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Promise Doctrine: Made to be Broken? Patent Law after *AstraZeneca**

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Abstract

In *AstraZeneca Canada Inc. v. Apotex Inc.*, 2017 SCC 36, the Supreme Court of Canada finally examined, and overturned, the Promise Doctrine. The Promise Doctrine had gradually emerged as the standard by which the Federal Courts determined whether a patent met the utility requirement for patentability. In this article, we examine the Supreme Court of Canada's decision and its new framework for utility, where the focus of the analysis is now the "subject-matter of the invention as claimed in the patent." We argue that with a renewed focus on the claims, this new framework paves the way to a more harmonious approach to patent law in Canada – one where the same "invention" is assessed for all purposes, and the "patent bargain" reflects not what is written in the patent itself, but rather the conditions for patentability in the *Patent Act*. We also address how the Federal Courts have interpreted the Supreme Court's decision since its release.

Résumé

Dans l'affaire *AstraZeneca Canada Inc. c. Apotex inc.*, 2017 CSC 36, la Cour suprême du Canada a finalement examiné et renversé la doctrine de la promesse. La doctrine de la promesse est progressivement devenue la norme adoptée par les tribunaux fédéraux pour déterminer la question à savoir si un brevet satisfait l'exigence d'utilité à titre de condition de brevetabilité. Dans cet article, nous examinons la décision rendue par la Cour suprême du Canada et son nouveau cadre d'utilité dans lequel l'emphase de l'analyse est désormais « l'objet de l'invention qui est revendiqué dans le brevet ». Nous prétendons qu'en raison de l'emphase réorientée des revendications, ce nouveau cadre ouvre la voie vers une approche plus harmonisée sur le droit des brevets au Canada – une approche selon laquelle la même « invention » est évaluée à toutes fins et le « pacte du brevet » ne reflète pas le libellé du brevet, mais plutôt les conditions de brevetabilité énoncées dans la *Loi sur les brevets*. Nous traiterons également de la façon dont les tribunaux fédéraux ont interprété la décision de la Cour suprême depuis sa publication.

Contents

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** Yael, Jon, and Andrew are litigation lawyers at Torys LLP. They have contributed this paper to provide their thoughts on recent cases, not so it can be cited against them in future ones. Obviously the law will continue to evolve and develop, and they will have to take various positions on behalf of their clients that may or may not be consistent with their own private opinions on this subject. So please don't throw the paper into your next argument case against our firm and tell the Court "even counsel for … thinks …" That just discourages the bar from contributing to thinking in this area, which seems to us to be an undesirable outcome. Thanks!

1.0 Introduction

In the early 2000s, the Promise Doctrine gradually emerged as the standard by which the Federal Courts determined whether a patent met the utility requirement for patentability. The doctrine had a plausible jurisprudential basis, most notably in the Supreme Court of Canada's decision in *Consolboard*. It also had a plausible theoretical basis in the "patent bargain" theory, in which the disclosure of an invention was viewed as the figurative *quid pro quo* for the patent monopoly. However, after several years of over-literal application by the Federal Courts, primarily in the context of pharmaceutical patents, it became clear that the doctrine led to absurd results. Patents for extremely useful inventions, where utility was not based on speculation but rather on a compound's biological activity, were invalidated on the basis of so-called "promises" made in the specification. These promises were typically based on language that spoke to the invention's potential benefits, such as fewer side effects, or the ability to be used chronically. The doctrine also often led to different inventions being assessed for different purposes: for novelty and non-obviousness, courts focused on the claimed invention; however, for utility, the "invention" could include a number of other properties and advantages based on "promises" made in the specification. Where those promises were not met at the time of filing (because they were not demonstrated and could not necessarily be soundly predicted), the "invention" lacked utility and the patent was invalid.

In *AstraZeneca Canada Inc. v. Apotex Inc.*,[1] the Supreme Court of Canada finally examined, and overturned, the Promise Doctrine. In doing so, the Court set out a new framework for utility, where the focus of the analysis is the "subject-matter of the invention as claimed in the patent." As we explain below, with a renewed focus on the claims, this new framework paves the way to a more harmonious approach to patent law in Canada – one where the same "invention" is assessed for all purposes, and the "patent bargain" reflects not what is written in the patent itself, but rather the conditions for patentability in the *Patent Act*.

2.0 The Rise and Fall of the Promise Doctrine

In 2002, the Supreme Court of Canada issued its landmark decision in *Apotex Inc. v. Wellcome Foundation Ltd.*[2] In the decision, the Court confirmed that the relevant time for assessing the utility of an invention was not when the patent was challenged. Rather, utility had to be either demonstrated or soundly predicted at the time the patent was filed.[3] Of course, that led to the question "what is it that has to be demonstrated or predicted?" Beginning in the early to mid-2000s, courts began to answer that question using what became known as the "Promise Doctrine."[4]

The utility requirement stems from section 2 of the *Patent Act*, which defines an "invention" as something "new and useful."[5] Historically, the standard for utility was fairly low – as long as the invention had a "scintilla" of utility, the requirement was satisfied.[6] While the Supreme Court's decision in *Wellcome* established that the time for assessing the utility requirement was at the time of filing (as opposed to the time of the challenge), the Promise Doctrine set out a new standard for utility. It required that in order to establish utility, the invention had to do what the "patent promises" it would do. As the Federal Court of Appeal explained:

> Where the specification does not promise a specific result, no particular level of utility is required; a "mere scintilla" of utility will suffice. However, where the specification sets out an explicit "promise", utility will be measured against that promise.[7]

The combination of the requirement that utility be assessed at the time of filing and the emergence of the Promise Doctrine proved to be a potent combination for invalidating patents, especially in pharmaceutical cases. Since patents are typically filed in the early stages of drug development, only limited data is usually available to the inventors at the time the patent is filed. The Promise Doctrine allowed challengers to argue that the patent contained numerous "promises" that set thresholds for utility that were out of touch with the reality of drug development. Since the available data could often not form the basis for soundly predicting that these promises would be met, the patents were invalid. For example, in his 2013 article on the Promise Doctrine, Norman Siebrasse concluded that of the 20 cases since 2005 in which the promise of the patent was a live issue, the courts construed the promised utility against the patentee in 12 cases, leading to a finding of invalidity in five cases.[8]

2.1 The Promise Doctrine: A Promising Beginning

When it was first argued and accepted by the Federal Courts, the Promise Doctrine appeared to have two important ingredients that would lead to its adoption by Canadian courts: it had some basis in the jurisprudence, and (at least at first glance) appeared consistent with the

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1 2017 SCC 36 *[AstraZeneca SCC]*.

