ARTICLE

REWARDING PHARMACEUTICAL INNOVATION FOR BEING *INNOVATIVE*: A SUMMARY OF THE PHARMACEUTICAL PATENT SYSTEM AND AN AMENDMENT TO THE *PATENT ACT* TO NEGATE "EVERGREENING" AND "PATENT THICKETS"

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CITED: (2024) 29 *Appeal* 1

ABSTRACT

This article proposes an amendment to the *Patent Act* that discourages anti-competitive patent practices in the pharmaceutical industry without interfering with follow-on innovation. It begins by introducing the pharmaceutical industry and its reliance on patents. It then explores pharmaceutical follow-on innovations that amount to "secondary patents" and the arising issues of "evergreening" and "patent thickets." While follow-on innovation is imperative to public health and a natural outcome of pharmaceutical innovation, the secondary patents essential to encourage such innovation are being used gratuitously, likely representing anti-competitive strategies. Next, this article analyzes comparative law that has addressed these anti-competitive concerns, the inadequacy of this comparative law, and advocates that patentability standards should not be heightened to combat anti-competitive patent strategy. Finally, the article analyzes Canadian case law on the doctrine of selection patents to draw inspiration for a *Patent Act* amendment designed to thwart anti-competitive patent practice without impairing genuine and beneficial follow-on innovation.

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INTRODUCTION AND ARTICLE GOAL

Literature on anti-competitive patent practices in the pharmaceutical industry is extensive. It has researched trends such as Research and Development ("R&D") costs and patent timelines, corporate and cross-national influences, innovation effects on public health, regulatory effects and resolutions, and much more. This article summarizes significant findings from this literature to lay out an understanding of the pharmaceutical patent system. Importantly, it also illustrates the problematic trends of "evergreening" and "patent thickets", and elaborates on substantial factors that should be considered when combatting these patent strategies.

This article identifies anti-competitive issues in the pharmaceutical patent system and formulates a legislative amendment to resolve this issue. At the same time, its proposed amendment is intended not to overburden pharmaceutical companies in appreciation of the difficult situations they navigate, as highlighted in this article. To this end, this article argues against heightening patentability standards and proposes an amendment to the *Patent Act* that is uniquely inspired by Canadian case law on "selection patents."[1] The amendment delicately incentivizes genuine follow-on innovation without overburdening pharmaceutical companies, simultaneously discouraging follow-on innovation for anti-competitive patent strategy.

I. INTRODUCTION TO THE PHARMACEUTICAL INDUSTRY

The pharmaceutical industry is a highly regulated conglomerate of companies responsible for public health influences stretching to public-serving institutions like hospitals, clinics, and schools worldwide. The industry's portfolio is primarily a group of the largest pharmaceutical companies. In 2019, the world's top 10 pharmaceutical companies constituted nearly 50% of the prescription drug market.[2] While startups and generic drug companies are part of this industry, the largest brand-name companies dominate the market. Most of this industry is headquartered in the United States of America (the "US").[3] Due to this concentration of companies in the US, the Canadian pharmaceutical sector relies heavily on pharmaceutical products conceptualized in the US, with over half of Canadian pharmaceutical sales originating from across the border.[4]

Having a suffusive influence across many facets of life that has increased life expectancies by implementing novel drugs and treatments, the pharmaceutical industry is pivotal to augmenting healthcare quality.[5] While it contributes to the furtherance of patient and public health, we must remember that as a dynamic interlinkage of companies, the industry's

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1 *Patent Act*, RSC 1985, c P-4 *[Patent Act]*.

2 Matej Mikulic, "Top 20 pharmaceutical companies worldwide based on prescription drug market share in 2019 and 2026*" (24 October 2022), online (Statistic): <statista.com/statistics/309425/prescription-drugs-market-shares-by-top-companies-globally> [perma.cc/9ABP-LMZ8].

3 *Ibid*.

4 *Pharmaceutical industry profile* (9 April 2021), online: <ised-isde.canada.ca/site/canadian-life-science-industries/en/biopharmaceuticals-and-pharmaceuticals/pharmaceutical-industry-profile> [perma.cc/W73H-PEL5].

5 Jason D. Buxbaum et al, "Contributions of Public Health, Pharmaceuticals, And Other Medical Care to US Life Expectancy Changes, 1990-2015" (2020) 39:9 Health Affairs 1546 at 1546.

priority is its commercial success. Businesses fail if revenues do not surpass costs, thus ceasing pharmaceutical innovation.

Patents are a crucial component of a business's portfolio. Companies obtain patents for innovations that grant the patent-holder the proprietary right to this innovation, entailing a period of exclusivity that the company utilizes to effectuate huge revenue. Rewarding patents for inventions is an important social policy instrument to incentivize inventors.

The pharmaceutical industry is dependent on patent protection, but its use of patents is widely shadowed by controversy.[6] Particularly contentious is "evergreening." Evergreening is when a patentee extends its patent monopoly by patenting multiple follow-on innovations derived from its previous patented innovation, focusing on generating further revenue. Technically, this is legal in principle; the right to exclude others is inherent to the patent, and the patentee is exercising this right. Everygreening exists when a company practices its right to unilaterally exclude at an *extreme* degree, and these marketed innovations offer marginal or no benefit to society. Evergreening occurs in valid and invalid patents, leaving policymakers uncertain about how to deduce a patent as anti-competitive. This is because identifying evergreening or patent thickets is a matter of proportionality: considering all factors, does the patentee's patent reflect anti-competitive business intent that has outweighed its purpose to innovate?

Evergreening is capable of blocking competitors to eliminate competitive pricing, thus allowing companies to keep drug prices high and increase revenue. The numerous patents filed for evergreening purposes can create shields of patent protection that force competitors to navigate and innovate in fear of infringing a patent minefield. These are colloquially referred to as "patent thickets."[7] Like evergreening, patent thickets are exercised through valid patents. It is also a matter of proportionality of whether a group of patents is obstructive and anti-competitive enough to be considered a patent thicket. Evergreening and patent thickets are similar and can be used together to prevent competitive market involvement. These strategies directly prevent follow-on innovation by discouraging other companies from researching and marketing new drugs. It also indirectly thwarts innovation by encouraging companies to specialize their R&D initiatives on follow-on innovation for patent acquisition rather than socially helpful innovation.

Follow-on innovation is a keystone in pharmaceutical innovation and in augmenting public health. Still, data and drug case studies suggest companies are inclined to focus R&D on empty, uninfluential follow-on innovation that likely demonstrates companies' near-exclusive goal of "innovating" to enhance patent protection. Research on existing drugs leads to many forms of follow-on innovation in chemical reconfigurations, such as chemical polymorphs, derivates, salts, esters, and others. Such innovation may also arise from ancillary developments, such as patents for alternative uses for the same active ingredient or the manufacturing method

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6 Typing the prompts "evergreening," "anti-competition," "pharma…," and "patents" into an internet search engine will provide a large amount of literature that generally addresses anti-competitive practices believed to be prevalent in the pharmaceutical patent system.

7 Congressional Research Service, *Drug Pricing and Pharmaceutical Patenting Practices* (Washington: Congressional Research Service, 2020) at 24.

of a drug. Patenting these innovations can extend patent terms and monopolies by either building upon the protection of an already patented drug or patenting a similar yet separate drug capable of maintaining a market presence. Partly due to the nature of pharmaceutical innovation often arising in incremental and continual development, evergreening is most prevalent in the pharmaceutical industry.[8] The current patent system correctly incentivizes genuine innovation, but the *Patent Act* is silent regarding follow-on innovation used for anti-competitive strategy. Thus, policymakers face the dilemma of deciphering frivolous, anti-competitive follow-on innovation from genuine follow-on innovation.

II. FOLLOW-ON INNOVATION AND SECONDARY PATENTS

Innovation does not occur in a vacuum. Instead, it is often built upon earlier innovation. This is known as follow-on innovation. Pharmaceutical follow-on innovation radically benefits public health by offering solutions to pharmacodynamic complexities, developing upon previous drugs to create a more appropriate, safe, or efficient treatment for diverse patients and conditions. Conclusively, the patent system must continue to incentivize follow-on innovation.

