THE PROMISE OF THE PATENT IN CANADA AND AROUND THE WORLD*

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ABSTRACT

All states require that patents be issued only for "useful" inventions. But recent decisions in Canada surrounding the invocation of the "promise of the patent" have provoked controversy both at home and internationally, with some alleging that they represent a novel and unjustified increase to the stringency of Canada's utility standard. This article shows that these allegations are unfounded. The promise of the patent has a long history in Canadian and British patent law, and one that possesses sound policy justifications. Equally, promises are recognized and enforced under various guises by the patent law of the United States, Australia, New Zealand, and the European Patent Office. The article concludes by examining some of the open issues and unanswered questions that exist in Canadian courts' approach to promises contained in patents.

RÉSUMÉ

Dans tous les États, les brevets ne doivent être délivrés que pour des inventions « utiles ». Toutefois, certaines allégations récentes au Canada entourant la notion de « promesse du brevet » ont suscité la controverse tant au pays qu'au sein de l'industrie pharmaceutique internationale, d'aucuns affirmant qu'elles représentent un rehaussement nouveau et injustifié de la norme d'utilité. L'article montre que ces allégations ne sont pas fondées. La promesse du brevet est une ancienne règle du droit des brevets au Canada, en Australie, en Nouvelle-Zélande et en Royaume-Uni, et cette règle y repose sur de solides justifications stratégiques. De la même manière, la notion

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de promesse du brevet existe sous différentes formes et est reconnue dans le droit des brevets des États-Unis, d'Australie, de Nouvelle-Zélande et de l'Office européen des brevets. L'article se termine par un examen de quelques questions laissées sans réponse par les tribunaux dans leur façon de traiter cette notion.

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1.0 INTRODUCTION

Apart from related developments in the field of sound prediction, the "promise of the patent" is probably the most controversial issue in contemporary Canadian patent law. Having failed to bring the issue before the Supreme Court of Canada when that court denied leave to appeal, Eli Lilly & Co launched a NAFTA direct investor challenge over Canadian courts' treatment of promises contained in patents.[1] Promises have also been mentioned in a recent Priority Watch List report by the United States Trade Representative[2] and have been the subject of doctrinal criticism.[3]

Most of those who argue against enforcing promises contend that doing so is a new and unjustified addition to Canadian law that is particularly detrimental to the pharmaceutical industry. Our research indicates that, far from being a recent Canadian innovation, the promise of the patent is a legal concept with deep historical roots and global reach. In particular, this article will show that the promise of the patent is a concept with a long history in Canadian, Australian, New Zealand, and British law. It will also show that under the laws of the United States and Europe patent holders are held to the promises they make in patents, albeit under different names and guises. We also show how the promise of the patent is not, strictly speaking, an independent legal rule but rather a corollary of the method of purposive construction for interpreting patent claims. Just as the scope of a patent claim is determined from the perspective of the skilled reader, so too is the promise of the patent.

Some of the strongest criticism of the promise of the patent occurs as a result of its interaction with the Canadian doctrine of sound prediction—that is, when the fulfillment of the promise is only soundly predicted by the inventor, and not demonstrated at the time of filing. This is because, despite veiled criticism by the Supreme Court,[4] Canadian courts have largely required that the patent specification contain the factual basis of the inventor's sound prediction of utility.[5] Some of this concern may be alleviated by the Federal Court of Appeal's decision in *Eurocopter v Bell Helicopter Textron Canada*, where the court stated that inventors can rely, to a significant extent, on the implicit general knowledge of the skilled reader to support

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[1] *Eli Lilly of Canada v Novopharm* (16 May 2013) (SCC case no 35067), refusing leave to appeal from 2012 FCA 232; *Eli Lilly v Canada*, Notice of Arbitration under the *North American Free Trade Agreement* (1993), 32 ILM 289 and 605 [NAFTA] Chapter 11 (12 September 2013), online: <http://www.international.gc.ca/trade-agreements-accords-commerciaux/assets/pdfs/disp-diff/eli-03.pdf> [Lilly Notice of Arbitration]. Although one of the drug patents about which Eli Lilly and Company complained also involved sound prediction, its complaint relating to Zyprexa focused solely on the law relating to promise of the patent.

[2] US Trade Representative, *2013 Special 301 Report* (Washington: Office of the USTR, 2013) at 46.

[3] Norman Siebrasse, "The False Doctrine of False Promise" (2013) 29:1 CIPR 3 [Siebrasse, "False Promise"].

[4] *Teva Canada v Pfizer Canada*, 2012 SCC 60, [2012] 3 SCR 625 [*Viagra* NOC].

[5] For a comprehensive review of recent developments in sound prediction, see Norman Siebrasse, "Must the Factual Basis for Sound Prediction Be Disclosed in the Patent?" (2012) 28:1 CIPR 39 [Siebrasse, "Sound Prediction"].

their sound prediction.[6] A full discussion of sound prediction in addition to the law of promises is beyond the scope of this article. In addition, the literature has treated the issues of sound prediction and promises separately,[7] largely due to their different histories and underlying policy concerns. We thus continue this practice and focus on the promise of the patent, although we acknowledge that the current prominence of the promise of the patent is undoubtedly related to the apparent rise of the disclosure requirement for sound prediction.

Analysis of the promise of the patent to date has been limited in two important ways, giving rise to the mistaken impression that the promise of the patent is new law or without policy justification. First, the extant literature has either missed or given insufficient attention to critical Canadian cases that developed the importance of a patent's promise in the mid- to late-20th century. Second, comparative legal analysis has been overly narrow, looking for exact equivalents within the utility or industrial application criterion in other jurisdictions rather than following the accepted comparative law practice of examining foreign legal systems as a whole and searching for functional equivalents to the promise of the patent. This article aims to remedy both the above issues. In so doing, it contributes to a small but growing literature on the promise of the patent.[8] In particular, it is the first to provide a rigorous comparative analysis of the Canadian promise of the patent in relation to that of the United States and Europe.[9]

We define a promise as a representation contained in a patent specification, whether implicit or explicit, that the patented invention will achieve one or more desirable outcomes, or will avoid one or more undesirable outcomes. Whereas some writers refer to the promise of the patent as the "promise doctrine," we find no support for a court ever referring to it as a doctrine unto itself.[10] We thus avoid the term.

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[6] 2013 FCA 219 at para 152 [*Eurocopter* (Appeal)]:

> In my opinion, the factual basis, the line of reasoning and the level of disclosure required by the doctrine of sound prediction are to be assessed as a function of the knowledge that the skilled person would have to base that prediction on, and as a function of what that skilled person would understand as a logical line of reasoning leading to the utility of the invention.

[7] E.g. Norman Siebrasse, "Sound Prediction," *supra* note 5; Siebrasse, "False Promise," *supra* note 3.

[8] See e.g. Siebrasse, *ibid*; Andrew Bernstein & Yael Bienenstock, "Unpacking the 'Promise of the Patent'" (2012) 28:2 CIPR 245; Mark Edward Davis "Holding Patentees to Account: Utility and the Promise of the Patent" (2012) 27:2 CIPR 355; Jenna Wilson & Cristina Mihalceanu, "When a Patent's Promise Is Put to the Test" (2012) 32:9 Lawyer's Weekly 13; Fiona E Legere, "The Pitfalls of 'the Promise of the Patent'" (2013) 29:1 CIPR 57.

[9] We note that an article prepared by lawyers for Eli Lilly—Jay A Erstling, Amy M Salmela & Justin N Woo, "Usefulness Varies by Country: The Utility Requirement of Patent Law in the United States, Europe and Canada" (2012) 3:1 Cybaris 1—attempts to undertake such an analysis. Unfortunately, it falls victim to the methodological shortcomings mentioned above.

[10] Based on a search of Carswell's Lawsource on 19 May 2013 using the search string <patent+ utility+(promise/s doctrine)> with no time limitation, only 8 decisions were identified, none of which involved a patent.

The argument advanced by this article is set out in Sections 2 through 8. Section 2 explains the policy goals achieved by the promise of the patent. Section 3 summarizes the current state of the law in Canada. Next, Section 4 reviews the origins of the promise of the patent in British jurisprudence of the 18th and 19th centuries (Section 4.1), and in Canadian jurisprudence of the 20th century (Section 4.2). Section 5 shows that there is no uniform international standard for patentable utility or industrial application. Sections 6 and 7 conduct a comparative law analysis that demonstrates how promises play an important role in both American and European patent law, albeit under different names and rules than in Canada. Section 8 concludes the article by examining open issues and unanswered questions in the Canadian law of promises.

2.0 POLICY GOALS OF ENFORCING A PATENT'S PROMISE

Patent law represents a balancing between maximizing technological innovation in the future and access to innovation today. Given that patent litigation in Canada is overwhelmingly directed at pharmaceutical patents, Canadian patent law has been largely shaped by the need to achieve balance between the interests of innovator pharmaceutical companies, their generic counterparts, patients, and the publicly funded health care system. This complex balance is reflected in the various requirements for patentability, of which the law of utility in general and the particular rules surrounding a patent's promise are components.

In examining how Canadian courts have approached the issue, we have identified three policy goals served by enforcing a patentee's promise contained within a patent specification: (1) holding patentees to account for the public benefit they promise in exchange for the patent monopoly; (2) ensuring that the patentee actually has conducted enough research and development to understand and communicate how the invention works in all its claimed instantiations; and (3) preventing double patenting, notably in respect of selection patents. We remain, however, mindful that legal rules rarely exist in perfect isolation; thus, other aspects of patent law may also contribute to achieving those same objectives.

First, the promise of the patent is a key element in ensuring that patentees actually deliver a concrete and tangible benefit to the public in exchange for their 20-year exclusivity. As the Supreme Court of the United States has stated: "[A] patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."[11] The House of Lords made a similar statement in the seminal promise case of *Hatmaker v Joseph Nathan & Co*: "In other words, [patent] protection is purchased by the promise of results. It does not, and ought not to, survive the proved failure of the promise to produce the results."[12] If a patentee claims to have successfully concluded the innovation process by promising that the invention will

[11] *Brenner v Manson*, 383 US 519 at 536, 1966 US LEXIS 2907 [*Brenner* cited to US].

[12] *Hatmaker v Joseph Nathan & Co* (1919), 36 RPC 231 (HL) at 237, Lord Birkenhead [*Hatmaker*].

achieve a certain result, 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.

This concern is particularly important given that promises of utility made by patentees during the prosecution process may influence the grant of the patent because an impressive promise of utility is likely to persuade the examiner that the patent is non-obvious. For example, an invention that promised to cure AIDS would almost certainly be found non-obvious, because there is currently no known or obvious cure for that disease. By contrast, an invention that mitigated the symptoms or slowed the progress of AIDS, although important, might or might not be found obvious, because there are existing comparable treatments that can achieve those goals. The fact that groundbreaking inventions are less likely to be found obvious may create temptations for patent applicants to overpromise on utility in order to protect their invention from obviousness challenges.

Second, because each claim in the patent must satisfy the promise, courts will strike down claims that are overly broad or include subject matter that cannot achieve the stated promise as of the filing date. This disciplines claim-drafting practices by patent applicants, requiring them to ensure that they do not claim subject matter that goes beyond known—that is, demonstrated—or soundly predicted results on that date.[13]

Third, enforcing the promise plays a special role in preventing the abuse of selection patents in order to "evergreen" an invention. Selection patents involve claims to a compound or a small number of compounds that belong to a broader class of compounds (often numbering in the millions) that have been previously patented. A valid selection patent must promise that a "substantial advantage" will be secured (or a substantial disadvantage will be avoided) by using the selected compounds relative to the class from which they were drawn.[14] This advantage must be clearly promised in the patent itself.[15] Substantially all members of the selected class must fulfill the promise, while almost none of the remaining class compounds may possess the same advantage.[16] In other words, all selection patents must contain a promise, and this promise must be fulfilled, both by the presence of the advantage in the selected compounds and by the absence of that advantage in the remaining compounds.

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[13] We note that Canadian law surrounding sufficiency of the specification also plays this role. See e.g. *Leithiser v Pengo Hydra-Pull of Canada*, [1974] 2 FC 954 (FCA) [*Leithiser*].

[14] *Apotex v Sanofi-Synthelabo Canada*, 2008 SCC 61, [2008] 3 SCR 265 at para 10 [*Plavix* NOC], citing *Re IG Farbenindustrie AG's Patent* (1930), 47 RPC 289 (Ch Div) [*IG Farbenindustrie*].

[15] *IG Farbenindustrie*, *ibid* at 318, 320.

[16] *Plavix* NOC, *supra* note 14 at para 10.

Although the three policy goals identified above are important, some argue that enforcing promises through invalidity—particularly when promises could have been avoided through careful drafting—harshly punishes inventors for the poor drafting choices of their patent agents. This argument is based on the idea that the inventor has contributed an invention of at least some utility, and it is only due to the form of the patent specification itself that the claims are held invalid. Because most disputes over promises revolve around commercially successful products possessing some utility, the argument continues, it is unfair to punish inventors because their patent applications, rather than their inventions, failed to meet the legal standard.

This argument ignores, however, the history of patent law and turns the bargain theory of patents on its head. From at least the early 17th century, the common law has viewed monopolies created by letters patent with suspicion, holding them illegitimate unless one was able to show some benefit to society accruing from their use. This philosophy was codified by the *Statute of Monopolies*,[17] which justified the issuance of letters patents for inventions on the basis that they led to the importation of new means of manufacture, thus increasing the state's wealth. The same theory continues to undergird Canada's *Patent Act* through the bargain theory of patents. As the Supreme Court explained in the *Viagra* NOC, this theory holds as follows: "The patent system is based on a 'bargain,' or *quid pro quo*: the inventor is granted exclusive rights in a new and useful invention for a limited period in exchange for disclosure of the invention so that society can benefit from this knowledge."[18] Thus, according to the Supreme Court, "sufficiency of disclosure lies at the very heart"[19] of the patent system.

In light of the bargain theory, an inventor who has not provided sufficient disclosure to justify the award of a patent—including its promise—is not entitled to a patent. It is the inventor and not the state (and still less the public) who bears the risk of overpromising or underdisclosing.[20] If the fault truly lies with the patent agent rather than with the inventor, the inventor can pursue that agent in negligence. If the rule were otherwise, inventors would have no incentive to ensure full compliance with that bargain from the time of its making. Fixing the problem years later—if and when someone notices that the inventor failed to live up to his or her side of the bargain—deprives the rest of the community of the knowledge from the time of publication, something for which it had bargained years earlier. This undermines the historical compromise embodied in modern patent laws.

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17 1623 21 Ja 1, c 3.

18 *Viagra* NOC, *supra* note 4 at para 32.

19 *Ibid* at para 31.

20 We note that similar rules apply to overly broad non-competition clauses: the court must strike down the entire clause if it is too broadly drafted, and may not substitute a more reasonable restraint (*Shafron v KRG Insurance Brokers (Western) Inc*, 2009 SCC 6, [2009] 1 SCR 157 at paras 33-42 (rejecting the application of notional severance to non-competition clauses)).

