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# THE BROKEN PROMISE DOCTRINE: *ASTRAZENECA CANADA INC V APOTEX INC* AND THE FUTURE OF PHARMACEUTICAL PATENTS

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## ABSTRACT

In *AstraZeneca Canada Inc v Apotex Inc,* the Supreme Court of Canada abolished the so-called promise doctrine in patent law. Large pharmaceutical companies that sought greater patent protections through litigation routinely mischaracterized the promise doctrine. To demonstrate that mischaracterization, this case comment begins by examining historical and international perspectives that informed the Supreme Court's decision. This paper then turns to a critical yet subjective element of the decision: the analysis of the meaning and purpose of "use" and "useful" in the *Patent Act.* The reasons for the decision are then considered against the advantages that more stringent utility requirements offer to both patent law and the pharmaceutical industry. This paper concludes with the recent legacy of the decision and recommendations for why and how the courts might seek a middle ground for utility promises in patents.

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## INTRODUCTION

In the 2005 decision *Merck & Co Inc v Apotex Inc*, the Federal Court of Canada confirmed and applied the test for sound prediction of utility in patent filings that the Supreme Court of Canada (the "Supreme Court") had set out two years earlier in *Apotex Inc v Wellcome Foundation Ltd*.[1] In the years following *Merck*, this approach to the utility requirement for patent validity became known in legal commentary as the promise doctrine.[2] The doctrine stipulates that any promised utility in a patent application must be fulfilled by the claimed invention. If the patent application describes no specific utility, the invention need only fulfill a mere scintilla of utility. In the eleven years following *Merck*, the Federal Court found 28 patents invalid either wholly or partially due to utility issues, representing a marked increase in such invalidations.[3] All the invalidations applied to pharmaceutical patents, three of which were wholly due to inutility. In 2017, Justice Rowe wrote a unanimous decision for the Supreme Court of Canada in *AstraZeneca Canada Inc v Apotex Inc*, effectively abolishing the promise doctrine by declaring it "not good law."[4] However, despite the unanimity, the Supreme Court's refutation of the promise doctrine is not beyond question and criticism as some of the arguments advanced are ill-founded and certain consequences of the decision are underappreciated.

This paper briefly sets out the background for *AstraZeneca* before discussing two persuasive but erroneous considerations of the Supreme Court: the promise doctrine's history and its potential conflict with treaty obligations. I then turn to the crux of the legal question unravelled by the Supreme Court: how to interpret the statutory meaning and effect of "use" and "useful." Lastly, I explore the advantages lost with the total abandonment of the promise doctrine: protections against "evergreening" patents, ensuring drug trials are of a standard, and providing access to reasonably priced, generic medications. Ultimately, *AstraZeneca* represents a needed correction towards greater fairness for the patentee but is also a missed opportunity to consolidate a middle ground for utility requirements and patent promises. In other words, the Supreme Court removed uncertainty and unfairness for patentees but, in so doing, discarded important public benefits from the patent bargain.

## I. BACKGROUND TO *ASTRAZENECA*

A patent is routinely described as a bargain struck between an inventor and the Crown: the former discloses their invention for the benefit of public knowledge and, in return, the latter grants the inventor a monopoly over that invention for a discrete period. In *Apotex*, Justice

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1 *Apotex Inc v Wellcome Foundation Ltd*, 2002 SCC 77 [*Apotex*]; *Merck & Co Inc v Apotex Inc* 2005 FC 755 [*Merck*].

2 I will use "promise doctrine" to mean the patent requirement for utility promises to be met or soundly made. Notably, "promise doctrine" was initially used by commentators to criticize the utility requirement, rather than by the courts. See Richard Gold & Michael Shortt, "The Promise of the Patent in Canada and Around the World" (2013) 30:1 CIPR 35.

3 Kristina M Lybecker, "Intellectual Property Rights Protection and the Biopharmaceutical Industry": How Canada Measures Up" (2017), online (pdf): *Fraser Institute* <fraserinstitute.org> [perma.cc/7MH6-5R98].

4 *AstraZeneca Canada Inc v Apotex Inc*, 2017 SCC 36 at para 51 [*AstraZeneca*].