To acquire a patent, applicants must apply to the Canadian Intellectual Property Office (the "CIPO") and meet the standard patentability criteria.[9] The innovation must demonstrate its non-obviousness and inventiveness.[10] It must also be useful.[11] Here, courts have held that a "scintilla of utility" suffices when proving an invention's utility.[12] Further, the patent application must sufficiently disclose the innovation by offering a "person skilled in the art" enough information to make, use, or improve upon the invention when the patent expires.[13] Presumably, once these patent application criteria are met, the applicant is granted 20 years of exclusivity.[14] For this 20-year term, the patentee holds the exclusive right to make, construct, use, and sell the invention.[15] While patent terms grant an exceptional monopoly to patent-holders, this monopoly is not a limitless grant.[16]

Follow-on innovations must also meet these patentability criteria. While not definitively defined, patents for follow-on innovation are generally called "secondary patents." "Secondary" identifies the factual distinction that the new patent protects a later, advantageous development on an existing patent. They are not inferior to the original patent, as they award as much protection.

With increasing pharmaceutical follow-on innovation and arising concerns about follow-on innovation conducted for anti-competitive purposes, the United Nations attacked the validity of follow-on innovations and their complimentary secondary patents in its *Guidelines for*

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8 Congressional Research Service, *Patent "Evergreening": Issues in Innovation and Competition* (Washington: Congressional Research Service, 2009) at 1.

9 *Patent Act, supra* note 1, ss 3, 4.

10 *Ibid*, s 28(3).

11 *Ibid*, s 2.

12 *AstraZeneca Canada Inc v Apotex Inc*, 2017 SCC 36 at para 55.

13 *Patent Act, supra* note 1, s 27(3).

14 *Ibid*, s 44.

15 *Ibid*, s 42.

16 *Apotex Inc v Wellcome Foundation Ltd*, 2002 SCC 77 at para 37.

Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective (the "*Guidelines*")*.*[17] The *Guidelines* criticized various follow-on innovations, alleging that these innovations were too uninventive or illegitimate to deserve an independent patent term and that policymakers should raise patentability standards to reduce secondary patent grants. While concern may be warranted – elaborated in Section III of this article – the *Guidelines*' arguments are erroneous.

For example, the *Guidelines* posit polymorphs are obvious and therefore unpatentable on the basis that it is "obvious for a person in the field to seek the most suitable polymorph… for pharmaceutical use."[18] This statement equivocates the meaning of "obvious" to support its argument that polymorphs are obvious follow-on innovations undeserving of patents. In Canadian legislation, reflected similarly in other jurisdictions, the obviousness standard does not solely assess the goal of the invention. It instead encompasses a broader range of factors, such as the method of discovery and mechanisms of achieving the goal.[19] It may be obvious that chemists should try to find the most effective polymorph for pharmaceutical use, but it remains unobvious which polymorph works best or how to isolate this polymorph.

Professor Christopher M. Holman offers an exhaustive criticism of the *Guidelines* while simultaneously offering strong support for follow-on innovations and their associated secondary patents.[20] He lists instances where patents were impactful incentives for important follow-on innovation, such as the breakthrough discovery of zidovudine ("AZT") to treat HIV/AIDS.[21] Initially, AZT was a failed cancer treatment drug, but further research discovered AZT as a prospective treatment for HIV.[22] A secondary patent incentivized this follow-on innovation that formed the first treatment for HIV/AIDS.

Follow-on innovation can also exemplify strides of inventiveness and ingenuity. In *Apotex v Sanofi-Synthelabo Canada Inc.*, the patent for Plavix® (protecting the active ingredient clopidogrel bisulfate), a follow-on innovation, was found non-obvious and inventive.[23] The earlier patent disclosed a class of over 250,000 compounds with anticoagulative properties, including the racemate clopidogrel bisulfate; however, it did not explicitly disclose the enantiomer of the racemate, which possessed unforeseen advantages.[24] Therefore, while the original patent disclosed a specific racemate, which theoretically entailed the existence

17 Carlos M Correa, *Guidelines for Pharmaceutical Patent Examination: Examining Pharmaceutical Patents from a Public Health Perspective*, (New York: United Nations Development Programme, 2016).

18 *Ibid* at 25.

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

20 Christopher M Holman, "In Defense of Secondary Pharmaceutical Patents: A Response to the UN's Guidelines for Pharmaceutical Patent Examination" (2017) 50:3 Ind L Rev 759.

21 *Ibid* at 807.

22 *Ibid* at 807–808.

23 *Ibid* at 774.

24 *Ibid* at 774–775.

of two enantiomers, it did not disclose the precise variations and their advantages.[25] In contrast, the latter patent disclosed these specific variations, having disclosed the *exact* compound. Furthermore, we see that despite the procedure and outcome being initially deemed theoretically unpropitious, the secondary patent incentivized the Sanofi researchers to formulate this beneficial follow-on innovation. The evidence showed that the Sanofi researchers faced many obstacles and spent a burdensome five months formulating a procedure that isolated the relevant enantiomer.[26]

It is a perverse and thin idea not to reward a patent simply because the degree of innovation seems less on its face. If the following innovation is better and different from the initial innovation, its development should not be discouraged. Follow-on innovation has positively affected patient health, and it must continue to be available as a route of innovation for companies. Extending from this, a proper amendment to the *Patent Act* would ensure free-flowing follow-on innovation.

III. SECONDARY PATENTS: USING FOLLOW-ON INNOVATION FOR TERM AND MONOPOLY EXTENSION

A. Focusing on Follow-on Innovation

The platitude "Too much of anything is bad" describes the current trend in the pharmaceutical industry. Concerns have arisen regarding excessive secondary patenting. There is a propensity in the pharmaceutical industry to excessively patent follow-on innovations, likely in pursuit of extending patent monopolies and preventing competitive imitation.

The number of secondary patents is currently growing. Between 1991 and 2005, approximately 50% of marketed drugs in the US held an accompanying secondary patent. Between 2005 and 2015, of patented drugs in the US Food and Drug Administration records, 78% were for existing drugs.[27] 80% of companies applying for secondary patents conducted more than one market extension; nearly half of these entities added at least four patent protection extensions.[28] Between 1988 and 2005, secondary patents for specific pharmaceutical preparations to administer a product added 6.5 years to patent life.[29] The average life extension of secondary patents on polymorphs, isomers, prodrugs, or salt claims added 6.3 years.[30] Depending on the number of patents and the type of secondary patent, averages of patent extension terms added nearly 11 years on patent terms.[31]

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25 Enantiomers are compounds with identical molecular formulas that are non-superimposable; being non-superimposable, the enantiomers form mirror images. In the context of enantiomers, racemates are 50:50 mixtures of enantiomers. Differences between racemates and their enantiomers can have important implications for drug development. A notable practice is to isolate an enantiomer from the racemate, as the enantiomeric selection can yield benefits to the drug's clinical effects or decrease its adverse effects.

26 *Ibid*.

27 Robin Feldman, "May your drug price be evergreen" (2018) 5:3 JL and the Biosciences 590 at 597.

28 *Ibid*.

29 *Ibid*.

30 *Ibid* at 602.

31 *Ibid* at 597.

