UTILITY: UNRAVELLING THE REAL DIFFERENCES WITH OUR CLOSEST TRADING PARTNER*

*Wendy Lamson***

ABSTRACT

This article analyzes modern Canadian case law on promises and reveals that some cases are promise-centric—that is, promises take on the central role of setting disclosure standards—while others adopt a more holistic approach. Whether a statement rises to the level of a promise can be highly dependent on an agent's particular drafting style. But if it does rise to this level, and the patent's promise is not met, a claim of the patent may be rendered invalid. This harsh outcome needs to be tempered by a more balanced approach to construction. Given other countries' criticism of the Canadian utility requirements as being out of line with those countries' laws, a comparative and historical analysis between Canada and other patent regimes, with a particular focus on the United States, is warranted. As demonstrated, the holistic approach to setting disclosure standards better serves policy objectives and is more in line with the laws in the United States.

RÉSUMÉ

Dans cet article, l'auteure analyse la jurisprudence moderne canadienne sur les promesses, en plus de révéler que certaines affaires sont axées sur une promesse — autrement dit, certaines promesses assument le rôle central de l'établissement des normes de divulgation — alors que d'autres adoptent une approche plus holistique. La question à savoir si un énoncé s'élève au niveau d'une promesse peut varier considérablement en fonction du style de rédaction particulier d'un agent. Mais si l'énoncé s'élève effectivement à ce niveau et si la promesse du brevet n'est pas satisfaite, une revendication du brevet pourrait être jugé invalide. Ce résultat difficile devra être atténué à l'aide d'une approche plus équilibrée en termes d'interprétation. Compte tenu de la critique de gouvernements étrangers à l'égard de l'incompatibilité des exigences canadiennes en matière d'utilité avec les lois de ces pays, il serait justifié d'effectuer une analyse comparative et historique du régime canadien des brevets et de

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celui d'autres pays, en mettant une emphase particulière sur les États-Unis. Tel que démontré, l'approche holistique sur l'établissement des normes de divulgation qui sert mieux les objectifs politiques est plus compatible avec les lois américaines.

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1.0 INTRODUCTION

It is not an overstatement to say that, at present, the utility requirement is one of the most contentious topics in Canadian patent law. Eli Lilly filed a notice of arbitration in a $500 million NAFTA dispute against Canada, arguing that Canadian patent law has a heightened utility requirement that is extra-statutory and out of step with other countries.[1] The government of Canada, in return, argued that utility is a long-standing

[1] *Eli Lilly and Company v Government of Canada*, Notice of Arbitration (12 September 2013), online: Government of Canada, Foreign Affairs, Trade and Development Canada <http://www.international.gc.ca/trade-agreements-accords-commerciaux/topics-domaines/disp-diff/eli.aspx?lang=eng> [Notice of Arbitration]; see also *Eli Lilly and Company v Government of Canada*, Second Notice of Intent to

requirement in Canadian patent law, and serves important policy objectives at the heart of the Canadian patent system.[2] For a country that is often perceived as a peacekeeper with values based on compromise, there is no compromise when it comes to views on utility. Opinions reside at opposite ends of the spectrum. No debate has ever been so heated in Canadian patent law. Who said intellectual property law is boring?

The issue underlying the debate is whether Canadian law on utility mandates a heightened disclosure standard that is out of step with the laws of other countries. Those who believe that it does argue that patent laws in mature regimes such as the United States and Europe require only that an invention be "capable of industrial application" or "useful"[3] in an economic sense and that Canada should set a similarly low bar to establish utility. This was a central argument advanced in Lilly's notice of arbitration. At the other end of the spectrum are those who argue that Canada is well aligned with other countries because, when foreign patent regimes are analyzed as a whole, it is apparent that they have functional equivalents to Canada's utility requirements.[4]

As with anything in a real-world context, the truth resides somewhere in the middle of these two extremes. A comparative analysis of the statutory provisions at play in Canada and the United States setting disclosure standards, and how the courts' interpretation of these provisions in each country has evolved to address challenges imposed by emerging technology, provides a backdrop against which similarities and differences can be delineated. What is revealed is that, although there are notable functional equivalents to laws in the United States and Europe dealing with disclosure requirements, there are also points on which the laws differ markedly. Where Canada is out of step is a line of cases that requires patentees to meet a disclosure threshold in which promissory language in the patent specification forms the focus of the analysis.