2 2002 SCC 77 *[Wellcome]*.

3 The doctrine of sound prediction has its roots in *Monsanto Company v. Commissioner of Patents,* [1979] 2 S.C.R. 1108, where the Supreme Court of Canada held that claims could only be rejected for lack of utility if there is evidence of lack of utility in respect of some area covered by the claim, or if there is no sound prediction.

4 See for example, *Apotex Inc. v. Wellcome Foundation Ltd.*, [2001] 1 FC 495, at para. 53 (F.C.A.); *Bayer AG v. Apotex Inc.*, 2003 FC 1199, at paras. 21, 83; *Aventis Pharma Inc. v. Apotex Inc.* 2005 FC 1283, at paras. 276-280.

5 *Patent Act,* R.S.C. 1985, c. P-4, s. 2.

6 See *Fox on the Canadian Law of Patents,* 5th ed. by Donald H. MacOdrum, (Toronto: Thomson Reuters, 2013) (loose-leaf revision 2018-1) at §6:6, citing *Prentice v. Dominion Rubber Co.*, [1928] Ex. C.R. 196 ("A definite amount of utility is not required by law to sustain an invention; a slight amount of utility is sufficient.").

7 *Eli Lilly Canada Inc. v. Novopharm Limited,* 2010 FCA 197, at para. 76.

8 Norman Siebrasse, "The False Doctrine of False Promise" (2013), 29 C.I.P.R. 3 at 33.

long-standing idea of a patent as a "bargain" between an inventor and the public.

The promise doctrine's kernel of jurisprudential support arose from Supreme Court of Canada (and U.K.) jurisprudence.[9] While there is support for the doctrine in earlier cases, courts have most frequently relied on the Supreme Court's decision in *Consolboard*.[10] In that case, Justice Dickson was describing the disclosure requirements under the pre-1989 *Patent Act*. He held that a patentee does not need to disclose the utility of an invention in the specification.[11] In reaching this conclusion, Justice Dickson defined "not useful" to mean "that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do."[12] Although this definition was not at issue in the case, *Consolboard* planted the seed of the Promise Doctrine in Canada.

The Promise Doctrine also had some intuitive appeal. It appeared to be consistent with the "bargain theory" of patent law where the "bargain" is that an inventor makes a new invention and discloses it to the public in a patent application, and in exchange, gets a temporary monopoly over its use. But, of course, that disclosure has to be accurate. An inventor who "over-promises and under-delivers" in his patent specification should not, according to this theory, be permitted to keep the monopoly that was granted in reliance.

This all sounds good or, dare we say, promising. The problem turned out not to be in the theory, but rather in the application. Instead of a common-sense reading of patent applications as reflecting useful inventions and aspirations for their application, courts, spurred on by patent challengers and their experts, began to read patent specifications as actual contracts, with a literalism previously unknown to law (or common sense). Worse yet, like contracts, the courts began to "imply" obligations that the inventors never intended and then invalidated patents on this basis. This caused the Promise Doctrine to spiral out of control, wreaking havoc with the Canadian patent system and earning Canada a reputation as an unfriendly country for innovators.[13] As a unanimous Supreme Court recently concluded, at the end of the day, the promise doctrine was "not good law."[14]

2.2 *AstraZeneca Canada Inc. v. Apotex Inc.*: the End of the Promise Doctrine

The Promise Doctrine finally met its end in the Supreme Court of Canada's decision in *AstraZeneca Canada Inc. v. Apotex Inc.* AstraZeneca is the owner of the patent that claims the optically pure salts of the (-) enantiomer of omeprazole, esomeprazole. Esomeprazole is a proton pump inhibitor that was commercialized under the name Nexium®. It is used in the reduction of gastric acid, reflux esophagitis and related maladies. Apotex brought a generic version of esomeprazole to market, and AstraZeneca commenced an action for patent infringement.[15] Apotex counterclaimed on the basis that the patent was invalid.

2.2.1 The Federal Court and the Federal Court of Appeal Decisions

Justice Rennie, a well-respected and thoughtful Federal Court judge, later promoted to the Federal Court of Appeal, heard the infringement action and found that while the invention was not obvious, the patent was invalid for lack of utility.[16]

Applying the Promise Doctrine, Justice Rennie explained that "the promise of the patent is the yardstick against which utility is measured."[17] Both sides' experts agreed that the patent promised that the compounds would be useful as a proton pump inhibitor. But they disagreed on whether the patent's promise of improved metabolic and pharmacokinetic properties included an improved therapeutic profile such as a lower degree of interindividual variation.[18] The case turned on a single passage in the disclosure:

> It is desirable to obtain compounds with improved pharmacokinetic and metabolic properties which will give an improved therapeutic profile such as a lower degree of interindividual variation. The present invention provides such compounds, which are novel salts of single enantiomers of omeprazole. ('653 patent, page 1, lines 18-22; emphasis added).