One may propose that the increasing number of secondary patents is a natural result of innovation since for every original innovation, many follow-on innovations stem from it. While this appeal to a Pareto-like principle seems attractive, further data signifies follow-on innovation is used for business strategy. Secondary patent usage was drastically emphasized with "blockbusters" being assigned at substantially higher rates for more profitable drugs: 70% of the top 100 best-selling drugs had patent terms extended, and 50% of these patents had more than one patent extension.[32]

Similarly in Europe, the European Commission found a disparity between primary and secondary patents in its 2009 report.[33] It discovered that the ratio between primary and secondary patents in the pharmaceutical industry was 1:7.[34] The proportion is larger when including pending patents: 1:13.[35] The increased discrepancy for pending patents may indicate lower quality patent applications for follow-on innovation, suggesting greater weight was assigned to these patents in the hope of prolonging patent terms than to innovate genuinely.[36] Similar to the US, the number of patent applications and grants correlated to the drug's value in that "blockbuster" drugs saw an increase in patent applications nearing expiration dates.[37]

Finally, these trends also exist in Canada. In 2008, 50% of the 494 medicines in the Patent Register had two or more patents attributed to one medicine, and some drugs had up to 22 patents.[38] Of drugs approved in Canada between 2014 and 2018, roughly three-quarters were for follow-on drugs.[39] The increasing number of patents per drug functions to delay other companies from entering the market as it did back in 1998 to 2008, where drugs with multiple patents delayed the decision to market a generic drug product for eight years.[40]

B. General Concerns

Many believe the increasing number of secondary patents is immoderate. In theory, excessive patent protections discourage research and marketing by drug companies who attempt to avoid patent infringement and litigation. Due to this, there are concerns about anti-competitive patents conflicting with competition law, believing that competition law should become increasingly involved as a means of intervention. The Canadian Competition Bureau (the "Bureau") has already shown its consternations regarding the overlap of secondary patents and anti-competitive practices: "There is a competition concern that [generic] entry may be

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32 *Ibid.*

33 European Commission, *Pharmaceutical Sector Inquiry Final Report* (Brussels: Department for Competition, 2009).

34 *Ibid* at para 427.

35 *Ibid*.

36 *Ibid* at paras 501–503.

37 *Ibid* at para 461.

38 Joel Lexchin, "Canada's Patented Medicine Notice of Compliance regulations: balancing the scales or tipping them?" (2011) 11:64 BioMed Central Health Services Research at 3 [Lexchin, "Effects of NOC Regulations"].

39 Joel Lexchin, "Time to market for drugs approved in Canada between 2014 and 2018: an observational study" (2021) 11:e047557 Brit Med J Open at 3 [Lexchin, "Time to market for Drugs in Canada"].

40 Lexchin, "Effects of NOC Regulations," *supra* note 38.

sufficiently impeded and that through an anti-competitive act, [brand-name companies] will successfully maintain its market power."[41]

Humira® and its many patents, the top-selling drug in 2020 sold by AbbVie, substantiates these concerns.[42] Humira's original patent expiration was in 2016, yet AbbVie applied for or obtained over 250 patents on ancillary developments of Humira.[43] Some of its secondary patents held expiration dates as late as 2037.[44] AbbVie filed 90% of its patent applications for Humira after it was brought to market – which likely suggests AbbVie anticipated Humira's patent expiration, strategically launching secondary patents to shield Humira from generic replication and to prolong Humira's monopoly. [45] An explicit example comes from the European pharmaceutical sector, where Servier Laboratories commented: "4 years gained – great success" regarding its patent term extension to block generic competition from marketing its product Coversyl®.[46] Excessive patenting can limit generic expansion into the market, and companies can enjoy setting high drug prices due to the lack of offsetting competition.

By now, the abundant diversity of secondary patents available for use by pharmaceutical companies is noticeable. Patent law embraces and accommodates the fluidity that creativity takes and protects a diverse spectrum of innovations. However, this correlates to an ampler arsenal of patents that pharmaceutical companies can procure for anti-competitive purposes.

Common practice is to "upgrade" a previous pharmaceutical agent and sell the new upgraded form. Here, the new drug is frequently preferred, achieving market control despite the patent expiration of the previous compound. Polymorph patents are an example. Polymorphism allows a molecule to assume multiple crystal structures, and these variations constitute the follow-on innovation. For example, Pfizer Inc.'s ("Pfizer") patent of their blockbuster drug Lipitor® protected the active ingredient atorvastatin.[47] The original patent expired in 2010, but Pfizer separately patented three polymorphic forms of the previous active ingredient, and these patents expired in 2017 – one of these three polymorphs continued to be marketed as the upgraded version of atorvastatin, thus extending the original patent lifespan.[48] Eli Lilly & Co. ("Eli Lilly") pursued a similar strategy to preserve billions of dollars of revenue from its blockbuster Prozac®.[49]

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41 Competition Bureau Canada, *Intellectual Property Enforcement Guidelines* (Competition Bureau Canada, 2019) at para 132.

42 Lisa Urquhart, "Top companies and drugs by sales in 2020" (2021) 20:253 Nature Reviews Drug Discovery.

43 US, Committee on Oversight and Reform, *Drug Pricing Investigation AbbVie—Humira and Imbruvica*, (Washington: Committee Print, 2021) at iv.

44 *Ibid* at 37.

45 *Ibid* at iv.

46 European Commission, *Competition Enforcement in the Pharmaceutical Sector (2009-2017): European competition authorities working together for affordable and innovative medicines* (Brussels: Department for Competition, 2019) at 40.

47 Runjjun Tandon, Nitin Tandon & Rajesh Kumar Thapar, "Patenting of polymorphs" (2018) 7:2 Pharmaceutical Patent Analyst 59 at 60.

48 *Ibid*.

49 Debra Robertson, "Pharma strategies extend drug lives" (1999) 17 Nature Biotechnology 220 at 220–221.

Eli Lilly's CEO, in reference to Eli Lilly considering producing a purified isomeric form of Prozac, stated this was to "face one of the biggest events of [Eli Lilly's] history – the Prozac patent expiration."[50]

Additionally, a secondary patent does not need to be of a distinct molecular compound. An innovation can be regarding the new use or indication of an already known compound. It may be a new fixed dosage form, new dosage range, or new dosage regimen of a known compound with a known use.[51] The subdivision of an innovation allows for many forms of secondary patents. Again, with good reason, these patents are encouraging beneficial follow-on innovation. This is shown by research on Pfizer's drug Mylotarg®, used to treat patients relapsing with acute myelogenous leukemia.[52] Mylotarg was found ineffective and was linked to cases of fatal toxicity; Pfizer removed it from the market and did not pay patent maintenance fees, so the patent expired.[53] The medication prescribed a recommended induction dose of 9 mg/m^2 on days one and 14.[54] Shortly after Pfizer's patent expired, researchers discovered that subdividing the recommended dosage into 3 mg/m^2 on days one, four, and seven improved overall survival in patients without increasing mortality rates.[55] Unfortunately, the researchers could not patent the new dosage regimen because Pfizer's expired patent was broad enough to anticipate this discovery.[56] Nonetheless, this research example shows minor alterations to a dosage regimen can be innovative and beneficial to public health.

Previously mentioned was the beneficial drug AZT. Initially a failed cancer treatment, it was innovated into a treatment for HIV/AIDS – this is a new medical use patent.[57] New medical use patents allow innovators to secure patents for preexisting drugs but for a new use. The patent would include a claim resembling the structure: "Use of compound X to treat Y."[58] Medical use patents provide 20 years of exclusivity with the caveat that the patent protects the newly indicated use rather than the compound itself. Because the original patent usually covers all uses of the previous compound, a new medical use patent can act to extend the patent protection of the compound.

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50 *Ibid*.

51 Canadian Intellectual Property Office, *Examples of purposive construction analysis of medical use claims for statutory subject-matter evaluation* (Ottawa: CIPO, 2015) at no 2 online: <ised-isde.canada.ca/site/canadian-intellectual-property-office/en/examples-purposive-construction-analysis-medical-use-claims-statutory-subject-matter-evaluation> [perma.cc/FU95-VXWP] [CIPO, *Examples of medical use claims*].

52 Ulrich Storz, "Extending the market exclusivity of therapeutic antibodies through dosage patents" (2016) 8:5 MAbs 841 at 843–844.

53 *Ibid*.

54 *Ibid*.

55 *Ibid*.

56 *Ibid*. "Anticipation" in patent law refers to a prior invention or disclosure of a given invention, implying that the newly founded invention would be found obvious and, therefore, unpatentable.

