trademarks Office of the Controller General of Patents, *Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals*, Library Catalogue (India: Indian Patent Office, 2014) at s 8.9

³⁸² *Apotex Inc. v. Sanofi-Synthelabo Canada Inc*, 2008 SCC 61

³⁸³ *Mylan Pharmaceuticals ULC v. Eli Lilly Canada Inc* 2016 FCA 119

³⁸⁴ Joshua Sealy-Harrington, “The inventive concept in patent law: not so obvious” (2015) 27:3 (Intellectual Property Journal) 385, online: <<https://search.proquest.com/docview/1716260615>> at 385.

³⁸⁵ *Ibid* 364 at para 62

³⁸⁶ *Ibid* 364 at para 93 quoting *Generics (UK) Ltd v Daiichi Pharmaceutical Co Ltd*, 2009 EWCA Civ 646; [2009] RPC 23 at para 17 per Jacob LJ

To summarise the above, Lord Hodge reiterates that the statutory requirement mandates the need for an inventive step. This should not be read as a statutory requirement to pass the *Windsurfing/Pozzoli* test. Rather that this test is one of many ‘tools’ which should be used by courts, to aid their assessment of the inventive step. It should not be considered as the overruling perspective to be taken by the courts, as appears to have been the result of *Sanofi* in Canada.³⁸⁷
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In Canada there is only one perspective from which the inventive step requirement is approached. Justice Binnie’s precedential reiteration of the four *Pozzoli* questions at paragraph 67 of *Sanofi* is the only way in which the inventive step has been assessed by the lower courts.³⁸⁹ ³⁹⁰ This is despite the Federal Court of Appeals recent comments that the obviousness inquiry should be “*Flexible, Contextual, Expansive, and Fact-driven.*”³⁹¹ Which seem to echo the words of the UK Supreme Court, rather than the current approach derived from *Sanofi*.³⁹²

Similarly, Indian courts also maintain one approach to the inventive step assessment. In comparison to this, Lord Hodge has seemingly introduced the potential for more than one approach to the inventive step, including an assessment of both the *Pozzoli* test and the EPO *problem/solution* approach within his judgement.³⁹³

Due to how recently *ICOS* has been heard, the consequences of this judgement and how it is to be interpreted by the lower courts has yet to be seen.³⁹⁴ Speculatively, if the *ICOS* case does confer a higher degree of flexibility in the court’s approach to an inventive step inquiry, this could lead to a comparatively more lenient inventive step threshold. This perhaps comes at the cost of predictability, which will be further explored later in the chapter.³⁹⁵ Alternatively, greater flexibility could lead to a more stringent standard being applied. For example it may translate in to a requirement for both the *Pozzoli* and *the problem/solution* approach to be passed. This would undoubtedly increase the stringency of the inventive step requirement, however it is the position of this paper that *ICOS* does not advocate this position. The ‘UK Manual of Patent Procedure’, provides further evidence for the adoption of the flexible approach applied in *ICOS*, advising:

*“Caution should be exercised in relying on precedent cases, since, more than with any other topic [the inventive step is] to be decided by the substantive examiner, attempts to line up a particular case with some decided case can mislead.”*³⁹⁶

As explained in the UK chapter, the *ICOS* judgement provides a non-exhaustive list of 10 case specific factors to be considered during the inventive step inquiry.³⁹⁷ Lord Hodge emphasised that these factors must be accounted for when assessing the inventive step. However the weight given to each of these factors should be determined on a case by case basis by the courts.³⁹⁸ Thus in

³⁸⁷ *Ibid* 364

³⁸⁸ *Apotex Inc. v. Sanofi-Synthelabo Canada Inc*, 2008 SCC 61

³⁸⁹ *Ibid* 115, 388

³⁹⁰ This is evident in the wealth of pharmaceutical litigation over lack of inventive step claims.

³⁹¹ *Teva Canada Limited v Pfizer Canada Inc*, 2019 FCA 15 at 35

³⁹² *Ibid* 388

³⁹³ *Ibid* 364

³⁹⁴ As of January 2020

³⁹⁵ under the predictability subheading of this chapter.

³⁹⁶ Intellectual Property Office “UK Manual of Patent Practice” 2019 at 18 s3.54

³⁹⁷ *Ibid* 113

³⁹⁸ *Ibid* 364 at para 65-74

order for the inventive step to be ascertained, all the relevant case specific factors must be accurately weighed and assessed by the trial judge. The argument here is the courts should not be bound to a singular common law approach. Rather, they should have the freedom to approach the inventive step requirement from more than one perspective.³⁹⁹ The courts should be able to utilise more than one common law test (*Windsurfing/Pozzoli*, *problem/solution* or both.⁴⁰⁰) in their pursuit to establish an inventive step, especially considering the fine margins involved when evaluating follow-on innovation.⁴⁰¹ Alternatively, the ICOS judgement may be interpreted as giving courts the freedom to choose one common law test over another rather than utilising both. In either scenario, this would allow for a less rigid approach to the assessment of the inventive step, as opposed to the Canadian approach which seems to provide the singular perspective of the *Pozzoli/Sanofi* test without inciting the courts to pursue an alternative.⁴⁰²

Potentially this cumulates in to an issue regarding certainty of approach. As established above, it has been stated by both UK and Canadian courts, that the inventive step inquiry should be flexible.⁴⁰³ ICOS highlighted the importance of the statutory requirement over the common law tests.⁴⁰⁴ Similarly in Canada, the flexible nature of the inquiry was emphasised.⁴⁰⁵ The cost of encouraging increased flexibility in the inventive step inquiry, is a decrease in the predictability of which approach will be used. This in turn increases the risk involved in patent litigation, which in nations such as Canada and the UK where there is a reliance on 'generic watchdog litigation'.⁴⁰⁶ In the Indian courts, the statutory questions (which are more detailed than the UK statute) are the focus of the inquiry.⁴⁰⁷ Although this may constitute uncertainty in its application, it follows that there remains high certainty in the selection of approach to the inventive step inquiry as there is currently only one 'choice.'

The *problem/solution* approach in Canada has not been utilised by the courts in their assessment of the inventive step.⁴⁰⁸ However, as previously discussed – the problem solution approach appears in the Canadian Manual of Patent Office Practice which highlights using such an approach to establish the purposive construct of a claim.⁴⁰⁹ This does not extend to the assessment of the inventive step as is the case in the United Kingdom.⁴¹⁰ It is evident therefore, that the problem solution approach, with regard to the inventive step, is not utilised in Canada nor in Indian case law.

³⁹⁹ *Ibid* 364

⁴⁰⁰ *Ibid* 98, 115, 116,

⁴⁰¹ *Ibid* 368

⁴⁰² *Ibid* 388

⁴⁰³ *Ibid* 364, 373

⁴⁰⁴ *Ibid* 364

⁴⁰⁵ *Ibid* 373

⁴⁰⁶ Roger Collier, "Drug patents: the high price of watchdog litigation" (2013) 185:9 (CMAJ : Canadian Medical Association journal)

⁴⁰⁷ *Ibid* 347

⁴⁰⁸ *Ibid* 86, 343

⁴⁰⁹ Canadian Manual of Patent Office Practice (MOPOP) chapter 12.02.02d

⁴¹⁰ *Ibid* 364

5.2.1 Conclusion

The standard for the inventive step between Canada and the UK is seemingly similar – both nations have relied upon the *Windsurfing/Pozzoli* test when the inventive step is in issue.⁴¹¹ Nonetheless it appears that the singular approach taken by the Canadian courts will no longer be the preferred approach in the United Kingdom.⁴¹² Potentially this bares a slight similarity with the codified nature of the inventive step requirement in India, where the test is contained within section 3 and 2(j)(a) of the Indian Patent Act. Subsequently, the *Windsurfing/Pozzoli* test in India has not received Supreme Court attention.

Ultimately, giving courts the freedom to assess the inventive step from a perspective which they see fit, confers a greater degree of flexibility in approaching the inventive step assessment. The effect this has on the threshold of inventiveness is still uncertain. The effect on predictability will be explored later in this chapter.