Binnie characterized disclosure in a patent application as "the quid pro quo for valuable proprietary rights to exclusivity which are entirely the statutory creature of the *Patent Act*."[5] Despite the common claim that patent law is an equal and universal set of rules for all varieties of invention, the patent bargain for pharmaceutical inventions is unique. The *Patent Act* includes many sections specific to medicines, including section 76.1 and sections 79–134, tallying to more than a third of that act.[6] In addition, there is an immense amount of special regulation for the creation, production, and marketing of pharmaceutical inventions.[7]

The public has a special interest in the disclosure of pharmaceutical inventions because of potential health benefits from the development of novel therapies. However, the patentee's monopoly can result in prohibitively high costs for desperately needed drugs.[8] To ameliorate this potential conflict, there are several regulatory instruments for balancing innovator and public interests in patented medicines, including the *Patented Medicines (Notice of Compliance) Regulations* ("*NOC Regulations*") and Canada's *Food and Drug Regulations*.[9] Nonetheless, the *Patent Act* is at the center of the disclosure-for-protection arrangement relating to pharmaceutical inventions.

Like many major pharmaceutical patent cases, *AstraZeneca* involved a large pharmaceutical research and development company litigating against a generic drug manufacturer, Apotex Inc. ("Apotex"). The drug in question was esomeprazole (marketed as Nexium), a proton pump inhibitor used in the reduction of gastric acid and the treatment of reflux esophagitis and related maladies. The appellant sought to overturn the Federal Court of Appeal's invalidation of their patent for esomeprazole, the 2,139,653 patent ("'653 patent"). The respondent, Apotex, had been granted permission under the *NOC Regulations* to sell a generic version of the appellant's successful drug, contrary to the appellant's presumed patent rights. AstraZeneca Canada Inc. ("AstraZeneca Inc.") had initially applied to have the generic drug prohibited under the *NOC Regulations*. The Ministry of Health rejected that application, and Apotex subsequently began to sell its generic version of the drug. AstraZeneca Inc. brought an action against Apotex for patent infringement, and Apotex counter-claimed to have the '653 patent declared invalid. Writing for the Federal Court of Appeal, Justice Rennie noted that the '653 patent contained two promises: 1) that the optically pure salt of esomeprazole would be useful as a proton pump inhibitor; and 2) that esomeprazole provided an improved therapeutic profile over the chemical's racemate omeprazole.[10] The Appellate Court found no demonstration or sound prediction of this second promise at the filing date and consequently invalidated the '653 patent.[11]

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5 *Apotex*, *supra* note 1 at para 37.

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

7 Lybecker, *supra* note 3 at 7.

8 John Ivison, "The Math of Saving Lives — Canada's Drug Battle Leaves Patients Caught in the Middle" *National Post* (31 Oct 2020), online: <nationalpost.com/opinion/john-ivison-the-mathof-Saving-lives-canadas-drug-battle-leaves-patients-caught-in-the-middle> [perma.cc/P88J-NMLV].

9 *Patented Medicines (Notice of Compliance) Regulations*, SOR/1993-133; *Food and Drug Regulations*, CRC 2020, c 870.

10 *AstraZeneca Canada Inc v Apotex Inc*, 2014 FC 638 at para 86.

11 John Norman & Alex Gloor, "Canada's Supreme Court Abolishes 'Promise of the Patent'" (2017) 7:1 Pharmaceutical Patent Analyst 1.

On appeal, the Supreme Court scrutinized and rejected the promise doctrine as a question of law and, therefore, held AstraZeneca Inc.'s patent to be valid. The Supreme Court held the promise doctrine to be an extra-statutory requirement in a purely statutory area of law. The doctrine was inimical to the patent bargain because it potentially discouraged full disclosure by patent applicants apprehensive of promising anything that appeared to not be "sufficiently demonstrated or soundly predicted by the filing date."[12] Policy-based criticisms described the promise doctrine as a notorious obstacle and an element of uncertainty for intellectual property protections, making Canada a less inviting arena for innovation investment.[13] The Supreme Court's decision followed the oft-cited observation that the promise doctrine imposed a singularly high standard for utility, unlike any other national or regional patenting schemes.[14] This observation, however, is inaccurate and misleading.