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9 Norman Siebrasse has outlined the history of the Promise Doctrine in detail in his article, *ibid.* He notes that this doctrine existed in England because courts were unwilling to second-guess the Crown's exercise of discretion in granting a patent. This patent system is no longer the law in England.

10 E. Richard Gold and Michael Shortt, "The Promise of the Patent in Canada and Around the World" (2014), 30 C.I.P.R. 35 at 54; *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.,* [1981] 1 S.C.R. 504 *[Consolboard].*

11 *Consolboard, supra* note 11, at 526.

12 *Consolboard, supra* note 11, at 525 [emphasis added].

13 In the 2015 Special 301 Report of the Office of the United States Trade Representative, Canada continued to appear on the "Watch List," in part because "courts have invalidated valuable patents held by U.S. pharmaceutical companies on utility grounds, by interpreting the 'promise' of the patent and finding that insufficient information was provided in the application to substantiate that promise." The report notes that these "recent decisions, which have affected products that have been in the market and benefiting patients for years, have led to uncertainty for patent holders and applicants, including with respect to how to effectively meet this standard."

14 *AstraZeneca SCC, supra* note 2, at para. 51.

15 A previous application by AstraZeneca for an order prohibiting the Minister of Health from granting a notice of compliance to Apotex for its esomeprazole product under the *Patented Medicines (Notice of Compliance) Regulations,* SOR/93-133, was dismissed by the Federal Court in *AstraZeneca Canada Inc. v. Apotex Inc.,* 2010 FC 714.

16 *AstraZeneca Canada Inc. v. Apotex Inc.*, 2014 FC 638 [*AstraZeneca FC*].

17 *Ibid,* at para. 86.

18 *Ibid,* at paras. 101-105.

Justice Rennie interpreted this passage to mean that the patent *promised* reduced interindividual variability.[19] Justice Rennie further concluded that the promise of the improved therapeutic profile was not demonstrated at the filing date and could not be soundly predicted. Justice Rennie therefore found the patent invalid.[20]

In a brief decision, a unanimous Court of Appeal affirmed Justice Rennie's decision. The Court held that Justice Rennie did not err in grouping the claims when construing the promises (rather than assessing promise on a claim-by-claim basis),[21] appropriately resorted to the disclosure in construing the promises[22] and purposively construed the promises.[23] The Court also rejected the argument that the inventive concept and the patent's utility had to be the same.[24]

2.2.2 Supreme Court of Canada

Once the Promise Doctrine was placed squarely before the Supreme Court of Canada, the Court unequivocally rejected it. Justice Rowe, writing for the unanimous Court, examined the arguments for and against the Promise Doctrine and concluded that it is "not good law."[25] The Court therefore allowed the appeal.

In overruling the Promise Doctrine, the Supreme Court of Canada articulated a myriad of problems with it as it had been applied by the Federal Courts: it was "incongruent with both the words and the scheme of the *Patent Act*;"[26] it conflated section 2 of the *Act*, which requires an "invention" to be useful, and 27(3) of the *Act*, which requires full and correct disclosure;[27] it was "excessively onerous" in that it measures utility "by reference to the promises expressed in the patent" and that in cases where there are multiple "promises," it required "that all be fulfilled for the patent to be valid"[28]; and by discouraging a patentee from disclosing too much, it was inconsistent with the purpose of section 27(3) of the *Act*, which requires an inventor to fully describe the invention and its operation or use.[29]

With the Promise Doctrine discarded, Justice Rowe set out a new approach to utility. He wrote that the subject-matter of an invention must be useful in a manner related to the nature of the invention. To assess utility, a court must first identify the subject-matter of the invention as claimed in the patent and then determine whether it is useful. He explained that an invention is "useful" when it is "capable of a practical purpose (i.e. an actual result)" or "carries out some useful known objective." He also recognized that "a scintilla of utility will do." Finally, he cautioned that "utility is to be interpreted in line with its purpose: to prevent the patenting of fanciful, speculative or inoperable inventions."[30]

Applying this new framework to the facts, he found AstraZeneca's patent to be valid and allowed the appeal. At the time of filing, it was soundly predicted that the optically pure salts of the enantiomer of omeprazole would be useful as a proton pump inhibitor. No further analysis was required.[31]

3.0 Promise Doctrine by Another Name?

Despite its clear view that the Promise Doctrine was problematic, Justice Rowe's reasons appear to leave open the possibility for it to remain part of patent law, albeit under a different name. In addressing Apotex's concerns that the Promise Doctrine protects against patentees "overpromising" in their patent applications, Justice Rowe explained at paragraph 46 of the decision that the "mischief of overpromising" may be caught under sections 27(3) and 53 of the *Patent Act*:

> The scheme of the Act treats the mischief of overpromising in multiple ways. There are consequences for failing to properly disclose an invention by claiming, for instance, that you have invented more than you have. A disclosure which is not correct and full, or states an unsubstantiated use or operation of the invention, may be found to fail to fulfill the requirements of s. 27(3). An overly broad claim may be declared invalid; however, under the operation of s. 58 of the *Patent Act*, remaining valid claims can be given effect. As well, this mischief may result in a patent being void under s. 53 of the Act, where overpromising in a specification amounts to an omission or addition that is "willfully made for the purpose of misleading."[32]

As set out below, although parties have since tried to resurrect the Promise Doctrine under these provisions, Justice Rowe's reasons are clear: the promise doctrine is "not good law." Whatever the Court intended in paragraph 46 of the decision, it could not possibly have been saying that the "Promise Doctrine as it has been applied up until now is good law but should really be argued under different sections of the *Patent Act*." As of the time of writing, the Federal Courts have so far agreed – in the months since

19 *Ibid,* at paras. 122, 126.
20 For conclusions on utility, see *AstraZeneca FC, supra* note 17, at paras. 214-218.
21 *AstraZeneca Canada Inc. v. Apotex Inc.,* 2015 FCA 158, at paras. 7-8 [*AstraZeneca* FCA]
22 *Ibid,* at para. 12.
23 *Ibid,* at para. 13.
24 *Ibid,* at paras. 10-11.
25 *AstraZeneca SCC, supra* note 2, at para. 51.
26 *Ibid,* at para. 36.
27 *Ibid,* at para. 38.
28 *Ibid,* at para. 37.
29 *Ibid,* at para. 51.
30 *Ibid,* at paras. 53-57.
31 *Ibid,* at paras. 61-63.
32 *Ibid,* at para. 46.