3.0 THE PROMISE OF THE PATENT IN CANADA

The law surrounding the "promise of the patent" holds a patent claim invalid for lack of utility if the patented invention fails to achieve a promise made in the specification, even if the invention may otherwise possess a scintilla of usefulness.[21]

Consider the facts of *Eurocopter*,[22] in which Eurocopter had patented an improved helicopter landing gear, which it promised would eliminate an undesirable phenomenon known as "ground resonance instability." In *Eurocopter*, the landing gear that was offset *forward* did in fact fulfill the promise of the patent, but the landing gear that was offset *backward* lacked sufficient evidence to be demonstrated or soundly predicted on the filing date. Thus, Eurocopter's promise with respect to the backward-offset landing gear was neither soundly predicted nor demonstrated at the relevant time. The fact that the backward-offset landing gear functioned as a normal helicopter landing gear (and thus had a scintilla of utility) would be irrelevant; once a patent's promise has been broken, the invention lacks utility as a matter of law, and the fact that the invention achieves some lower level of usefulness will not save it.

3.1 Current State of the Law

As a general matter, the Federal Court of Appeal has integrated issues relating to a patent's promise into the larger purposive construction paradigm (Section 3.1.1). This leads to four specific issues: where in the patent should courts look to find the promise (Section 3.1.2); who is the skilled reader and how does this identification affect the interpretation of the promise (Section 3.1.3); to what extent does the nature of the patented invention affect the promise (Section 3.1.4); and how ought courts to deal with patents containing multiple promises (Section 3.1.5)?

3.1.1 Purposive Construction and a Patent's Promise

According to the Federal Court of Appeal, interpreting the promise of the patent is an aspect of construing the patent,[23] and thus courts are to approach promises by employing purposive construction:

> The promise is to be construed by the trial judge within the context of the patent as a whole, through the eyes of the POSITA [that is, the skilled reader] in relation to the science and information available at the time of filing. The promise of the patent is fundamental to the utility analysis.[24]

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[21] *Sanofi-Aventis v Apotex Inc*, 2013 FCA 186 at paras 47-49 [*Plavix Impeachment*].

[22] *Supra* note 6, aff'g 2012 FC 113 [*Eurocopter* (Trial)].

[23] *Apotex v ADIR*, 2009 FCA 222 at para 101 [*ADIR*]; *Plavix Impeachment*, *supra* note 21 at para 55.

[24] *Eli Lilly Canada v Novopharm*, 2010 FCA 197 at para 93 [*Eli Lilly*] (citations omitted).

Thus, just as purposive construction aids courts in discerning the scope of a patent claim,[25] so it assists courts in determining whether a patent contains a promise and, if so, how a skilled reader would interpret that promise. In conducting their analysis, courts are to construe the patent in its entirety, examining both claims and the disclosure.[26]

Courts' use of purposive construction to identify the promise of a patent not only follows naturally from the law on purposive construction, but aligns patent law with business practice. On the first point, the Supreme Court in *Whirlpool Corp* established the centrality of purposive construction as a necessary first step prior to analysis of either patent validity or infringement.[27] Because a purposive construction would be necessary for the novelty and non-obviousness analysis, it would be strange indeed if it did not also underlie the utility analysis. As to the second point, the skilled reader is not just a hypothetical person conjured up to solve legal questions; the skilled reader is a reflection of the real-world readership of issued patents. Patents are commonly read and relied on by experts in the relevant field for research purposes. It is these real-life skilled readers who will rely on the promises contained in patents and this, in turn, makes it sensible to interpret the promise through their eyes.

3.1.2 Location of the Promise of the Patent

Assessing the promise of the patent through purposive construction and using the "patent as a whole" still leaves open the question of how much weight ought to be given to the various elements of the patent—for example, claims, disclosure, abstract, and drawings.

We can begin by stating unequivocally where the promise is *not* found: in the patent's abstract.[28] The Federal Court of Appeal held that because the promise of the patent is "an aspect of claims construction," it falls within the scope of r 175(1) of the *Patent Rules*,[29] and thus no reference to the patent abstract is permitted. This represents an overruling of earlier cases that relied on the patent's abstract.[30]

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[25] *Whirlpool Corp v Camco Inc*, 2000 SCC 67, [2000] 2 SCR 1067 at para 45.

[26] *Metalliflex Ltd v Rodi & Wienenberger AG* (1959), 19 Fox Pat C 49, 1959 CarswellQue 14 (Qc QB (App Div)) at paras 16-18, aff'd [1961] SCR 117; *Eli Lilly*, *supra* note 24 at para 93; *Feherguard Products Ltd v Rocky's of BC Leisure Ltd* (1959), 60 CPR (3d) 512, [1995] FCJ 620 at para 19 [*Feherguard Products*].

[27] *Supra* note 25.

[28] *ADIR*, *supra* note 23 at para 104, aff'g on this point 2008 FC 825.

[29] *ADIR*, *supra* note 23 at para 105; see *Patent Rules*, SOR/96-423, r 175(1): "An application shall contain an abstract that provides technical information and that cannot be taken into account for the purpose of interpreting the scope of protection sought or obtained."

[30] See e.g. *Pfizer Canada v Canada (Minister of Health)*, 2005 FC 1205 at para 64, aff'd without discussion on this point 2007 FCA 209.

Some cases have placed significant emphasis on the claims themselves. In a 2012 decision, Justice Zinn took the position that, absent exceptionally clear language, promises should normally be found in the claims, not the description:

> Where that promise … is clearly and unequivocally expressed by the inventor in the claims of the patent, then that expression ought to be viewed as the promise of the patent. Any statement found elsewhere should be presumed to be a mere statement of advantage unless the inventor clearly and unequivocally states that it is part of the promised utility.[31]

Although Justice Zinn's view is the most extreme example of this position, there are other cases that adopt a similar approach. For example, in *Bauer Hockey Corp v Easton Sports Canada*, Justice Gauthier stated that "[i]t is settled law that results or advantages *included in the claims* must be met."[32] Other judges have justified focusing primarily on the claims by invoking the general rule of purposive construction that the claims have primacy over the disclosure in the interpretative process.[33] Some writers have also taken the position that only promises contained in the claims should be enforced by the courts.[34]

The majority tendency is, however, to look to the patent as a whole, including both the claims and the disclosure, in order to construe the promise.[35] As long ago as 1959, in a decision affirmed by the Supreme Court of Canada, the Quebec Court of Queen's Bench (Appeal Side) held that an invention's utility is to be assessed on the basis of a holistic reading of both the claims and the description:

> The answer is to be found in Fox—*Canadian Patent Law and Practice*—3rd Ed. Vol. I, p. 301:
>
> > The invention must … be useful as specified and for the purpose stated in the specifications and claims (*Von der Linde v. Brummerstaedt & Co.* (1909), 26 R.P.C. 289)

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[31] *Fournier Pharma v Canada (Health)*, 2012 FC 741 at para 126.

[32] 2010 FC 361 at para 289 (emphasis added) (although most of the evidence Justice Gauthier relies on in interpreting the promise is drawn from the disclosure!).

[33] *Teva Canada v Novartis AG*, 2013 FC 141 at paras 76-77 [*Novartis AG*].

[34] See e.g. Legere, *supra* note 8 at 60-61. Legere incorrectly asserts that leading British promise cases enforced only promises that were found in a patent's claims, based on a misreading of the relevant case law. The promise in *Alsop* was located in the description (*Alsop*, *infra* note 61 at 734, 738, 752-53), as were the promises in *Hatmaker*. The promise in *Alsop* was thus derived from the description alone, while in *Hatmaker*, Lord Birkenhead held that promise emerged when the claims and specification were read together (*Hatmaker*, *supra* note 12 at 236).

[35] See e.g. *Metalliflex*, *supra* note 26 at paras 16-18, aff'd [1961] SCR 117; *Amfac Foods v Irving Pulp & Paper* (1986), 12 CPR (3d) 193, [1986] FCJ 659 (FCA) [*Amfac Foods* cited to Quicklaw]; *Pfizer Canada v Canada (Health)*, 2008 FCA 108 [*Pfizer Canada*]; *Laboratoires Servier v Apotex*, 2008 FC 825 at para 270; *Eli Lilly*, *supra* 24 at para 93; *Feherguard Products*, *supra* note 26 at para 19.

> As to the meaning of "utility as specified," Fox, at p. 300, borrows the following explanation from Bennett J. in *Unifloc Reagents Ltd. v. Newstead Colliery Ltd.* [1943], 60 R.P.C. 165 at 184):
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> > If when used in accordance with the directions contained in the specifications, the promised results are obtained, the invention is useful in the sense in which that term is used in the patent law.[36]

The inevitable result of looking to the patent specification as a whole is that the disclosure will furnish most promises because patentees are rarely required to discuss utility directly in the claims.[37] In most promise cases, the promise is found in an explicit statement in the disclosure that explains the invention's intended purpose, such as "carboxyalkyldipeptides … are useful as inhibitors of angiotensin-converting enzyme and as anti-hypertensive agents … . The compounds of this invention have useful pharmacological properties. They are useful in the treatment of high blood pressure."[38] Some courts have found implicit promises, such as an implicit promise of clinical effectiveness that is deducible from the use of phrases such as "the medicine of the patent," along with references to "effective amounts" of the drug, and the presence of dosage regimes in the patent itself.[39]

Attempts to read promises into tables of data or isolated statistics have generally proven unsuccessful. Most trial judges have rejected the idea that a table of data, without more, can give rise to a promise.[40] Where trial judges have found promises based primarily on numerical tables, they have been overturned by the Federal Court of Appeal.[41] Thus far, no promise cases have been decided on the basis of drawings contained in the patent, although the drawings are occasionally discussed.[42]

3.1.3 The Importance of the Skilled Reader

Because the promise of the patent is assessed using purposive construction, the identity of the skilled reader should have a strong impact on the interpretation of

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[36] *Metalliflex*, *supra* note 26 at paras 16-17.

[37] *Shell Oil Co v Canada (Commissioner of Patents)*, [1982] 2 SCR 536 [*Shell Oil*]; *Aventis Pharma v Apotex*, 2005 FC 1283 at para 82 [*Aventis Pharma*]; *Janssen-Ortho Inc v Novopharm Limited*, 2006 FC 1234 at para 96 [*Janssen-Ortho*].

[38] *Aventis Pharma*, *supra* note 37 at para 279.

[39] These three examples are drawn from *Apotex v Sanofi-Aventis*, 2011 FC 1486 at paras 93, 114, 116-118 [*Sanofi-Aventis*]; see, however, *Plavix Impeachment*, *supra* note 21 at para 49, which suggests that promises can only be explicit.

[40] See e.g. *Apotex v H Lundebeck A/S*, 2012 FC 192 at paras 244-253; see also *Eurocopter* (Trial), *supra* note 22 at paras 340-344.

[41] *Pfizer Canada*, *supra* note 35 at paras 54-55, rev'g 2007 FC 91.

[42] See *Eurocopter* (Trial), *supra* note 22 at para 350; *Wandscheer v Sicard Ltd*, [1948] SCR 1 at 14-17, 19, Kellock J, dissenting, 1947 CanLII 27 [*Wandscheer*]. See also *Gold v Serratus Mountain Products*, 2004 FC 815 at para 53.

the promise. And indeed, where the skilled reader of a pharmaceutical patent is or includes a practising physician or psychiatrist, courts have been more likely to find a promise of therapeutic effectiveness.[43] Some doubt was, however, cast on this conclusion recently by the Federal Court of Appeal in *Plavix Impeachment*, a case to which we return below.

The reason that holding the skilled reader of a pharmaceutical patent application to be a medical practitioner normally results in a finding that the promise relates to clinical or therapeutic efficacy is straightforward: the practitioner is only interested in how a drug actually acts on a patient. Thus a practitioner is likely to read a statement such as "useful in the treatment of hypertension" as a promise of clinical effectiveness because a drug that has no therapeutically useful effect in humans would not actually be useful to a practising physician.

This understanding of what a medical practitioner is likely to expect is best illustrated by the Federal Court of Appeal's judgment in *Eli Lilly & Co v Teva Canada Ltd*.[44] In that case, the skilled reader of the patent had been found to include psychiatrists and pediatricians, and the court made this finding a key factor in its interpretation of the patent's promise that it offered a "treatment for ADHD":

> In my view, this definition of the qualifications of the POSITA relevant to this patent, and especially the inclusion of a psychiatrist and a paediatrician, indicates that he or she would interpret the promise from the perspective of a person involved in the clinical treatment of ADHD. A POSITA would thus understand the promise to mean that atomoxetine will alleviate the symptoms of the disorder in some patients to a clinically meaningful extent. This is not to say that the promise means that clinicians will necessarily prescribe atomoxetine for their patients, because there may be more effective medicines available on the market. The promise does mean, however, that atomoxetine would be regarded by a physician as a realistic option for the treatment of ADHD.[45]

As noted above, however, this trend of giving greater voice to medical practitioners has been called into question by the Federal Court of Appeal's recent decision in *Plavix Impeachment*.[46] There, the court held that the trial judge was wrong to rely on the evidence of a clinical hematologist to find a promise of therapeutic effectiveness, because the remaining experts (all of whom were pharmaceutical formulators, rather than clinicians) did not believe that the patent promised therapeutic effectiveness in humans.[47]

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[43] See e.g. *Apotex v Pfizer Canada*, 2011 FCA 236 [*Apotex*]; *Sanofi-Aventis*, *supra* note 39; *Novartis AG*, *supra* note 33; *Pfizer Canada v Pharmascience*, 2013 FC 120; however, this rule is by no means absolute, and more modest promises have been found despite the skilled reader being a medical practitioner: *Pfizer Canada v Canada (Health)*, 2009 FC 1294, aff'd 2011 FCA 102.

[44] 2011 FCA 220 [*Teva Canada*], aff'g 2010 FC 915.

[45] *Teva Canada*, *ibid* at paras 22-23.

[46] *Supra* note 21.

[47] *Ibid* at paras 55-63.

3.1.4 The Importance of the Invention

As mentioned in Section 3.1.2, promises can theoretically be classified as either implicit or explicit. This section examines how the nature of the invention itself will influence the interpretation of explicit promises, or even lead to the recognition of implicit promises. It focuses on three areas: medicines that treat chronic diseases, selection patents, and patents for new uses of existing compounds.

Patents for medicines that treat chronic diseases have generally been interpreted as promising chronic treatment. This interpretation has been accepted for patents dealing with the treatment of glaucoma,[48] attention deficit hyperactivity disorder,[49] and schizophrenia.[50] However, it seems to have been a rule of general application, because in two leading cases,[51] the Federal Court of Appeal stated the proposition in very broad terms applicable to all chronic diseases or conditions.

In other words, if a medicine targets a chronic disease and there is nothing in the specification to the contrary, the medicine will be held to promise chronic treatment. Thus, it will not be enough that the medicine will work only for a short time. Because the disease is a chronic, long-term condition, a claim to a pharmaceutical treatment has been typically interpreted as promising long-term effectiveness, although effective treatment need not last a lifetime.[52]

In its recent *Plavix Impeachment* decision, the Federal Court of Appeal cast doubt on this entire line of cases, holding that a promise exists only "if a person skilled in the art would understand [the patent] to contain an *explicit* promise that the invention will achieve a specific result … . If there is no explicit promise of a specific result, then a mere scintilla of utility will do."[53] Because the court did not overturn its previous decisions, it is uncertain how clear a statement must be in order for the skilled reader to find an explicit promise, with the result that the current status of implicit promises in Canadian law is unresolved.