57 CIPO, *Examples of medical use claims*, *supra* note 51 at no 7.

58 *Ibid*.

AZT resembles a positive and socially beneficial innovation. However, see an antithesis such as Eli Lilly's Sarafem®, the new medical use patented drug corresponding to its earlier drug Prozac.[59] Prozac's patent expired in 2001, while Sarafem's expired in 2007. Despite the two drugs containing the same active ingredient, fluoxetine, and at identical dosages, Sarafem's cost was over 1000% more per pill.[60] Does the R&D for the new medical use elicit a price tag 10 times more than the R%D conducted for the compound itself? It follows that Eli Lilly prolonged its protection for fluoxetine, albeit for a new use, maintaining market exclusivity and strategically reaping the profits from this strategy. Some adjudge new medical use patents to be exceptionally powerful tools within the US' orphan drug framework, where companies actively manoeuvre orphan drug exclusivity schemes.[61] Orphan drugs are designated to treat rare diseases in small patient populations. Some speculate that pharmaceutical companies can manipulate who these target populations are, correspondingly able to create a plethora of orphan drugs by virtue of the many target populations that can be identified – this is colloquially referred to as "salami slicing."[62] While Canada does not have an orphan drug framework, this anti-competitive strategy should not entirely be dismissed; Canadian patent law allows quasi-medical use patents where a known compound can be patented against a new beneficial effect found for a specific group of patients.[63]

New medical use patents in Canada have blocked generic competition from entering the market. In *Apotex Inc. v. Ontario (Minister of Health)*, the drug in dispute was Zoloft® after Apotex's medication Apo-Sertraline® was found only partially interchangeable with Zoloft under the *Drug Interchangeability and Dispensing Fee Act*.[64] Pfizer's Zoloft patent, related to its use of treating depression expired, yet Pfizer held unexpired patents regarding its new use of treating obsessive-compulsive disorder ("OCD") and panic disorders. Due to these secondary patents, Apotex's drug was found not fully interchangeable to the extent of the persisting patents. For this reason, Apotex's alternative treatment option could not be offered to patients expecting cheaper alternatives for OCD and panic disorder treatments.

All secondary patents must still meet patentability requirements. Of course, researching and understanding the positive and negative effects of a drug and its many configurations significantly prospers society. However, when these innovations incur 20-year patent monopolies that act to uphold market presence, we must reevaluate the competitive landscape

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59 Himanshu Gupta et al, "Patent protection strategies" (2010) 2:1 JPharmacy and Bioallied Sciences 2 at note "New formulations".

60 World Trade Organization, World Intellectual Property Organization & World Health Organization, *Promoting Access to Medical Technologies and Innovation: Intersections between public health, intellectual property and trade*, 2nd ed Trilateral Study (Switzerland: Trilateral study by the World Health Organization (WHO), World Intellectual Property Organization (WIPO) and World Trade Organization (WTO), 2020) at Box 3.16.

61 Note that Canada does not have an orphan drug framework. Orphan drugs are pharmaceutical agents that are designated for the treatment of rare medical conditions that impact a small number of the population. Due to the nonviable cost-to-profit ratio associated with R&D for orphan drugs, certain market exclusivity periods are granted to encourage the innovation of orphan drugs.

62 Matthew Herder, "Orphan drug incentives in the pharmacogenomic context: policy responses in the USA and Canada" (2016) 3:1 JL and the Biosciences 158 at 158–159.

63 CIPO, *Examples of medical use claims*, *supra* note 51 at no 7.

64 *Apotex Inc v Ontario (Minister of Health)*, 2000 CanLII 22671 (ONSC)

these patents confer. Excessive patenting is especially suspicious for anti-competition if the patent protects an innovation with only slight improvements compared to the initial innovation from which it derives. Coversyl was found to have no clinical benefit over its initial innovation.[65] Another example is Lexapro® (protecting escitalopram), the follow-on innovation from Celexa® (protecting citalopram), demonstrating marginal increased benefit. Escitalopram is the chiral switch of citalopram, also intended to decrease depressive symptoms.[66] Lexapro's market penetration maintained the company's significant market share, suppressing generic drug imitations that offered a cost-effective option.[67] Despite Lexapro's dominant market share, its clinical benefits over Celexa were uncertain.[68] Therefore, the follow-on drug took control of the market and profited from this control while having no observed advantage over its parent drug. As mentioned before, determining a patent as evergreening or part of a patent thicket is undefinable. However, when the effects of the innovation are minimal and pale in comparison to the beneficial effects of the original innovation, the secondary patent is more likely an instance of anti-competitive strategy.

Innovators cooperate, build upon, and refute other innovators' ideas to advance innovation. However, an entity may be unable to market an exceptional feat of innovation if blocked by patents. The innovator may need to purchase the transference or licensing agreement of many other patents related to the innovation. Maybe the price is not the issue, but the patentee denies any transference or licensing agreement, even if the innovation is unused. Such scenarios have occurred before, where Michael Heller describes a treatment for Alzheimer's that could not reach the market because of numerous obstructing patents that required cumbersome and costly licensing negotiations.[69] In such cases, the collaborative nature of innovation is lost, and inevitably, pharmaceutical firms avoid researching scientific areas and previous innovations with too many patents.[70]

IV. VIVACIOUS LITIGATION

A. Obstructions and Costs

Competitors attempt to enter the market faster by invalidating impeding patents that slow their market entry. This has caused astronomical growth in pharmaceutical litigation that is both costly and inadequate for combatting anti-competitive patents. In 1990, there were fewer than 25 Federal Court cases (applications for prohibition orders, judicial review,

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65 *Ibid*.

66 Ali A Alkhafaji et al, "Impact of evergreening on patients and health insurance: a meta analysis and reimbursement cost analysis of citalopram/escitalopram antidepressants" (2012) 10:142 BMC Medicine at 6.

67 *Ibid* at 8.

68 *Ibid*.

69 Michael Heller, *The Gridlock Economy: How Too Much Ownership Wrecks Markets Stops Innovation, and Costs Lives* (New York: Basic Books, 2008) at ii.

70 Richard E Gold et al, "Are Patents Impeding Medical Care and Innovation?" (2009) 7:1 e1000208 PLoS Medicine at 3.

and appeals) where a generic drug company was involved.[71] In 2010, there were over 100.[72]

Such litigation discourages innovation and is one of many mechanisms for actuating anti-competitive strategy. Increased litigation arose from the enactment of the *Patented Medicines (Notice of Compliance) Regulations* (the "*NOC Regulations*"), requiring patented drugs to receive regulatory approval from Health Canada for marketing.[73] Brand-name companies utilized patents for follow-on innovations to burden generic competition by forcing competitors to complete an elaborate list of Notice of Allegations to ensure they did not infringe on one of many patent claims during market entry.[74] For example, GlaxoSmithKline navigated its use of *NOC Regulations* to delay Apotex Inc. from marketing Paxil®, contributing to an additional $300 million of revenue for GlaxoSmithKline from Paxil.[75]

Even if pharmaceutical competitors successfully fight anti-competitive patents, these victories are rendered pyrrhic due to high costs. From 2000 to 2012, Apotex Inc. claimed it spent $300-$400 million for litigation in Canada.[76] Extrapolated data shows that pharmaceutical patent litigation costs were well over $100 million annually.[77] Similar to how R&D costs are argued to contribute to higher drug prices in brand-name drugs, litigation costs for generic drug companies also lead to higher drug costs for generic drugs.[78] To avoid time-consuming and costly litigation, a company may be disincentivized from researching and marketing its product.

In the US, the recent emergence of biologic and biosimilar drugs has resulted in notable large-scale litigation.[79] Between 2010 and 2023, 271 patents were litigated, and manufacturers of 12 biologic drugs were litigated against 48 biosimilar manufacturers.[80] Of these 271 cases, 95% were concerning secondary patents.[81] Clearly, secondary patents are instrumental in invoking litigation that potentially prevents competitive R&D and imitation. Important to note from the 271 patents are the 8% of ancillary secondary patents – patents relating to complementary products or components of the original patent.[82] Although not a large segment of the litigated patents, they were acquired 18.3 years after the original patent

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71 "Paul Grootendorst, Ron Bouchard & Aidan Hollis, "Canada's laws on pharmaceutical intellectual property: the case for fundamental reform" (2012) 184:4 CMAJ 543 at 546 [Grootendorst]."