Both the jurisdictions of Canada and India, seemingly rely on their own singular approach to the inventive step. Whereas the *Windsurfing/Pozzoli* test retains its predominance in the United Kingdom as the favoured approach to the inventive step, however unlike in Canada, it is not the only method through which the inventive step should be assessed.⁴¹³

The UN guidelines do not offer a recommendation on which approach to the inventive step is correct. However, the guidelines do suggest that applying the problem solution approach should be not an adequate means for the assessment of the inventive step when pharmaceutical inventions are concerned:

*“finding a solution to a problem is not sufficient to establish a patentable invention. The solution must be, in itself, the outcome of an inventive activity. In particular, a claim that the proposed solution offers certain advantages (for instance, increased bioavailability of a medicine) is not enough to establish an inventive step.”*⁴¹⁴

In this regard, India falls closest in line with the recommendations proposed by Correa.⁴¹⁵ Both the United Kingdom and Canada utilise the *problem/solution* approach in one capacity or another. The United Kingdom allows judges to utilise the problem/solution approach to inform the assessment of the inventive step through the *Windsurfing/Pozzoli* test.⁴¹⁶ Furthermore, conventionally the settled jurisprudence of the EPO (whom apply the *problem/solution* approach) tends to be followed in the UK although not legally bound to do so. Canada expresses the problem/solution approach in the Manual of Patent office guidelines, however this approach is also utilised when “construing the inventive concept.”⁴¹⁷ The inventive concept is considered to be “*the solution taught by the patent.*”^{418 419}

⁴¹¹ *Ibid* 115, 116

⁴¹² *Ibid* 364

⁴¹³ *Ibid* 364, 373

⁴¹⁴ *Guidelines for pharmaceutical patent examination : examining pharmaceutical patents from a public health perspective*, by Carlos M Correa (United Nations Development Programme, 2016) at 16

⁴¹⁵ *Ibid* 414

⁴¹⁶ *Ibid* 115, 116

⁴¹⁷ Canadian Manual of Patent Office Practice (MOPOP) chapter 12.02.02d

⁴¹⁸ *Bristol-Myers Squibb Canada Co. v. Teva Canada Limited*, 2017 FCA 76 at 35

⁴¹⁹ *Beloit Canada Ltd. v. Valmet OY* (1986), 64 N.R. 287 at 294

The rift between Canada and the United Kingdom versus India, with regard to common law approaches is further exasperated by the lack of Supreme Court attention given to the *Pozzoli* reiteration provided in the Indian guidelines.⁴²⁰

5.3 Dosage Patents:

As previously established, dosage patents are a common form of follow-on pharmaceutical innovation.⁴²¹ Furthermore, the *ICOS* and *Mylan* cases are both inventive step inquiries, regarding the same patent, in the UK and Canada respectively.⁴²² This sub heading will compare these two case. Following which, the relevance of section 3(d) will be discussed, allowing for the order of stringency to be concluded. Dosage patents are almost always the result of follow-on innovation, thus this section will utilise case law as an insight in to the treatment of follow-on innovation by the judiciary.⁴²³ This paper takes the position that stand-alone dosage patents have been shown as capable of providing significant therapeutic advantages.⁴²⁴ Therefore they should still be assessed on a case by case basis and should not be dismissed due to a blanket ban on dosage patent, as per the UN guidelines.⁴²⁵

Dosage patents, such as that in *ICOS* and *Mylan*, are often the subject of criticism regarding the patentability of follow-on pharmaceutical innovation as a whole.^{426 427 428} Indeed the UN guidelines set out by Correa, recommend that dosage patents fail to meet the “*industrial applicability requirement*” and should subsequently not be patentable.⁴²⁹ The analysis by Holman et al. on this point further highlight that the guidelines miss an important element in this regard:

“a new and nonobvious dosage of a known drug can provide significant benefits in terms of both safety and efficacy, and investment in the research and development of new and improved dosages of existing drugs should not be discouraged by a blanket prohibition on patent protection for new dosages (which is what the Guidelines seem to recommend).”⁴³⁰

⁴²⁰ *Ibid* 115, 116, 366

⁴²¹ Gaurav Dwivedi, Sharanabasava Hallihosur & Latha Rangan, “Evergreening: A deceptive device in patent rights” (2010) 32:4 (Technology in Society) 324–330, online: <<http://dx.doi.org/10.1016/j.techsoc.2010.10.009>> at 324–330.

⁴²² *Ibid* 364, 365

⁴²³ *Ibid* 364

⁴²⁴ *Ibid* 364, 368

⁴²⁵ *Ibid* 368, 414

⁴²⁶ Gaurav Dwivedi, Sharanabasava Hallihosur & Latha Rangan, “Evergreening: A deceptive device in patent rights” (2010) 32:4 (Technology in Society) 324–330, online: <<http://dx.doi.org/10.1016/j.techsoc.2010.10.009>> at 324–330.

⁴²⁷ C Scott Hemphill & Bhaven N Sampat, “Evergreening, patent challenges, and effective market life in pharmaceuticals” (2012) 31:2 (Journal of Health Economics) 327–339, online: <<http://dx.doi.org/10.1016/j.jhealeco.2012.01.004>> at 327–339.

⁴²⁸ Bhaven N Sampat & Kenneth C Shadlen, “Secondary pharmaceutical patenting: A global perspective” (2017) 46:3 (Research Policy) 693–707, online: <<http://dx.doi.org/10.1016/j.respol.2017.01.005>> at 693–707.

⁴²⁹ *Ibid* 414

⁴³⁰ *Ibid* 368

It is obvious that the “blanket ban” on dosage patents which (Holman et al claim the UN guidelines recommend) is not a prevalent policy in the United Kingdom nor in Canada. However as previously established, there are concerns that section 3(d) may operate in this manner in India.⁴³¹

It can be seen from *Mylan* and *ICOS* that dosage patents in premise, remain lawful. Indeed *ICOS* specifically reiterates this fact.⁴³² Nonetheless, due to aspects such as the routine nature and predictability of clinical trials, it is unlikely for an inventive step in this instance to be found. Holman et al touch on this point, arguing that the essence of the inventive step requirement means it is naturally harder for follow-on innovation to receive a patent.⁴³³ A similar point is raised by Lord Hodge echoing the words of LJ Jacob in *Actavis UK Ltd v Merck & Co Inc*⁴³⁴

*“Nearly always such dosage regimes will be obvious - it is standard practice to investigate appropriate dosage regimes. Only in an unusual case such as the present (where, see below, treatment for the condition with the substance had ceased to be worth investigating with any dosage regime) could specifying a dosage regime as part of the therapeutic use confer validity on an otherwise invalid claim.”*⁴³⁵

The dosage patent in *ICOS* was not only heard before the Supreme Court in the United Kingdom, but also before the Canadian Federal Court of Appeal in the case of *Eli Lilly Canada Inc. v. Mylan Pharmaceuticals ULC (Mylan)*⁴³⁶ *Mylan* concerns the same issues heard before the United Kingdom Supreme Court (UKSC); both cases concern the same invention and in both cases the inventive step is in issue.⁴³⁷

The Federal Court of Appeal (FCA) came to a similar conclusion as the UKSC, albeit in less detail. The FCA determined that the identification of the Tadalafil’s lowest effective dose was routine and obvious.⁴³⁸ The fact that Tadalafil had less side effects than its counterpart sildenafil was deemed to be both obvious and evident in the prior art.⁴³⁹ A big indicator of this was the presence of the therapeutic plateau and the ease with which the lowest effective dose was found. This was coupled with the fact that finding the lowest effective dosage of a drug is standard practice in drug development for the last “20-30 years”⁴⁴⁰

In India, any given dosage patent would have to adhere to section 3(d), meaning the new dosage regime specified in the patent would have to improve therapeutic efficacy.⁴⁴¹ Consequently, academics such as Thambisetty have raised concerns over section 3(d). Arguing that section 3(d) serves as a de-facto ‘blanket ban’ on secondary pharmaceutical products.⁴⁴²

⁴³¹ Sivaramjani Thambisetty, “Novartis v Union of India and the person skilled in the art: a missed opportunity” (2014) 4:1 (Queen Mary Journal of Intellectual Property)