Equipped with an understanding of the real differences with foreign jurisdictions, we can analyze whether a "promise-centric" yardstick for measuring adequate disclosure is good law and sound policy or whether a more holistic approach to the patent is a better basis on which to set disclosure standards. By viewing this

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Submit a Claim to Arbitration Under NAFTA Chapter Eleven (13 June 2013), online: Government of Canada, Foreign Affairs, Trade and Development Canada <http://www.international.gc.ca/trade-agreements-accords-commerciaux/assets/pdfs/disp-diff/eli-02.pdf> [Second Notice of Intent].

[2] *Eli Lilly and Company v Government of Canada*, Government of Canada Counter Memorial (27 January 2015) at paras 91 and 100, online: Government of Canada, Foreign Affairs, Trade and Development Canada <http://www.international.gc.ca/trade-agreements-accords-commerciaux/topics-domaines/disp-diff/eli-counter-memorial.aspx?lang=eng> [Counter Memorial].

[3] Second Notice of Intent, *supra* note 1 at para 90.

[4] Richard Gold & Michael Shortt, "The Promise of the Patent in Canada and Around the World" (2014) 30:1 CIPR at 37 [Gold & Shortt]; *Eli Lilly and Company v Government of Canada*, Expert Report of Timothy R Holbrook (26 January 2015) online: italaw <http://www.italaw.com/sites/default/files/case-documents/italaw4137.pdf>.

inquiry through the lens of the utilitarian justification for intellectual property rights, it becomes apparent not only that a more holistic approach better serves the policy objectives underlying the patent regime, but also that such an approach is more in line with that taken by foreign jurisdictions.

2.0 THE EVOLUTION OF CANADA'S LAW ON UTILITY

Historically, section 2 of the *Patent Act*[5] has defined "useful" subject matter in the context of defining statutory subject matter eligible for patentability. The history of the judicial construction of the word "useful" and the evolution of section 2 to take on a separate and distinct role in defining disclosure standards is examined below.

2.1 The Meaning of "Useful" in Section 2 of the Patent Act

To fall within the definition of "invention," section 2 of the *Patent Act* requires that an invention be both "new and useful." Nonetheless, in Canada a patent cannot be obtained for "anything under the sun that is made by man."[6] Fields of endeavour to which patent law protection applies are called "statutory," and those excluded are termed "non-statutory." The definition of "invention" in section 2 of the *Patent Act* generally defines what subject matter is eligible for a patent and reads as follows:

> In this Act … "invention" means any new and useful art, process, machine, manufacture or composition of matter or any new and useful improvement in any art, process, machine, manufacture or composition of matter.

The courts have said that the term "useful" in section 2 points to "practicality as opposed to theory."[7] The judicial construction of the term has arisen in the case law when determining whether subject matter relates to a useful art. At first blush, the interpretation of "useful art" seems to be limited to the narrow issue of whether an art is useful, but the term "art" has actually been given an expansive interpretation that overlaps with other statutory categories of invention. The decision of *Lawson v Canada (Commissioner of Patents)* in 1970 has defined "art" as "an act or series of acts performed by some physical agent upon some physical object and producing in such object some change of character or of condition."[8] This implies that art relates to a method or process. More recently, however, art has been interpreted to broadly encompass "any applied learning or knowledge, including its resulting product or effect."[9] Thus the interpretation of the word "useful" in section 2 is broadly applicable,

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[5] RSC 01985, c P-4.

[6] *Harvard College v Canada (Commissioner of Patents)*, 2002 SCC 76 at para 185, [2002] 4 SCR 45.

[7] *Calgon Carbon Corporation v North Bay, City*, 2005 FCA 410 at para 10 [*Calgon*].

[8] *Lawson v Canada (Commissioner of Patents)* (1970), 62 CPR 101 (Can Ex Ct) at 109 [*Lawson*].

[9] *Shell Oil Co v Commissioner of Patents*, [1982] 2 SCR 536 [*Shell Oil*]; *Progressive Games, Inc v Canada (Commissioner of Patents)* (1999), 3 CPR (4th); see also *Calgon*, *supra* note 7.

and is not confined to inventions in which there is some "act or series of actions on some physical agent" as articulated by *Lawson*.[10]

Nonetheless, *Lawson* provides some insight into the meaning of the term "useful" in section 2. In determining whether a method for parcelling land was a patentable art, the court stated:

> The point is that a process, to fall within the limits of patentability which the context of the Statutes of Monopolies has supplied, must be one that offers some advantage which is material, in the sense that the process belongs to a *useful art as distinct from a fine art* (see Virginia-Carolina Chemical Corporation's Application, [1958] R.P.C. 35 at p. 36)—that its value to the country is in the *field of economic endeavour*.[11]