72 *Ibid*.

73 *Patented Medicines (Notice of Compliance) Regulations*, SOR/93-133.

74 *Ibid*, s 5(2.1).

75 Grootendorst, *supra* note 71 at 545.

76 *Ibid* at 546.

77 *Ibid* at 547.

78 *Ibid*.

79 Biologic drugs are organically produced through the protein expressions of living systems. Biosimilars are drugs that are deemed highly similar to a preceding biologic drug, which may be marketed after the biologic drug patent expires. For the purposes of this article, the relationship between biosimilars and biologics can be conceptualized as similar (but not identical) to the relationship between generics and brand-name drugs, respectively.

80 Rachel Goode, William B Feldman & S Sean Tu, "Ancillary Product Patents to Extend Biologic Patent Life" (2023) 330:21 JAm Medical Assoc 2117 at 2117.

81 *Ibid*.

82 *Ibid*.

and are believed to extend original patents' durations by approximately 10 years.[83] Therefore, the litigation in question problematically depicts companies focusing their effort and resources on combating intentionally frivolous patents.

B. "Valid" Anti-competitive Patents Unbothered

Another issue is that during litigation, courts are limited when addressing anti-competitive allegations because they can only invalidate invalid patents. Consequently, anti-competitive yet valid patents are unbothered. In *AstraZeneca Canada Inc. v. Canada (Minister of Health)*, the Supreme Court of Canada (the "SCC") was explicitly aware of evergreening practices that barred generic company market entry: "[Accepting AstraZeneca's interpretation of *NOC Regulations*] would reward evergreening even if the generic manufacturer (and thus the public) does not thereby derive any benefit."[84] But its mention of evergreening is a corollary, claiming AstraZeneca's argument would result in the court rewarding evergreening.[85] The SCC's judgement does not consider whether AstraZeneca was evergreening. Rather, it is derived from assessing the validity of the Notice of Compliance issued to Apotex Inc.[86]

Courts also use the "obviousness-type double-patenting" judge-made law laid out in *Whirlpool Corp. v. Camco Inc.*[87] to address evergreening allegations. In this case, the SCC recognized two forms of double-patenting.[88] The first is where the secondary patent is outright "identical or coterminous" to the original, and the second is where the second patent is not "patentably distinct" from the first.[89] The double-patenting analysis emerges from interpreting the *Patent Act*, which states that no invention can have more than one patent.[90] But like *AstraZeneca Cana*da *Inc v Canada (Minister of Health),* the court applies a core tenant of the *Patent Act* to invalidate patents. This approach stands on a different footing from a system that considers allegations of evergreening when invalidating patents. Courts cannot use the argument of evergreening or patent thickets to invalidate a patent. This is articulated in *Apotex Inc v Sanofi-Synthelabo Canada Inc,* where the SCC notes that the mere concern for evergreening practices cannot overrule the validity of selection patents (a secondary patent).[91] Therefore, the courts currently operate with the assumption that evergreening and other anti-competitive patent techniques are prevented by voiding invalid patents, leaving valid secondary patents that intimate anti-competitive strategy untouched.

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83 *Ibid*.
84 *AstraZeneca Canada Inc v Canada (Minister of Health)*, 2006 SCC 49 at para 39 [*AstraZeneca 2006*].
85 *Ibid*.
86 *Ibid* at para 17.
87 *Whirlpool Corp v Camco Inc*, 2000 SCC 67.
88 *Ibid* at paras 64–66.
89 *Ibid*.
90 *Patent Act, supra* note 1, s 28.2(1).
91 *Apotex 2008, supra* note 19 at para 98.

V. COMPARATIVE LAW

Some countries have altered their legislation pursuant to The Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS").[92] TRIPS offers flexibility for member countries to implement stricter patent rights if it does not contravene its other articles.[93] This flexibility led to varying patentability standards between countries.[94] Brazil and India are notable countries that raised patentability criteria in response to pharmaceutical follow-on innovation and anti-competitive concerns; however, the results are dissatisfactory.

Brazil enacted a triumvirate examination system involving health ministries during patent examinations, where pharmaceutical patents are subject to the patentability criteria of Brazil's patent office, the National Institute for Industrial Property, and must receive the prior consent of the National Agency for Sanitary Vigilance.[95] Brazil enacted strict patent application examinations by requiring multiple agencies to review and regulate patent applications, intending to decrease grants for secondary patents.[96]

On application, Brazil's patent system has not achieved its intentions. The patent scheme has lowered grants of secondary patents, as intended; among secondary patent applications through the Patent Cooperation Treaty, only 5% of applications are accepted.[97] Yet, there is a backlog of applications where 11% of patent applications are pending.[98] 60% of patent applicants withdraw their applications before examinations are complete.[99] Therefore, the low approval rate of secondary patents is due to high withdrawal rates.[100] Furthermore, despite a low grant rate for secondary patents, low grant rates for primary patents were found to be approximately equal to secondary patent grants.[101] The equivalently low grant rate of primary patents and high withdrawal rate demonstrate ineffective legislation, where the patent system fails to provide patent grants promptly and has reduced grants for ingenuine secondary patent applications to the detriment of reducing all patent grants.

India enacted explicit legislation that provides additional inspection for secondary patents. Section 3(d) of India's *The Patent Act, 1970* raises patentability standards for follow-on innovation.[102] This provision intended to impede excessive patenting for anti-competitive purposes, hoping to

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92 TRIPS: Agreement on Trade-related Aspects of Intellectual Property Rights, 15 April 1994, 1869 UNTS 299 [*TRIPS*].

93 *Ibid*, art 1.1.

94 Bhaven N. Sampat & Kenneth C. Shadlen, "The Effects of Restrictions on Secondary Pharmaceutical Patents: Brazil and India in Comparative Perspective" (2016) Harvard University at 10.

95 Bhaven N. Sampat & Kenneth C. Shadlen, "Secondary pharmaceutical patenting: A global perspective" (2017) 46:3 Research Policy 693 at 695 [Sampat, "Secondary pharmaceutical patenting"].

96 *Ibid*.

97 *Ibid* at 700.

98 *Ibid*.

99 *Ibid*.

100 *Ibid*.

101 *Ibid* at 699.

102 *Ibid* at 695.

structure a fairer pharmaceutical marketplace. It clarifies that "salts, esters, ethers, polymorphs, metabolites, pure form, particle size, isomers, mixtures of isomers, complexes, combinations and other derivatives of known substance[s] shall be *considered to be the same substance* unless they differ significantly in properties with regard to efficacy."[103] Thus, it presumes follow-on innovations are unpatentable unless the applicant demonstrates the innovation's increased efficacy. The follow-on innovation must "*differ significantly* in properties with regard to efficacy," offering the India Patent Office flexibility in determining what degree of effectiveness suffices.[104]

However, section 3(d) was also unsuccessful upon application. Recently, section 3(d)'s usage has increased and has been limiting patent grants, likely due to its flexible language. Its overuse resulted in India's patent office increasingly denying non-follow-on patent applications.[105] Now, secondary patents are granted at similar rates to primary patents.[106] Policymakers drafted section 3(d) to decrease secondary patents to prevent anti-competitive follow-on patents; but like Brazil, the equal grant rate between secondary and primary patents suggests that the legislative amendment has failed.

VI. DO NOT RAISE PATENTABILITY STANDARDS

Negating anti-competitive patents by raising patentability standards for all follow-on innovations is an obtuse and overinclusive approach. It will likely disincentivize innovation, running counter to the patent system's goal of incentivizing innovation.