AstraZeneca was released, they have rejected arguments of "promise by another name."

The first two decisions to engage with *AstraZeneca* concerned Pfizer's patent for Pristiq®, an anti-depressant.[33] Two generic drug manufacturers, Apotex and Teva, each sought to produce generic versions of Pristiq®. Pfizer thus brought applications to prevent Apotex and Teva's generic versions of Pristiq® from receiving notices of compliance from the Minister. After the hearing, but before the decisions, the Supreme Court released its reasons in *AstraZeneca*. Thus, Justice Brown provided an opportunity for the parties to make additional submissions. Apotex approached this by recasting its utility arguments as arguments under section 27(3).[34] Teva also addressed section 27(3) when given this new opportunity, even though it had not raised section 27(3) earlier.[35]

Justice Brown of the Federal Court rejected these arguments. As he wrote in *Apotex Pristiq*, "[i]f the Supreme Court intended to say, in effect, that the Promise Doctrine was not good law in terms of utility under s 2, but was good law in terms of patent specifications under subsection 27(3) it could have done so; it did not."[36] Justice Brown noted that he was "unable to see a rationale for the argument that the Supreme Court of Canada removed the Promise Doctrine from the utility analysis yet simultaneously required it to be considered, in the manner Apotex proposes, in the specification analysis."[37]

Justice Phelan reached a similar conclusion in another recent decision, *Hospira Healthcare Corporation v. Kennedy Trust for Rheumatology Research*. The patent at issue detailed an adjunctive use of methotrexate [MTX] and the anti-tumour necrosis factor- α[anti-TNF-α] antibody "infliximab" for the treatment of rheumatoid arthritis [RA] and other autoimmune diseases. He concluded that "it would be inconsistent to discard [the promise] doctrine only to have it resurface under another principle without clear language to do so."[38] He wrote that, in light of *AstraZeneca*, an argument about sufficiency under section 27(3) that is tied to "promised utility" is one "based on a shaky foundation."[39]

Prothonotary Tabib also rejected similar arguments in *Apotex Inc. v. Shire LLC* when Apotex brought a motion to amend its pleadings in another case, purportedly to recast its pleading in a form that accords with the law as set out by the Supreme Court in *AstraZeneca*.[40] As she colourfully observed:

> Although Apotex portrays its amendments as being made in accordance with the Supreme Court's teachings on the correct approach to utility, they reflect, in my view, an obtuse application of selected passages of the Supreme Court's decision, a refusal to come to terms with and embrace the essence of the Supreme Court's teachings, and a fairly desperate attempt to shoehorn Apotex's promise allegations into each and every ground of invalidity known to law. The resulting pleading remains haunted by the ghost of the now defunct promise doctrine and is neither particularly helpful nor illuminating.[41]

However, Prothonotary Tabib did not completely reject Apotex's arguments – she largely allowed the amendments on the basis that they were not devoid of any chance of success and would not delay the action or cause prejudice to Shire that could not be compensated by costs, leaving the question of whether the Promise Doctrine could be resurrected to another day.[42]

The Federal Court of Appeal's first take on *AstraZeneca* came shortly after the Pristiq® decisions in *Bristol-Myers Squibb Canada Co. v. Apotex Inc.*[43] The patent was for BMS' leukemia treatment dasatinib, a drug commercially known as Sprycel®. At trial, the court held the patent to be invalid for inutility on the basis that the patent promised that dasatinib would be therapeutically useful, but this use had not been demonstrated or soundly predicted as of the claim date.[44] The Federal Court of Appeal overturned the trial judge's decision on the basis of the new utility framework and rejected Apotex's attempts to raise section 27(3) in its supplementary submissions because Apotex had not appealed that issue.[45] So while we still await the Court of Appeal's take on section 27(3) post-*AstraZeneca*, the lower court decisions so far suggest that the Promise Doctrine will not be revived under the sufficiency requirement.[46]

The other section that the Supreme Court alluded to

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33 *Pfizer Canada Inc. v. Apotex Inc., 2017* FC 774 *[Pristiq Apotex]; Pfizer Canada Inc. v. Teva Canada Ltd.,* 2017 FC 777 *[Pristiq Teva].*
34 *Pristiq Apotex, supra* note 34, at para. 356.
35 *Pristiq Teva, supra* note 34, at paras. 313-14.
36 *Pristiq Apotex, supra* note 34, at para. 360.
37 *Ibid,* at para. 363.
38 *Hospira Healthcare Corporation v. Kennedy Trust for Rheumatology Research,* 2018 FC 259, at para. 258 *[Hospira].*
39 *Ibid,* at para. 244.
40 *Apotex Inc. v. Shire LLC,* 2017 FC 831 *[Shire].*
41 *Ibid,* at para. 6.
42 *Ibid,* at paras. 11-12; see also Lantech.com, LLC v. Wulftec International Inc., 2018 FC 41.
43 *Bristol-Myers Squibb Canada Co. v. Apotex Inc.,* 2017 FCA 190 *[BMS Apotex].*
44 *Ibid,* at paras. 31-34.
45 *Ibid,* at para. 43.
46 While this paper was under review, the Federal Court released its decision in *Safe Gaming System v. Atlantic Lottery Corporation,* 2018 FC 542. The Federal Court's analysis of utility in this decision appears to be inconsistent with AstraZeneca. For a more detailed analysis of this decision, see Norman Siebrasse, "Last Spasms of the Corpse of the Promise Doctrine" (June 4, 2018) Sufficient Description, online:

was section 53(1), which requires that the patentee not willfully mislead in the specification. This section captures material allegations in the petition or specification that are false or misleading, including omissions or allegations that are untrue or misleading because of an omission to disclose relevant material facts.[47] Where one makes such an allegation willfully for purpose of misleading, the entire patent is invalid (as opposed to just certain claims). Section 53(2) provides that where the misleading allegation or omission was an involuntary error, the patent may be saved.