The later decision of *Shell Oil v Commissioner of Patents* went even further in stating that a new and useful art is the "practical embodiment of … new knowledge."[12] The patentee discovered that known compounds could be put to a new use as plant growth regulators. Wilson J explained that the new use for an old compound was an invention within the meaning of section 2:

> What then is the "invention" under s. 2? I believe it is the application of this new knowledge to effect the desired result which has an undisputed commercial value and that it falls within the words "any new and useful art." I think the word "art" in the context of the definition must be given its general connotation of "learning" or "knowledge" as commonly used in expressions such as "the state of the art" or "the prior art." The appellant's discovery in this case is added to the cumulative wisdom on the subject of these compounds by a recognition of their hitherto unrecognized properties and it has established the method whereby these properties may be realized through practical application. In my view, this constitutes a "new and useful art" and the compositions are the *practical embodiment of the new knowledge*.[13]

The requirement that subject matter be "useful" excludes the patenting of arts that are non-economic in nature or, as enunciated in the 2011 decision of *Amazon v Commissioner of Patents*,[14] subject matter directed to "practicality as opposed to theory."[15] This excludes things such as concepts or discoveries, artistic methods, methods of exercising professional skill and judgment, scientific principles, and abstract theories.[16]

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[10] *Supra* note 8.

[11] *Ibid* at 111, citing *In National Research Development Corporation's Application (Australia)*, [1961] RPC 135 at 145 (emphasis added).

[12] *Shell Oil*, *supra* note 9 at 552.

[13] *Ibid* at 549 (emphasis added).

[14] *Canada (Attorney General) v Amazon.com, Inc*, 2011 FCA 328 [*Amazon*].

[15] *Ibid* at para 40.

[16] See Patent Office, *Manual of Patent Office Practice* (Ottawa-Gatineau: Canadian Intellectual Property Office, July 2015) ch 12, "Subject Matter and Utility."

There is sound policy rationale for not awarding patent rights to inventions that relate to disembodied ideas. Although such information might have some economic use to the extent that it can be used during downstream research endeavours to gain insight that might ultimately lead to an invention, this should not justify a monopoly on the information itself. Preventing a monopoly on such information serves the important public policy function of ensuring that the public domain remains a vibrant repository of information that can be used by society without restriction.

The interpretation of the term "useful" also arises outside the context of determining whether an invention is a practical embodiment of new knowledge. Inventions that do not work at all, such as perpetual motion machines, are also considered non-statutory under section 2 of the *Patent Act*. The most commonly cited case in this regard is *X v Canada (Commissioner of Patents)*,[17] where an application was made for a patent to an invention titled "Death Ray." A "death ray" is a theoretical device that creates a path of ionized air using a laser beam to transmit electrical energy without wires. The Patent Office held that the invention was inoperable for the purpose for which it was designed and the commissioner's decision was not reversed on appeal. This makes sense in that if an invention does not function at all, it cannot have any economic applicability and thus is not useful in industry.

2.2 Section 27(3) of the Patent Act: The Quid Pro Quo

Even if an invention is "new and useful" and falls within a specific statutory category enumerated in section 2 of the *Patent Act*, it is not necessarily patentable. The remainder of the *Patent Act* sets out further requirements for patentability. One of the most important of those requirements, because of the central role that it plays in patent policy, is the disclosure requirement. In fact, in terms of the economic justification for intellectual property rights, disclosure of the invention to the public is said to lie at "the heart of the whole patent system."[18] Disclosure requirements are set out in section 27(3) of the *Patent Act*, which reads (in part) as follows:

> 27(3) The specification of an invention must
>
> (a) correctly and fully describe the invention and its operation or use as contemplated by the inventor;
>
> (b) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it.

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[17] *X v Canada (Commissioner of Patents)*, [1981] FCJ No 1013, 59 CPR (2d) 7 [*X v Commissioner of Patents*].

[18] *Consolboard v MacMillan Bloedel (Sask) Ltd*, [1981] 1 SCR 504 at 517, 56 CPR (2d) 145 [*Consolboard*].