Promises contained in selection patents have also received special consideration. The classic case of *Re IG Farbenindustrie AG's Patent* involved a selection patent over a class of compounds used to make dyes for clothing.[54] The compounds within the class had low "fastness"—that is, resistance to the dye leaching out of the fabric—when subjected to a process called "kier boiling." Their fastness was so low, in fact, that fabrics dyed with them could not be kier-boiled at all. The selection patent

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[48] *Apotex*, *supra* note 43 at paras 24-31, rev'g 2010 FC 447.

[49] *Teva Canada*, *supra* note 44 at paras 18-27.

[50] *Eli Lilly Canada v Novopharm*, 2011 FC 1288 at paras 230, 232.

[51] *Teva Canada*, *supra* note 44; *Apotex*, *supra* note 43.

[52] *Teva Canada*, *ibid* at paras 26-27.

[53] *Plavix Impeachment*, *supra* note 21 at para 50 (emphasis added).

[54] *Supra* note 14. The relevant claims did not contain any promise, but merely recited the claimed chemical formulae.

at issue promised "quite excellent" fastness with respect to kier boiling. The question that arose in *IG Farbenindustrie* was whether the promise of "quite excellent" fastness referred to a *relative* improvement over the genus patent's fastness or an *absolutely* excellent fastness. Justice Maugham determined that the promise must be one of absolute excellence, pointing out that a relative improvement would be of little practical utility, because even improved fastness might still leave the dyes unable to be kier-boiled given the genus patent's poor fastness.[55] Only a promise of "absolutely" excellent fastness would guarantee that the selection patent provided a substantial advantage over the genus patent.[56]

The reasoning of *IG Farbenindustrie* can be interpreted in two ways: narrowly, it stands for the proposition that a patentee must promise a substantial advantage in a selection patent; more broadly, it stands for the proposition that a patentee cannot make a promise devoid of practical utility. The broader ground, which could be called a "rule against useless promises," would explain the outcome of the Canadian chronic disease cases: a promise of treating a lifelong condition for a week or a day is simply not a meaningful promise.

Similar reasoning has been adopted in Canadian selection patent cases, but faces an uncertain future after *Plavix Impeachment*. At trial, Justice Boivin had interpreted a selection patent as promising use in humans partially on the basis that the genus patent promised utility in humans, and thus the selection patent could not adopt a less-useful promise of mere *potential* use in humans.[57] The Federal Court of Appeal reversed on this point, arguing that the selection patent ought to be viewed independently of the underlying genus claims and not limited to the uses to which that genus patent were put.[58] According to the court, the patentee of a selection patent is the sole author of the invention's advantages, and recourse should not be had to the genus patent.

3.1.5 Multiple Promises

Although legal and academic debate typically refers to *the* promise of the patent, there is no legal rule that limits a patent to a single promise. Canadian courts have often been willing to find multiple promises in a single patent. For example, in *Allergan v Canada (Health)*, Justice Hughes found no less than seven promises in the patent at issue, each applicable to the inventive concept of the patent as a whole.[59] In *Novartis AG*, Justice Snider found four promises in the patent, each one covering

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[55] *Ibid* at 318, 321.

[56] *Ibid*.

[57] *Sanofi-Aventis*, *supra* note 39 at paras 169-170. See also *Glaxosmithkline v Pharmascience*, 2008 FC 593 at para 66; *Eurocopter* (Trial), *supra* note 22 at para 337.

[58] *Plavix Impeachment*, *supra* note 21 at para 69.

[59] 2012 FC 767 at para 114 [*Allergan*], rev'd on other grounds 2012 FCA 308.

a different claim or group of claims.[60] Multi-promise patents also feature prominently in the British and Australian jurisprudence.[61]

This raises the obvious question of what to do with a patent claim in which the invention fulfills some, but not all, of the promises. The traditional British position is that a claim that does not fulfill *all* of its promises is void.[62] In *Hatmaker*, the patented process fulfilled its first promise—namely, to create dried milk of "excellent quality."[63] However, the House of Lords found that it failed to achieve its second promise—namely, that the milk would be transformed into a "dry but otherwise unaltered condition," because experiments showed that the casein proteins in the milk were altered by the evaporation process, and the lipids in the milk would separate into a fatty layer if the reconstituted milk were allowed to stand.[64] Having failed one of its two promises, the patent was void. The ruling in *Alsop* was to the same effect: the patented process was successful in bleaching flour, but failed to either increase the protein content of the flour or decrease its carbohydrate content as promised.[65] Failure to achieve the latter two promises voided the patent.[66]

The Canadian position on multi-promise patents is less clear. To date, the question has not been explicitly raised, and thus not explicitly answered.[67] However, the Canadian Intellectual Property Office (CIPO) takes the position that all promises appearing in a patent must be fulfilled.[68] We return to the issue of multiple promises in Canadian law in our conclusion.

4.0 THE ORIGINS OF THE PROMISE OF THE PATENT IN BRITISH AND CANADIAN LAW

This section discusses the origins of the patent's promise in British and Canadian law, including both the key jurisprudence and the legal/policy justifications that judges provided for in their rulings.

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60 *Novartis AG*, *supra* note 33 at para 194.

61 See e.g. *Re Alsop's Patent* (1907), 24 RPC 733 (Ch D) [*Alsop*]; *Hatmaker*, *supra* note 12; *Pracdes Pty Ltd v Stanilite Electroncis Pty Ltd* (1995), 35 IPR 259 at 273-75 (Sup Ct NSW) [*Pracdes*].

62 *Alsop*, *supra* note 61; *Hatmaker*, *supra* note 12.

63 *Hatmaker*, *ibid* at 238.

64 *Ibid* at 239.

65 *Alsop*, *supra* note 61 at 754.

66 *Ibid* at 754-55.

67 One anonymous reviewer suggested that *Leithiser*, *supra* note 13, effectively involved multiple promises relating to each claim. Although the outcome of this case may have been similar to law relating to promise of the patent—a subject to which we return in Section 8.0, Conclusion—the decision did not discuss either utility or promises per se, but was rather a determination of whether, on a purposive construction, the claims revealed an invention. The Federal Court of Appeal concluded that it did not.

68 Canadian Intellectual Property Office (CIPO), *Manual of Patent Office Practice* (Ottawa: CIPO, 2009) at 12.08.01, online: CIPO <http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr03153.html> [MPOP].

4.1 British Origins

We focus on British law prior to 1977, since the *Patents Act, 1977*[69] removed any reference to "utility" from the statute, substituting the concept of "industrial application" in order to bring UK law into compliance with the *European Patent Convention* (EPC).[70] Thus, although British jurisprudence rendered under the pre-1977 *Patent Acts* is relevant to the Canadian law relating to promises, developments since 1977 are not.[71]

The law surrounding a patent's promise in the United Kingdom emerged as an outgrowth of the rule that the patentee could not receive a patent on the basis of false representations.[72] The importance of the patentee's representations (as contained in the specification) related to the discretionary nature of patent grants in early British patent law.[73] Because the Crown exercised its discretion to grant a patent on the basis of the representations contained in the patent itself, any patent that issued on the basis of misrepresentations was void because the Crown had been deceived in the exercise of its discretion.[74] A single material misrepresentation—that is, a single failed promise—would suffice to invalidate a patent, because British courts refused to second-guess whether the Crown would have exercised its discretion to grant a patent that achieved less than the applicant had promised in the specification.[75]

According to one thoughtful analysis of the origins of the law surrounding promise of the patent, because the requirement that a patent fulfill its promise derives from the deception of the Crown, it is rooted in the discretionary prerogative power on which the British patent system depended at the time. Because Canadian patent law does not depend on discretion, the argument goes, the British promise cases should not have been applied by Canadian courts. Further, apart from deception of the Crown, there is no policy justification for those cases.

Our review of the British authorities reveals a broader legal–policy justification for the law surrounding a patent's promise: avoidance of restraint of trade and deception of the *public*, rather than simply deception of the *Crown*. One of the oldest promise cases is *Turner v Winter*, a case that concerned a process patent for the production of "white lead" and two other compounds.[76] The Court of King's Bench

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[69] (UK), c 37.

[70] *Convention on the Grant of European Patents*, 1065 UNTS 199 (5 October 1973), subsequently revised in 1991 (*Act revising the Convention on the Grant of European Patents*, reprinted in [1992] OJEPO 1) and 2000 (*European Patent Convention (2000)*, reprinted in [2007] OJEPO Special Edition 3) [collectively, the EPC].

[71] Alan W White, "The Function and Structure of Patent Claims" (1993) 15:7 Eur IP Rev 243 at 247.

[72] Siebrasse, "False Promise," *supra* note 3 at 9-13.

[73] *Ibid* at 14-17.

[74] *Ibid* at 11-12.

[75] *Ibid* at 16-17.

[76] (1787), 99 ER 1274, 1 TR 602 (KB) [*Winter* cited to ER]. *Winter* appears to be the oldest case that invalidated a patent on the basis of an unfulfilled promise. Professor Siebrasse identifies *Morgan v*

found that the patented process failed to produce white lead and also that the patentee had included unnecessary steps and ingredients in the disclosure of the process.

Justice Ashurst delivered the first judgment of the case, and focused on the interplay between the promise of the patent, deception of the public, and the doctrine of restraint on trade:

> I think that, as every patent is calculated to give a monopoly to the patentee, it is so far against the principles of law, and would be a reason against it, were it not for the advantages which the public derive from the communication of the invention after the expiration of the time for which the patent is granted. It is therefore incumbent on the patentee to give a specification of the invention in the clearest and most unequivocal terms of which the subject is capable. And if it appears that there is any unnecessary ambiguity affectedly introduced into the specification or *any thing which tends to mislead the public, in that case the patent is void*. …
>
> But in truth the patent is for making white lead and two other things by one process. Therefore, if the process, as directed by the specification, *does not produce that which the patent professes to do, the patent itself is void*.[77]

According to Justice Ashurst, all patents are presumptively void at common law as restraints on trade, and they are saved only by the benefit that they confer on the public through the disclosure of a useful invention. Thus, a flawed and misleading disclosure, including one that contains false promises, will negate the benefit to the public and lead to the invalidity of the patent as a whole. This is a policy-driven justification for the promise theory that does not depend on deception of the *Crown*, but rather on deception of the *public*. The patent at issue was invalidated for failure to fulfill the promise of making white lead, even though it could be used to produce the other substances claimed.

Justice Buller concurred in *Winter*, and similarly delivered a judgment based in part on deception of the public and restraint of trade, although his reasons focused on the inclusion of unnecessary materials and superfluous steps in the disclosure.[78] Justice Buller also discussed the failure of the invention to produce white lead under the classic deception of the Crown theory.[79]

Winter shows that a doctrinal concern over deception of the Crown was not the sole justification offered to support the legal requirement that a patent fulfill its promise in early British patent law. *Winter* also demonstrates a concern for policy—

Seaward (1836), 1 WPC 187 (Ex Ct) as the first promise case (*Siebrasse*, "False Promise," *supra* note 3 at 12). Although *Seaward* is a clear example of courts enforcing the patent's promise, *Winter* seems to be older authority for the rule. Another case which predates *Seaward* is *Bloxam v Elsee*, [1827] EngR 269, 172 ER 293 [*Bloxam*], where failure to fulfill a promise was the sole ground on which a patent for a paper-making machine was invalidated.

[77] *Winter*, *supra* note 76 at 1276, Ashurst J.

[78] *Ibid* at 1277, Buller J.

[79] *Ibid*.

in particular, the need to protect the public from misrepresentations contained in the patent—and the need to hold inventors to account for the claims they make in their patents. These are broad public policy concerns the relevance of which is universal and not limited to the fact that, at that time, Britain had a discretionary patent system.

Despite *Winter*'s focus on restraint of trade and deception of the public, it is true that deception of the Crown would be the predominant explanation of the promise theory in British law for many years. The leading case of *Re Alsop's Patent*, in particular, justified the promissory approach on this basis.[80] However, *Hatmaker*, which is the earliest House of Lords decision on the promissory approach, did not rely on deception of the Crown. Instead, the House of Lords treated the promise of the patent as a freestanding legal rule.[81] Indeed, Lord Parmoor's concurrence explicitly stated that there had been no deception of the Crown, but he nonetheless invalidated the patent for failure to fulfill its promise.[82]

That the House of Lords did not rely on deception of the Crown should be unsurprising, because the theoretical justification for the deception theory was the discretionary nature of patent grants and the United Kingdom had switched to a non-discretionary patent system decades before *Hatmaker* was decided. After the adoption of the *Patent Law Amendment Act, 1852*,[83] and the *Patents, Designs, and Trade Marks Act, 1883*,[84] patents became available as of right. Thus the deception of the Crown theory, based as it was on the discretionary nature of pre-1852 patent grants, could no longer serve as the primary justification for the promissory approach. This reality was recognized by the House of Lords in *Hatmaker* and the line of cases that followed it under the post-1852 *Patent Acts*.

Although some confusion over the origins of the promissory approach persisted in British jurisprudence,[85] it incorrect to say that the promise of the patent depends

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[80] *Alsop*, *supra* note 61.

[81] *Hatmaker*, *supra* note 12 at 236-37 (Lord Birkenhead for himself and three other judges), 239 (Lord Parmoor, concurring).

[82] *Ibid* at 239 lines 27-34 (setting out the deception of the Crown approach and stating that it does not apply), lines 35-47 (invalidating the patent for failure to fulfill its promise).

[83] (UK), 15 & 16 Vic, c 83, ss 8-9, 16. (Although s 16 preserved the prerogative power of the Crown to grant or deny letters patent, this power was no longer the source of patent rights; the Crown could merely use its prerogative in reaction to administrative decisions by the patent commissioners to issue or not issue patents.) See also Brad Sherman & Lionel Bently, *The Making of Modern Intellectual Property Law* (Cambridge, UK: Cambridge University Press, 2002) at 134.

[84] (UK), 46 & 47 Vic, c 57, s 116. This Act removed any residual discretion from British patent law that had been preserved by s 16 of the previous Act. Although both this Act and the subsequent revision in 1907 (*Patents and Designs Act, 1907* (UK), 7 Edw 7, c 29) stated that the Act did not abridge the prerogative of the Crown in relation to the granting of letters patent, this applied to the grant of letters patent *outside* the field of patent law. This was made most explicit in the 1907 Act, where the saving provision in s 97 related to "letters patent," but the remainder of the Act spoke only of "patents," defined in s 93 as "letters patent for an invention." Letters patent have applications, of course, far beyond patent law (see generally Siebrasse, "False Promise," *supra* note 3).

[85] See e.g. *American Cyanamid v Ethicon Ltd*, [1979] RPC 215 (Ch D); *IG Farbenindustrie*, *supra* note 14.

on the exercise of Crown discretion. In *Hatmaker*, the House of Lords applied the promise theory as a freestanding and self-justifying legal rule. In sum, not only does the promise of the patent achieve cogent policy goals, but it also has legal justifications that go beyond those peculiar to the British patent system in the 18th and 19th centuries.

Indeed, the promise of the patent is routinely enforced in Commonwealth countries, the patent systems of which are derived from the United Kingdom. Australian case law recognizes that utility is determined by reference to the promise of the patent: " 'Inutility' means that the invention as claimed in the patent does not attain the result promised for it by the patentee."[86] Although Australian law also invalidates patents based on deception of the Crown, this is considered a separate ground of invalidity from lack of utility due to a failed promise.[87] Accordingly, Australian courts have invalidated patents over inventions that fail to achieve their promise despite having some level of utility.[88] New Zealand case law is to similar effect: "So where the patentee promises (expressly or impliedly) the attainment of a certain result and this is not obtained, or what is stated as the main object of the invention is not obtained, the patent will be invalid."[89] Recent amendments to both countries' *Patent Acts* have shifted these jurisdictions toward a US-style approach to utility,[90] but these changes are unlikely to affect the promise of the patent.