## II. LEGAL HISTORY AND INTERNATIONAL COMPARISONS

In *AstraZeneca*, the Supreme Court referred to the research of Norman Siebrasse, an expert in Canadian intellectual property law. Siebrasse characterizes the doctrine as a legal construct abandoned in English law and inadvertently straying into Canadian jurisprudence.[15] Siebrasse's assessment of the promise doctrine—as a historical oddity without current-day equivalents in other jurisdictions—is patently wrong. The research of two Montreal-based authorities in intellectual property Richard Gold and Michael Shortt rigorously refuted many of Siebrasse's characterizations of Canada's pre-*AstraZeneca* utility requirement.[16] Gold and Shortt demonstrate that "the promise of the patent has a long history in Canadian and British (pre-1977) patent law, and that similar tests are used in other Commonwealth countries, notably Australia and New Zealand."[17] The Australian utility requirement in patent law is remarkably similar, reading as "claims that do not fulfil each aspect of the stated advantages listed in the patent specification will fail."[18] Canada's promise doctrine was not as inconsistent with other national and regional patent regimes as Siebrasse and many other commentators insisted.[19] There are also analogs in European and American patenting schemes.[20] In 2005, for instance, US courts addressed overly broad claims in pharmaceutical patents by raising the utility requirement to "specific and substantial utility."[21] Despite these analogous approaches to utility and promise, some academics

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12 *AstraZeneca*, *supra* note 4 at para 50.

13 Norman & Gloor, *supra* note 11 at 2.

14 *AstraZeneca*, *supra* note 4 at para 21.

15 Norman Siebrasse, "The False Doctrine of False Promise" (2013) 29 CIPR 3, cited in *AstraZeneca*, *supra* note 4 at paras 33–35.

16 Gold & Shortt, *supra* note 2. See also Norman Siebrasse, "Form and Function in the Law of Utility: A Reply to Gold & Shortt" (2015) 30:2 CIPR 109.

17 Jerome H Reichman, "Compliance of Canada's Utility Doctrine with International Minimum Standards of Patent Protection" (2014) 108 Proceedings Annual Meeting Am Society Intl L 313 at 314. See Gold & Shortt, *supra* note 2.

18 Jane Nielsen & Dianne Nicol, "Patent Law and the March of Technology – Did the Productivity Commission Get It Right?" (2017) 28:1 Australian Intellectual Property J 4.

19 Gold & Shortt, *supra* note 2; Reichman, *supra* note 17.

20 Gold & Shortt, *supra* note 2.

21 Reichman, *supra* note 17 at 314.

and commentators depicted the promise doctrine as rendering "Canadian law highly divergent from the worldwide norm."[22] This view bolstered the ill-founded arguments that Canadian utility requirements breached international treaty obligations.

## III. INTERNATIONAL OBLIGATIONS

In the period preceding *AstraZeneca*, many academics, lobbyists, advisors, and jurists argued that Canada's patent utility standard was higher than, and inconsistent with, international norms. The utility standard, which represented the lowest hurdle in patenting before *Merck*, became a major stumbling block for pharmaceutical companies regarding intellectual property rights protection in Canada.[23] According to a 2017 Fraser Institute report, Canada's patent utility requirement "creates significant uncertainty for innovators and undermines the incentives for investment, especially in the biopharmaceutical sector."[24] However, such industry analyses routinely included mistakes and inaccuracies about the legal relationship of promises, utility, and validity. For instance, the Fraser Institute report wrongly noted that a drug patent would be invalidated if an additional application for the drug was discovered after the patent was granted.[25]

A more common error was cited by Fédération internationale des conseils en propriété intellectuelle, an intervenor at the Supreme Court on behalf of AstraZenca Inc. That intervenor argued that Canada's promise doctrine was so at variance with international standards as to be in breach of obligations under the *North American Free Trade Agreement* ("*NAFTA*") and the World Trade Organization's *Agreement on Trade-Related Aspects of Intellectual Property Rights* ("*TRIPS*").[26] These treaties purportedly created an obligation to directly align Canadian patent law with American practices. Such claims cropped up in financial reports, industry summaries, and law reviews, occasionally with unfettered hyperbole: "a new, unprecedented super-utility test is introduced [in Canada] that goes radically far beyond the traditional test (in place when [*TRIPS*] was signed), that new test violates the treaty obligation."[27] Contrary to what many legal writers believed, no international agreement obliges Canada to keep its laws static or fixedly aligned with American standards. As American professor of intellectual property law Jerome Reichmann observes, such an obligation would be akin to France prescribing uniform patent law since 1883, following the adoption of the Paris Convention.[28] Yet, this same argument was at the center of similar patent litigation initiated by another major pharmaceutical company and running concurrent to *AstraZeneca.*

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22 Robert Merges, "National Sovereignty and International Patent Law" (2019) Mich L Rev 1249.