Although Justice Rowe in *AstraZeneca* clearly stated that overpromising in a specification could amount to an omission or addition that falls under section 53, he did not alter the high burden that must be met for a section 53 allegation to succeed. First, the allegation must be "material."[48] Second, the allegation must be "willfully made for the purpose of misleading." As courts have recognized, this is a significant burden, and therefore a "party should not merely speculate or make imputations as to motive in a reckless manner or without sufficient evidence."[49] Because a claim under section 53 is a type of fraud, failing to follow through with the claim or failing to prove it also carries significant costs consequences.[50] Given the high burden for section 53, the Promise Doctrine is likely to only be relevant under section 53 in the most egregious cases. But until courts consider this issue more closely, we cannot predict the breadth of cases in which arguing fraud on the basis of overpromising will be successful.

4.0 Obviousness and Utility: Harmony at Last?

As the Supreme Court recognized, one of the fundamental problems with the Promise Doctrine as applied by the Federal Courts is that it was unconstrained by the claim(s) at issue. Instead, it allowed challengers to comb through the specification in search of unmet "promises" that could then be used to invalidate any claim. The Federal Courts' approach to the now defunct Promise Doctrine highlights perhaps a more fundamental controversy in Canadian patent law: are obviousness and utility really two different ways of assessing whether the subject-matter of the claim is an "invention"? Or are they entirely separate concepts, to be determined independently?

As we discuss below, to this point there have been no clear pronouncements from the courts on this issue. Moreover, because obviousness was not at issue before the Supreme Court in *AstraZeneca*, the Court did not consider the relationship between obviousness and utility or how the inventive concept fits into the analysis. Nevertheless, the Court's new framework for assessing utility, where the focus of the inquiry is "the subject-matter of the invention as claimed in the patent" (as opposed to the nebulous "promise of the patent"), may finally open the door to a more coherent approach to utility and obviousness.

4.1 Obviousness and Utility – Two Sides of the Same Coin?

Obviousness and utility are plainly different inquiries, but at their heart, they both ask whether the inventor has provided enough information to the public to deserve a monopoly. In considering whether there are any parallels between obviousness and utility, it is helpful to frame them in similar terms. As the Court of Appeal recently phrased the question, the "obviousness analysis asks whether the distance between two points in the development of the art can be bridged by the Skilled Person using only the common general knowledge available to such a person,"[51] supplemented by the prior art.[52] The first point is the prior art, and the second point is the "invention" (referred to as "the subject-matter defined by the claim" in the *Patent Act*, but also called "the inventive concept," "the solution taught by the patent" and "what is claimed").[53]

It is possible to frame the utility inquiry in similar terms. As explained above, in order to satisfy the utility requirement, an inventor must be able to either demonstrate or soundly predict that the invention will work. In the sound prediction context, one could ask whether the inventors were able to make a *prima facie* reasonable inference from two points, based on the common general knowledge. The first point is the information available to the inventors (which is often – but not always – more than is available to the skilled person in the obviousness inquiry). The second point should be the same as for obviousness – it is the "invention." [54] (Where utility is demonstrated, the same framework is applicable but there is no distance between the two points, because the inventor already knows that that the invention will work.) Under a coherent patent law framework the same "invention" should be assessed for both obviousness and utility.

Thus far, courts have largely resisted seeing the parallels between obviousness and utility. The Court of Appeal

<http://www.sufficientdescription.com/2018/06/last-spasms-of-corpse-of-promise.html>.

47 *Brown v. Canada*, 2014 FC 831, at para. 80.

48 See *Fox on the Canadian Law of Patents*, 5th ed. by Donald H. MacOdrum, (Toronto: Thomson Reuters, 2013) (loose-leaf revision 2018-1) at §9:25, citing *Bombardier Recreational Products Inc. v. Arctic Cat Inc. et al*, 2017 FC 207 at para. 577 ("The test is whether or not the misrepresentation made a difference to the issuance of the patent"); *Uponor AB v. Heatlink Group Inc. et al.*, 2016 FC 320, at para. 59 ("For an allegation to be material it must somehow affect how the public makes use of the invention").

49 *Eli Lilly Canada Inc. v. Apotex Inc.*, 2008 FC 142, at para. 62.

50 *Ibid,* at para. 63.

51 *Bristol-Myers Squibb Canada Co. v. Teva Canada Ltd.*, 2017 FCA 76, at para. 65 [BMS Teva].

52 *Ciba Specialty Chemicals Water Treatments Ltd. v. SNF Inc.*, 2017 FCA 225, at para. 62 [Ciba].

53 *Ibid,* at para. 66.

54 Where utility is demonstrated, there is no distance between the two points, because the inventor already knows that that the invention will work.

squarely considered this issue in *Genpharm Inc. v. Procter & Gamble Pharmaceuticals Canada Inc.*[55] The patent at issue claimed a new way of using an old drug (etidronate) to treat osteoporosis. Genpharm argued that as a result of the Supreme Court of Canada's decisions in *Whirlpool* and *Apotex Inc. v. Wellcome Foundation* the Court had altered the test for obviousness (lowering the threshold) because obviousness and sound prediction were essentially the same thing. The Court of Appeal rejected this argument, concluding that obviousness and sound prediction are "different concepts and they are not to be conflated."[56] It held that the "doctrine of sound prediction has no application to the doctrine of obviousness."[57] Similarly, in applying the Promise Doctrine, courts have often rejected a harmonious approach between obviousness and utility, to the point that vastly different "inventions" were considered depending on the allegation at issue.