The patent system must remain optimal for recouping R&D costs and achieving business interests. Patents help companies recoup high R&D costs. Considering average R&D costs – depending on drug type, treatment, and success rate – ranging from $300 million to over $2.8 billion US dollars, these price tags pressure companies to obtain patents to recoup their expenses and profit as a business.[107] Overall, statistics demonstrate astronomical costs for pharmaceutical innovation.[108] Despite patents granting 20 years of unilateral exclusion beginning on the patent's filing date,[109] companies must extract revenue within short market exclusivity windows to ensure their R&D expenditure is not rendered prodigal. Regulatory variables in the patent system delay a drug's market entry so that market exclusivity periods do not run concurrently with the patent period. In the US, top-selling prescription brand-name drugs had an effective market exclusivity period of 12.4 years between 2000 and 2011. Similarly, in Canada, between 2014

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103 *Ibid* [emphasis added].

104 *Ibid* [emphasis added].

105 Bhaven N Sampat & Kenneth C Shadlen, "Indian pharmaceutical patent prosecution: The changing role of Section 3(d)" (2018) PLoS One 13:4 at 8.

106 Sampat, "Secondary pharmaceutical patenting", *supra* note 95 at 17.

107 Olivier J Wouters, Martin McKee & Jeroen Luyten, "Estimated Research and Development Investment Needed to Bring a New Medicine to Market, 2009-2018" (2020) 323:9 JAm Medical Assoc 844 at 844.

108 Steven Simoens & Isabelle Huys, "R&D Costs of New Medicines: A Landscape Analysis" (2021) 26:8 Frontiers in Medicine 760762; Alex Philippidis, "The Unbearable Cost of Drug Development: Deloitte Report Shows 15% Jump in R&D to $2.3 Billion", Genetic Engineering and Biotechnology News (28 February 2023).

109 *Ibid*, s 44.

and 2018, the average market exclusivity for drugs was eight years.[110] Some brand-name drugs experienced incredibly short market exclusivity periods. Lamictal® (protecting lamotrigine) only had market exclusivity for 4.8 years in Canada.[111] Remeron® (protecting mirtazapine) had a market exclusivity period of just 2.7 years.[112] This lends credence to the idea that the problematic reliance on follow-on innovation and other post-patent strategies is somewhat endogenously caused by the patent system, where companies use anti-competitive methods because the original patent term was insufficient for commercial purposes.

Early patenting strategies deployed by pharmaceutical companies will also be hindered by heightened patentability standards, further disincentivizing innovation. Most patent systems in the world encourage early patenting;[113] in a competitive industry, waiting too long to patent will essentially forfeit your patent rights to competitors with similar R&D trajectories. R&D is inherently laborious; in the US, only 0.001% of potential drugs surpass the pre-clinical testing phase of R&D, and less than 10% of drugs pass the human clinical trials phase.[114] Under ideal circumstances, marketing a new drug takes 10 to 15 years.[115] Thus, early patenting allows companies to gauge the risk of their R&D endeavours and protect their innovations from competitive imitation.[116] Additionally, innovators confident in their patent protection can comfortably share information with other innovators in order to improve their innovations.[117] However, early patenting is also risky, where companies must patent before a well-grounded understanding of their product and its market success probability. Due to the imperative role that early patenting has within the pharmaceutical patent system, preserving this strategy's efficacy must be considered when assessing potential legislative amendments.

Startup companies will be especially disincentivized if patent standards hinder early patenting availability. Decreasing early patent acquisitions for startups will likely stunt startup growth, as quick patent acquisition is correlated to startups' growth and success.[118] Startups typically take risks and explore new avenues of drugs and treatments, and heightened patent standards will deter startups from undertaking audacious research. Startups rely on early patenting to improve company status. They may secure patents to increase company evaluation when pitching to venture capitalists, hoping to fund their R&D when under financial pressure.

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110 Lexchin, "Time to market for Drugs in Canada," *supra* note 39 at 4.

111 Grootendorst, *supra* note 71 at 545.

112 *Ibid*.

113 Christopher A Cotropia, "The Folly of Early Filing in Patent Law" (2009) 61:1 Hastings Law Journal at 9.

114 Gail A Van Norman, "Drugs, Devices, and the FDA: Part 1: An Overview of Approval Processes for Drugs" (2016) 1:3 JACC Basic to Translational Science at 170.

115 Peter Corr & David Williams, *Conflict of Interest in Medical Research, Education, and Practice*, (Washington DC: National Academics Press 2009) at 375.

116 *Ibid* at 22.

117 *Ibid*.

118 Joan Farre-Mensa, Deepak Hegde & Alexander Ljungqvist, "The Bright Side of Patents" (2016) National Bureau of Economic Research, Working Paper No 21959 at 30–32; Annamaria Conti, Jerry Thursby & Marie Thursby, "Patents as Signals for Startup Financing" (2013) 61:3 The Journal of Industrial Economics 592 at 618; Masatoshi Kato, Koichiro Onishi & Yuji Honjo, "Does patenting always help new firm survival? Understanding heterogeneity among exit routes" (2022) 59:2 Small Business Economics 449 at 451, 455.

They may also patent early to encourage partnerships with large pharmaceutical entities, assuring funding and a more impactful influence on public health. Raising patentability standards for startups interferes with startup prosperity.

VII. WARRANTED CHANGE: LOOKING AT SELECTION PATENTS FOR GUIDANCE

Patent protection is not an unconditional grant. Patent law rests on the idea of a "bargain" between the inventor and the public; the invention benefits the people, and the patentee receives a monopoly for it.[119] The excessive number of secondary patents, likely anti-competitive, means such companies are not meeting their end of the bargain. These anti-competitive patents are associated with diminished public health and dive deep into patients' pockets. To ensure companies comply with this bargain, policymakers are pressured to combat prospective anti-competitive behaviour. However, they must carefully avoid overburdening the pharmaceutical industry, as the patent system must remain a strong incentive for pharmaceutical innovation. After all, the other side of the bargain is an effective and encouraging monopoly granted to patentees. A *Patent Act* reform that disincentivizes innovation by overstraining the sector and threatening early patenting strategies, subsequently affecting startup growth, is inadequate. A reasonable approach is not an overbroad change to legislation or a reassertion of patent rights from companies; instead, it is a nuanced reform that can delicately stun anti-competitive practices.

Canadian case law on the doctrine of "selection patents" offers such an approach, establishing a way to differentiate frivolous and genuine follow-on innovation. Selection patents are a type of secondary patent where the innovator selects a subset chemical from a previously patented class of solutions for its advantageous characteristics. Thus, the molecule is disclosed in the initial patent, but the later discovery of its unique and advantageous properties, inexistent in the initial compound family, is undisclosed. The SCC in *Apotex Inc v Sanofi-Synthelabo Canada Inc* upheld selection patents as valid in principle under the *Patent Act*.[120] Along with verifying their validity, the SCC laid down the requirements for a valid selection patent: 1) the selection must possess some substantive advantage over the genus; 2) all selected members must possess this advantage; 3) the advantage must be peculiar to the selected group and not be attributable to the general group chosen from.[121]

Courts have directed much attention to the first requirement, which entails an analysis of the inventiveness required for selection patents. The SCC concluded that "some substantive advantage" claimed by selection patents comprises the inventiveness of the invention.[122] Therefore, the advantageous utility of selection patents does not satisfy the utility requirement; rather, it is encapsulated within the inventiveness of the invention. What makes selection patents inventive is not limited to the compound but is reflected in its unique and advanced

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119 *Free World Trust v* Électro *Santé Inc*, 2000 SCC 66 at para 13 [*Free World Trust*]; *AstraZeneca 2006*, *supra* note 84.

120 *Apotex 2008*, *supra* note 19 at para 98.

121 *Ibid* at para 10 [emphasis added].

122 *Apotex 2008*, *supra* note 19 at paras 9, 78.

functionality.[123] The mere selection of a compound from the original compound family is insufficient for inventiveness, regardless of its utility, if the selected compound does not possess a substantive advantage relative to the original compound family. Hence, we reward selection patents for the peculiar form of inventiveness associated with them: their newly discovered distinct and substantively advantageous utility.