4.2 Canadian Origins

The Supreme Court of Canada's most-cited endorsement of the promissory approach to utility is *Consolboard v MacMillan Bloedel (Saskatchewan) Ltd*,[91] in which Justice Dickson wrote for a unanimous court:

> In my respectful opinion the Federal Court of Appeal erred also in holding that s. 36(1) requires distinct indication of the real utility of the invention in question. There is a helpful discussion in *Halsbury's Laws of England* (3rd ed.), vol. 29, at p. 59, on the meaning of "not useful" in patent law. *It means "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."* There is no suggestion here that the invention will not give the result promised. The discussion in *Halsbury's Laws of England*, ibid., continues:

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[86] *Décor Corporation Pty Ltd v Dart Industries Inc* (1988), 13 IPR 385 at 394 (FCA (Gen Div)); *Rehm Pty Ltd v Webster's Security Systems (International) Pty Ltd* (1988), 11 IPR 289 (FCA).

[87] *Nesbit Evan Group Australia Pty Ltd v Impro Ltd* (1997), 39 IPR 56 at 96-99 (FCA (Gen Div)).

[88] *Pracdes*, *supra* note 61 (patent for improved control circuit for gas discharge lamps invalidated because the circuit fulfilled only five of six promised improvements over the prior art).

[89] *Hammar Maskin AB v Steelbro New Zealand Limited*, [2010] NZCA 83 at para 76 (citations omitted).

[90] *Patents Act 1990*, 1990 No 83 s 7A (Austl) as am by *Intellectual Property Laws Amendment (Raising the Bar) Act 2012*, 2012 No 35 (the *Raising the Bar Act* implements the *US–Australia Free Trade Agreement*, 43 ILM 1248, art 17.9(13) (18 May 2004)); *Patents Act 2013*, 2013 No 68 (NZ).

[91] [1981] 1 SCR 504, 1981 CanLII 15 [*Consolboard*].

> … the practical usefulness of the invention does not matter, nor does its commercial utility, unless the specification promises commercial utility, nor does it matter whether the invention is of any real benefit to the public, or particularly suitable for the purposes suggested. [Footnotes omitted.]

and concludes:

> … it is sufficient utility to support a patent that the invention gives either a new article, or a better article, or a cheaper article, or affords the public a useful choice. [Footnotes omitted.]

Canadian law is to the same effect.[92]

Relying on the emphasized passages above, most Canadian courts cite *Consolboard* for the definition of utility in Canadian patent law. This definition has two components. First, where the patent document itself makes no promise of utility, a mere "scintilla of utility" will suffice; this requirement has normally been interpreted as requiring that the invention produce some minimally useful result. Second, where the inventor makes a promise, the patent will have utility only if it fulfills that promise, regardless of whether it possesses a scintilla of utility. Understanding this bifurcated structure is crucial: writers who characterize *Consolboard* as standing for a "very low threshold"[93] of utility overlook its explicit endorsement of the promise of the patent.

Despite its frequent citation, *Consolboard* was not the first time the Supreme Court considered a patent's promise. In *Wandscheer v Sicard Ltd*, a majority of the court explicitly defined "utility" from a promissory perspective. Justice Taschereau, for two of the three judges in the majority, wrote: "[T]he [invention] had no usefulness and was not workable. It could not do what it was intended to do, and *could not serve the purposes mentioned in the patent*."[94] *Wandscheer* concerned a snow blower with a tendency to "choke" on heavy snow. The promissory approach was crucial in the court's determination of invalidity, because some evidence showed that the machine was useful in light snow conditions even though it did not meet its promise of working in all winter conditions. Indeed, Justice Estey's dissent was based primarily on the machine's operability in light, dry snow conditions—in other words, that it possessed a scintilla of utility despite failure to fulfill its promise.[95]

The case that introduced the precise phrase "the promise of the patent" into Canadian law is the 1961 decision of *New Process Screw Corp v PL Robertson Manufacturing Co* rendered by President Thorson of the Exchequer Court.[96] Harold Fox acted successfully for the defendant in that case, relying in part on the promise of

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[92] *Ibid* at 525 (emphasis added).

[93] Legere, *supra* note 8 at 61.

[94] *Wandscheer*, *supra* note 42 at 5.

[95] *Ibid* at 24, Estey J, dissenting.

[96] (1961), 39 CPR 31, 1961 CarswellNat 40 (Ex Ct) [*New Process Screw* cited to CarswellNat].

the patent. The patent in *New Process Screw* concerned improvements to the methods and machines used in the making of screws.[97] In particular, the patent promised that the process it disclosed could manufacture many sizes of screw depending on the "pitch angle" used in the machine, ranging from a no 2 double-threaded screw at 12 degrees, to a no 18 double-threaded screw at 22 degrees.[98]

However, cross-examinations revealed that the plaintiff's employees never actually used the angles disclosed in the patent. The inventor even admitted that if someone attempted to produce a no 18 screw using a pitch angle of 22 degrees, the resulting screw would be "rough and not a good commercial product."[99] For President Thorson, the admission was conclusive: "This statement was enough in itself to destroy the patent … . *[T]here was a failure of the promise of the patent which was fatal to it*."[100] But the admission was not the only evidence before President Thorson: more damning still was an experiment by the defendant showing that a 12-degree pitch would roll a *single*-threaded screw, and that a 22-degree pitch would roll a *triple*-threaded screw, rather than the promised double-threaded screw in each case.[101] Thus even though the machine was capable of producing minimally workable screws, it failed to create the types of screws promised in the patent.[102] Although this might seem to raise a sufficient description issue, President Thorson discussed sufficient disclosure issues separately, and only as an alternative ground after invalidating the patent for lack of utility.[103] The promissory reasoning in *New Process Screw* is thus entirely utility-based, without any appeal to sufficient disclosure or to misleading the Patent Office.

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[97] Claim 1 of patent 477,665 reads in relevant part:

> A pair of relatively movable screw thread rolling dies capable of only rolling double threads … extending obliquely thereof at a pitch angle varying from substantially 12° for a No. 2 screw to substantially 22° for a No. 18 screw of progressively decreasing depth and width along the length thereof and with successive groove means of progressively decreasing relative depth and width throughout the length of the cavity, … so that their entire faces remain at a spaced distance from each other with their groove means oppositely inclined to roll by axial and radial extrusion double screw threads on a screw blank rolled between them with similar portions of similar grooves in each die continuously opposite similar portions of respective oppositely inclined grooves in the opposite die along the respective successive lines of contact of said dies with said screw blank.

[98] The promise was also contained in the description, *supra* note 96 at para 38.

[99] *Ibid* at para 39.

[100] *Ibid*.

[101] *Ibid*. ("Only a further brief comment need be made. In *claims 1 and 3* there was a specific reference to the use of dies with a 12° pitch angle for a No. 2 screw and a 22° pitch angle for a No. 18 screw. The screws produced by the use of such dies would not be operative for the purpose for which they were intended and the claims would be invalid for lack of utility in the invention purported to be defined by them." By contrast, claims 2, 4, and 5 were invalid due to insufficient disclosure.)

[102] *Ibid* at paras 12, 39. In this respect the patent resembles the paper-making machine in *Bloxam*, *supra* note 76.

[103] *Ibid* at para 39.

One commentator reads *New Process Screw* very differently, arguing that the utility standard applied by the court was the scintilla standard, and the promissory language was mere verbiage.[104] In our view, however, the promissory aspects of the judgment cannot be dismissed so easily. The apparatus in *New Process Screw* could make screws, which would normally qualify as the scintilla of utility necessary to support a patent, because commercial utility is not the required standard in patent law. Nor would the screw rolled at 12-degree pitch lack utility simply by virtue of being single-threaded. The fact that the patented machine could operate as a screw-making device makes it difficult to understand how the invention could lack utility without taking seriously President Thorson's invocation of the "promise of the patent." The better reading of *New Process Screw* is that it fully embraced the importance of the promise contained in the patent specification.

Another important promise case was *Amfac Foods v Irving Pulp & Paper*, a 1986 decision by the Federal Court of Appeal.[105] The patent litigated in *Amfac* concerned a machine that sliced the centre of a potato into french fries, while diverting the outside sections of the potato to other uses. The Court of Appeal began by noting that the specification must be construed as a whole when determining the promise of the patent.[106] After undertaking purposive construction of the patent, the Federal Court of Appeal determined that the promise of the patent was to "maximize the long uniform center cuts and eliminate or minimize the presence of outside cuts of potatoes in the processing of frozen french fried potatoes."[107] Claim 16, the crucial claim of the patent,[108] was held invalid for failure to fulfill the promise:

> *The device claimed in Claim 16 will not produce the promised result* since no reference is made to the essential outer slabbing blades and the separation of such outer slabs at the cutter. Therefore, applying the principles derived from the foregoing jurisprudence, it is clear that Claim 16 is broader than the invention disclosed and was properly held to be invalid by Strayer J.[109]

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[104] Siebrasse, "False Promise," *supra* note 3 at 8-9.

[105] *Amfac Foods*, *supra* note 35.

[106] *Ibid* at paras 12, 17.

[107] *Ibid* at para 20.

[108] Claim 16 read as follows:

> In a system for the cutting of vegetable products into sections, a hydraulic food pump, a product cutter, said pump being arranged to continuously and sequentially feed said products through said product cutter at relatively high speed, said cutter comprising a plurality of cutter blades arranged in spaced relation with their cutting edges lying in planes normal to the longitudinal axis of said cutters, said cutter blades being arranged in two sets, the cutting edges in the one set being at right angles to the cutting edges in the other set, each of said sets being disposed symmetrically with respect to said axis, the outer faces of said blades being inclined outwardly with respect to said axis in the direction of product feed, and the inner faces of said blades being substantially parallel to said axis ("Vegetable Slicing Apparatus," Can Patent No 773,884 (19 December 1967)).

[109] *Amfac Foods*, *supra* note 35 at para 35.

The Federal Court of Appeal's reasoning is explicable only via the promissory approach to utility, because the device claimed by Claim 16 could still slice french fries and thus possessed a scintilla of utility. It was the failure of the device to go beyond a mere scintilla of utility and to actually fulfill the promise of the patent that rendered Claim 16 invalid.

The above cases demonstrate that the promise of the patent was present in Canadian law as early as 1947 at the Supreme Court level. Clear applications of this law can be seen in *New Process Screw* and *Amfac Foods* by Federal Court judges with considerable expertise in intellectual property law, but these are by no means the only cases that invoked or relied on promises.[110]

At this point it is useful to revisit *Consolboard* and assess its authority in light of the decided cases. One commentator argues that *Consolboard* is "very weak authority" for holding patent holders to promised utilities because the promise of the patent was "not a live issue" in the litigation.[111] This interpretation is not in line with the Supreme Court's explanation that lower courts should apply previous Supreme Court rulings that might technically be considered *obiter* if they were nonetheless "obviously intended for guidance."[112] Furthermore, while it is true that the main issue in *Consolboard* concerned the *disclosure* of utility, this does not mean that lower courts are free to ignore or trivialize the *definition* of utility underlying the Supreme Court's analysis in the case. The definition of utility is obviously closely related to the issue of whether utility must be disclosed in the patent. In fact, until one has decided what "utility" is, it is difficult to see how one can decide whether it needs to be disclosed in the patent. Thus, even if lack of utility was not a pleaded ground of invalidity in *Consolboard*, the definition of "utility" nonetheless constituted a fundamental aspect of the Supreme Court's ruling.

Based on our review of the 20th-century patent jurisprudence, we conclude that, for at least the last 60 years, Canadian law has held a patent invalid if the skilled reader, looking at the specification as a whole, would find that the patent promised a certain utility that the patent holder did not possess on the filing date.

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110 See also *Wellcome Foundation v Apotex* (1995), 60 CPR (3d) 135, [1995] FCJ 226 at para 46 (CA); *Mobil Oil Corp v Hercules Canada* (1994), 57 CPR (3d) 488, [1994] FCJ 1391 (TD), rev'd on other grounds [1995] FCJ 1243 (CA); *Corning Glass Works v Canada Wire & Cable*, [1984] FCJ 353 (TD) (interestingly, the promise standard was mentioned, but the result seems to have been dictated by the scintilla standard); *Wandscheer v Sicard Ltd* (1944), [1946] Ex CR 112 at para 24 (QL), aff'd *Wandscheer*, *supra* note 42.

111 Siebrasse, "False Promise," *supra* note 3 at 23, 26.

112 *R v Henry*, 2005 SCC 76, [2005] 3 SCR 609 at para 57.

5.0 LACK OF INTERNATIONAL STANDARDS ON UTILITY OR INDUSTRIAL APPLICABILITY

The previous two sections of this article have established that the promise of the patent is not a new idea in the domestic patent systems of Canada, (pre-1977) Britain, New Zealand, or Australia. This section and those that follow will demonstrate that promises are not unique to the Commonwealth patent tradition. In fact, promises are an integral part of American and European patent law, albeit through different legal rules.

Before turning to examine the American and European law of promises, this section establishes the absence of any international standard of utility, whether by treaty or by international customary norm.

5.1 International Agreements Do Not Specify Substantive Patent Content

Article 27.1 of the *Agreement on Trade-Related Aspects of Intellectual Property Rights* (TRIPS) mandates that every state impose either a utility requirement or an industrial applicability requirement.[113] However, neither TRIPS nor any other agreement attempts to set out the *substantive content* of these requirements.

Given the lack of explicit substantive rules for the utility requirement, it becomes impossible to argue that TRIPS contains an implicit or indirect regulation of the utility standard. The basic rule for interpreting TRIPS is established in art 1.1, which states:

> Members shall give effect to the provisions of this Agreement. Members may, but shall not be obliged to, implement in their law more extensive protection than is required by this Agreement, provided that such protection does not contravene the provisions of this Agreement. *Members shall be free to determine the appropriate method of implementing the provisions of this Agreement within their own legal system and practice*.[114]

This permissive attitude to the rights of member states to implement TRIPS as they deem best is reinforced by art 19.2 of the Dispute Resolution Understanding

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[113] *Agreement on Trade-Related Aspects of Intellectual Property Rights*, being Annex 1C of the *Marrakesh Agreement Establishing the World Trade Organization*, 15 April 1994, 1869 UNTS (1994), art 27.1 [TRIPS]. Despite statements to the contrary by some—e.g. Lilly Notice of Arbitration, *supra* note 1 at para 40—neither TRIPS nor NAFTA states that the criteria of novelty, inventive step, and industrial application are the same or even equivalent to those of novelty, non-obviousness, and utility—e.g., NAFTA art 1709.1 provides only that "[f]or the purposes of this Article, a Party *may* deem the terms 'inventive step' and 'capable of industrial application' to be synonymous with the terms 'non-obvious' and 'useful,' respectively." The plain meaning of this sentence is not that the terms are in substance the same but, for the limited purposes of setting out the obligations in art 1709, a party may substitute the terms "inventive step" with "non-obvious" and "capable of industrial application" with "useful." If the parties had intended to actually require equivalency between the terms, not only would they have said so, but most of the US jurisprudence on patent law since NAFTA came into effect would be in violation of that agreement.