Adequate disclosure specifically speaks to the utilitarian justification for patent rights, which is the strongest economic argument for patent protection and most commonly relied on by the courts in Canada.[19]

In Canada, the utilitarian theory is firmly entrenched in the case law through the repeated endorsement of the "patent bargain" or *quid pro quo*. Indeed, the Supreme Court of Canada in two separate decisions has emphasized that sufficiency of disclosure under section 27(3) is central to the patent bargain.[20] As articulated by Binnie J, "[a] patent, as has been said many times, is not intended as an accolade or civic award."[21] Something needs to be given in return to the public and that something is an

> adequate description of the invention with sufficiently complete and accurate details as will enable a workman, skilled in the art to which the invention relates, to construct or use that invention when the period of the monopoly has expired.[22]

The more recent Supreme Court of Canada decision in *Pfizer*[23] further expounded on the specific requirements of section 27(3), relying heavily on an earlier landmark SCC decision, *Consolboard v MacMillan Bloedel*.[24] In particular, the court stated that "the nature of the invention must be disclosed and that the entire specification, including the claims, must be considered in determining the nature of the invention and whether disclosure was sufficient."[25] Citing specific passages from *Consolboard*, the court said that the specification should contain a "description of the invention and the method of producing or constructing it,"[26] and that "[t]he specification must define the precise and exact extent of the exclusive property and privilege claimed."[27] Further, the description must be correct and full in order that

> when the period of monopoly has expired the public will be able, having only the specification, to make the same successful use of the invention as the inventor could at the time of his application.[28]

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[19] William Fisher, "Theories of Intellectual Property" in Stephen R Munzer, ed, *New Essays in the Legal and Political Theory of Property* (Cambridge: Cambridge University Press, 2001) 168 at 169 [Fisher].

[20] *Teva Canada Ltd v Pfizer Canada Inc*, 2012 SCC 60 at para 45, [2012 3 SCR 625 [*Pfizer*]; *Consolboard*, *supra* note 18 at 517, which states that "[s]ection 36 of the *Patent Act* lies at the heart of the whole patent system." Section 36 corresponds to current section 27(3) of the *Patent Act*. As stated in *Pfizer* at para 49, "[a]lthough there are variations in wording between that section and the current s. 27(3), the substance of the disclosure requirements has remained the same."

[21] *Apotex Inc v Wellcome Foundation Ltd*, 2002 SCC 77 at para 37, [2002] 4 SCR 153 [*AZT*].

[22] *Consolboard*, *supra* note 18 at 517.

[23] *Pfizer*, *supra* note 20.

[24] *Consolboard*, *supra* note 18.

[25] *Pfizer*, *supra* note 20 at para 50.

[26] *Ibid*.

[27] *Ibid*.

[28] *Ibid*.

While devoting extensive discussion to the importance of adequate disclosure in the context of satisfying the patent bargain,[29] LeBel J also stated that section 27(3) "does not impose upon a patentee the obligation of establishing the utility of the invention" and "there is no requirement *whatsoever* in section 27(3) to disclose the utility of the invention."[30] In other words, establishing utility under section 2 and meeting disclosure requirements under section 27(3) are mutually exclusive requirements. While these statements were made in *obiter dictum*,[31] since the utility was met at the time of filing, the force of the language used to convey this point cannot be disregarded. However, despite this, another line of cases supports the argument that there is a strong interplay between section 2 and section 27(3), as discussed below.

2.3 Utility Requirements Under Section 2 of the Patent Act

The statutory function of section 2 of the *Patent Act*, in particular the judicial construction of the word "useful," has evolved beyond the mere stipulation that subject matter must be a "practical embodiment of knowledge,"[32] or operable, and has now taken on an additional role of setting the standard for disclosure through what has been referred to by some as the "promise doctrine."[33] Indeed, the courts have even gone so far as to say that section 2 is the key statutory provision to police the *quid pro quo*,[34] despite the two Supreme Court decisions of *Consolboard*[35] and *Pfizer*[36] specifically assigning that role to section 27(3) of the *Patent Act*.

2.3.1 The Origin of Section 2 to Set Disclosure Standards

The requirement for a separate and distinct utility requirement under section 2 for setting the disclosure standard has its origins in English law.[37] Two decisions most often quoted in this connection are *Hatmaker v Joseph Nathan & Co Ltd*[38] and *Re Alsop's*

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[29] *Ibid* at paras 31-35.

[30] *Ibid* at para 40 (citing *Consolboard*, *supra* note 18 at 521, Dickson J: "I am further of the opinion that s. 36(1) [now s 27(3)] does not impose upon a patentee the obligation of establishing the utility of the invention") (emphasis added).