⁴³² *Ibid* 364 & 365

⁴³³ *Ibid* 368

⁴³⁴ *Actavis UK Ltd v Merck & Co Inc* [2009] 1 WLR 1186

⁴³⁵ *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15 at 76: *Actavis UK Ltd v Merck & Co Inc* 2009 1 WLR 1186 at 32

⁴³⁶ *Mylan Pharmaceuticals ULC v. Eli Lilly Canada Inc* 2016 FCA 119

⁴³⁷ *Ibid* 364

⁴³⁸ *Mylan Pharmaceuticals ULC v. Eli Lilly Canada Inc* 2016 FCA 119 at para 1 & 79

⁴³⁹ *Mylan Pharmaceuticals ULC v. Eli Lilly Canada Inc* 2016 FCA 119

⁴⁴⁰ *Eli Lilly Canada Inc. v. Mylan Pharmaceuticals ULC* 2-15 FC 125 at 169

⁴⁴¹ *Novartis v Union of India & Others*, AIR 2013 SC, App. No. 2706-2716 of 2013 at para 180

⁴⁴² *Ibid* 414

5.3.1 Conclusion:

The Indian Supreme Court Case of *Novartis* held the potentially for a common law inventive step test to be refined. If this has been accomplished, it would bring the three jurisdictions on par in terms of a common law test having being set out by each jurisdictions highest court, however this opportunity was not taken due to the case being dismissed on the basis of section 3(d) prior to the application of the inventive step test.

Sampat highlights that in many circumstances section 3(d) is being invoked prior to an assessment of the inventive step.⁴⁴³ If section 3(d) was indeed serving as a strengthening of the inventive step requirement, this section would be invoked during this inventive step analysis. This indicates that section 3(d) could be operating as a de-facto blanket ban on secondary pharmaceutical products.⁴⁴⁴ Furthermore, section 3(d) was introduced as anti-evergreening measure, which (at the time of introduction) was a TRIPs compliant strengthening of the inventive step.⁴⁴⁵ A de-facto blanket ban application of section 3(d) could be interpreted as contravening the TRIPs agreement on grounds of industrial discrimination.^{446 447}

It is clear from *Mylan* and *ICOS*, that dosage patents will struggle to pass the inventive step test. In Canada and the United Kingdom, this is through the application of the *Windsurfing/Pozzoli/Sanofi* test.⁴⁴⁸ It appears that both jurisdictions concur with Holman et al; that a naturally higher stringency runs in the inventive step test, when it comes to follow-on innovation. Therefore it can be inferred that additional provisions, such as section 3(d), are not necessary.⁴⁴⁹

In India, through the enforcement of section 3(d), a higher threshold for the inventiveness is applied to dosage patents and other forms of secondary innovation. A dosage patent would have to meet this requirement and therefore the arguments presented in *ICOS* and *Mylan* would not be of relevance to a section 3(d) challenge.⁴⁵⁰ As a further point of comparison, Thambisetty's concerns seemingly hold true and section 3(d) currently serves as a de-facto ban on follow-on pharmaceutical innovation.⁴⁵¹ In this instance the UN guidelines falls in support of section 3(d) to the extent that dosage patents would likely become un-patentable.⁴⁵² Clearly, regardless of whether section 3(d) serves as a defacto ban – the inventive threshold has seen an increase. The only question that remains is whether this amounts to a defacto blanket ban.⁴⁵³

⁴⁴³ Bhaven N Sampat & Kenneth C Shadlen, "Indian pharmaceutical patent prosecution: The changing role of Section 3(d)" (2018) 13:4 (PloS one) e0194714, online: <<https://www.ncbi.nlm.nih.gov/pubmed/29608604>>

⁴⁴⁴ *Ibid* 391

⁴⁴⁵ *Ibid* 332

⁴⁴⁶ Agreement On Trade-Related Aspects Of Intellectual Property Rights art 27(1)

⁴⁴⁷ Christopher M Holman, Timo Minssen & Eric M Solovy, "Patentability Standards for Follow-On Pharmaceutical Innovation" (2018) 37:3 (Biotechnology Law Report) 131–161, online: <<https://www.liebertpub.com/doi/abs/10.1089/blr.2018.29073.cmh>> at 131–161.

⁴⁴⁸ *Ibid* 115 116, 364, 365

⁴⁴⁹ *Ibid* 365, 447

⁴⁵⁰ *Ibid* 364, 365

⁴⁵¹ Indian Patent Act, 1970 s3(d), *Ibid* 443

⁴⁵² *Ibid* 414

⁴⁵³ *Ibid* 431, 443

It is therefore evident that dosage patents are unlikely to be a patentable form of follow-on innovation in any of the jurisdictions. The UK and Canadian approaches are very similar in their inventive step inquiry.⁴⁵⁴ It is clear that section 3(d) serves as an additional barrier to dosage patents in India which is further clarified by the support of the UN guidelines.⁴⁵⁵ Therefore, it can be concluded that the most stringent approach to dosage patents (and arguably follow-on innovation as a whole), is certainly the approach taken by the Indian Courts and IPAB.

5.4 Person Skilled in the Art and Inventive Capacity:

An inevitable determination which must be made in an inventive step inquiry (in all three jurisdictions), is the identification of the person skilled in the art.^{456 457 458} This is a fundamental component of patent law in all three of the selected jurisdictions.⁴⁵⁹ Consequently, the UN guidelines make recommendations regarding this determination and suggest what this legally fictitious operators' base knowledge should be.⁴⁶⁰ This subheading will explore the differences in the jurisdictions' interpretation of the person skilled in the art, utilising judicial commentary and patent office guidelines.^{461 462 463} This paper takes the position that the perspective of the person skilled in the art utilised in the United Kingdom, is the correct standard to be applied. Importantly, this sub section is less concerned with the identification of the person skilled in the art, than with when the perspective is utilised and what the presumed inventive capacity of this person (or team) should be.

As previously established, in the United Kingdom, the inventive step requirement concerning the person skilled in the art, is found under section 3 of the Patents Act. The most recent reiteration of the United Kingdom's interpretation of this can be found in *ICOS*. Thus, as with the inventive step requirement as a whole – the requirement is found in statute and the guidance directed towards its interpretation, is found in common law.⁴⁶⁴

*“The notional skilled person, while having the compendious knowledge of the state of the art which section 2(2) requires, has no inventive capacity. But that does not mean that the skilled person has no skill to take forward in an uninventive way the teaching of the prior art.”*⁴⁶⁵

This is very similar to section 28.3 of the Canadian Patent Act, where the person skilled in the art requirement is disclosed. This section was famously further interpreted in *Beloit Canada Ltd. v.*

⁴⁵⁴ *Ibid* 364, 365

⁴⁵⁵ *Ibid* 365, 373

⁴⁵⁶ *Ibid* 98 115, 116, 364, 374, 388

⁴⁵⁷ *Novartis v Union of India & Others*, AIR 2013 SC, App. No. 2706-2716 of 2013

⁴⁵⁸ Indian Patent Act 1970, 2(j) a, Canada Patent Act RSC 1985 s28.3, Patent Act 1977 UK s.3

⁴⁵⁹ *Ibid* 458

⁴⁶⁰ *Ibid* 414

⁴⁶¹ Designs and Trademarks Office of the Controller General of Patents, *Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals*, Library Catalogue (India: Indian Patent Office, 2014).