23 Lybecker, *supra* note 3.

24 *Ibid* at 14.

25 *Ibid* at 15.

26 John McDermid, "A NAFTA Challenge to Canada's Patent Utility Doctrine is Necessary" (11 June 2014), IP Watchdog (blog), online: <www.ipwatchdog.com/2014/06/11/a-nafta-challengeto-canadas-patent-utility-doctrine-is-necessary/id=49994/> [perma.cc/AXP8-GBJS].

27 Merges, *supra* note 22 at 1274.

28 Reichman, *supra* note 17 at 317.

*Eli Lilly and Company v The Government of Canada* was heard by the International Centre for Settlement of Investment Disputes ("ICSID").[29] The case relates to patents for olanzapine (Zyprexa) and atomoxetine (Strattera) that the pharmaceutical company, Eli Lilly and Company ("Eli Lilly"), had lost in Canada partly due to their not meeting the promised utility. For instance, Eli Lilly's Canadian patent for Strattera claimed effective long-term treatment of attention-deficit/hyperactivity disorder ("ADHD"). In support of their promise, Eli Lilly disclosed their pilot study of 21 patients treated over seven weeks with Strattera. Eleven of the patients showed a 30 percent or greater reduction in ADHD symptoms during the study.[30] The Canadian Federal Court found this study to fall short of a sufficiently demonstrated or soundly predicted promise.[31] With much noise and sabre-rattling, Eli Lilly launched a suit against Canada, claiming a breach of international treaty obligations under *NAFTA* and *TRIPS*.[32] While advancing this claim against Canada, Eli Lilly remained quiet about the invalidation of its Strattera patent by the U.S. District Court of New Jersey on inutility grounds just prior to the Canadian Federal Court's decision.[33] To Eli Lilly's disappointment, and in direct refutation of those suggesting the promise doctrine was a radical new invention in Canadian law, the ICSID Tribunal found that "Canada's current promise utility doctrine was somehow part of Canadian law when Lilly's patents were granted."[34] This decision confirmed state sovereignty in determining and balancing national patent schemes and public interests; it also put to rest arguments that Canada's promise doctrine is at odds with treaty obligations.[35]

## IV. "USE" AND "USEFUL"

Patent law is a statutory creation that is revealed and fine-tuned by judicial interpretation. Section 2 of the *Patent Act* defines "invention" as "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."[36] Subsection 27(3) sets out the requirements for patent applications, including that specifications:

> (a) correctly and fully describe the invention and its operation or use as contemplated by the inventor;

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29 *Eli Lilly and Company v The Government of Canada*, UNCITRAL, ICSID Case No. UNCT/14/2.

30 Merges, *supra* note 22 at 1274–75.

31 *Eli Lilly & Co v Teva Canada Ltd,* 2011 FCA 220.

32 James Billingsley, "*Eli Lilly and Company v The Government of Canada* and the Perils of Investor-State Arbitration" (2015) 20 Appeal 27 at 27.

33 Brook K Baker & Katrina Geddes, "Corporate Power Unbound: Investor-State Arbitration of IP Monopolies on Medicines – Eli Lilly v. Canada and the Trans-Pacific Partnership Agreement" (2015) 23:1 J Intell Prop L 1 at 40.

34 Paul Webster, "Canada Wins Legal Battle to Set Patent Rules" (2017) 189:15 Can Med Assoc J E578, online: <www.cmaj.ca/content/189/15/E578> [perma.cc/U3DL-XAZZ].

35 These issues were thrown into sharp relief by the recent Investor-State Dispute Settlement mechanism introduced in the Trans-Pacific Partnership. See Rochelle Cooper Dreyfuss & Susy Frankel, "Reconceptualizing ISDS: When Is IP an Investment and How Much Can States Regulate It" (2018) New York University School of Law [working paper].

36 *Patent Act*, *supra* note 6.