[31] *Ibid* at para 43: "[T]he question of whether there is an 'enhanced' or 'heightened' disclosure requirement with respect to sound predictions does not arise in this case and need not be addressed."

[32] *Shell Oil*, *supra* note 9 at 549.

[33] Norman Siebrasse, "The False Doctrine of False Promise" (2013) 29:1 CIPR 3 at 8-11 [Siebrasse, "False Promise"].

[34] *AZT*, *supra* note 21: see also Notice of Arbitration, *supra* note 1 at para 3.

[35] *Supra* note 18.

[36] *Supra* note 20.

[37] See discussion in Douglas S Johnson, "Utility: A Mixed Question of Fact and Construction" in Gordon F Henderson & National Judicial Institute (Canada), ed, *Patent Law of Canada* (Toronto: Carswell, 1994) 63 at 64-65 and Siebrasse, "False Promise," *supra* note 33 at 8-11.

[38] (1919), 36 RPC 231 (HL) [*Hatmaker*].

Patent.[39] In *Hatmaker*, the court said that the patentee "must be judged by the test which he himself imposed."[40] In a similar vein, *Alsop's Patent* stated that "the utility of the invention depends upon whether, by following the directions of the patentee, the result which the patentee professed to produce can in fact be produced."[41]

However, as articulated by Siebrasse, the "promise doctrine" is based on an outdated requirement of English patent law dating back to an era when "patents" were royal grants, not just including inventions but broadly encompassing grants of land or privileges. The promise doctrine is rooted in the English Crown prerogative that representations made in "letters patent" must be strictly met since the "monopoly was granted on the faith of the representations made by the applicant."[42]

In contrast to present day, the policy at the time was not to reward inventors for disclosure of innovation in exchange for a limited monopoly.[43] Rather, the granting of such rights by the Crown was discretionary, and if the Crown had been deceived, then the grant of the "patent" was invalid. This requirement became less important as patents shifted from being granted by the discretion of the Crown to a system based on grant by meeting a "fixed set of criteria that could be independently applied by the courts"[44]—namely, a patent act.

Much to the chagrin of patentees, the principles laid down in *Hatmaker* and *Alsop's Patent* gained traction and have taken on a life of their own from 2005 and onward.[45] Rather ironically, in the meantime, this requirement was jettisoned under English patent law in 1977, when the United Kingdom harmonized its laws with the *European Patent Convention*.[46]

Interestingly, section 53(1),[47] a provision dealing with misrepresentation, is rarely invoked when dealing with promissory language. The problem with this section of the *Patent Act* is that the jurisprudence shows that it is effectively toothless because it must be demonstrated that the misrepresentation was wilfully made for the purpose of misleading. This is difficult to show in practice.[48]

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[39] (1907), 24 RPC 733 [*Alsop's Patent*].

[40] *Supra* note 38 at 329.

[41] *Alsop's Patent*, *supra* note 39 at 753.

[42] Siebrasse, "False Promise," *supra* note 33 at 15.

[43] *Ibid* at 16.

[44] *Ibid* at 16 and 17.

[45] *Ibid* at 5.

[46] *Ibid*.

[47] Section 53(1) of the *Patent Act* states:

> A patent is void if any material allegation in the petition of the applicant in respect of the patent is untrue, or if the specification and drawings contain more or less than is necessary for obtaining the end for which they purport to be made, and the omission or addition is wilfully made for the purpose of misleading.

[48] See especially *671905 Alberta Inc v Q'Max Solutions Inc* (2003), 27 CPR (4th) 385 (FCA).

2.3.2 Modern Supreme Court of Canada Decisions on Section 2

Despite these earlier English cases, the landmark SCC *Consolboard*[49] decision is the most frequently cited decision around section 2 utility requirements. Moreover, this decision has been cited not only in support of a "heightened" section 2 utility requirement[50] but also as authority supporting the lower scintilla standard.[51]

On the one hand, *Consolboard* stated that the meaning of "not useful" in patent law is 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*.[52]

This passage has been cited to support the proposition that section 2 mandates construction of promises.[53] On the other hand, there are passages in the decision stating that sections 2 and 27(3) are mutually exclusive requirements. In this regard, Dickson J stated:

> [T]he Federal Court of Appeal has confused the requirement of s. 2 of the *Patent Act* defining an invention as new and "useful," with the requirement of s. 36(1) [now s 27(3)] of the *Patent Act* that the specification disclose the "use" to which the inventor conceived the invention could be put. The first is a condition precedent to an invention, and the second is a disclosure requirement, *independent of the first*.[54]

Because of their frequency of citation around the concept of utility and the conflicting views regarding the legal precedence it establishes, these passages bear further discussion. First, it is important to note that *Consolboard* was decided before section 27(3) was enacted. At the time of the *Consolboard* decision, the relevant provision for determining whether a patent complied with disclosure requirements was section 36(1). Most of section 36(1) was substantially the same as section 27(3), except for the concluding clause, which required that the applicant shall "particularly indicate and distinctly claim the part, improvement or combination which he claims as his invention."