[114] TRIPS, art 1.1 (emphasis added).

(DSU), which states that "in their findings and recommendations, the panel and Appellate Body cannot add to or diminish the rights and obligations provided in the covered agreements."[115]

The narrow approach to understanding the impact of TRIPS on substantive patent law was confirmed by the World Trade Organization's (WTO) Appellate Body in the *India Mailbox Case*, in which it chastised the original panel for reading in obligations not clearly specified in TRIPS regarding patents. The Appellate Body stated that TRIPS art 1.1 and the DSU art 19.2 "speak for themselves" and it was inappropriate for either the panel or the Appellate Body to broaden TRIPS protection in order to take into account "the legitimate expectations of Members *and* private rights holders."[116] Subsequent decisions of dispute resolution panels have similarly pointed to the freedom of WTO member states outside the *explicit* obligations within TRIPS.[117]

Moreover, the use of two legal concepts (utility and industrial applicability) drawn from two very different legal traditions is strong evidence that TRIPS did not intend to legislate a global standard for patentable utility:

> From their inclusion as alternatives in TRIPs, it may be supposed that the two concepts are related, but not necessarily that they are … identical. All that can be deduced with certainty is that the deliberate inclusion of these two alternatives precludes any inference that the draftsmen of TRIPS intended to incorporate by reference or implication any single existing standard of patentability, whether national or regional.[118]

Thus, beyond the requirement that a state's patent laws must contain a utility or industrial applicability requirement, the existing global intellectual property regime does not impose a uniform standard as to the substantive content of the two requirements.

5.2 Absence of International Norms Relating to Substantive Patent Content

Beyond the absence of formal law requiring any level of harmonization of the substantive contents of the novelty, non-obviousness/inventive step, and utility/industrial applicability requirements, no informal norms exist as to those contents. In fact, at least two competing systems coexist in international patent law: the novelty, non-obviousness and utility approach used in Anglo-Canadian-American law (although

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[115] *Understanding on Rules and Procedures Governing the Settlement of Disputes*, 15 April 1994, being Annex 2 of the *Marrakesh Agreement Establishing the World Trade Organization*, 1869 UNTS 299, 33 ILM 1197, reprinted in *The Legal Texts: The Results of the Uruguay Round of Multilateral Trade Negotiations* (Cambridge, UK: Cambridge University Press, 1999).

[116] Appellate Body, *India—Patent Protection for Pharmaceutical and Agricultural Chemical Products* (1997) WT/DS50/AB/R at paras 47-48 (emphasis in original).

[117] See e.g. Panel Report, *China—Measures Affecting the Protection and Enforcement of Intellectual Property Rights* (2009) WT/DS362/R at para 7.513.

[118] Christopher Wadlow, "Utility and Industrial Applicability" in Toshiko Takenaka, ed, *Patent Law and Theory: A Handbook of Contemporary Research* (Cheltenham, UK: Edward Elgar, 2008).

only to 1977 in Britain), and the technical character, novelty, inventive step and industrial applicability approach used in most of the rest of the world. Although, in their totality, both approaches address fundamentally the same issues, they do so differently and under different guises. Thus, notwithstanding the fact that trade agreements may suggest the similarity of industrial application and utility, for example, problems and issues addressed by utility/industrial application in one system may actually be dealt with through another criterion (such as non-obviousness or sufficiency of disclosure) in the other system.

The WTO, the World Intellectual Property Organization (WIPO), and the World Health Organization recently concluded in a joint report that "*there is no agreed international understanding about the definition and interpretation of these [including utility/industrial applicability] criteria*."[119] Scholars of international trade and intellectual property law have echoed this conclusion.[120]

In fact, it was the very lack of uniform rules on substantive patent law (including utility and industrial applicability) that led states to begin negotiation of the *Substantive Patent Law Treaty* (SPLT). As Reichman and Cooper Dreyfus note, there had been hope that the SPLT could lead to the type of harmonization that previous instruments had not: "Ideally, member states would agree to adopt identical rules concerning what constitutes a novel and useful invention, when a technical advance meets the requirement for an 'inventive step' (non-obviousness), and how much information must be revealed by the patent disclosure."[121] However, because of discordant views among participating states, the attempt at substantive patent law harmonization through the SPLT was abandoned in 2006.[122]

Thus, not only do international agreements, including TRIPS, *not* establish any international norm on the substantive criteria of patent law, the sole attempt to create such norms failed due to divergent views on the contents of those criteria.

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[119] World Health Organization, World Intellectual Property Organization (WIPO), World Trade Organization (WTO), *Promoting Access to Medical Innovation and Technology: Intersections Between Health, Intellectual Property and Trade* (Geneva: WTO, 2012) at 57 (emphasis added), online: WTO <http://wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf>.

[120] See e.g. Jerome H Reichman & Rochelle Cooper Dreyfuss, "Harmonization Without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty" (2007) 57 Duke LJ 85 at 89; Michael N Meller, "Principles of Patentability and Some Other Basics for a Global Patent System" (2001) 83 JPTOS 359 at 359.

[121] Reichman & Dreyfuss, *supra* note 120 at 89-90.

[122] See WIPO, "Draft Substantive Patent Law Treaty," online: WIPO <http://www.wipo.int/patent-law/en/draft_splt.htm>.

5.3 The Need for Holistic Comparative Law Analysis

The literature reveals relatively little rigorous comparative law analysis of patent law.[123] It is therefore useful to briefly review how such an analysis should proceed. First, one must be careful not to examine legal rules in isolation from the broader system in which they operate, because one would miss the subtle compromises and countervailing forces that exist in every legal system. To take a non-patent example, any comparative discussion of the common law requirement that a contract be supported by consideration would be incomplete unless it also addressed promissory estoppel and sealed documents (for Anglo-Canadian legal systems), detrimental reliance (for the United States), as well as various equitable doctrines applicable to a failure of consideration (for example, equitable estoppel and resulting and constructive trusts). In other words, one must take a holistic approach to comparing law in order to avoid distorting one's analysis.[124] One must not simply look at whether a given system uses the word "promise" or how it employs a concept called "utility," because different legal systems may achieve similar results using different legal concepts or the same concept under a different label. The key to a rigorous comparative patent law analysis is an investigation of functionally equivalent legal rules.

This holistic and functional approach can be seen in the jurisprudence of the Supreme Court of Canada dealing with the application of common law rules in Quebec. In *Globe & Mail v Canada (AG)*,[125] the court carefully considered how the common and civil law rules of evidence are intertwined in Quebec in order to determine the applicability of the Wigmore doctrine in that province. Similarly, in *Prud'homme v Prud'homme*,[126] the court was careful to note the differences between the civil and common law with respect to defamation, and opted for an approach that reconciled public law common law defences to defamation with a foundation of private law civil law liability rules. The Supreme Court's jurisprudence on comparative civil and common law issues demonstrates the importance of comparing legal systems as a whole, rather than isolating and transplanting individual legal rules.

A comparative analysis can be undertaken at one of two levels: (1) in respect of judicial decisions, or (2) in respect of patent office practice. Although, at least in theory, patent offices are bound to follow judicial rulings (while patent office decisions are

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123 As one of the few exceptions, we note the oft-cited Kelvin W Willoughby, "How Much Does Technology Really Matter in Patent Law? A Comparative Analysis of Doctrines of Appropriate Patentable Subject Matter in American and European Patent Law" (2009) 18 Fed Circuit BJ 63 at 121.

124 Catherine Valcke, "Comparative History and the Internal View of French, German, and English Private Law" (2006) 19 Can JL & Jur 133; Ralf Michaels, "The Functional Method of Comparative Law" in Mathias Reimann & Reinhard Zimmermann, eds, *The Oxford Handbook of Comparative Law* (Oxford, UK: Oxford University Press, 2006) 339.

125 2010 SCC 41, [2010] 2 SCR 592.

126 2002 SCC 85, [2002] 4 SCR 663.

not binding on courts[127]), patent office practice may effectively limit or undermine judicial holdings.[128] Because our focus here is on the legal rules that apply to patents rather than on how patent agents and patent examiners deal with those rules in practice, we focus our comparative analysis on judicial and quasi-judicial determinations.

In conducting a comparative analysis, one must be careful to examine legal *rules* and not merely the *result of litigation* involving the same (or similar) patents in different jurisdictions. The Federal Court of Appeal stated in *Re Amazon.com Inc* that "it would not be helpful in the disposition of this appeal to attempt to explain the results of Amazon's patent applications in other jurisdictions. It is enough to say that every jurisdiction has its own patent laws and administrative practices, and they are inconsistent with one another in important respects."[129] Beyond differences in patent law, it is particularly dangerous to compare the results of trials decided under different procedures and with different facts and witnesses. This was noted by Lord Hoffmann in *Conor Medsystems v Angiotech Pharmaceuticals* when he concluded that "[i]t is therefore inevitable that [different courts] will occasionally give inconsistent decisions about the same patent. Sometimes this is because the evidence is different."[130]

Taking a holistic approach when comparing national laws is particularly important with respect to the substantive criteria of patentability, because these are well known to be deeply interconnected. The WIPO Standing Committee on the Law of Patents explicitly recognized this in 2001: "Therefore, for the purposes of full harmonization of substantive patent law, the industrial applicability/utility requirement cannot be considered separately from other requirements."[131] Indeed, as the American law illustrates, deep links exist between utility and other patent law concepts.

6.0 THE AMERICAN LAW OF PROMISES

6.1 Utility in American Patent Law

This section begins by setting out some general propositions about the American law of utility, in order to provide the necessary context for a discussion of promises in US patent law.[132] These general propositions are that the utility analysis in the

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[127] This was made clear by the US Supreme Court in *Association for Molecular Pathology v Myriad Genetics* 133 S Ct 2107 at 2118 (2013): "Finally, Myriad argues that the PTO's past practice of awarding gene patents is entitled to deference … . We disagree."

[128] See e.g. *Brenner*, *supra* note 11 at 529-32; see also Sivaramjani Thambisetty, "Legal Transplants in Patent Law: Why 'Utility' Is the New 'Industrial Applicability'" (2009) 48 Jurimetrics 155 (noting that the European Patent Office's (EPO) view that its task is to issue patents leads it to adopt expansive views of patentability).

[129] 2011 FCA 328 at para 16; see also *Apotex v H Lundebeck A/S*, 2013 FC 192 at para 65.

[130] [2008] UKHL 49 at para 3.

[131] WIPO Standing Committee on the Law of Patents, "The Practical Application of Industrial Applicability/Utility Requirements Under National and Regional Laws" (2001) SPC5/Inf at para 24.

[132] We leave aside other rules in US patent law that may generally serve some of the same functions as does the Canadian promise of the patent, such as ensuring that patent applicants fully possess the

United States can be conceptually divided into two steps, which we can call utility and operativeness, respectively (Section 6.1.1); despite the constitutional status of utility in American patent law, several evidentiary doctrines discourage American litigants from raising inutility arguments (Section 6.1.2); in order to avoid those difficulties, many litigants prefer to reframe utility issues and plead them as failures of "enablement," with the result that the doctrine of enablement does much of the work handled by utility in Canada (Section 6.1.3).[133]

6.1.1 A Bifurcated Concept of Utility

Both in theory and practice,[134] the American concept of utility can be subdivided into two distinct concepts or stages of analysis. This bifurcated structure is important to understand, because each concept fulfills different purposes and requires judges to ask different questions. Reflecting the usage of the jurisprudence, we call these stages "utility" and "operativeness," respectively.

The "utility" concept is used to ask the question "does the invention have a use?" or "what can you do with the invention?" Any purported use must meet the threshold test imposed by American patent law. An invention has utility if it offers "a significant and presently available benefit to the public."[135] Classic examples of patents lacking utility are patents over inventions that are physically impossible,[136] patents for substances with no known use,[137] and inventions that, without being physically impossible, are highly implausible in light of current scientific knowledge.[138]

It would be a mistake, however, to think that lack of utility is confined to the extreme cases listed above. All inventors are required to include an assertion—which

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invention on the date of filing. The development of the non-obviousness criterion following the decision of the US Supreme Court in *KSR International v Teleflex*, 550 US 398 (2007) in relation to mechanical patents is a case in point. If the more recent decision applying that criterion in relation to the pharmaceutical sector is upheld in an eventual appeal of *Bristol-Myers Squibb Company v Teva Pharmaceuticals USA*, 2013 WL 509152 (D Del), it would represent a significant change to existing practice.

133 Our review of American jurisprudence includes cases from both the Court of Customs and Patent Appeals (CCPA) and its successor, the Federal Circuit. The Federal Circuit explicitly adopted all precedents rendered by the CCPA in *South Corp v United States*, 690 F 2d 1368 at 1369, 1370-71 (Fed Cir 1982) (*en banc* hearing).

134 *Process Control Corporation v Hydreclaim Corporation*, 190 F 3d 1350 at 1358 (CAFC 1999) [*Hydreclaim*], rehearing denied 1999 US App LEXIS 31878, cert denied 2000 US LEXIS 2216.

135 *In re Fisher*, 421 F 3d 1365 at 1371 (Fed Cir 2005). Accord *Brenner*, *supra* note 11 at 534: "The basic *quid pro quo* contemplated by the Constitution and Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility … [and] a specific benefit exists in a currently available form."

136 See e.g. *Raytheon Company v Roper Corporation*, 724 F 2d 951 (Fed Cir 1983) [*Raytheon*] (patent over a microwave oven with physically impossible claim limitation); *Hydreclaim*, *supra* note 134 at 1359 (invention violated principle of conservation of mass).

137 *Brenner*, *supra* note 11.

138 See e.g. *In re Houghton*, 433 F 2d 820 (a flying machine that operated by wing-flapping); *In re Eltgroth*, 419 F 2d 918 (control over the aging process); *In re Ferens*, 417 F 2d 1072 (cure for baldness).

is functionally equivalent to a mandatory promise—of utility in their patent, unless the use of the patent is self-evident.[139] Additionally, US patent law imposes requirements on the content of the assertion of utility (in contrast to Canadian law, which leaves the content of the promise up to inventors)—for example, failure to assert a sufficiently specific and substantial utility voids the patent.[140] Famously, the Court of Customs and Patent Appeals (CCPA) (predecessor to the United States Court of Appeals for the Federal Circuit) struck down a patent for polypropylene—one of the most widely used plastics of the 20th century—because the patent's assertion that polypropylene was "plastic-like" did not convey a sufficiently specific utility.[141] It is important to emphasize that the concept of "utility" is confined to "having a use"; the question whether an invention actually fulfills that use is analyzed under the separate concept of "operativeness."

The "operativeness" inquiry asks, "does the invention achieve its asserted utility?" The standard for operativeness is low: an invention will be inoperative only if it is "totally incapable of achieving a useful result."[142] To give a simple analogy: a lawnmower that works poorly can still be used as a lawnmower, and it is only when it stops working entirely—that is, becomes totally inoperative—that it ceases to have a use as a lawnmower. The requirement of proving total inoperability often renders it very difficult to prove that an American patent is not useful; however, as Section 6.1.3 will demonstrate, those challenging patents face a much less stringent test when they plead inoperativeness issues through the lens of enablement rather than utility.