⁴⁶² *Ibid* 340, 365, 376

⁴⁶³ Intellectual Property Office “UK Manual of Patent Practice” (UK Intellectual Property office) 2019 at 18 s3.54

⁴⁶⁴ *Ibid* 364

⁴⁶⁵ *Ibid* 364 at para 59

*Valmet Oy*⁴⁶⁶ where it was stated that the person skilled in the art, is considered to not have any degree of inventiveness:

*“The test for obviousness is not to ask what competent inventors did or would have done to solve the problem. Inventors are by definition inventive. The classical touchstone for obviousness is the technician skilled in the art but having no scintilla of inventiveness or imagination; a paragon of deduction and dexterity, wholly devoid of intuition; a triumph of the left hemisphere over the right.”*⁴⁶⁷

The above definition of the person skilled in the art is not only confirmed in the SCC case of *Apotex v Sanofi*, but it is directly quoted.⁴⁶⁸ It can be seen, therefore, that both the United Kingdom and Canada hold similar interpretations towards the ‘person skilled in the art’ and the skills on which their interpretation of the prior art rely upon.⁴⁶⁹ Both describe the person’s inventive capacity and both nations utilise the person skilled in the art as directed by the *Windsurfing/Pozzoli* test.⁴⁷⁰ ⁴⁷¹ Nonetheless, the interpretation of the person skilled in the art has received less academic attention than many of the debates in this area.⁴⁷²

The UN guidelines relies on the Indian Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals issued by the Indian Patent Office (IPO):

“[t]his hypothetical person [the person skilled in the art] is presumed to know all the prior arts as on that date, even non-patent prior art available to the public. He has knowledge of the technical advancement as on that date, and the skill to perform experiments with the knowledge of state of the art. He is not a dullard and has a certain modicum of creativity”^{473 474}

It can be seen therefore that India and consequently the UN guidelines use alternative terminology to that of United Kingdom and Canada. The latter relies on the concept of inventiveness, expressing that the person skilled in the art does not have even a “mere scintilla” of inventive capability.⁴⁷⁵ This poses the question as to the distinction between “creativity” and “inventiveness.” The Indian guidelines on pharmaceutical claims, relies on the case of *Enercons v alloys Wobben*⁴⁷⁶ which introduces the creative capacity of the person skilled in the art:

⁴⁶⁶ *Beloit Canada Ltd. v. Valmet Oy*, 1986 64 N.R. 287

⁴⁶⁷ *Ibid* 466

⁴⁶⁸ *Apotex Inc. v. Sanofi-Synthelabo Canada Inc*, 2008 SCC 61

⁴⁶⁹ *Ibid* 364, 388, 458

⁴⁷⁰ *Ibid* 364, 468

⁴⁷¹ *Ibid* 115, 116

⁴⁷² N Naina & Jasmeet Gulati, “Knowledge / skill standards of a ‘person skilled in art’: A concern less visited” (2018) 17:4 (The John Marshall Review of Intellectual Property Law) 588–607, online: <<https://www.narcis.nl/publication/RecordID/oai:cris.maastrichtuniversity.nl:publications%2F4f9a1f30-be98-46bd-a1f9-bc5c97dc758a>> at 588–607.

⁴⁷³ Designs and Trademarks Office of the Controller General of Patents, *Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals*, Library Catalogue (India: Indian Patent Office, 2014) at 18

⁴⁷⁴ *Guidelines for pharmaceutical patent examination : examining pharmaceutical patents from a public health perspective*, by Carlos M Correa (United Nations Development Programme, 2016).

⁴⁷⁵ *Ibid* 473

⁴⁷⁶ *Enercons v alloys Wobben*, 2013 IPAB No. 109 of 2013

“We do not intend to visualize a person who has super skills, but we do not think we should make this person skilled in the art to be incapable of carrying out anything but basic instructions.”⁴⁷⁷

While this in itself does not suggest a higher standard for the inventive step over the Canadian and UK standards, it furthers establishes that the capacity of the person skilled includes the ability ‘create something new.’ If this was not the case, then arguably this requirement would merely mirror the requirements of novelty and prior disclosure and is therefore a redundant specification. It is unclear as to whether the “creative capacity” of the person skilled in the art is different to “the inventive capacity.” It appears that the difference between these two terminologies lies in fundamental difference between the novelty requirement and the inventive step.

Canada and the United Kingdom veer away from the notion of creativity, using terminology such as “take forward in an uninventive way”⁴⁷⁸ and does it “require any degree of inventiveness”⁴⁷⁹ These phrases focus far more on encapsulating the statutory requirement of the inventive step, compared to the “creativity” phrasing utilised in India. In order for the ‘modicum of creativity’ phrase to avoid redundancy as a requirement, it must pertain to the ‘imaginative’ capacity of the person skilled in the art.⁴⁸⁰ Potentially suggesting a higher inventive capacity than the standard applied in the UK and Canada.

In both of these jurisdictions, there is only one standard for the person skilled in the art. Unlike in India where there is a duality in skill.⁴⁸¹ Gulati applauds the Indian Patent Office for providing the enablement/obviousness man distinction.⁴⁸² However, as previously noted, Professor Sivaramjani Thambisetty highlighted that despite this distinction, it has not gone so far as to apply to section 3(d) and has consequently caused a de-facto blanket ban on follow-on pharmaceutical innovation.⁴⁸³

In the United Kingdom and indeed in Canada, the courts use a singular perspective of the person skilled in the art, in order to determine whether the claimed subject matter “qualifies as an invention”.^{484 485} It is within this analysis that evergreening concerns are addressed. Thambisetty argues that section 3(d) should be applied at this stage, from the perspective of the person skilled in the art – allowing for a wealth of case law to be relied upon and ultimately, heightening the inventive step requirement;

“Methodologically, the advantages of such approaches within patentability criteria are many. Drawing on the role and attitudes of the person skilled in the art within inventive step assessments allows patent offices and courts to draw on a solid body of case law and perspectives that are tailored to chemical and pharmaceutical compositions and molecules. In this respect use of the person skilled in the art is a crucial and oft used ‘policy lever’. Reversing this to eschew

⁴⁷⁷ *Ibid* 473 at 8.6, *Ibid* 476

⁴⁷⁸ *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15

⁴⁷⁹ *Ibid* 468 at 80

⁴⁸⁰ Redundant as in this case it would simply reiterate the novelty requirement

⁴⁸¹ N Naina & Jasmeet Gulati, “Knowledge / skill standards of a ‘person skilled in art’: A concern less visited” (2018) 17:4 (The John Marshall Review of Intellectual Property Law) 588–607

⁴⁸² *Ibid* 481

⁴⁸³ *Ibid* 431

⁴⁸⁴ Canada Patent Act RSC 1985 s28.3

⁴⁸⁵ Patent Act 1977 UK s.3

*the person skilled in the art to blanket some secondary pharmaceutical inventions under patent ineligibility is unprecedented and remains potentially problematic under the TRIPS Agreement.*⁴⁸⁶

Thambisetty further observes that the UK (and Canada) include the analysis of the patentability of secondary pharmaceutical innovation within their assessment of the inventive step (which assumes the perspective of the person skilled in the art.) As discussed in the previous chapter, Thambisetty concludes that if section 3(d) were to be assessed from the perspective of the person skilled in the art, it would allow for greater room to “maneuver” compared to a complete ban on secondary products.⁴⁸⁷ Furthermore, this would address some of the claims made by academics and politicians that potentially revolutionary drugs were being denied patents in India, despite receiving patents in other jurisdictions.⁴⁸⁸

Although the UK and Canada view secondary patents from the perspective of the person skilled in the art, this analysis does not heighten the inventive step requirement for follow-on innovation. Whereas this was the clear, stated objective of section 3(d) in both *Novartis* and at its introduction.⁴⁸⁹ It has been established in the previous chapter, that section 3(d) requires follow on pharmaceutical innovation to show a suitable level of therapeutic efficacy over the prior art, in order for it to be patentable. In the United Kingdom the efficacy of a drug is one of the many factors which a judge may assess and give weight to.⁴⁹⁰ Again, one of points made in *ICOS* was there is no reason why follow-on innovation (in that case a dosage patent) should be automatically excluded from receiving patent protection.⁴⁹¹

The approach of the Canadian Courts towards ‘section 3(d) type subject matter’ can be gleaned from the words of Justice Binnie in *Sanofi* where it was stated that “a generalized concern about evergreening is not a justification for an attack on the doctrine of selection patents.”⁴⁹² As previously established, selection patents (like dosage patents) are a common form of follow on pharmaceutical innovation and as such would have to meet the section 3(d) requirement in India. It is clear that the improved therapeutic efficacy as assessed under section 3(d), is also assessed in Canada. However, in Canada and the United Kingdom, the therapeutic efficacy of a drug is merely one factor amongst many which should be weighed and assessed in each specific instance, rather than the enforcement of a section 3(d) type de-facto blanket ban. The UK and Canadian approach towards therapeutic efficacy, contains a greater element of flexibility. In contrast, section 3(d) seemingly imposes a much more stringent ‘pass/fail type’ standard.⁴⁹³