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[49] *Supra* note 18.

[50] *Counter Memorial*, *supra* note 2 at paras 92 and 93, where it was stated at para 92 that "[t]he leading case on the law of utility, including the promise requirement, is the Supreme Court of Canada's 1981 decision in *Consolboard v MacMillan Bloedel (Sask) Ltd*." After citing various passages of *Consolboard* discussing promises, the conclusion was made at para 93 that "the 'promise of the patent,' as applied to invalidate Claimant's patents, was recognized as an integral part of Canadian law by the Supreme Court of Canada long before Claimant filed its patent applications."

[51] Robert HC MacFarlane, "Probable Utility" (2014) 30:2 CIPR 199 at 227: "[t]he proposition that the patentee must establish the utility of the invention in the specification has been clearly rejected by the Supreme Court in *Consolboard*" [MacFarlane].

[52] *Consolboard*, *supra* note 18 at 525, citing *Halsbury's Laws of England*, 3rd ed, vol 29 at 59. This passage was cited in *Counter Memorial*, *supra* note 2 at para 92 (emphasis added).

[53] *Ibid*.

[54] *Consolboard*, *supra* note 18 at 527 (emphasis added).

Although it could be inferred from the language of the statute that it was referring to the claims, section 36(2) set forth the claims requirement. Section 36(2) stated:

> The specification shall end with a claim or claims stating distinctly and in explicit terms the things or combinations that the applicant regards as new and in which he claims an exclusive property or privilege.

Thus the concluding clause of section 36(1) must have been referring to the description—otherwise, the two parts of the statute would have been redundant.

Understandably, the concluding clause of section 36(1) has since been removed from the statute. However, as expressly stated by Dickson J, the concluding words of section 36(1) were central to the appeal.[55] In that regard, the respondent contended that to comply with section 36(1), the description needed to particularly point out the attributes of patentability in the patent specification—namely, novelty, inventive step, and utility.

The particular facts that were at issue are also important in understanding the precedent that the decision sets. The invention related to the production of fibreboard from wood flakes, also referred to in the decision as "wafers," derived from wood waste. The product was produced by preparing a "felt" from the wood fibres and adding a binder of resin and applying heat and pressure. The patent disclosed cross-cutting the fibres so that the wafers were cut across the grain of the wood, as opposed to planar action, where the grain is parallel to and extends along the length of the wafer. Cross-cutting added strength to the fibreboard produced. Further, the ends of the wafers were tapered, which provided a stronger and smoother board compared with wafers with blunt ends. At issue was whether the particular benefits flowing from the cross-cutting and tapered ends needed to be clearly described in the patent to satisfy section 36(1). Whether the invention described could be reproduced following its teachings or whether there was sufficient information to support any benefits extolled by the patentee was clearly not in question.

Dickson J, in making the following statement, rejected that the utility resulting from cross-cutting and tapering the ends of wafers had to be specifically described:

> I do not read the concluding words of s. 36(1) as obligating the inventor in his disclosure or claims to describe in what respect the invention is new or in what way it is useful. He must say what it is he claims to have invented. *He is not obliged to extol the effect or advantage of his discovery, if he describes his invention so as to produce it.*[56]

In coming to this conclusion, Dickson J devoted about 10 pages of the decision to a discussion of the requirements of section 36(1).[57] In doing so, he made various

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[55] *Ibid* at 518-19.

[56] *Ibid* at 526, and further stating *ibid*: "If an inventor has adequately defined his invention he is entitled to its benefit even if he does not fully appreciate or realize *the advantages that flow from it* or cannot give the scientific reasons for them" (emphasis added).