4.2 The Inventive Concept and the Utility Under the Promise Doctrine

The Supreme Court first introduced the "inventive concept" in *Apotex Inc. v. Sanofi-Synthelabo Canada Inc.*, but the Court did not provide much explanation of what it means.[58] The term has since proven difficult to define. So much so that the Federal Court of Appeal has recently held that until "the Supreme Court is able to develop a workable definition of the inventive concept," "uncertainty can be reduced by simply avoiding the inventive concept altogether and pursuing the alternate course of construing the claim."[59]

Nonetheless, until the Supreme Court says otherwise, the inventive concept remains essential to the obviousness analysis. The jurisprudence has provided some guidance at defining it. In *Allergan Inc. v. Canada (Health)*, Justice Hughes held that the inventive concept is a "statement of what the claim, properly construed, says 'stripped of unnecessary verbiage.' It is not a reformulation of the claim."[60] Ultimately, "[o]ne is trying to identify the essence of the claim in this exercise."[61]

The "inventive concept" of the claim is not restricted to the claim itself – one is permitted to resort to the specification in construing it. As a result, in the case of a bare compound claim, the inventive concept can include the properties of the compound and sometimes even what it might be used for. In *Sanofi Plavix*, the claim itself was simply a bare chemical formula. However, the Supreme Court unanimously included in the inventive concept not only the compound (clopidogrel bisulfate), and its pharmacological activity (inhibiting platelet aggregation), but even its advantages over the prior art class from which it had been selected (greater therapeutic effect and less toxicity than the [prior art compounds]).[62]

Under the *Patent Act*, the focus of the utility analysis is supposed to be the "invention." However, under the Promise Doctrine, the "invention" that was considered was not the invention set out in the claim – it was the "promised utility" or sometimes the "promise of the patent." As a result, unlike the inventive concept where the focus is on the claims (although resort to the specification is permitted), the determination of promise was often largely based on the specification (and sometimes had little or even nothing to do with what was set out in the claims(s) at issue).

4.3 Courts Have Been Inconsistent in Their Approaches to Inventive Concept and Utility

Under the Promise Doctrine, the jurisprudence was unpredictable in how it looked at utility in relation to the inventive concept. Sometimes courts looked at the claimed invention, and held that the promised utility and the inventive concept were similar, or at least consistent with one another. In other cases, the Promise Doctrine led the parties to argue for and the courts to find "promises" that strayed far from the "invention" as claimed and differed dramatically from the inventive concept.

For example, in a case about an eye drop containing olopatadine, Justice Gleason stated, "I find it incongruous, in the context of this patent, to argue that the inventive concept is something different from the promise made in the patent."[63] Similarly, in *Eli Lilly Canada Inc. v. Mylan Pharmaceuticals ULC*, in explaining the principles that govern the Promise Doctrine, the Court noted that the "promise must also be interpreted consistently with the inventive concept."[64] And Justice Hughes specifically

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55 *Genpharm Inc. v. Procter & Gamble Pharmaceuticals Canada Inc.*, 2004 FCA 393 *[Genpharm].*

56 *Ibid,* at para. 47.

57 *Ibid;* See also *Sanofi-Aventis Canada Inc. v. Apotex Inc.*, 2009 FC 676, at para. 265, aff'd 2011 FCA 300 ("As noted by all parties, there are significant differences between the tests for obviousness and utility. Obviousness is not merely the reverse of sound prediction. A finding that an invention is based on a sound prediction does not necessarily mean that the invention was obvious."); *BMS Apotex,* supra note 44, at para. 61 ("I agree with BMS that the tests for assessing obviousness and sound prediction are different").

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

59 *Ciba, supra* note 53, at para. 77.

60 *Allergan Inc. v. Canada (Minister of Health),* 2012 FC 767, at para. 137. Although Justice Hughes' decision was overturned because the appellate court disagreed with his construction of the inventive concept, Justice Hughes' definition of inventive concept has been subsequently cited with approval. See e.g. *Alcon Canada Inc. v. Cobalt Pharmaceuticals Company,* 2014 FC 149, at para. 48; *BMS Teva, supra* note 52, at para. 64.

61 *Unilever v. Chefaro,* [1994] R.P.C. 567 at 580, cited with approval in *Ciba, supra* note 53, at para. 72.

62 *Sanofi SCC, supra* note 59, at paras. 77-78.

63 *Alcon Canada Inc. v. Cobalt Pharmaceuticals Company,* 2014 FC 149, at para. 63.

64 *Eli Lilly Canada Inc. v. Mylan Pharmaceuticals ULC,* 2015 FC 17, at para. 71, aff'd 2016 FCA 119 (no analysis of promise at Court of Appeal).

explained that in chemical compound cases, it is permissible to combine "utility with what is said in the claim in order to determine the 'inventive concept.'"[65]

However, some of the cases that involved the most elevated promises (compared to what was actually in the claims) were those where there was no consideration of inventive concept at all. For example, in a case that involved Pfizer's glaucoma drug, latanoprost, commercialized as Xalatan®, both obviousness and utility were at issue before the trial judge.[66] She held the inventive concept was "a synthetic prostaglandin that was used to treat IOP [intraocular pressure] without substantial ocular irritation," and rejected Apotex's argument that the patent promises that the compound could be used chronically without toxicity.[67] As a result, she held that the patent was valid. On appeal, the Court held that the trial judge had erred in her construction of promise, but did not consider obviousness or the inventive concept at all. It accepted Apotex's view that "the promise of the patent was to treat glaucoma and intraocular hypertension on a chronic basis without causing substantial side effects," but never considered the inconsistency between that promise and the inventive concept.[68] Since the promised utility was found not to be demonstrated or soundly predicted, the patent was invalid for lack of utility.