> (b) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it.[37]

The Supreme Court has repeatedly stated that patent law is wholly statutory. Yet, the courts interpret and apply that statutory law with reference to jurisprudence. To elucidate the utility requirements set out in sections 2 and 27(3) of the *Patent Act*, Canadian courts routinely refer to the landmark Supreme Court decision *Consolboard Inc v MacMillan Bloedel (Sask) Ltd.*[38] As Justice Dickson stated in *Consolboard*, a patent is "not useful" if it "will not do what the specification promises that it will do."[39] In *AstraZeneca*, the Supreme Court offered a *de minimis* interpretation of "useful," construing it to mean "any single use of that subject-matter that is demonstrated or soundly predicted by the filing date is sufficient to make an invention useful for the purposes of s. 2."[40] The purpose of the section 2 utility requirement is, according to the reasoning in *AstraZeneca*, "to prevent the patenting of fanciful, speculative or inoperable inventions."[41] If a patent description fails to meet the section 2 requirement, it is not an invention and is therefore unpatentable or invalid.

The promise doctrine derived from a constructive interpretation, which held the utility requirement as both a matter of disclosure (section 27) and a principal part of defining invention (section 2).[42] However, courts interpreted utility promises disclosed for section 27 purposes as setting the standard for section 2 utility requirements, leading to severe all-or-nothing results in validity disputes. A seemingly small mistake could unfairly lead to complete invalidation. Yet, as Gold and Shortt reason, "it would be unjust if the patentee suffered no disadvantage when it subsequently came to light that he or she did not, in fact, have a sufficient basis on which to support the promise on the filing date."[43] The promise doctrine functioned as a mechanism to ensure an invention's usefulness derived from sufficient demonstrations or sound predictions rather than misleading fabrications or groundless speculations. For pharmaceutical patents, use is crucial to defining the invention. Even a person skilled in the art or science (a "POSITA") needs to be told what a new pharmacological compound does.[44] Esomeprazole, sildenafil, or atomoxetine did not have apparent or implicit uses. As inventions, these compounds are defined by their physiological actions and therapeutic applications. In other words, the use of these compounds, as described in the patent application, is essential to their definition as inventions.

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37 *Ibid*.

38 *Consolboard Inc v MacMillan Bloedel (Sask) Ltd*, [1981] 1 SCR 504.

39 *Ibid* at 525, Dickson quoting Halsbury's Laws of England, (3rd ed).

40 *AstraZeneca, supra* note 4 at para 49.

41 *Ibid* at para 57.

42 *Ibid* at para 31.

43 Gold & Shortt, *supra* note 2 at 40.

44 POSITA properly refers to a person of ordinary skill in the art, the approximate equivalent of Canada's legal fiction.

A balance should be struck between requiring a full disclosure that soundly promises what a would-be invention does and allowing for reasonable mistakes in those promises. A candid and reasonable disclosure of potential utility should not result in a fatal "self-inflicted wound," to use Justice Pelletier's phrase.[45] On the other hand, it is unfair to grant a patent and, in so doing, a major competitive advantage for a drug without reasonably certain or reliably predicted uses. Nor is it fair to grant patents with multiple false or speculative promises that mislead competitors and the public. This balance does not square easily with Justice Rowe's pronouncement that "promises are not the yardstick against which utility is to be measured."[46] If a patent applicant's promises about use do not speak to their prospective invention's utility, what purpose do such promises serve and how is utility to be discerned? Moreover, requiring only a mere scintilla of use will not prevent "the patenting of fanciful, speculative or inoperable inventions."[47] As the Supreme Court noted, the creation of statutes is a legislative prerogative. However, the interpretation of statutes is the responsibility of the courts. The Supreme Court chose a pared-down interpretation of utility requirements, leaving it as a meager statutory condition. The relative centrality of "use" and "useful" in the *Patent Act* conveys a more significant meaning. Requiring a full disclosure of a prospective invention's use based on soundly predicted and sufficiently demonstrated promises is a standard that strikes an appropriate balance between the interests of the patentee and the public.

## V. ADVANTAGES OF KEEPING PROMISES

The *Patent Act* is designed to apply special scrutiny to medicines. The promise doctrine was, in effect, an additional restriction on granting advantageous patent protections to innovator pharmaceutical companies. A meaningful utility requirement provides many benefits for the public but also the pharmaceutical industry.