[57] *Ibid* at 517-27.

observations about that section, including promissory language. In rejecting the notion that section 36(1) "requires distinct indication of the real utility of the invention in question," he referred to a discussion[58] on the meaning of "not useful" in patent law.[59] It was in this context that he said 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."[60] However, this statement was made to support the conclusion that the description need not devote itself to particularly pointing out the benefits of the invention to comply with the concluding portion of section 36(1),[61] which has since been repealed and so has no counterpart in section 27(3). Dickson J also said in arriving at this conclusion that "[t]here is no suggestion here that the invention will not give the result promised."[62] Thus, the passage relied on as authority for promissory language was made in *obiter dictum*.[63] *Consolboard* is accordingly shaky precedent on which to rely for establishing that there is an interplay between the utility requirement under section 2 and the disclosure requirement under section 27(3).

Despite this, the Supreme Court of Canada decision of *Apotex Inc and Novopharm Ltd v Wellcome* (*AZT*)[64] stated that "utility is an essential part of the definition of an 'invention'"[65] and that

> [u]nless the inventor is in a position to establish utility as of the time the patent is applied for, on the basis of either demonstration or sound prediction, the Commissioner "by law" is required to refuse the patent.[66]

AZT stated that proof of such utility could be in the form of either demonstrated utility or a sound prediction if the utility was not specifically demonstrated.[67] In other

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[58] In *Halsbury's Laws of England*, *supra* note 52 at 59.

[59] *Consolboard*, *supra* note 18 at 525.

[60] *Ibid*, citing *Halsbury's Laws of England*, *supra* note 52 at 59.

[61] See note 56 above.

[62] *Consolboard*, *supra* note 18 at 525.

[63] However, see Gerald Gall, *The Canadian Legal System*, 5th ed (Toronto: Thomson Carswell, 2004) at 453, citing *Sellars v The Queen*, [1980] 1 SCR 527, in which the court stated that even *obiter dicta* emanating from the Supreme Court are binding on lower courts. More recently, in *R v Henry*, 2005 SCC 76 at para 57, [2005] 3 SCR 609, it was stated that "[t]he issue in each case … is what did the case decide? … All *obiter* do not have, and are not intended to have, the same weight. The weight decreases as one moves from the dispositive *ratio decidendi* to a wider circle of analysis which is obviously intended for guidance and which should be accepted as authoritative." In *Consolboard*, *supra* note 18, the issue at the heart of the appeal was whether the specification needed to meet the requirements of the concluding words of section 36(1). As noted, this part of the statute has been repealed. Nonetheless, for patent applications filed prior to 1 October 1989, the disclosure requirement is set out in section 34(1). This provision contains wording that corresponds to the concluding part of section 36(1).

[64] *AZT*, *supra* note 21.

[65] *Ibid* at para 46.

[66] *Ibid*.

[67] *Ibid*.

words, if there was no utility actually demonstrated at the filing date, it could be buttressed by sound prediction. Sound prediction, however, must include (1) a factual basis for the prediction, (2) an articulable and sound line of reasoning from which the desired result can be inferred from the factual basis, and (3) proper disclosure.[68]

Since this decision came down in 2002, it has been held by the Federal Court of Appeal that the *Patent Act* does not set a separate disclosure requirement for utility under section 2, or at most that such utility requirement relates only to "statutory appeals brought under s. 41 of the *Patent Act*."[69] Moreover, because the patent at issue related to an old drug (AZT) with a newly discovered "use" for treatment of AIDS, the decision has been referred to as having no applicability outside this context.[70] Further, as noted above, LeBel J said in *obiter* that "there is no requirement in section 27(3) to disclose the utility of the invention."[71] More recently, however, Barnes J disagreed, stating that "it would take something more than LeBel J's apparent reservations to displace the requirement for disclosure described by Binnie J [in *AZT*]."[72]

In any event, what is quite notable about this decision is that it is completely silent on construing any promises. Yet this sort of invention did lend itself to this type of inquiry. One can easily conceptualize that the "promise" in the patent was a new use for the known compound, AZT. Instead, Binnie J's analysis as to whether the utility was supported by the disclosure simply turned on whether the invention was "useful for the purpose claimed."[73]

Thus, both leading SCC decisions on utility and disclosure requirements do not provide any clear authority on construing the specification for promises. However, as examined below, subsequent case law has evolved into what has been characterized by some as a "heightened requirement" for meeting "promises of utility."

2.3.3 Case Law on the Promise of the Patent Post-AZT

Despite *AZT*, the statement in *Consolboard* that the promise must be met[74] gained traction in subsequent case law. Indeed, the frequency at which patents are invalidated for lack of utility has increased significantly since 2002, when the *AZT* decision came down.[75]

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[68] *Ibid* at para 70, which sets forth these three requirements.