5.4.1 Conclusion:

This section has established that there exists a distinction between the person skilled in the art in the jurisdictions; the standard as applied by the Canadian and UK courts versus the duality

⁴⁸⁶ Sivaramjani Thambisetty, “Novartis v Union of India and the person skilled in the art: a missed opportunity” (2014) 4:1 (Queen Mary Journal of Intellectual Property)

⁴⁸⁷ *Ibid* 486

⁴⁸⁸ United States Trade Representative “2012 Special 301 Report” 2012 USTR

⁴⁸⁹ *Novartis v Union of India & Others*, AIR 2013 SC, App. No. 2706-2716 of 2013 at para 17

⁴⁹⁰ *Ibid* 478

⁴⁹¹ *Ibid* 478 at para 103

⁴⁹² *Ibid* 478 at para 98

⁴⁹³ *Novartis v Union of India & Others*, AIR 2013 SC, App. No. 2706-2716 of 2013

standard as applied in India. Academics have noted the potential benefits of a dual standard for the person skilled in the art, however the full potential of such an interpretation has yet to be achieved in India.⁴⁹⁴ Critics have noted that the primary reason for this is because section 3(d) not being interpreted from the perspective of the person skilled in the art.⁴⁹⁵

The inclusions of a section 3(d) provision which does not utilise the person skilled in the art, makes the legal test objective, rather than subjective. In the UK and Canada, the person skilled in the art makes the inventive step test subjective to a skilled person in the relevant field, which increases the threshold of inventiveness whilst avoiding the danger of enacting a blanket ban.⁴⁹⁶ Something obvious to a person skilled in the art, would likely not be obvious to a person 'not-skilled' in the art. Therefore a subject interpretation and application of the person skilled in the art test, undoubtedly contributes to a higher threshold of inventiveness than objective one. A factor which applies to all three of the jurisdictions.⁴⁹⁷

India maintains a focus on the creative capacity of the person skilled in the art. However there is little guidance provided for its interpretation in comparison to the "inventive capacity" determination, as applied in the UK and Canada. Arguably, the perspective taken in India contributes to a higher standard of inventiveness than its commonwealth counterparts. The standards in the UK and Canada offer little divergence from one another. The three jurisdictions do share similarities, indicative of the somewhat accepted aspects of patent law seen in WIPO agreements and EU jurisprudence. For example all three recognise that the person skilled in the art is capable of being a team of skilled individuals and all three rely on common law definitions. Nonetheless it appears that the Indian courts credit the person skilled in the art as more capable than the standard applied in Canada and the UK.⁴⁹⁸

The UN guidelines recommendations for the person skilled in the art (pertaining to follow-on pharmaceutical innovation) are closely aligned with the approach in India;

"This means that the person skilled in the art should be deemed to be a person who can derive new knowledge from the prior art, even with experimentation when it does not entail methods unknown to an expert in the field."⁴⁹⁹

Indeed the UN guidelines rely heavily on the Indian pharmaceutical patent guidelines for the definition of the person skilled in art.⁵⁰⁰ Correa endorsed the creative capacity of the fictitious person, rather than the exclusion of an inventive capacity, as favoured by Canada and the United Kingdom.⁵⁰¹ Again, this implies a higher stringency in the Indian approach compared to the Canadian or United Kingdom approaches.

⁴⁹⁴ N Naina & Jasmeet Gulati, "Knowledge / skill standards of a 'person skilled in art': A concern less visited" (2018) 17:4 (The John Marshall Review of Intellectual Property Law) 588–607

⁴⁹⁵ *Ibid* 486

⁴⁹⁶ *Ibid* 478

⁴⁹⁷ *Ibid* 466, 478, 493

⁴⁹⁸ *Ibid* 497

⁴⁹⁹ *Ibid* 474 at 15

⁵⁰⁰ Designs and Trademarks Office of the Controller General of Patents, *Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals*, Library Catalogue (India: Indian Patent Office, 2014).

⁵⁰¹ *Ibid* 478, 479, 480

5.5 Routine Nature & Predictability:

This section will look at predictability from two important perspectives. The first is the role that predictability plays in establishing the existence of an inventive step. Second, is the importance that ‘predictability and consistency of application’ play in patent systems as a whole. This paper takes the stance that the correlation between unpredictability and patentability, is detrimental to the progression of medical science, this relationship will be explored further in this section.

Both the *Mylan* and *ICOS* cases picked up on the role that predictability plays, when assessing the inventive step of follow-on innovation.⁵⁰² All three jurisdictions highlight that the more certain it is that clinical test will yield the sought after result, the less likely it is to have contained an inventive step.^{503 504 505} For example Lord Hodge identified predictability as one of many factors that should be considered, when ascertaining the inventive step. This is also highlighted as a factor in the UN guidelines and has become one of the many ways used by Canadian and UK courts, to determine the presence of an inventive step.⁵⁰⁶

The routine nature of the selected tests, were also highlighted as being contributing factors towards the denial of the inventive step. These two cases highlight the increasing similarity between how follow-on pharmaceutical innovation is being viewed by these two jurisdictions. Both reached the conclusion that the dosage patent lacked an inventive step, due in part, to the routine nature of the clinical tests carried when ascertaining the “*lowest effective dosage*.”⁵⁰⁷

It has already been established in this paper that pharmaceutical research and development is a high risk investment.^{508 509} It is this risk which justifies the monopoly granted by patents.⁵¹⁰ Therefore, having predictability in how patent offices and courts interpret the laws around pharmaceutical patents is imperative to stimulating private investment in this area. In light of this, consistency and predictability is of great importance.⁵¹¹

As previously discussed in this paper, the concept of inventiveness in Canada has been an area which has lacked clarity. These issues were addressed by Harrington, whom states that until the inventive concept of claims can be made tangibly clear in the jurisprudence, there will be a continued inconsistency in the judgement of Canadian patents.⁵¹² The concerns of Harrington

⁵⁰² This will be further discussed towards the end of this chapter.

⁵⁰³ *Mylan Pharmaceuticals ULC v. Eli Lilly Canada Inc* 2016 FCA 119

⁵⁰⁴ *Ibid* 500

⁵⁰⁵ *Ibid* 468, 478, 493, 500

⁵⁰⁶ As exhibited in *ICOS* and *Mylan*

⁵⁰⁷ *Ibid* 478, 503

⁵⁰⁸ Jack W Scannell et al, “Diagnosing the decline in pharmaceutical R&D efficiency” (2012) 11:3 (Nature reviews. Drug discovery) 191–200, online: <<https://www.ncbi.nlm.nih.gov/pubmed/22378269>> at 191–200.

⁵⁰⁹ Colleen Chien, *Cheap Drugs at What Price to Innovation: Does the Compulsory Licensing of Pharmaceuticals Hurt Innovation* (btlj, 2003).

⁵¹⁰ Joseph A DiMasi, Henry G Grabowski & Ronald W Hansen, “Innovation in the pharmaceutical industry: New estimates of R&D costs” (2016) 47 (Journal of Health Economics) 20–33, online: <<http://dx.doi.org/10.1016/j.jhealeco.2016.01.012>> at 20–33.

⁵¹¹ John J Castellani, “Engineered in India — Patent Law 2.0” (2013) 369:22 (The New England Journal of Medicine) 2163, online: <<http://dx.doi.org/10.1056/NEJMc1311602>> at 2163.

⁵¹² Joshua Sealy-Harrington, “The inventive concept in patent law: not so obvious” (2015) 27:3 (Intellectual Property Journal) 385

were mirrored at the Federal Court of Appeal where Justice Pelletier in *CIBA specialty chemicals water treatments limited v SNF inc* stated;

*“There may be cases in which the inventive concept can be grasped without difficulty but it appears to me that because “inventive concept” remains undefined, the search for it has brought considerable confusion into the law of obviousness. That uncertainty can be reduced by simply avoiding the inventive concept altogether and pursuing the alternate course of construing the claim. Until such time as the Supreme Court is able to develop a workable definition of the inventive concept, that appears to me to be a more useful use of the parties’ and the Federal Court’s time than arguing about a distraction or engaging in an unnecessary satellite debate.”*⁵¹³

Arguably, these criticisms do not only hold truth in Canada, but the same criticisms can also be made about the United Kingdom’s system. If the “inventive concept of a claim” is not expressed in any jurisprudence, it makes it difficult to establish whether the person skilled in the art, could have reached the invention “without undue burden”⁵¹⁴ or “in an uninventive way.”⁵¹⁵

In light of the increasing efforts to synergise or harmonise patent laws internationally, it is likely that the differences in terminologies need to be clarified. Not only would this aid international harmonisation of patent laws, it would also help increase the predictability of judgements.