Case law on selection patents demonstrates not all forms of intellectual property are alike and that different patents may require other considerations. Understanding what makes selection patents uniquely inventive can help policymakers interpret the inventive quality in all secondary patents. Selection patents are a form of secondary patents and commonly overlap with other secondary patents. Selection patents have applied to the selection of salts and polymorphs.[124] They have pertained to the choice of esters and derivatives.[125] Selections of an advantageous enantiomer were concluded to be a patentable selection.[126] Conclusively, secondary patents are inventive because they have unique and new advantageous qualities the initial patent does not disclose. Earlier mentioned were new medical use patents, whose protections only extend to the claimed new utility for the preexisting compound. The rationale is that the invention is the new use, not the preexisting compound. Likewise, the inventive component of secondary patents is afforded by their unique and new advantageous qualities, as defined in case law. Despite this overlap, the patent protection for secondary patents of polymorphs or selections, for example, still relates to the compound itself and not their unique and new advantageous qualities.

Policymakers can interpret case law's understanding of *why* we grant patents for selection patents to determine *how* we should grant patents for secondary patents. This article's proposal implements the above rationale to organize the rights that secondary patents provide.

VIII. PROPOSAL

Policymakers should avoid raising patentability standards and apply case law's customized interpretation of selection patents to tailor the exclusivity rights accorded to secondary patents. The *Patent Act* should require the CIPO to focus on the advantageous and unique utility of the follow-on innovation to form a reasonable limitation on the rights of secondary patents. This requires the *Patent Act* to properly define and categorize secondary patents when dealing with pharmaceutical follow-on innovations.

A. Properly Defining Secondary Patents

The *Patent Act* should categorize secondary patents. Secondary patents should not be defined as patents for follow-on innovations, as it is stark and misidentifies what is "secondary." They are not "secondary" merely because the innovation arose afterward; if this were the case, every patent would be deemed a secondary patent except for the inaugural first-ever patent.

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123 *Janssen Inc v Teva Canada Limited*, 2015 FC 247 at para 100.

124 *Merck Sharp and Dohme Corp v Pharmascience Inc*, 2022 FC 417 at para 92.

125 *Hoffman-La Roche Ltd v Apotex Inc*, 2013 FC 718 at para 142.

126 *Pfizer Canada Inc v Canada (Minister of Health)*, 2008 FCA 108 at para 46.

Secondary patents are not classified as secondary solely because they are subsequent innovations but also because they are intrinsically linked to the innovator's preceding innovation. Classifying a patent as secondary is contingent on the proprietor's identity. Secondary patents should differentiate companies that conduct follow-on innovation on their patented innovations versus companies involved in follow-on innovation who do not own the previous patent.

Accordingly, secondary patents are more precisely defined as patents awarded to patentees follow-on innovating based on their previously patented innovations. A patent for a follow-on innovation is a secondary patent only if the same entity is the one who secured the patent for the earlier innovation and its follow-on. Thus, all secondary patents protect follow-on innovations, but not all follow-on innovations are protected by secondary patents. Entities separate from the original patentee conducting follow-on innovation on the other company's innovation will be eligible for a standard patent.

B. A Proviso for Every Secondary Patent

Following the recommended categorization of secondary patents, every pharmaceutical secondary patent should possess a unique proviso. The proviso should be constructed by the patent's claims and restrict the exclusivity rights granted for secondary patents. The restriction is that the patent's rights will only apply to the innovation's disclosed and claimed utility, which is sufficiently unique and advantageous to render the innovation inventive, as inspired by the legal precedent regarding selection patents. The patentee will have all the rights of a typical patent. However, its exclusionary discretion will only apply if it pertains to the disclosed substantive, advantageous quality that sufficiently constitutes its inventiveness. Therefore, the patent protects only the "inventive heart" of the innovation.

The CIPO will formulate and apply provisos by interpreting the patent's claims. The patent's disclosure will follow the statutory requirements in the *Patent Act* that require patent applicants to describe the invention fully and completely.[127] Following, the advantageous utility of follow-on innovations is disclosed pursuant to the *Patent Rules*; disclosure mandates the applicant to describe the utility and background art significant for understanding the invention.[128] Note that the CIPO, never the patentee, will construct each secondary patent's provisos. This prevents applicants from drafting their provisos broadly intended to enlarge the scope of claims they cover, which would diminish the proviso's limitation effects.

For example, a patentee holds the patent for "Drug A," which protects an active ingredient. They discover a polymorph of the active ingredient in Drug A and call it "Drug B." Drug B can treat schizophrenia, a utility that is absent from the predecessor drug. The patentee of Drug A applies for a patent for Drug B, acquiring a secondary patent. The inventiveness sufficient to make the polymorph of Drug A's active ingredient into an independent drug, Drug B, will be disclosed. The patentee will have the exclusive right to make, use, offer for sale, sell, and import drug B for 20 years, but only *regarding its claimed substantive, advantageous, and unique quality that composes its inventiveness.* The patentee possesses control

127 *Patent Act*, *supra* note 1 at s 27(3).

128 *Patent Rules*, SOR/2019-251, s 56(1)(c)–(d).

to exploit their innovation for its substantive, advantageous quality of treating schizophrenia. The patentee may sue for patent infringement if another company imitates Drug B with the same substantive, advantageous quality. However, if a company sells Drug B for another quality that is unmentioned or dissimilar to the proviso, they have not infringed the secondary patent. Perhaps another company discovers that the active ingredient in Drug B can also treat bipolar disorder or, in combination with some other isomer, treat schizophrenia for a certain class of individuals better than Drug B. This displays an advantageous, unique quality that is distinguishable from Drug B. Here, the other company's innovation would not infringe the proviso and not lead to a patent infringement.

Applying provisos will weaken the effects of evergreening and patent thickets. Once the initial patent expires, the secondary patent tapers the patentee's rights by having the secondary patent's rights only apply to the innovation's claimed substantive, advantageous, and unique utility. This weakens evergreening by limiting the market share of a secondary patent. The proviso provides other companies with more maneuverability to sell the same product for another inventive reason. As the earlier hypothetical shows, a company can enter the market to sell the polymorph found in Drug B for treating schizophrenia and bipolar disorder. Therefore, qualifying secondary patent protection to only its inventive qualities correlates to a decrease in market share that combats evergreening.

Fair competition will emerge, where companies can research and market their innovations on already marketed follow-on drugs without fear of patent infringement. This arises from provisos and their limitations eroding the strength of patent thickets, where these impervious patent protection "shields" will be chipped due to the restrictions imposed by provisos. Competitors will be less worried about accidental patent encroachments, and elaborate patent thickets will not disincentivize follow-on innovation from competitors. Companies will be more willing to research and explore highly patented drugs; knowledge exchanges and continuous, collaborative innovation will be encouraged, contributing to higher rates of follow-on innovation from competitors.

Not only will this *Patent Act* amendment function to develop a fair pharmaceutical market, but the market itself will assist with this amendment's goal to discourage anti-competitive patents and encourage genuine follow-on patents. Provisos will trouble companies that engage in follow-on innovation solely or primarily for anti-competitive purposes because, presumably, they are selling an uninventive product. The effects of anti-competitive strategy companies obtained with secondary patents will weaken, and the patent will only protect innovation with little or stodgy utility that is unlikely to extract revenue. Invoking provisos will allow companies to enter the market more efficiently, increasing competitive presence and pricing. Naturally, products representing genuine follow-on innovation will be clinically and commercially superior.

These results are instantiations of the underlying logic of the patent system: the patent system fosters monopoly but does not guarantee it. It does not guarantee a patent monopoly because a patented invention's commercial success is partially accredited to its inherent inventiveness. Canadian courts have long held commercial success as an indicium for the

"inventive ingenuity" of an invention.[129] The Supreme Court of the United States holds the same assumption.[130] Secondary patents will not provide as much protection as before; implementing provisos will incentivize inventors to conduct R&D on projects they trust will bring about market success through the invention's inventiveness. Companies engaging in genuine follow-on innovation of their previous innovations will be unaffected since they intend to benefit public health and profit through the innovation's claimed inventiveness.