For the public, scrutiny of pharmaceutical patents helps moderate prohibitively high costs and restricted access to valuable medical treatments. This issue is so pressing that the US Congress introduced legislation attempting to remedy the high costs of pharmaceuticals by allowing third-party importation of pharmaceuticals, thereby sidestepping their own patent scheme.[48] The promise doctrine ensured that pharmaceutical innovators did not obtain a legal monopoly on the basis of speculative claims about increased utility—especially claims about therapeutic efficacy—that were unsubstantiated at the time of filing.[49] Uncertainty in the patent scheme leads to higher application and litigation costs, which, in turn, adds to the costs incurred by pharmaceutical developers and their customers. A clear and robust utility requirement results in either better quality patent applications by pharmaceutical innovators or the invalidation of patents allowing for use by generic producers. Such a requirement also prevents so-called evergreening of pharmaceutical patents. Evergreening occurs when patents

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45 *Sanofi-Aventis v Apotex Inc.*, 2013 FCA 186 at para 54.

46 *AstraZeneca, supra* note 4 at para 63.

47 *Ibid* at para 57.

48 Frederick M Abbott, "Legislative and Regulatory Takings of Intellectual Property: Early Stage Intervention Against a New Jurisprudential Virus" in Carlos M Correa & Xavier Seuba, eds, *Intellectual Property Development: Understanding Interfaces* (Singapore: Springer Nature Singapore, 2019) 21 at 22.

49 Reichman, *supra* note 17 at 313.

are sought for minor variations to existing patented products, thereby lengthening the effective term of the patent holder's monopoly, and thus keeping drug prices high.[50] Pharmaceutical companies attempt this through selection patents, which claim a new patent for a small number of compounds within a larger category of previously patented compounds.[51] In protecting against evergreening, Canadian law guarantees the availability of generic drugs in Canada without undue delay.[52]

For the pharmaceutical industry, there are also advantages to a more stringent utility requirement that holds would-be patentees to their promises. More rigorous utility standards guard against false claims and overpromises, ultimately encouraging fair and open competition. As the Supreme Court noted in *AstraZeneca*, the *Patent Act* guards against the mischief of overpromising. Section 27(3) of the *Patent Act* requires correct and full disclosure that includes substantiated uses or operation.[53] Section 53 stipulates that a promise "wilfully made for the purpose of misleading" can void a patent. Overly broad claims can also be declared invalid (although remaining valid claims can be saved by section 58). Yet, under the current patent regime, pharmaceutical companies file as early as possible, often sacrificing conclusive results for the competitive advantage of a patent.[54] This over-eager filing promotes overpromise. Patent application examiners may be convinced of an invention by impressive promises of utility.[55] A minimal utility requirement also impairs "follow-on" innovators by allowing for ill-devised patents with broad, speculative claims.[56] Canada suffers from a low number of small and medium-sized pharmaceutical companies.[57] Narrowing patents through stricter utility requirements could promote smaller pharmaceutical developers that tend to pursue follow-on innovations.[58] The promise of the patent ensures that patentees are careful and disciplined in drafting applications, and eventually realize the promises they disclosed.[59] The promise doctrine also has the potential to encourage and regulate reproducibility within science innovation, which is an expanding crisis.[60] Robust utility requirements can correct some of the problems now plaguing the pharmaceutical industry.

A more-than-minimal utility requirement that enforces patent promises also protects against fraudulent medical products. Some bemoaned the constraints that the promise doctrine placed on the medical industry and especially in the patenting of alternative therapies.

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50 Arne Ruckert, Ashley Schram & Ronald Labonté, "The Trans-Pacific Partnership Agreement: Trading Away our Health?" (2015) 106:4 Canadian Public Health Association 249.

51 Reichman, *supra* note 17 at 313.

52 Webster, *supra* note 34.

53 *AstraZeneca*, *supra* note 4 at para 46.

54 Jacob S Sherkow, "Patents, Promises, and Reproductibility" (2017) 49 Geo J Intl L.

55 *Ibid*.

56 Nielsen & Nicol, *supra* note 18; Norman Siebrasse, "Overbreadth in Canadian Patent Law" (2019) SSRN Electron J (preprint), online: <papers.ssrn.com/abstract=3393044> [perma.cc/2CWA-LQRC].

57 "CABC Policy Recommendations to Enhance Innovation in Canada" (summer 2016), Canadian American Business Council (report), at 22–23, online: <cabc.co/wp-content/uploads/2020/06/CABC_innovation_paper.pdf> [perma.cc/29W9-2RR4].

58 *Ibid*.