6.1.2 Evidentiary Barriers to Pleading Inutility

From its earliest patent statute[143] to the current day[144] the United States has required inventions to be "useful" in order to be patentable. This language can be traced to the US Constitution, which authorizes Congress to grant patents that promote "the

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[139] *In re Bremner*, 182 F 2d 216 at 216 (CCPA 1950) [*Bremner*]; *Cross v Iizuka*, 753 F 2d 1040 at 1044 (Fed Cir 1985); Manual of Patent Examining Procedure 2017(II)(A)-(B).

[140] *Bremner*, *supra* note 139; *Fisher*, *supra* note 135; *Anderson v Natta*, 480 F 2d 1392 (CCPA 1973) [*Anderson*]; *In re Ziegler*, 992 F 2d 1197 (Fed Cir 1993) [*Ziegler*]; *Petrocarbon Ltd v Watson*, 247 F 2d 800 (DC App 1957); *In re '318 Patent Infringement Litigation*, 583 F 3d 1317 at 1327 (Fed Cir 2009) [*'318 Litigation*].

[141] *Anderson*, *supra* note 140; *Zeigler*, *supra* note 140.

[142] *Brooktree Corp v Advanced Micro Devices*, 977 F 2d 1555 at 1557 (Fed Cir 1992); see also *EMI Group North America v Cypress Semiconductor Corp*, 268 F 3d 1342 at 1349 (Fed Cir 2001) [*EMI Group*]; *EI du Pont de Nemours & Co v Berkley & Co Inc*, 620 F 2d 1247 at 1260 n 17 (8th Cir 1980) [*EI du Pont de Nemours & Co*]; *Atlas Powder Co v EI du Pont de Nemours & Co*, 750 F 2d 1569 at 1576 (CAFC 1984) [*Atlas*].

[143] *Patent Act of 1790*, c 7, § 1, 1 Stat 109.

[144] 35 USC § 101 (1952). Between 1790 and 1793, and again between 1836 and 1952, the US *Patent Act* would require inventions to be "*sufficiently* useful and important" to merit a patent, rather than merely "useful." In practice the "sufficient" component of the utility requirement was rarely invoked (Michael Risch, "Reinventing Usefulness" (2010) BYUL Rev 1195 at 1236).

Sciences and useful Arts."[145] As a result, many judges see the utility standard as a constitutional one.[146] Yet despite its constitutional importance, lack of utility is a rarely invoked ground of invalidity. It would be a mistake to conclude that the reasons for this are substantive and that the utility requirement is a "toothless doctrine."[147] Rather, there are two significant evidentiary and procedural reasons why utility arguments are unattractive to litigants.

First, many US courts apply a rule that once infringement is proved, the infringer is estopped from denying the utility of the invention.[148] This rule is not always applied consistently,[149] and has been heavily criticized by academic writers,[150] yet it has had a chilling effect on invalidity litigation strategies. This "infringement estoppel" has resulted in largely confining inutility arguments to patent prosecution and interference proceedings.

Second, American patentees may prove utility using post-filing evidence.[151] This contrasts with the Canadian position that (at least when utility is proved via sound prediction) such "after the fact" evidence is inadmissible.[152] Because American law lacks a rule excluding post-filing evidence of utility, the incentive to raise such challenges diminishes because it is relatively easier for patentees to generate proof of utility by the time of litigation than it is at the time of filing of the patent application.

The result of the above rules has been that, for strategic reasons, utility arguments are not a preferred defence in American infringement litigation, although they remain viable in prosecution and interference contexts. Additionally, these two rules create incentives to reframe issues that may have been dealt with in Canada as

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145 US Const art 1, § 8, cl 8. On the "intellectual property clause" of the US Constitution, see generally Edward C Walterscheid, "To Promote the Progress of Science and the Useful Arts: The Background and Origin of the Intellectual Property Clause of the United States Constitution" (1994) 2 J Intell Prop L 1.

146 See e.g. *Great Atlantic and Pacific Tea Co v Supermarket Equipment Corp*, 340 US 147 at 154-55, Douglas and Black JJ (concurring) (1950); *Brenner*, *supra* note 11 at 534; *Graham v John Deere Co*, 383 US 1 at 5-6 (1966).

147 Risch, *supra* note 144 at 1195.

148 *EI du Pont de Nemours & Co*, *supra* note 142 at 128 (accepting as "axiomatic" that infringers are estopped from denying utility); see also *Westinghouse Electric and Manufacturing Co v Wagner Electric and Manufacturing Co*, 225 US 604 at 616 (1912); *Balban v Polyfoto Corp*, 47 F Supp 472 at 478 (D Del 1942); *Panduit Corp v Stahlin Brothers Fibre Works*, 575 F 2d 1152 at 1160 (6th Cir 1978); *Raytheon*, *supra* note 136; *Otsuka Pharamceutical Co v Sandoz Inc*, 2010 US Dist LEXIS 132595 at 92 n 22 (DNJ 2010), aff'd 678 F 3d 1280 (Fed Cir 2012).

149 Defendants have successfully pled disutility in e.g. *Raytheon*, *supra* note 136; *Hydreclaim*, *supra* note 134.

150 John R Thomas, *Pharmaceutical Patent Law*, 2d ed (Bethesda, Md: BNA Books, 2010) at 95; Donald S Chisum, *Chisum on Patents*, loose-leaf (New York: M Bender, 1997) at 4-106–4-108.

151 *Eli Lilly v Actavis Elizabeth LLC*, 435 Fed Appx 917 (Fed Cir 2011) (although this is the strongest recent authority on the issue, it was issued on a non-precedential basis); *In re Brana*, F 3d 1560 at 1567 n 19 (Fed Cir 1995).

152 *Apotex v Wellcome Foundation Ltd*, 2002 SCC 77, [2002] 4 SCR 153 at paras 46, 78-85.

problems of utility and plead them as an argument based on a failure to enable the invention.[153]

6.1.3 Overlap Between Enablement and Utility

Enablement (together with the "written description" requirement[154]) is the US counterpart to Canada's sufficient description requirement. The source of the enablement requirement is statutory: 35 USC § 112 mandates that the patent specification contain "a written description … of the manner and process of making and using [the invention], in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains … to make and use the same." In other words, "[t]o be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without 'undue experimentation.'"[155]

Beginning in the second half of the 20th century, American courts began to recognize an important conceptual overlap between utility and enablement. This recognition was sparked by the simple insight that an invention that does not work cannot be enabled.[156] By 1993, the Federal Circuit would declare that

> the how to use prong of section 112 [that is, enablement] incorporates as a matter of law the requirement of 35 U.S.C. §101 that the specification disclose as a matter of fact a practical utility for the invention … . If the application fails as a matter of fact to satisfy 35 U.S.C. §101, then the application also fails as a matter of law to enable one of ordinary skill in the art to use the invention under 35 U.S.C. §112.[157]

Indeed, the distinction between the two concepts is arguably metaphysical. It is difficult to see a practical distinction between alleging that "your invention does not

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[153] Indeed, in *'318 Litigation*, *supra* note 140, the defendant pleaded lack of enablement *due to lack of utility*. Even though utility was at the core of the defendant's argument, enablement was still the preferred vector of attack.

[154] *Ariad Pharamceuticals v Eli Lilly & Co*, 598 F 3d 1336 (Fed Cir 2010) (holding that § 112 contains distinct enablement and written description requirements), rehearing *en banc* of 560 F 3d 1366 (Fed Cir 2009). For an example of a case which addresses utility through the lens of the written description requirement, see *CreAgi v Pinnaclife inc*, 2013 US Dist LEXIS 179253 (ND Cal 2013) at 17 [*CreAgi*].

[155] *In re Wright*, 999 F 2d 1557 at 1561 (1993) [*Wright*]; see also *In re Vaeck*, 947 F 2d 488 at 495-96 (Fed Cir 1991) (discussing necessity of a "reasonable correlation" between scope of disclosure and scope of claims).

[156] *In re Fouche*, 439 F 2d 1237 at 1243 (CCPA 1971): "While this position could have led to a rejection under § 101, it also leads to a rejection under the how-to-use provision of § 112, since if such compositions are in fact useless, appellant's specification cannot have taught how to use them." See also *Raytheon*, *supra* note 136 at 957; *Hydreclaim*, *supra* note 134; *In re Swartz*, 232 F 2d 862 at 863 (Fed Cir 2000); *Rasmusson v Smithkline Beecham Corp*, 413 F 3d 1318 (Fed Cir 2005) [*Rasmusson*].

[157] *In re Ziegler*, *supra* note 140 at 1200-1. For a more recent statement of this overlap, see *'318 Litigation*, *supra* note 140 at 1327: "The '318 patent's description of using galantamine to treat Alzheimer's disease thus does not satisfy the enablement requirement because the '318 patent's application did not establish utility."

work," on the one hand, and, on the other, alleging "your invention, *as described in the patent*, does not work."

The conceptual overlap between enablement and utility in American patent law allows issues that would be litigated as utility attacks in Canada to be brought under the heading of enablement in the United States. Thus a patent for a medicine that fails to treat its target disease can be invalidated under enablement because following the teachings of the specification will not result in a medicine that treats the target disease.[158] Likewise, a process claim that is missing a crucial step and cannot achieve its stated goals is invalid under enablement,[159] as are claims encompassing large numbers of inoperative embodiments, because following the specification will not guarantee an operative version of the invention without unreasonable experimentation.[160]

Despite their conceptual overlap, in practice the courts treat enablement and utility differently, and do so in ways that allow enablement to serve as a stronger means of attacking a patent than utility.

First, a patent must be enabling as of its filing date, which generally precludes the patentee from relying on post-filing evidence of any kind.[161] This strict evidence regime for enablement contrasts with the more lenient rules for proving utility using post-filing evidence. In fact, the American position on the use of evidence in an enablement analysis closely resembles the Canadian rules concerning evidence of utility within the doctrine of sound prediction. Thus, by framing an argument in terms of enablement rather than utility, a defendant can limit the evidence base on which the patentee may rely. Obviously, any restriction on the evidence base available to the patentee will render enablement a more effective ground on which to attack a patent.

Second, the test for enablement is relatively strict: the patent must allow the skilled addressee to practise the "full scope"[162] of the invention without undue experimentation.[163] The importance of this standard can be illustrated by comparing

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158 *In re Sichert*, 566 F 2d 1154 at 1162 (CCPA 1970) [*Sichert*]; *CreAgi*, *supra* note 154.

159 *United Pacific Resources Co v Chesapeake Energy Corp*, 236 F 3d 684 at 690-91 (Fed Cir 2001); *National Recovery Technologies v Magnetic Separation Systems*, 166 F 3d 1190 at 1196 (Fed Cir 1999).

160 *In re Corkill*, 771 F 2d 1495 at 1501 (Fed Cir 1985); see also *EMI Group*, *supra* note 142 at 1348 (impossible inventions "may" lack utility but "certainly" lack enablement).

161 *'318 Litigation*, *supra* note 140 at 1325; *Rasmusson*, *supra* note 156 at 1324; *In re Glass*, 492 F 2d 1228 at 1232 (CCPA 1974).

162 *In re Wright*, *supra* note 155 at 1561.

163 The leading case on undue experimentation and the factors to be considered is *In re Wands*, 858 F 2d 731 (Fed Cir 1988). For examples of cases finding undue experimentation, see *White Consolidated Industries v Vega Servo-Control*, 713 F 2d 788 at 790-92 (Fed Cir 1983) (18 months' to two years' work was undue); *In re Ghiron*, 442 F 2d 985 at 992 (CCPA 1971) ("many months or years" is not routine but rather undue).

how inoperative embodiments within a claim are treated under the utility and enablement approaches. Pleading inoperativeness through the lens of utility requires the defendant to prove that every single embodiment of the invention is inoperative. On the other hand, pleading inoperativeness through enablement merely requires the defendant to show that enough inoperative embodiments exist to require undue experimentation before the invention can be practised. American courts have been vague about the exact proportion of inoperative embodiments that render a claim invalid under enablement, but one court suggested perhaps half.[164] In any case, whatever the proportion of inoperative embodiments, if undue experimentation is required to sort operative from inoperative embodiments, the patent will fail for lack of enablement, even though it contains some operative embodiments.[165]

6.2 Promises in American Patent Law

Armed with the above contextual knowledge, we can now turn to the issue of how American patent law deals with promises. The first point to note is that the United States does not have an explicitly recognized and distinct legal rule known as the "promise of the patent." However, this section will demonstrate that much like Molière's bourgeois gentleman—who spoke prose for decades without even knowing it—American patent law applies many of the same techniques, and reaches many of the same results, as does the Canadian law of promises, even without explicit acknowledgment of the promissory approach. Second, the United States does not follow the Anglo-Canadian approach of purposive construction (in which the nature of the invention and scope of the claims are determined by how a skilled reader would understand the whole of the patent specification). Rather, US law relies on a complex and sometimes contradictory set of rules of construction that places attention squarely on the claims and on the file wrapper, according much less significance to the description than would a purposive construction.[166]

The remainder of this section will demonstrate that American patent law recognizes and enforces "promises" in patents (Section 6.2.1); the requirement that patents include an "assertion of utility" is functionally equivalent to a mandatory promise (Section 6.2.2); American law goes beyond the Canadian law of promises by imposing minimum standards on the nature of promises that must be made (Section 6.2.3); and if a patent contains multiple promises, only one need be true for the patent to be valid (Section 6.2.4).

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[164] *In re Brimonidine Patent Litigation*, 2009 US Dist LEXIS 10329 at para 105 (D Del 2009).

[165] See e.g. *Sichert*, *supra* note 158 at 1162; *Atlas*, *supra* note 142 at 1576; *AK Steel Corp v Sollac*, 344 F 3d 1234 at1244 (Fed Cir 2003).

[166] See *Warner-Jenkinson Co v Hilton Davis Chemical Co*, 520 US 17 (1997); *Festo Corporation v Shoketsu Kinzoku Kogyo Kabushiki Ltd*, 535 US 722 (2002).

6.2.1 Recognition and Enforcement of Promises

American patent law is replete with promissory language. Although it is universally acknowledged that the amount of utility required to support a patent is small,[167] American judges and commentators never refer to an isolated "scintilla"-type standard. Instead, "utility" is invariably defined by reference to the purpose and objective of the invention—that is, to its promise. The invention must "be capable of doing the things claimed,"[168] fulfill "its intended purpose,"[169] and "exhibit the characteristics claimed."[170] As a general rule, utility is always "measured against the patent's objectives."[171] Although these decisions do not use the word "promise," the doctrinal position is the same: a patentee cannot claim to have provided a "scintilla of utility" despite having failed to fulfill the purpose of the invention. Instead, the invention's utility and enablement will be judged against the objectives set out in the patent itself. Of course, given the emphasis placed on the claims in American patent law, promises are generally, but not always, found in the claims rather than in the description.

Promissory reasoning can also be seen in how American courts have treated asserted utilities. For example, in *In re Hartop*, a case concerning an anaesthetic, the patentees attempted to argue that they had no burden of demonstrating that their medicine was effective in humans, because such use was not explicitly expressed in the patent. The CCPA was unimpressed by this argument, noting that the use of the word "doctors" and the phrase "large institutional users" in the patent were incompatible with a promise of mere veterinary applications for the invention.[172] The court also pointed out that the reference works cited in the patent were standard pharmaceutical reference texts, again suggesting treatment was aimed at humans rather than at animals.[173] This chain of reasoning is very close to the kind followed by Canadian courts when they identify the appropriate skilled reader and purposefully construe a patent's promise.