Hence, adopting a proviso-based approach for secondary patents will disincentivize uninspiring, empty follow-on innovation due to the diminished market returns and weakened anti-competitive consequences from marketing these products. Conversely, gifted and authentic follow-on innovation will be incentivized due to the presumed market returns resulting from their inventiveness. This recommendation does not raise patentability standards. Unlike the *Guidelines* or Brazilian and Indian patent laws, it does not disincentivize follow-on innovation or hinder early patenting strategies. Startups will be unaffected and can continue taking on risky and novel R&D projects. Hopefully, this recommendation may soothe the blistering conflict between competition and patent law, lessening the opportunity for companies to block competition through mass patenting.

A secondary patent's proviso would not "unreasonably conflict with the…normal exploitation of the patent and…unreasonably prejudice [the patentee's] legitimate interests."[131] To meet the sufficient disclosure required for patent applications, the patent applicant must circumscribe the perimeters of the invention, identifying what the patent does and does not cover; this is the "specification" of the patent.[132] The inventive quality of follow-on innovations is its substantive, advantageous, and unique utility, which the patent application claims. Thus, the legitimate interest of a patentee is to commercialize their product for its inventive qualities. Pharmaceutical entities cannot allege that the recommended proviso conflicts with the normal exploitation of their patent because the normal exploitation of secondary patents is using the product for its claimed substantive, advantageous, and unique utility. If a company has suffered economically by focusing its R&D on dull innovation, it is not the patent's proviso that causes this economic loss. The reality is that the company has "kneecapped" itself by focusing its efforts on a product whose inventive characteristics were commercially unwanted.

IX. IMPLICATIONS AND EXTENSIONS

A. Implications

Inevitably, legislative changes produce social and legal implications. Future pharmaceutical litigation will require the courts to interpret the claims and the assigned proviso of secondary patents, which is unprecedented. However, this interpretation can be governed by the doctrine

129 *AstraZeneca Canada Inc v Apotex Inc*, 2014 FC 638 at para 342–343; *Coca-Cola Co v Canada (Attorney General)*, 2023 FC 424 at paras 50–54.

130 *KSR Int'l Co v Teleflex Inc*, 550 US 398 (2007).

131 *TRIPS*, *supra* note 92 at 26.

132 *Patent Act*, *supra* note 1 at ss 27(3)-(4).

of "purposive construction."[133] This is because the provisos for secondary patents will be derived from patent claims, so the interpretation of its claims will guide the interpretation of the proviso and allow the courts to read the patent claims and its derived proviso in the sense the patentee intended.[134] The CIPO will also be tasked with interpretative work. They must engage in quasi-purposive construction by configuring patent claims into adequate provisos. At first, it might be unusual or difficult for the CIPO to develop an approach to drafting provisos. However, the CIPO is not completely unacquainted with the use of provisos. Patent applications already allow for the use of provisos to exclude known subject-matter for the purposes of clarifying an invention's novelty or inventive step.[135] Although these provisos are applied differently, the CIPO nonetheless has experience analyzing provisos and how they interact with patent application claims. This makes this article's proposal promising with respect to its practicality.

Drug companies submitting Notice of Allegations must be informed of provisos and their respective secondary patents when navigating their intellectual property rights and alter their allegations in correspondence. *NOC Regulations* will have the new consideration that certain patents are categorized as secondary patents. If a company mistakenly believes a secondary patent to be a primary patent, the validity and success of its Notice of Allegation will be unpredictable. Over time, companies will become increasingly aware of how to manoeuvre their submissions per the distinct characteristics of secondary patents.

A potential drawback of this recommendation is its complexity. Legislative change could be more effective if kept as simple as possible to avoid misinterpretation and misapplication. As seen before, India's heightened patentability criteria for follow-on innovation were unsuccessful in its application. It follows *a fortiori* that the greater complexity of this recommendation will result in greater difficulties during application. However, the abundance of case law on selection patents provides plenty of discussion and guidance in determining the inventiveness of secondary patents. The courts, CIPO, and pharmaceutical entities can analyze this case law to predict the form a secondary patent's proviso should take.

B. Extensions

This article only recommends a *Patent Act* reform specifically for the pharmaceutical patent system. However, such a proposal may extend to other sectors where excessive patenting can actuate anti-competitive strategies, such as nanotechnology. Nanotechnological innovation is like pharmaceutical innovation in that follow-on innovation is critical to these industries. Nanotechnology companies prioritize their inventions to be smaller and compartmentalized from previous nanotechnologies. The large number of prospective secondary patents makes this article's proposal applicable.

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133 *Free World Trust*, *supra* note 119 at para 50; Purposive construction is intended to balance the needs of the patentee and public by parting from the literal interpretation of a patent's claims to determine the essential claims of the patent.

134 *Ibid* at para 51.

135 Canadian Intellectual Property Office, Manual of Patent Office Practice (Ottawa: Industry Canada, 1998) at ch 18.08, online: <ised-isde.canada.ca/site/canadian-intellectual-property-office/en/manual-patent-office-practice-mopop> [perma.cc/E4TX-7CX8].

Beyond the scope of this article's proposal, future research should address other forms of anti-competitive behaviour. This paper only mentions evergreening and patent thickets, yet many other anti-competitive behaviours exist. "Product hopping," "pay-for-delay," "patent pools," "submarine patents," and "pre-emptive patents" are all informal terms that relate to other anti-competitive practices similar to evergreening and patent thickets.[136] Anti-competitive patents can act concurrently, and considering these anti-competitive strategies can be convoluted. For example, the fragmentation of patent rights between entities which are considered to accentuate patent thicket effects.[137] The collaboration of these anti-competitive strategies may be used by companies to circumvent this article's recommendation for secondary patents and their complimentary provisos. New anti-competitive strategies will emerge in response to a legislative reform that attempts to prevent such strategies. Therefore, researching and predicting anti-competitive reactions to this article's proposal is necessary to guarantee a successful legislative amendment.

IMPORTANT TAKEAWAYS AND CONCLUSION

Creating and applying any legislative reform is extremely difficult due to the multiplicity of factors that affect and are affected by the pharmaceutical patent system. This article's proposal is not a dispositive solution to evergreening and patent thickets. However, a critical point of this article's proposal is the need to meet a "golden mean" when considering legislative reform. Proposals to combat anti-competitive patenting include raising patentability criteria. Some have advocated raising patent application fees.[138] Others have advocated fines for application rejections, aiming to encourage only promising applications.[139] Often recommended are proposals focusing on punishing wrongdoing, hoping the outcome will promote innovation. Such proposals ignore the fact that the pharmaceutical industry is highly regulated and faces numerous disheartening conditions – such as short market exclusivity and high R&D costs. This article's proposal does not worsen anyone's status, including the patentees who bear the conditions conferred by provisos. Instead, it engineers a patent system that facilitates only genuine innovation without unrealistically punishing patentees or applicants to incentivize innovation.

Pharmaceutical companies are business-oriented. Their success directly equates to their innovation output, and legislative reform should motivate innovation. Unduly burdening the parties participating in the pharmaceutical patent system will contravene this by discouraging innovation. The underlying notion of the patent system is to cultivate innovation, and this article's proposal remains deferential to this ideology.

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136 These forms of anti-competitive patenting can be used together.

137 Mahdiyeh Entezarkheir, "Patent thickets, defensive patenting, and induced R&D: an empirical analysis of the costs and potential benefits of fragmentation in patent ownership" (2017) 52 Empirical Economics 599 at 600.

138 Julien Pénin & Daniel Neicu, "Patents and Open Innovation: Bad Fences Do Not Make Good Neighbors" (2018) 25:1 Journal of Innovation Economics & Management 57 at 78.

139 *Ibid*.