59 Nielsen & Nicol, *supra* note 18.

60 Sherkow, *supra* note 54.

For instance, a research paper published in the *Boston College Intellectual Property and Technology Forum* challenged this very issue regarding unproven ultraviolet light therapy for treating Lyme disease.[61] Contrary to what that author argues, the gatekeeping effect of the promise doctrine is a valuable social benefit. Alternative medicines of unproven efficacy are roundly disparaged by reputable health authorities and professionals as grievous impositions on the public, and especially the ailing and the vulnerable.[62] The health and finances of Canadians are better off if unproven "cures" and speculative treatments with no demonstrable use remain unpatentable. The history of pharmaceuticals illuminates this gatekeeping feature of patent law. Prior to the twentieth century, American medical professionals generally viewed pharmaceutical patents as unethical.[63] Medicines that typically had proprietary protections were then known as patent medicines—remedies and nostra of uncertain virtue granted patent letters and representing notorious impositions on the public. The history of patent law reveals its crucial role as a quality check on medicines that cannot fulfil a promised use. As Eli Lilly's Strattera aptly instances, new drugs without proven or demonstrated therapeutic use should not receive the benefit of a patent.

By encouraging competition from other pharmaceutical companies of various sizes and kinds, less intervention is required in the pharmaceutical market through the patent bargain and government actors. As a single-payer insurer, Canada mandates the Patented Medicine Prices Review Board to negotiate prices for pharmaceuticals under patent protection. A return to a mere scintilla utility requirement further strains the bargaining between pharmaceutical innovators and the public.

## CONCLUSION

Innovator pharmaceutical companies are at the forefront of the legal resistance to the utility requirements, and for good reason, as patent litigation is largely directed at pharmaceutical patents. In that effort, *AstraZeneca* represents a major win. This decision was predicted to benefit innovators in high-technology areas, especially pharmaceutical patent applicants.[64] *AstraZeneca* is now a well-cited decision, appearing in no less than 41 decisions in the subsequent three years to date. Cases citing *AstraZeneca* have mostly involved patent claims for pharmaceuticals, but also include patents relating to everything from natural gas pipelines, packing wrap, and track assemblies on all-terrain vehicles to ice skates, gaming software, and digital networks of patient files. Ultimately, the Supreme Court pursued fairness in the patent bargain and, in doing so, instanced the true impartiality of the courts, with no special preference given to a particular industry, the Canadian government, or the public.[65] For pharmaceutical companies, the doctrine resulted in severe and unfair consequences for promises disclosed in

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61 Sarah Murphy, "The Patent Utility Requirement and its Impact on Alternative Medical Treatments for Lyme Disease" (2017) Boston College Intellectual Property and Technology Forum 1.

62 Franklin G Miller et al, "Ethical Issues Concerning Research in Complementary and Alternative Medicine" (2004) 291:5 JAMA 599.

63 Joseph M Gabriel, *Medical Monopoly: Intellectual Property Rights and the Origins of the Modern Pharmaceutical Industry* (Chicago: University of Chicago Press, 2014) at 7– 41.

64 Nielsen & Nicol, *supra* note 18 at 19.

65 Contrary to the assertions made by Eli Lilly.

good faith that remained—contrary to reasonable expectation—unrealized.

However, in doing away with the promise doctrine, the Supreme Court may have discarded real benefits for the public and the pharmaceutical industry. The Supreme Court heard and cited misleading arguments about the legal history and international analogs of the promise doctrine. These arguments were not only incorrect but also distracted from the real issue: the proper interpretation of "use" and "useful" as a patent requirement. That issue allows for consideration of the patent bargain and the proper role of promises about utility. The courts have articulated that such promises should be "sufficiently demonstrated or soundly predicted by the filing date."[66] For the sake of fair patent practices, upholding patent standards, and guarding against unproven medicines, these promises should be closely scrutinized by the courts. A patent should fail to the extent that its subject matter relates to a promise made without sufficient demonstration or sound prediction. If that promised use is central to the subject matter of the invention, the patent should fail entirely. If that promised use relates to an ancillary aspect of the invention, the patent should fail to the extent of that promise for the invention. In the absence of statutory amendment, this interpretation is in keeping with the legislative intention of the *Patent Act*, encourages careful disclosure, ensures public benefit in exchange for the monopoly, and significantly improves the operation of patents. Some promises are meant to be kept.

66 *AstraZeneca*, *supra* note 4 at para 50.