One of the larger concerns in this particular industry, is the amount of money, time and other resources which are invested in to litigation in this area.^{516 517 518} Many academics, such as Feldman, argue that a large reason for this litigation is a result of evergreening, or tactical originator litigation & settlements, to extend the product lifecycle of blockbuster drugs.⁵¹⁹ The type of ‘evergreening litigation’ documented by Feldman, could be further avoided if the inventive concept was further defined by the courts, as it would provide a clearer line on patentable and un-patentable products.

In India, the effect that the routine nature of clinical trials have on the assessment of the inventive step, can be seen from the *Indian Revised Draft Guidelines for Examination of Patent Applications in the Field of Pharmaceuticals*:

“Obviousness cannot be avoided simply by showing of some degree of unpredictability in the art so long as there was a reasonable probability of success. Obviousness does not require absolute predictability of success. All that is required is a reasonable expectation of success. In the matter of pharmaceutical inventions, structural and functional similarity of the product provides this motivation to combine the teachings of the prior arts. A surprising effect, synergistic outcome of

⁵¹³ *Ciba Specialty Chemicals Water Treatments Limited v SNF Inc.*, 2017 FCA 225 at para 77

⁵¹⁴ *Apotex Inc. v. Sanofi-Synthelabo Canada Inc*, 2008 SCC 61

⁵¹⁵ *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15 at para 59

⁵¹⁶ P Toll’s-Hertogenbosch & T van Gelder, “The truth about drug companies: how they deceive us and what to do about it” (2006) 44:3 (MFM) 77 at 77.

⁵¹⁷ Donald W Light & Joel R Lexchin, “Pharmaceutical research and development: what do we get for all that money?” (2012) 345:aug07 1 (BMJ : British Medical Journal) e4348, online: <<http://dx.doi.org/10.1136/bmj.e4348>> at e4348.

⁵¹⁸ Merrill Goozner, *The \$800 Million Pill*, 1st ed (US: University Of California Press, 2004).

⁵¹⁹ Robin Feldman & Evan Frondorf, *Drug wars* (New York, NY: Cambridge University Press, 2017).

the combinations, prior art prejudice etc. usually demonstrates the non-obvious nature of the invention.

As previously established, in India an invention can still be deemed to be obvious, even if the outcome of the trial was unexpected. This highlights an adoption of the EPO *would/could approach* (so called ‘obvious to try’ in Canada).⁵²⁰

5.5.1 Conclusion:

Evidently, the routine nature of clinical trials has an effect on the patentability of certain products. Ultimately a discussion around the use of routine clinical trials falls, in line with ‘obvious to try test’. This test remains a factor in the inventive step assessment in all three jurisdictions.

There is a harmony between the jurisdictions regarding the influence of certain objective factors. These are summarised as follows:

“These objective indicators of non-obviousness include commercial success, acclaim for the invention, previous failed attempts by others, and success in the face of prior art teaching away from the invention.”⁵²¹

If these factors can be applied to the product of a routine clinical trial, then it increases the chance that an inventive step will be present. However, an issue which remains prevalent in all three jurisdictions, is the correlation between a surprising outcome to a routine clinical trial and patentability. As previously argued, predictability in the pharmaceutical industry is more than ideal from a social and economic stand-point.⁵²² Nonetheless, an assessment of this nature almost reinforces a legal pre-requisite for un-predictable or surprising outcomes, a point which is reinforced by the UN guidelines.⁵²³ Arguably this situation as described above is unavoidable, patents can only be granted for inventive, non-obvious activity. This somewhat goes hand in hand with unpredictable or surprising results. Although as stated by Lord Hodge

“A fortiori, efficacious drugs discovered by research involving standard pre-clinical and clinical tests should be rewarded with a patent if they meet the statutory tests... The use of well-known research tests of itself does not render such selections and improvements obvious.”⁵²⁴

In opposition to this, the UN guidelines recommend that:

⁵²⁰ Guidelines for Examination in the European Patent Office, *Chapter 7 Part 5.3 Could – Would Approach* (2019), online: <https://www.epo.org/law-practice/legal-texts/html/guidelines/e/g_vii_5_3.htm>

⁵²¹ Christopher M Holman, Timo Minssen & Eric M Solovy, “Patentability Standards for Follow-On Pharmaceutical Innovation” (2018) 37:3 (Biotechnology Law Report) 131–161, online:

⁵²² John J Castellani, “Engineered in India — Patent Law 2.0” (2013) 369:22 (The New England Journal of Medicine)

⁵²³ *Guidelines for pharmaceutical patent examination : examining pharmaceutical patents from a public health perspective*, by Carlos M Correa (United Nations Development Programme, 2016).

⁵²⁴ *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15 at para 103-104

“Patents should only be granted when the claimed object is the result of an inventive activity. The fact that ... an advantage has been obtained, even if unexpected, is not sufficient to prove the existence of such activity.”⁵²⁵

Seemingly the UN guidelines and the Obiter Dictum provided by Lord Hodge advocate for differing levels of inventiveness in this regard. The UN guidelines highlight that even surprising outcomes, may not always result in patentable material. This further advocates for therapeutic efficacy principles encapsulated by section 3(d). The narrow interpretation taken by the Indian Supreme Court regarding “therapeutic efficacy” in *Novartis*, is also indirectly endorsed by the UN guidelines.^{526 527} In *Novartis*, one of the argued advantages of Imatinib was (amongst other factors) increased bioavailability.⁵²⁸ The Supreme Court rejected this argument, applying a narrow scope to therapeutic efficacy. The UN guidelines further indirectly endorse this application stating: *“certain advantages (for instance, increased bioavailability of a medicine) is not enough to establish an inventive step.”⁵²⁹*

Overall, it appears that Canada and the United Kingdom gives marginally more weight to a surprising outcome of a routine clinical trial, as opposed to India which is more closely aligned with the recommendation of the UN guidelines. This again reinforces the increased threshold for a finding of an inventive step in India, over the UK and Canada. This occurs despite the similarity in the factors which indicate a likely finding of an inventive step.⁵³⁰

5.6 Grace Period & Disclosure:

Grace period and disclosure will be dealt with in the same section, as the grace period relates to a set period of time whereby disclosure of an invention will not invalidate a patent application. The inventive step requirement in the United Kingdom is codified in section 2 of the Patents Act 1977. The requirement is contained within one short, succinct provision. The Canadian Patents act however, contains slightly more guidance than the UK statute. This is achieved through the inclusions of subsections A and B under section 28.3.⁵³¹ These additional subsections provide further information with respect to identifying the relevant prior art.

The UN guidelines seemingly advocate against the inclusion of such provisions:

“While some patent offices have limited the number of documents that may be considered in assessing inventive step, there is no rationale for such limitations. The assessment should include the prior art as a whole.”⁵³²

“The grace period” is one of the bigger difference between patent laws around the globe and is subsequently important to discussions, revolving around the harmonization of international patent

⁵²⁵ *Ibid* 523 at 16

⁵²⁶ *Novartis v Union of India & Others*, AIR 2013 SC, App. No. 2706-2716 of 2013

⁵²⁷ *Guidelines for pharmaceutical patent examination : examining pharmaceutical patents from a public health perspective*, by Carlos M Correa (United Nations Development Programme, 2016) at 15 - 16

⁵²⁸ *Ibid* 489 at 188

⁵²⁹ *Ibid* 527 at 16

⁵³⁰ For example unpredictable results

⁵³¹ The Patents Act RSC 1988 s28.3

⁵³² *Ibid* 527

laws (a process which TRIPs attempted to begin). The disparity between jurisdictions in this area, is reflected in this paper. In Canada any disclosure made within the grace period is not utilised when assessing the inventive step. On the other hand, the United Kingdom⁵³³ and India do not allow for the “grace period” as specified in section 28.3 of the Canadian Patent Act. Arguably, grace period provisions hold the most relevance to anticipation or novelty inquiries, however it also maintains relevance to the inventive step, as will be discussed below.