The next question is whether this promissory language and reasoning is matched by promissory results—that is, by cases in which a patent with at least some usefulness is struck down because it fails to meet a promise. The following examples are

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167 See e.g. *In re Oberwerger*, 115 F 2d 826 at 826 (CCPA 1940) [*Oberwerger*]; *National Slug Rejectors v ABT Manufacturing Co*, 164 F 2d 333 (7th Cir 1947); *EI du Pont de Nemours & Co*, *supra* note 142 at 1260 n 17.

168 *In re Perrigo*, 48 F 2d 965 at 965 (1931); *Oberwerger*, *supra* note 167 at 826.

169 *Conner v Joris*, 241 F 2d 944 at 947 (CCPA 1957) [*Conner*].

170 *Harris Corp v Ixys Corp*, 114 F 2d 1149 at 1155-56 (Fed Cir 1997).

171 *Wesley Jessen Corp v Bausch & Lomb Inc*, 209 F Supp 2d 348 at 398 (D Del 2002), aff'd 56 Fed Appx 503 (Fed Cir 2003) [*Bausch & Lomb*] (the Federal Circuit's judgment consisted of a non-precedential endorsement of trial judge's reasons); *CreAgi*, *supra* note 154.

172 311 F 2d 249, 135 USPQ 419 at 252 (CCPA 1962).

173 *Ibid*.

illustrative: in both cases, a patent for an invention that clearly possessed *some* utility was invalidated because the invention failed to achieve a promise set out in the patent itself.

In re Harwoord[174] concerned a patent over a method of sterilizing "insects" for extermination and pest-control purposes. This process operated by killing symbionts, the presence of which in the host insect was necessary for reproduction. By killing the symbiont, the host was rendered sterile. The patent was rejected for lack of utility because not all insects depend on symbionts for their reproduction. Thus, while the process was unquestionably useful for at least a subset of all insects (those that relied on symbionts for their reproduction), it failed to achieve its promise of sterilizing "insects" in a general, unqualified sense, and failure to fulfill the promise was fatal to its utility.

Harris Corp v Ixys Corp[175] concerned a patent for an electronic circuit that the patent asserted would avoid undesirable "latching" behaviour.[176] The patent contained a statement that the circuit would avoid latching "at all times" when, in fact, it was prone to latching under normal operating conditions and represented no particular improvement over the prior art in this respect. Thus, although the circuit was perfectly functional at a practically useful level as a standard electronic circuit, the patent's failure to teach how to avoid latching behaviour was a fatal lack of enablement.

As the above examples illustrate, promises are recognized and enforced in American patent law. Sometimes this is done under the heading of utility, but more frequently under enablement. The remainder of this section will show that American analogs to Canada's promise doctrine can, in some ways, be even stricter.

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[174] 390 F 2d 985 (CCPA 1968). Several claims of the patent were in issue; claim 32 was described by the court as representative and read as follows: "A method of causing sexual sterility in insects which comprises administering to the insect a 2-nitrofuran."

[175] *Supra* note 170. The sole independent claim of the patent read as follows:

> A vertical MOSFET device, comprising:
>
> - a semiconductor substrate, including in series, adjacent source, body, drain and anode regions of alternate conductivity type;
> - the body region being adjacent to a surface of the substrate;
> - the source and drain regions being spaced so as to define a channel portion in the body region at said surface;
> - the source, body and drain regions having a first forward current gain *alpha* [1] and the anode, drain and body regions having a second forward current gain *alpha* [2], such that the sum *alpha* [1] + *alpha* [2] is less than unity, and no thyristor action occurs under any device operating conditions.

[176] A circuit that "latches" cannot be closed until the flow of power to the entire electronic system is reduced below a certain threshold.

6.2.2 The Assertion of Utility as a Mandatory Promise

Recall that American patent applications must assert a utility unless the utility is self-evident.[177] In practice, utility will almost never be "self-evident" for chemical or pharmaceutical inventions, so in those fields utility will virtually always be expressly asserted. This is functionally equivalent to a mandatory promise for pharmaceutical and chemical inventions because, as was discussed in the previous section, enablement and utility are measured against the asserted utility of the patent. Canadian law also requires disclosure of utility where it would not be self-evident—for example, when a new chemical compound has been discovered[178]—but this disclosure is not automatically treated as a promise, because promises are the result of purposive construction. As the difference in terminology suggests, the "disclosure" of utility in Canada does not carry with it the same legal consequences as the American "assertion" of utility. In the final analysis, "assertions of utility" are similar to promises, because the utility and enablement of a patent are measured against the assertion, and assertions are mandatory in all patents without self-evident utility. This contrasts with the Canadian position, which does not require patentees to make a promise.

6.2.3 Minimum Requirements for Assertions

In addition to requiring patentees to make promises in a broad array of circumstances, American law will invalidate patents if those promises are not *specific* and *substantial*. We saw an example of this earlier, when the Federal Circuit and its predecessor court invalidated the polypropylene patent on the ground that "plastic-like" was not a specific enough assertion of utility.[179] More recently, in *Fisher*, the Federal Circuit struck down a patent for expressed sequence tags (ESTs), a genetic invention aimed at identifying the expression of certain genes in an organism's DNA.[180] The Federal Circuit found that the seven asserted utilities for the ESTs in question were neither specific enough, nor substantial enough, to satisfy the statutory utility requirement.[181] Thus the problem with the ESTs in *Fisher* was not that they failed to achieve their asserted purpose, but rather that the asserted purposes were not sufficiently useful.

This approach is stricter than is required by Canadian law, which so far does not impose a minimum level of specificity or quality of utility on promises (apart from promises contained in selection patents): as a general rule, a Canadian patent applicant is free to make (or not make) any promise in the patent. Although those promises will influence the utility analysis if the patent is litigated, Canadian courts do not

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177 See cases cited *supra* note 139.

178 *Shell Oil*, *supra* note 37; *Janssen-Ortho*, *supra* note 37 at para 74, aff'd 2007 FCA 217.

179 *Anderson*, *supra* note 140; *Ziegler*, *supra* note 140.

180 *Fisher*, *supra* note 135.

181 *Ibid* at 1373-74.

investigate the "sufficiency" of the promise in their utility analyses, nor can a patent be invalidated on the grounds that its promise does not meet a legal threshold.

6.2.4 Only One Promise Need Be Fulfilled

It is well settled in American law that if a patent makes multiple promises, only one needs to be fulfilled in order for the patent to have utility.[182] For example, a chemical patent that asserts that the disclosed compound can be used as a fungicide for crops, an anti-fungal skin cream for humans, and an abortion-inducing chemical for cows, will have utility upon proof of any one of the three uses.[183] It need not fulfill all three. This approach to multiple promises is far more generous than the traditional English approach, which required all promises made in a patent to be met. The American position flows from the American definition of utility as "having a use," because as long as at least one promise is fulfilled, the invention does indeed have a use.

7.0 THE EUROPEAN LAW OF PROMISES

This section examines the role that promises play in the patent law of the EPC. The focus is on the European Patent Office (EPO), with some attention to member states, in particular the United Kingdom post-1977. Just as the Canadian law of promises is related to two US patent law concepts (utility and enablement), so too do we find that European patent law deals with promises under two headings: "industrial applicability" and the definition of "invention." The European industrial application criterion requires that an invention contain a promise (often called a "function"), but does not require that the promise be a high one. On the other hand, the EPC requires that inventions possess a technical effect or object (which is functionally equivalent to a promise) that must be in the possession of the patent applicant. We investigate each in turn.

7.1 Promises and Industrial Applicability

The EPC requires that an invention be "susceptible to industrial application."[184] The concept of "industrial application" is further defined at art 57, which states: "An invention shall be considered as susceptible of industrial application if it can be made or used in any kind of industry, including agriculture."[185]

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[182] *Conner*, *supra* note 169 at 947; *In re Gottlieb*, 328 F 2d 1016 at 1071 (CCPA 1964) [*Gottlieb*]; *Standard Oil Co (Indiana) v Montedison SpA*, 664 F 2d 356 at 375 (3d Cir 1981); *Bausch & Lomb*, *supra* note 171 at 398.

[183] *Gottlieb*, *supra* note 182.

[184] EPC, *supra* note 70, art 52(1). For a general review of patentability requirements under the EPC, especially the technicality requirement, see T0154/04 (method of estimating product distribution (2006), [2008] OJ 46 at 60-61.

[185] EPC, *supra* note 70, art 57.

While industrial applicability should not be equated with utility—the two requirements constitute substantively different standards—they achieve some of the same *functional* goals. Thus, physically impossible inventions are neither industrially applicable nor useful;[186] similarly, substances without a known use fail to meet both standards.[187] In addition, the industrial applicability requirement has been used to exclude inventions that are believed by the examiner to be inoperable as disclosed in the patent.[188]

Additionally, industrial applicability requires that the patent disclose how the invention can be used in industry, if that function would not otherwise be obvious.[189] This has similar effect to the American requirement that patents contain an assertion of utility, although the EPC does not subject this assertion to the "specific, substantial, and credible" standard that applies in the United States.[190] The degree of function is unimportant to industrial applicability, so long as there is a "practical application,"[191] or "some financial or commercial benefit,"[192] or an "immediate concrete benefit."[193] As in the United States, this is tantamount to a mandatory promise for all inventions without a self-evident industrial application. However, in contrast to the United States, there is no minimum threshold of industrial applicability that must be achieved and thus the standard is generally considered to be low.

Although industrial applicability establishes a low bar to patentability in Europe,[194] it is not trivial. Patent applicants whose promises of industrial applicability are not credible at the date of patent filing will see their patents rejected as lacking industrial applicability.[195] In particular, if a patent's proposed industrial application

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186 *Thompson's Application*, [2005] EWHC 3065 (a "flying saucer" that violated Newton's third law of motion and the first law of thermodynamics); *Duckett v Comptroller*, [2005] EWHC 3140 (perpetual motion machine); T0005/86, [1988] EPOR 301 (another perpetual motion machine).

187 *Chiron Corp v Murex Diagnostics Ltd*, [1995] RPC 535 (CA). This result is identical to that arrived at by the US Supreme Court applying the law of utility in *Brenner*, *supra* note 11.

188 *Eastman Kodak Co v American Photo Booths Inc* (BLO/457/02), online: Intellectual Property Office <http://www.ipo.gov.uk/pro-types/pro-patent/pro-p-os/p-challenge-decision-results-bl?BL_Number=O/457/02>. See also T0451/89 (power generator) (1993), [1998] EPOR 333.

189 EPC, *supra* note 70, r 27(1)(f); T0898/05 (hematopoietic receptor) (2006), unpublished at para 6 [*Hematopoietic Receptor*]; T0870/04 (BDP1 phosphatase) (2005), unpublished at para 21 [*BDP1 Phosphatase*]; T0604/04 (PF4A receptors) (2006), unpublished at paras 14-15 (concurring with *BDP1 Phosphatase*) [*PF4A Receptors*].

190 Thambisetty, *supra* note 128, argues that the European industrial applicability standard is, at least in respect of biotechnology, increasingly moving toward "specific, substantial and credible" standard.

191 *BDP1 Phosphatase*, *supra* note 189 at para 4.

192 *Hematopoietic Receptor*, *supra* note 189 at para 4.

193 *Ibid* at para 6; *Eli Lilly v Human Genome Sciences*, [2011] UKSC 51 at para 121.

194 See e.g. Julia Powles, "Industrial Applicability of Bioscience Inventions in the Supreme Court" (2012) 71 Cambridge LJ 50 at 51.

195 *BDP1 Phosphatase*, *supra* note 189 at para 21; *Hematopoietic Receptor*, *supra* note 189 at paras 6, 20-22.

is merely "speculative"[196] at the date of patent filing, or if it would require the skilled person to undertake a "research programme,"[197] then the invention will lack industrial applicability. Thus, the industrial applicability requirement achieves some of the same policy goals as does the Canadian law on promises.

7.2 Promises and the Definition of "Invention" Under the EPC

Promises take on greater importance within the very definition of invention in Europe.[198] Under the EPC, an invention must have a technical character even to be considered an invention.[199] Thus, the first step in the analysis of the patentability of any invention is the identification of its technical features.[200] One starts this analysis by identifying the technical problem that the inventor, in the specification, promises to address.[201] Although this can be modified in the light of prior art, the problem must be "derivable from [the specification] by a skilled person."[202] One then asks whether the invention solves this problem (or, in our terms, fulfills the promise).

An "invention" that fails to offer at least a plausible solution (beyond mere informed speculation) to the technical problem revealed by the specification in light of the prior art (on the filing date) is not an invention.[203] Two cases from the EPO Board of Appeals illustrate this point well.

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196 *BDP1 Phosphatase*, *supra* note 189 at para 21.

197 *PF4A Receptors*, *supra* note 189 at para 22.

198 EPC art 52(1) states: "European patents shall be granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application."

199 T931/95 (controlling pension benefits system) (2000), [2001] OJ 441 at para 6: "Having technical character is an implicit requirement of the EPC to be met by an invention in order to be an invention."

200 T154/04 (estimating service activity) (2006), [2008] OJ 46 at para 5(E): "[T]he claim must be construed to determine the technical features of the invention, i.e. the features which contribute to the technical character of the invention."

201 T386/89 (tractor wheel) (1992), unpublished at para 4.3 [*Tractor Wheel*]; T240/91 (divisional/Ampex) (1992), unpublished at para 4. The Board of Appeals in *Tractor Wheel* acknowledged that this would not be the case, however, where the stated promise was not technical in nature: "The Board acknowledges that … there may be circumstances in which a statement of an object of an invention may not be considered as a disclosure of the invention itself. The Board is, however, of the opinion that this is not necessarily the case under all circumstances."

202 *Tractor Wheel*, *ibid*. EPO examiners can go beyond the applicant's statements to identify promises on the basis of materials outside the patent itself, such as prior art or statements made by the patentee during prosecution: *Guidelines for Examination in the European Patent Office* (Munich: EPO, 2012) part G, ch 7 at 5.2

203 T1329/04 (factor-9) (2005), unpublished at paras 4-6, 9, 11-12, 15 [*Factor-9*]; T0939/92 (triazoles) (1992), [1996] OJEPO 309 at paras 2.4-2.4.1, 2.5-2.5.1, 2.5.3-2.5.4, [1996] EPOR 171 [*Triazoles*]; *Actavis v Norvartis*, [2010] EWCA Civ 82 at paras 36-37; *Generics (UK) Ltd v Yeda Research and Development*, [2013] EWCA Civ 925 at para 55 [*Generics (UK)*]. However, no "absolute proof of usefulness" is required; the technical problem must be solved and no more (T0716/08 (infectious salmon anaemia virus vaccine) (2010), unpublished at para 28) [*Salmon Anaemia Vaccine*].