The Federal Courts' reluctance to take a consistent view of obviousness and utility was especially evident in the lower court cases of *AstraZeneca*. At the trial level, both obviousness and lack of utility were at issue. AstraZeneca argued for a lower promise for the purposes of utility (which is easier to meet) and a higher inventive concept for the purposes of obviousness (also easier to meet). Apotex did just the opposite, arguing for a higher promise for utility and a lower inventive concept for the purposes of obviousness. The trial judge noted that in closing, while AstraZeneca argued that both the inventive concept and the promise of the patent are simply "one construction for all purposes," Apotex argued that they were distinct inquiries. The trial judge observed that "[s]uch a stark contrast in the basic legal framework underlying key doctrines in patent law, between two highly sophisticated litigants, is alarming to say the least."[69]

The trial judge ultimately held that the inventive concept of the claims was "the compound with the highest extent of purity claimed" (which was held not be obvious).[70] However, for the purposes of utility, he held the promise to include an improved therapeutic profile, including a lower degree of interindividual variation than the closest prior art compound.[71] Thus in this case, the "invention" for the purposes of obviousness was a compound with a certain level of purity. For the purposes of utility, the "invention" was a compound with a certain level of purity *and* an improved therapeutic profile.

On appeal, AstraZeneca argued that the trial judge had erred in construing the utility of the claims in a manner that was inconsistent with the inventive concept, arguing that "there must be a unitary, harmonious understanding of the essential elements of the claim, inventive concept and utility."[72] The Court of Appeal rejected this argument without any real consideration of it, because "AstraZeneca was unable to show that its submission was supported by the jurisprudence."[73]

Similarly, in *Gilead Sciences, Inc. v. Canada (Health)*, Justice Brown expressly stated that the inventive concept and the promise of the patent are not coterminous:[74]

> The inventive concept is different from the promise of the patent. While the promise of the patent is measured in the context of utility, the inventive concept goes to the obviousness inquiry concerning the 619 Patent. In this case, the parties argue the inventive concept is the addition of the bis(POC) moiety to PMPA. The promise of efficient oral delivery is not part of this inventive concept.

Thus, under the promise doctrine, the relationship between the relevant "invention" for obviousness and the "invention" for utility was alarmingly (to use Justice Rennie's language) unsettled. However, in setting out a framework for utility where the focus is the "subject-matter of an invention," the Supreme Court appears to have paved the way for a coherent approach to patent law.

4.4 Inventive Concept and the New Test for Utility

As explained above, the new framework for utility involves "identify[ing] the subject-matter of the invention claimed in the patent" and "ask[ing] whether that subject-matter is useful – is it capable of a practical purpose (i.e. an actual result)."[75] In our view, the Supreme Court's new ap-

65 *Allergan Inc. v. Canada (Health),* 2012 FC 767, at para. 141, var'd 2012 FCA 308; see also *Alcon Canada Inc. v. Apotex Inc.*, 2014 FC 699, at para. 242: "Although Apotex has advanced credible arguments that the patent promises more and that the promised IOP and Side Effects utility have not been soundly predicted, the inventive concept of the claims and the promised utility, in this case, are consistent."

66 *Pfizer Canada Inc. v. Canada (Health),* 2010 FC 447 *[Pfizer Latanoprost FC].*

67 *Ibid,* at paras. 69-71, 152.

68 *Apotex Inc. v. Pfizer Canada Inc.,* 2011 FCA 236, at para. 38.

69 *AstraZeneca FC, supra* note 17, at para. 266.

70 *Ibid,* at para. 274.

71 *Ibid,* at paras. 113-126.

72 *AstraZeneca FCA, supra* note 22, at para. 10.

73 *Ibid,* at para. 11.

74 *Gilead Sciences, Inc. v. Canada (Health),* 2016 FC 857, at para. 96.

75 *AstraZeneca SCC, supra* note 2, at para. 54.

proach to utility – which focuses on the claims – aligns it with the inventive concept such that the same "invention" must be considered for both utility and obviousness.

Both concepts – the inventive concept and utility – have the same baseline (the subject-matter of the claim). And both inquiries are similar – they look to the practical use or contribution of the invention. The utility analysis ends once the court is satisfied that the "subject-matter is useful" and is capable of a practical purpose.[76] The obviousness analysis continues. Even if the invention has a practical purpose, it asks whether that purpose or use would have been obvious to a skilled person based on his or her common general knowledge, supplemented by the relevant prior art.[77]

It is worth noting that in *Apotex Pristiq*, Justice Brown held that *AstraZeneca* did not change the law of obviousness.[78] However, while *AstraZeneca* did not change the framework for obviousness, it did provide a framework for utility that mirrors the inventive concept step in the obviousness analysis. Whereas before, the answer to the question "useful for what" was answered by looking for promises in the specification, it can now be answered by looking to the inventive concept. To the extent that the inventive concept includes properties or uses, those properties or uses should be "utility" that must be demonstrated or soundly predicted by the filing date.