To recap, the *ICOS* case refers to the UK Supreme Court case *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr*. This case concerns a dosage patent of the drug Tadalafil.⁵³⁴ The dosage patent was a form of follow-on innovation and thus the inventiveness of said dosage patent had to be assessed by the courts.⁵³⁵ One of the elements which was of paramount importance in this, was the ability of the courts to follow the process, through which the lower dosage of Tadalafil was found.⁵³⁶ In order for this to be done successfully, the courts had to determine the “closest prior art.”⁵³⁷ This would be inclusive of any disclosure made by ICOS Lilly prior to the filing date. However, when this was heard before the Canadian Federal Court of Appeal, the courts were precluded from looking to any disclosure made by the applicants in the year prior to filing, due to the nation’s grace period clause.^{538 539} Indian patent law takes an approach closer to that of the United Kingdom, where a grace period is only authorised under specific circumstances, as provided by the statute.⁵⁴⁰ Grace periods as lenient as the one provided by the Canadian statute, are not particularly common place globally.⁵⁴¹ Thus the Canadian approach to disclosure and the grace period which it provides, is the most lenient of the three jurisdictions. India takes a more stringent approach in comparison to Canada, however provides far more circumstances than the United Kingdom statute.⁵⁴² The United Kingdom takes the most stringent approach of the three, providing only very specific circumstances by which disclosure will not result in patent disqualification.⁵⁴³

5.6.1 Conclusion:

Pharmaceutical companies have expressed that it is common practice to assess the stringency of patent laws in target market. This is done in an attempt to tailor their patent application to the most stringent of the target markets. Therefore, if a follow-on innovation product was to be released in all three of the jurisdictions discussed in this paper, it is likely that the company would not disclose any information about said product, as only Canada allows for a grace period.⁵⁴⁴ This practice highlights the impact that stringent standards in one jurisdiction can have on pharmaceutical practices globally, which inadvertent discourages originator R&D cooperation.

⁵³³ Nor the European Union

⁵³⁴ *Actavis Group PTC EHF & Ors v ICOS Corporation & Anr* [2019] UKSC 15

⁵³⁵ *Ibid* 534

⁵³⁶ *Ibid* 534

⁵³⁷ *Ibid* 534 at para 61 - 62

⁵³⁸ *Mylan Pharmaceuticals ULC v. Eli Lilly Canada Inc* 2016 FCA 119

⁵³⁹ Canadian Patent Act 1988 S 28.3(a)

⁵⁴⁰ India Patent Act 1977 s29 to 32

⁵⁴¹ World Intellectual Property Office “Certain Aspects Of National/Regional Patent Laws (5) Sufficiency Of Disclosure” 2019, online: https://www.wipo.int/export/sites/www/scp/en/national_laws/grace_period.pdf

⁵⁴² *Ibid* 541

⁵⁴³ *Ibid* 541

⁵⁴⁴ *Ibid* 539

Pharmaceutical companies are transnational corporations, whereas patent laws are jurisdictional. Despite this, patent applications are defeated by information which is not bound to a jurisdiction. In other words, disclosure in Canada, (abiding by the lenient grace period) would render a patent application in jurisdictions like India and the UK (where there is not a lenient grace period) invalid. Therefore, stringent domestic patent laws in one key market, can affect the global practices of pharmaceutical companies – which effects their behaviour in multiple jurisdictions.

The UN guidelines recommend that

*“while some patent offices have limited the number of documents that may be considered in assessing inventive step, there is no rationale for such limitations. The assessment should include the prior art as a whole.”*⁵⁴⁵

Indeed, this puts the United Kingdom most in line with the guidelines recommendations, allowing for very few circumstances in which disclosure will not count against a patent application.⁵⁴⁶ India enforces a grace period most similar to the U.K however, allows for additional circumstances in which a grace period is allowed. Canada enforces the most liberal grace period, which could only be relaxed by increasing the time frame in which disclosure is allowed.⁵⁴⁷

In this instance therefore, the United Kingdom and India provide the most stringent grace periods which are much closer to the UN guidelines than the very lenient provisions provided in Canada.

⁵⁴⁸

⁵⁴⁵ *Ibid* 523 at 16

⁵⁴⁶ *Ibid* 541

⁵⁴⁷ *Ibid* 539

⁵⁴⁸ *Ibid* 527 , 539, 540, 541

Chapter 6: Conclusion

6.1 Summary:

This paper has examined the inventive step requirement in three jurisdictions with the aim of assessing the ‘threshold of inventiveness’ in each. The order of stringency from, most to least, is India, the United Kingdom and finally Canada. The claims that Canada is ‘friendly to evergreening’ likely stems from the apparent lower threshold required for the inventive step, combined with the reliance on ‘watchdog litigation’.^{549 550} The inclusion of section 3(d) in India clearly increases the threshold of inventiveness, required by follow on pharmaceutical innovation. The effectiveness of this provision at stimulating “usefulness” research and development has been difficult to quantify, in India’s emerging pharmaceutical market.^{551 552}

In conclusion, due to the addition of section 3(d) in Indian patent law and the obiter dictum from the Novartis case, it is evident that India currently maintains a higher standard of the inventive step requirement in comparison to Canada and the United Kingdom. Historically, the United Kingdom has held a relatively stringent patentability standards, enforcing a strict disclosure policy disallowing a grace period. Nonetheless, In terms of follow-on pharmaceutical innovation, it is evident that the UK and Canada hold a lower threshold of inventiveness compared to India. In India there has to be a consolidated proof of enhanced efficacy.^{553 554}

Patent law in the United Kingdom and India have benefited from recent judgements provided by their respective Supreme Courts.⁵⁵⁵ In this respect, it is clear that where follow on pharmaceutical innovation is dealt with under section 3(d), enhanced efficacy is dealt with as an integral part of the inventive step inquiry in the UK and Canada. The UK has reiterated that dosage patents (which are representative of follow-on innovation) are subject to the same patentability standards as first generation innovation and provided the inventive step requirement is met, should be awarded a patent. Nonetheless, it was acknowledged to be harder for secondary innovation, to achieve patent protection largely due to the effect of “routine clinical trials.”⁵⁵⁶ Although not universally the case, routine clinical trials are considered by the courts, in all three jurisdictions, to be an indication that the inventive step may be lacking.⁵⁵⁷

⁵⁴⁹ Matthew B Stanbrook, “Limiting ‘evergreening’ for a better balance of drug innovation incentives” (2013) 185:11 (CMAJ : Canadian Medical Association journal = journal de l’Association medicale canadienne) 939, online: <<https://www.ncbi.nlm.nih.gov/pubmed/23877665>> at 939.

⁵⁵⁰ Roger Collier, “Drug patents: the high price of watchdog litigation” (2013) 185:9 (CMAJ : Canadian Medical Association journal = journal de l’Association medicale canadienne) E387–E388, online: <<https://www.ncbi.nlm.nih.gov/pubmed/23649414>> at E387–E388.

⁵⁵¹ Bhaven N Sampat & Kenneth C Shadlen, “Indian pharmaceutical patent prosecution: The changing role of Section 3(d)” (2018) 13:4 (PloS one) e0194714, online: <<https://www.ncbi.nlm.nih.gov/pubmed/29608604>> at e0194714.

⁵⁵² Janice M Mueller, “The Tiger Awakens: The Tumultuous Transformation of India’s Patent System and the Rise of Indian Pharmaceutical Innovation” (2007) 68:3 (University of Pittsburgh Law Review) , online: <<https://search.datacite.org/works/10.5195/LAWREVIEW.2007.79>> no 3.