In *Factor-9*, the patent applicant claimed a polynucleotide encoding a growth differentiation factor.[204] The Board of Appeals identified the technical problem to be the isolation of a new member of a family of growth-related compounds.[205] The patent applicant put forward evidence of structural similarity between the claimed compounds and the family of compounds. The Board of Appeals held this to be inconclusive.[206] The applicant also put forward informed speculation—based on functions tentatively attributed to the claimed compounds—that the compounds solved the technical problem. This, the Board held, was not enough to render the "invention" patentable despite the applicant's plea for flexibility, given that it had to file its patent early in the research and development process:

> At oral proceedings, it was argued that speculations of this kind should be permitted because of the "first to file approach" of the European patent system which forced the applicant to cover any and all subject-matter connected with its invention. The board is unable to endorse this reasoning. On the contrary, in a first-to-file system the (earlier) filing date of the application, not the date at which the invention was made determines to whom of several persons having made an invention independently of each other, the right to a European patent belongs (cf. Article 60(2) EPC). Hence, it is particularly important in such a system that the application allows [one] to conclude that the invention had been made, i.e. that a problem had indeed been solved, not merely put forward at the filing date of the application. Therefore, the issue here is rather how much weight can be given to speculations in the application in the framework of assessing inventive step, which assessment requires that facts be established before starting the relevant reasoning. In the board's judgment, enumerating any and all putative functions of a given compound is not the same as providing technical evidence as regard a specific one.[207]

Similarly, in the *Triazoles* decision, the patent applicant claimed to have invented compounds with herbicidal activity. He supported his assertion with "a great number of examples and activity data on the basis of which," he argued, "it was reasonable to predict that all compounds covered by the present claims would have the stated activity."[208] The Board of Appeals held, in that case, that "the assessment of the technical contribution to the art must take account of the actual technical reason [that is, the technical problem] for providing the very compounds now being claimed, as distinct from the host of other theoretically possible modified chemical compounds. In this respect, the description … asserts that all claimed compounds do have herbicidal activity." Having identified this promise, the Board concluded that the patent applicant had failed to demonstrate that the compounds achieved this purpose:

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[204] *Factor-9*, *supra* note 203.

[205] *Ibid* at para 4.

[206] *Ibid* at para 8.

[207] *Ibid* at para 10.

[208] *Triazoles*, *supra* note 203 at para V.

> [T]he test results contained in the description show that some of the claimed compounds are indeed herbicidally active, [but this] cannot be regarded as sufficient evidence to lead to the inference that substantially all the claimed compounds possess this activity. The reason for this is that there is no proven common general knowledge to show that the type of substituent that may be present in the claimed compounds would be irrelevant to the existence of the alleged herbicidal activity.[209]

Given this finding, the Board held the claim to the compounds to be invalid: "[T]he Board is not convinced that, in the absence of any technically useful properties, the claimed compounds could be regarded as being a technical invention at all."[210]

The evidence used to prove that an invention solves a technical problem must, as a rule, be available by the filing date, and post-filing evidence will be excluded.[211] As the EPO Board of Appeals stated in *Factor-9*:

> The appellant filed post-published evidence … establishing that GDF-9 was indeed a growth differentiation factor. This cannot be regarded as supportive of an evidence which would have been given in the application as filed since there was not any. The said post-published documents are indeed the first disclosures going beyond speculation. For this reason, the post-published evidence may not be considered at all.[212]

The Board held that accepting this evidence would "be in contradiction with the principle that inventive step, as all other criteria for patentability, must be ascertained as from the effective date of the patent. The definition of an invention as being a contribution to the art, i.e. as solving a technical problem and not merely putting forward one, requires that it is at least made plausible by the disclosure in the application that its teaching solves indeed the problem it purports to solve."[213]

According to Minssen and Nilsson, writing on the European disclosure requirements: "This decision [*Factor-9*] established the important subjective 'at least plausible' or plausibility test, meaning that there is a high risk that a patent application is rejected if the applicant has not presented sufficient 'plausible' technical evidence for the predicted functions in the application, on the grounds of lacking inventive step, even though experimental evidence was submitted at a later stage that establishes that the predictions in the application were accurate."[214] Subsequent to the *Factor-9* decision, the EPO Board of Appeals has allowed applicants to submit post-filing evidence in order to "confirm" evidence that the invention was capable of

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209 *Ibid* at para. 2.6.2.

210 *Ibid* at para. 2.5.1.

211 *Factor-9*, *supra* note 203 at para 12.

212 *Ibid*. See also *Generics (UK)*, *supra* note 203 at paras 64-65 (noting that the party attacking the patent will always be entitled to introduce post-filing evidence to disprove the inventive step).

213 *Ibid*.

214 Timo Minssen & David Nilsson, "The Industrial Application Requirement for Biotech Inventions in Light of Recent EPO & UK Case Law: A Plausible Approach or a Mere 'Hunting License'?" (2012) 34 EIPR 689 at 695.

plausibly solving the objective technical problem on the filing date, but not to establish that evidence in the first place.[215] Thus, although the EPO allows applicants to introduce post-filing evidence that their invention fulfills its promise, the ability to file this evidence is conditional on first plausibly demonstrating that the promise was fulfilled in the application itself.

In summary, the EPC's definition of invention implicitly recognizes promises. The evidentiary burden on patent applicants is, however, lower than that in Canada, due in part to EPO's willingness to allow post-filing confirmatory evidence.

8.0 CONCLUSION

As our comparative law analysis demonstrates, the promise of the patent is not a concept unique to Canada.[216] In the conclusion, however, we return to Canada to examine some of the unanswered questions within the promise rules in operation.

Perhaps the most fundamental unanswered question is the continued relevance of the scintilla standard of utility in Canada. To put it more bluntly, does every patent have a promise? The traditional position endorsed by the Supreme Court in *Consolboard* is a bifurcated standard: if a patent contains a promise, then the promise must be met; but absent a promise, the patented invention need only display a "scintilla" of utility.[217] The Federal Court of Appeal recently reaffirmed this position, stating that not every patent has a promise.[218] But, in practice, the number of cases decided on the scintilla standard in the last few years has significantly declined.[219] Indeed, there are several Federal Court judgments in which any discussion of the scintilla standard is studiously avoided and the promise of the patent is treated as if it were the sole measure of utility.[220] For its part, the CIPO *Manual of Patent Office Practice* (MPOP) makes no mention of the scintilla standard, instead speaking only of self-evident utilities, on the one hand, and promises, on the other.[221]

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215 T0018/09 (neutrokine) (2009), unpublished at 14-15. Certain cases have taken this approach even farther, such as *Hematopoietic Receptor*, *supra* note 189 at para 24, where the Board of Appeals declared that "post-published evidence, which confirms the preliminary finding and actually supports the conclusion, cannot be ignored." See also *Salmon Anaemia Vaccine*, *supra* note 203 at para 16 (standard of plausibility is not "absolute proof"; *in vitro* tests sufficient to prove that vaccine plausibly solves technical problem).

216 We are not alone in reaching this conclusion: Jennifer L Wilkie & Jay Zakaib, "Utility, Sound Prediction and Promise of the Patent" (2013) Life Sciences and Law: Current Issues 33 at 34: "However, where one promises more than one's claimed invention can deliver, a *patentee may face jeopardy in numerous jurisdictions*, not just Canada" (emphasis added), online: <http://www.gowlings.com/KnowledgeCentre/PDFs/LSIG-Current-Issues_Broch-2013.pdf>.

217 *Consolboard*, *supra* note 91 at 525.

218 *Plavix Impeachment*, *supra* note 21.

219 See e.g. *Allergan v Canada (Health)*, 2011 FC 1316 at para 209; *Lundebeck Canada v Ratiopharm*, 2009 FC 1102 at para 212.

220 See e.g. *Eurocopter* (Trial), *supra* note 22 at paras 58-59.

221 MPOP, *supra* note 68 at 12.08.01.

In part, the reason for the near-disappearance of the scintilla standard in recent years may be that the freedom to abstain from making a promise is largely illusory for chemical and pharmaceutical patents in which there is but a single embodiment, and these patents make up the majority of modern Canadian case law. The utility of chemical or pharmaceutical compounds will rarely be self-evident, and thus will need to be disclosed in the patent specification. Any such disclosure will, in turn, give litigants an opportunity to argue that it is a promise. Given the reassertion of the *Consolboard* bifurcated approach to utility in *Plavix Impeachment*, only time will tell how this tension is resolved.

A second important question that remains unresolved in Canadian law is how to treat a patent that contains multiple promises. As mentioned previously, MPOP requires that all promises be met,[222] but no Canadian court has directly ruled on the issue.[223] When discussing multi-promise patents, it is important to distinguish a "true" situation of multiple promises (in which the subject matter covered by a single claim is subject to more than one promise[224]) from a "false" situation of multiple promises (in which different promises apply to different claims in the patent, with no single claim being subject to the multiple promises[225]). Only when a patent involves a true situation of multiple promises will a single claim be subject to two or more promises simultaneously.

A true situation of multiple promises naturally raises the question of what should happen if a claim fulfills some, but not all, of its promises. As mentioned above, there are two possible approaches to the issue. The American position is that as long as at least one promise is satisfied, the invention possesses utility. The British position is that all promises must be satisfied, otherwise the invention lacks utility. Although Canadian cases often cite *Alsop* and *Hatmaker*, two British multi-promise cases, the issue has yet to be decided in Canada.

Arguments can be made in favour of both approaches. The British position has the weight of authority on its side, including authority seminal to the promissory approach as a whole. The British position will also impose discipline on patent applicants by invalidating patents that contain a mixture of true and false representations as to what the invention can accomplish. By contrast, the American position avoids the seemingly harsh results of the British rule, which can invalidate a patent over an invention that successfully achieves one or more useful results simply because it falls short of fulfilling every promise. Under the American view, where an inventor has actual possession of the invention and its utility—and not simply a hoped-for or after-confirmed utility—at the filing date, the inventor has satisfied the

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222 *Ibid*.

223 Although see discussion *supra* note 67.

224 See e.g. *Allergan*, *supra* note 59.

225 The "false" situation can arise, for example, where a patent includes both a process claim and a product claim, because the differences between the two claims will necessitate different promises. See e.g. *Novartis AG*, *supra* note 33.

bargain of providing the public with tangible knowledge and thus, arguably, should receive the exclusive rights that the patent system pays in return.

A third area that requires further development is the role of the skilled reader in the interpretation of promises. Prior to the *Plavix Impeachment* decision, when the skilled reader of a pharmaceutical patent included a clinician, the patent would normally be interpreted as promising clinical or therapeutical effectiveness.[226] Similarly, when the skilled reader is a pharmaceutical industry professional, the promise may be found to be either clinical/therapeutical effectiveness or mere pharmacological activity.[227] This rule would be unproblematic if each patent had only one skilled reader. But in all of the clinical skilled-reader cases, the clinician was an extra skilled reader in addition to the traditional pharmacological readers. This begs the question of why the clinician's interpretation of the promise is automatically preferred to that of the pharmacologist. The *Plavix Impeachment* decision reversed the dominant approach and accorded primacy to the interpretation of skilled readers with expertise in pharmaceutical formulation.[228] However, Canadian courts have thus far not explained how one should decide between conflicting interpretations of the promise when the reason for the conflict lies in the professional identity and training of the skilled readers. This issue is likely to grow in importance given the increasing tendency to identify multiple skilled readers or to characterize the "skilled reader" as a team.[229]

A fourth issue is the need for courts to systematize and place on a principled foundation the reliance, if any, they will place on implicit promises derived from the nature of the invention. The *Plavix Impeachment* decision appears to repudiate any reliance on "implicit" promises.[230] Unfortunately, this decision fails to cite, let alone reconcile, several previous decisions by the Federal Court of Appeal itself that found and enforced implicit promises.[231] *Plavix Impeachment* has thus introduced conflicting case law at the appellate level, creating considerable uncertainty in the law of promises. This uncertainty is compounded because *Plavix Impeachment* does not explain how trial judges should differentiate between an "explicit" and "implicit" promise. One approach, which is perhaps most consistent with the law prior to *Plavix Impeachment*, is to simply ignore differences between explicit and implicit promises and leave it to purposive construction and the skilled reader to determine which promises have been made.

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226 See above Section 3.1.3.

227 *Ibid*.

228 *Plavix Impeachment*, *supra* note 21 at paras 55-66.

229 See e.g. *Sanofi-Aventis*, *supra* note 39 at para 77; *Novartis AG*, *supra* note 33 at para 82.

230 *Plavix Impeachment*, *supra* note 21 at para 49.

231 E.g. *Apotex*, *supra* note 43 at paras 24-28; *Teva Canada*, *supra* note 44 at paras 18-27. In both cases, the Federal Court of Appeal found an implicit promise of long-term treatment of a chronic disease.

Fifth, it remains an open question whether the promise of the patent is the only or the best way within existing Canadian patent law to deal with the policy concerns discussed earlier: (1) holding inventors to account for the public benefit they promise; (2) ensuring that the patent applicant has actually conducted enough research and development; and (3) preventing double patenting. Canadian law on sufficiency of disclosure, as illustrated in the Federal Court of Appeal's decision in *Leithiser*,[232] provides a possible alternative basis to deal with these policy issues. The law in this area is currently underdeveloped as a mechanism of holding inventors to the assertions of utility that they make, but it offers an approach that is more in accord with the approach taken in the United States to these issues. Whether and if Canadian courts ought to move in the direction of sufficiency to replace the utility analysis examined here is a complex issue we leave for another day.

That there are unanswered questions and unresolved tensions within the law relating to promise of the patent is not unusual, because the common law advances incrementally and progress on a given question often depends on whether litigants are interested in debating it. Nor is it unusual that progress takes the form of judicial interpretation of the *Patent Act*. Some may take issue with what they view as judicial activism lying behind the promise of the patent.[233] Judge-made law is, however, an integral part of patent law. In fact, the non-obviousness requirement—one of the most fundamental requirements for patentability—owes its very existence to case law.[234] As such, it was once considered quite controversial by many members of the patent bar. For example, Harold Fox attacked the non-obviousness requirement as little more than a "value judgment" by judges lacking scientific expertise,[235] and concluded that "from this doctrine much evil has resulted … . If it had never found its way into the law, we should have had a much more satisfactory and workable system."[236] Yet within a few decades the non-obviousness requirement became a settled part of Canadian patent law, and few would today argue that patents should be granted for obvious inventions. It is arguable that the promise of the patent is going through the same cycle of innovation, criticism, and response that lead to the codification of the non-obviousness requirement in 1993.

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[232] *Supra* note 13; see also *Re Prendergast's Application* (1999), [2000] RPC 446 (Pat Ct) for a UK case adopting a similar approach.

[233] Siebrasse, "False Promise," *supra* note 3; Legere, *supra* note 8. The Federal Court of Appeal in *Plavix Impeachment*, *supra* note 21 at paras 35-37, found a statutory basis for the promise of the patent in s 27(3) of the *Patent Act*, RSC 1985, c P-4.

[234] The non-obviousness requirement would be codified only in 1993: *Patent Act*, RSC 1985, c P-4, s 28.3 as am by SC 1993, c 15, s 33.

[235] Harold G Fox, *Monopolies and Patents: A Study of the History and Future of the Patent Monopoly* (Toronto: University of Toronto Press, 1947) at 253.

[236] *Ibid* at 212.

This article has demonstrated that the law of promises is neither new nor uniquely Canadian and is based on policy considerations shared by other mature patent systems. What one can conclude with some certainty is that, insofar as the promise of the patent is concerned, Canadian law not only does not violate any formal international treaty but has strong historical roots in British law and shares common elements with the laws of the United States, Australia, New Zealand, and Europe. Thus, although one can ask whether the promise of the patent is the best approach to the policies it furthers, one must ultimately acknowledge its validity under Canadian and international law.