In *Pristiq*, we can begin to see this alignment. In that case, Justice Brown found the utility of the claims to the novel crystalline Form I ODV succinate to be the properties of the novel form itself – it was a stable, solid state form of ODV succinate. When determining the inventive concept of these claims, Justice Brown arrived at the same place: the inventive concept was "the novel crystal Form I ODV succinate."[79] Similarly, the claim to the use of Form I ODV succinate in the treatment of depression (which was its utility) was also found to be its inventive concept: "the use of an effective amount of the crystalline Form I ODV (mono) succinate monohydrate for the treatment of depression."[80] And the claim to using a sustained release formulation of Form I ODV succinate and any other form of ODV succinate – whose utility was reducing side effects compared to immediate release formulations – was also the inventive concept of these claims.[81]

In the *Hospira*, Justice Phelan found the inventive concept to be the "manufacture of a medicament using anti-human TNF-α that can be used in combination with MTX in the treatment of RA [and] a pharmaceutical composition containing an anti-human TNF-α monoclonal antibody that can be used in combination with MTX in the treatment of RA."[82] The utility arguments were not pursued with "much emphasis or vigour," so the Court's reasons on utility are somewhat cursory. Nonetheless, the findings on utility closely resemble the inventive concept: "the 630 Patent gave a new and useful choice supported by three clinical studies showing that treatment with TNF-α and MTX reduced the signs and symptoms of RA."[83]

While *Pristiq* and *Hospira* are the only post-*AstraZeneca* cases to consider patent validity to date, we suspect that alignment between utility and the inventive concept will continue.

4.5 Alignment is Desirable

It should be no surprise that utility and the inventive concept are now aligned – the original justification for obviousness was section 2 of the *Patent Act*, the provision that remains the basis for the utility requirement. Until 1989, the *Patent Act* did not mention obviousness. But courts read the definition of "invention" under section 2 to mean that an obvious invention would not be patentable. As David Vaver explains in a passage cited by the Supreme Court in *Sanofi*, "Courts implied [obviousness] from the notion of 'invention.' Inventions implied inventive ingenuity, without which an advance was obvious; and patents are not granted for the obvious."[84]

In our view, the alignment between utility and the inventive concept is a good development in Canadian patent law. Not only does alignment provide analytical clarity, but it also means that a court will assess the same invention under each ground of invalidity. The subject-matter defined by the claims should not shift on the basis of the allegation. The Federal Court of Appeal has already held that the subject of each ground of invalidity – patentable subject-matter, novelty, utility, obviousness and statutory prohibition – is "the subject matter defined by the claim" [85] (although this was held to be *obiter* in *AstraZeneca FCA* in rejecting AstraZeneca's arguments for consistency).[86]

Alignment between the inventive concept and utility also promotes fairness. As the Federal Court has recognized, "[a] patent holder cannot read up the invention

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76 *Ibid.*
77 *Ciba, supra* note 53, at para. 62.
78 *Apotex Pristiq, supra* note 34, at para. 203.
79 *Teva Pristiq, supra* note 34, at paras. 211, 328.
80 *Ibid,* at paras. 218, 340.
81 *Ibid,* at paras. 225, 345.
82 *Hospira, supra* note 39, at para. 212.
83 *Hospira, supra* note 39, at para. 259.
84 David Vaver, *Intellectual Property Law: Copyright, Patents, Trade-marks* (Concord, Ont.: Irwin Law, 1997) at 136, cited in *Sanofi SCC, supra* note 63, at para. 51.
85 *Canada (Attorney General) v. Amazon.com Inc.,* 2011 FCA 328, at paras. 37-41.
86 *AstraZeneca FCA, supra* note 22, at para. 11.

for obviousness and read it down for utility."[87] To allow disparate readings "would be unfairly advantageous for a patent holder who might wish to assert that its invention was an unforeseeable innovation (and, therefore, not obvious) and, at the same time, contend that the invention's useful properties could be readily inferred (and, therefore, soundly predictable)."[88] Under the Promise Doctrine, companies challenging patents tried to do just the opposite – to read up the invention for utility and read it down for obviousness. However, a harmonious approach to both obviousness and utility means that in playing up an invention for the purposes of obviousness, an inventor will be constrained by what he or she actually invented – what was demonstrated or soundly predicted by the filing date. Conversely, in trying to read down the invention for the purposes of utility, an inventor will be constrained by the obviousness requirement – if the utility standard is too low, an inventor will risk the invention being useful but not actually inventive.

5.0 Conclusion

Those who do not practice patent law imagine it to consist of the application of 19th century cases to a 20th century statute, where the technologies might change, but the law rarely does. In fact, as illustrated by the dramatic rise and fall of the Promise Doctrine, while the *Patent Act* rarely changes, its interpretation is surprisingly dynamic. As discussed above, we hope that in the next phase of this evolution, courts will take a coherent approach to patent law, where utility and obviousness assess the same subject-matter to determine whether the claimed subject-matter truly is an "invention."

The rise and fall of the Promise Doctrine is also a cautionary tale. As discussed above, one of the reasons that courts were so enthusiastic about the Promise Doctrine is that, at least at first blush, it seemed to be consistent with the bargain theory of patent law. If the disclosure was viewed as the *quid pro quo* for the monopoly, then it was only natural to view it as containing the terms of the patent bargain. By extension, if any language in the disclosure was inaccurate, then surely the inventor should lose their monopoly. However, in applying the Promise Doctrine, the Federal Courts lost sight of the fact that while the patent bargain is often a useful analogy, any particular patent is not a contract in which the terms of that bargain are set out. Rather, the bargain at the heart of patent law is contained in the *Patent Act*, whose various sections stipulate the only applicable standard for measuring patent validity. As the Supreme Court has reminded the bar (and the lower courts) several times, "[a]n inventor gets his patent according to the terms of the *Patent Act*, no more and no less."[89]

87 *Hoffmann-La Roche Limited v. Apotex Inc.*, 2011 FC 875, at para. 22.
88 *Allergan Inc. v. Canada (Health)*, 2014 FC 567, at para. 24, aff'd 2015 FCA 137.
89 *Commissioner of Patents v. Farbwerke Hoechst Aktiengesellschaft Vormals Meister Lucius & Bruningin* [1964] S.C.R. 49, at 57.