⁵⁵³ Indian Patent Act 1970 s3(d)

⁵⁵⁴ *Novartis v Union of India & Others*, AIR 2013 SC, App. No. 2706-2716 of 2013

⁵⁵⁵ *Ibid* 478, 554

⁵⁵⁶ *Ibid* 548

⁵⁵⁷ *Ibid* 548

The UN guidelines seemingly advocate for more stringent patentability standards.^{558 559} The recommendations largely resemble (or overtly rely on) provisions of the Indian Patent Act, including section 3(d).⁵⁶⁰ However, it is the position of this paper that an increased inventiveness standard for follow-on innovation naturally exists. This notion has been acknowledged by academics and eluded to by the UK Supreme Court.^{561 562}

The controversy of the *Novartis* Judgement reflects the more stringent approach taken in India.⁵⁶³ Clearly the addition of section 3(d), is a decisive step towards curbing the patentability of follow-on pharmaceutical innovation.⁵⁶⁴ Nonetheless, there have been concerns raised regarding the efficiency and discriminatory manner in which this section may be operating.^{565 566 567}

Canada and the United Kingdom hold a very similar standard for inventiveness, when it comes to follow-on pharmaceutical innovation. Historically, Canada has been perceived by academics as the corner-stone of leniency, regarding the patentability of follow-on pharmaceutical innovation.⁵⁶⁸⁵⁶⁹ The difference between the approaches taken by India and the UK & Canada is indicative of the disparity in patent laws internationally, despite attempts to harmonise patent laws internationally.⁵⁷⁰ In field of pharmaceutical patents, international harmony has increased importance. This paper has established the 'knock-on global effect' that stringent patent laws in one jurisdiction, can have on the global practices of big originator pharmaceutical companies in another.⁵⁷¹

It is the position of this paper that the strength of a patent law, suited to the pharmaceutical industry, is one which contains a strong element of flexibility. Flexible enough to incentivise "useful research & development" but stringent enough to prevent unlawful lifecycle management plans.⁵⁷²⁵⁷³ Flexibility of approach has been endorsed by the United Kingdom Supreme Court.

⁵⁵⁸ *Guidelines for pharmaceutical patent examination : examining pharmaceutical patents from a public health perspective*, by Carlos M Correa (United Nations Development Programme, 2016).

⁵⁵⁹ Christopher M Holman, Timo Minssen & Eric M Solovy, "Patentability Standards for Follow-On Pharmaceutical Innovation" (2018) 37:3 (Biotechnology Law Report)

⁵⁶⁰ *Ibid* 558 at 15 - 16

⁵⁶¹ *Ibid* 548

⁵⁶² *Ibid* 559

⁵⁶³ *Ibid* 554

⁵⁶⁴ Amy Kapczynski, "Engineered in India — Patent Law 2.0" (2013) 369:6 (The New England Journal of Medicine) 497–499, online: <<http://dx.doi.org/10.1056/NEJMp1304400>> at 497–499.

⁵⁶⁵ *Ibid* 558

⁵⁶⁶ Sivaramjani Thambisetty, "Novartis v Union of India and the person skilled in the art: a missed opportunity" (2014) 4:1 (Queen Mary Journal of Intellectual Property) 79 at 79.

⁵⁶⁷ Bhaven N Sampat & Kenneth C Shadlen, "Indian pharmaceutical patent prosecution: The changing role of Section 3(d)" (2018) 13:4 (PloS one) e0194714, online: <<https://www.ncbi.nlm.nih.gov/pubmed/29608604>>

⁵⁶⁸ Paul Grootendorst, Ron Bouchard & Aidan Hollis, "Canada's laws on pharmaceutical intellectual property: the case for fundamental reform" (2012) 184:5 (CMAJ : Canadian Medical Association journal)

⁵⁶⁹ Matthew B Stanbrook, "Limiting 'evergreening' for a better balance of drug innovation incentives" (2013) 185:11 (CMAJ : Canadian Medical Association journal)

⁵⁷⁰ *The World Intellectual Property Organization and the World Trade Organization "Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement)"* (1994)

⁵⁷¹ Page 56

⁵⁷² *Ibid* 564

⁵⁷³ Roger Collier, "Drug patents: innovation v. accessibility" (2013) 185:9 (CMAJ : Canadian Medical Association journal)

Nonetheless, there remains the potential for flexibility of the courts approach to come at the cost of predictability and consistency. Much like the balance of innovation v accessibility, there must be a compromise made between the court's flexibility in assessment and their consistency of application. Academics have noted that Section 3(d) hinders the ability of courts to be flexible in their approach to the inventive step.⁵⁷⁴ Based on the controversy surrounding the decision, it is evident that this took a diminishing step towards the incentive for pharmaceutical companies to invest in vital follow-on research and development.^{575 576}

6.2 Erooms law:

Erooms law is a trend which has been noted since the 1900s. It states that while drug research and development is seeing an increase in expenditure, the number of new drugs making it to market is halving. Cynics will argue that this trend is through originator pharmaceutical companies increasingly focusing on life cycle management and other forms of "non-useful research and development."⁵⁷⁷ However, research and development investment has become stagnant in recent years, rather than increasing. Once inflation is accounted, this translates in to a decrease in R&D expenditure, potentially worsening the Erooms law downwards trend. The strengthening of inventive step criteria further diminishes the incentive for research and development in the pharmaceutical sector.⁵⁷⁸

6.3 To the Future:

The divergence and differences in nation's patents laws has different implications for different industries. Certain industries, such as that of pharmaceuticals, are accepted to be of particular importance.⁵⁷⁹ This paper has already established that originator companies are responsible for the introduction of lifesaving treatments, drugs and other medication. This is made possible through the protection that patents offer. Patents in the pharmaceutical industry must be economically valuable enough to incentivise the extremely risky investment of pharmaceutical research and development.⁵⁸⁰ It is for this reason that advocating for a higher standard of inventiveness for follow-on pharmaceutical innovation is miss-placed. Rather, the current standards for the inventive step, as applied in either the UK or Canada should be enforced. For the reasons discussed throughout this paper, it appears that the current application of India's section 3(d) does not appear to be in line with the anti-evergreening rhetoric under which it was introduced.

⁵⁷⁴ *Ibid* 566

⁵⁷⁵ *Ibid* 559

⁵⁷⁶ John J Castellani, "Engineered in India — Patent Law 2.0" (2013) 369:22 (The New England Journal of Medicine) 2163, online: <<http://dx.doi.org/10.1056/NEJMc1311602>> at 2163.

⁵⁷⁷ *Ibid* 564

⁵⁷⁸ *Ibid* 559, 522

⁵⁷⁹ Are drugs morally justified?

⁵⁸⁰ *Ibid* 558, 559, 564, 573, 576

Academics have noted that this area of intellectual property is ripe for reformation.^{581 582 583} Many academics have advocated for section 3(d) type clauses to be incorporated in to other jurisdictions, in an attempt to stimulate “useful research and development.” However, it has also been suggested that the current patent model, which is reliant on risky generic litigation to test the validity of pharmaceutical patents, needs to provide further incentives to encourage this type of litigation.⁵⁸⁴ If the process for testing pharmaceutical patents can be improved in this manner, it diminishes the need for the inventive step inquiry to be made more stringent. Consequently preventing originator innovation from being discouraged. This would potentially help a balance to be found between innovation and accessibility, whilst protecting an incentive to develop, hopefully maximizing the number of new drugs – 1st generation or second - reaching the market and more importantly, patients.⁵⁸⁵

⁵⁸¹ Robin Feldman & Evan Frondorf, *Drug wars* (New York, NY: Cambridge University Press, 2017).

⁵⁸² Sigrid Sterckx, “Can drug patents be morally justified?” (2005) 11:1 (Science and Engineering Ethics) 81–92, online: <<https://www.ncbi.nlm.nih.gov/pubmed/15727003>> at 81–92.

⁵⁸³ Paul Grootendorst, Ron Bouchard & Aidan Hollis, “Canada’s laws on pharmaceutical intellectual property: the case for fundamental reform” (2012) 184:5 (CMAJ : Canadian Medical Association journal) 543–549, online: <<https://www.ncbi.nlm.nih.gov/pubmed/22065362>> at 543–549.

⁵⁸⁴ Roger Collier, “Drug patents: the high price of watchdog litigation” (2013) 185:9 (CMAJ : Canadian Medical Association journal)

⁵⁸⁵ *Ibid* 584

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