[69] *Novopharm Limited v Eli Lilly and Company*, 2010 FC 915 at para 29, aff'd 2011 FCA 220 [*Atomoxetine*].

[70] See *AstraZeneca Canada Inc v Apotex inc*, 2014 FC 638, aff'd 2015 FCA 158 [*Esomeprazole*], in which Rennie J noted at para 141 that "the jurisprudence suggests that the requirement for proper disclosure of utility is limited to the context of 'new use' patents, assuming such a utility disclosure requirement exists at all."

[71] *Pfizer*, *supra* note 20 at para 40; see also note 30 above.

[72] *Eli Lilly Canada Inc v Hospira Healthcare Corporation*, 2016 FC 47 at para 48.

[73] *AZT*, *supra* note 21 at para 54.

[74] See note 52 above.

[75] MacFarlane, *supra* note 51 at 203.

The promise of the patent is described in these recent decisions as playing a vital role in that analysis. What is particularly illuminating about many of these decisions, however, is that while construction of promises is, in theory, at the forefront of the analysis, in many instances, the patent is construed as a whole to determine the "promise of the patent" rather than focusing on specific passages. In fact, as described in *Novopharm Limited v Eli Lilly* (*Atomoxetine*),[76] discussed below, the promise was characterized as the "inventive promise," implying that the promise is strongly tied to the underlying inventive concept of the patent.[77] Other decisions give promissory passages in the specification a more central role in the analysis, referred to herein as "promise-centric" decisions. Examples of post-*AZT* decisions that can be characterized as holistic and those that adopt a more promise-centric approach are examined below. The intent here is not to provide a comprehensive study of all cases decided since *AZT*, but rather to give the reader a flavour of how judges have differed in their application of setting the disclosure standard.

2.3.3.1 Holistic Line of Cases

Similar to *AZT*, *Eli Lilly Canada v Apotex Inc* (*Raloxifene*)[78] related to an old compound, raloxifene, with a newly discovered use. The new use was for treating osteoporosis in post-menopausal women. Estrogen therapy was the previous treatment of choice, but had some undesirable toxic side effects. Raloxifene, on the other hand, inhibited bone loss but did not elicit undesirable estrogenic responses.

The court identified a number of promises made in the disclosure of the patent at issue. In particular, the following passage on page 3 of the patent was quoted as making a promise:

> The current invention provides methods of inhibiting the loss of bone without the associated adverse effects of estrogen therapy, and thus serves as an effective and acceptable treatment for osteoporosis.[79]

Another promise was identified in subsequent passages of the disclosure:

> At pages 6 and 7 the promise of the invention is made, namely that this group of compounds [benzothiophene compounds, of which raloxifene is a member] inhibits bone loss but does not elicit significant estrogenic responses in primary sex tissues. At page 11, we are told that the most preferred compound is raloxifene particularly as a hydrochloride salt.[80]

It could thus be implied from these two passages of the *Raloxifene* decision that only treatment of bone loss without undesirable side effects usually associated with

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[76] *Supra* note 69.

[77] See also Andrew Bernstein & Yael Bienenstock, "Unpacking the Promise of the Patent" (2012) 28:2 CIPR 245 at 257 [Bernstein & Bienenstock], which discusses that promise construction should be more focused on the invention.

[78] *Eli Lilly Canada Inc v Apotex Inc*, 2008 FC 142 [*Raloxifene*].

[79] *Ibid* at para 78.

[80] *Ibid*.

estrogen was promised, and that disclosure standards should be set accordingly.[81] However, little regard was made to the above-noted promissory passages for setting the disclosure standard. When determining issues of validity related to anticipation, obviousness, sound prediction, and sufficiency of disclosure, the court noted:

> There is a tendency in the jurisprudence to pigeonhole arguments respecting validity into certain categories such as "anticipation" or "obviousness" and so forth. Each category has collected about itself an accumulation of jurisprudence. Each category tends to be argued separately creating, on occasion, contradictions, inconsistencies and gaps. This is an occasion when one should step back and examine the fundamentals of the patent system and determine whether a more holistic approach is appropriate.[82]

The judge then reviewed jurisprudence on disclosure requirements, particularly the requirement that the disclosure forms the *quid pro quo* for securing a monopoly[83] and that "in order to earn the monopoly, 'hard coinage' must be paid."[84] The following quote from *Raloxifene* aptly describes that the disclosure requirements need to be consistent with the specific monopoly sought:

> [O]ne must both advance the state of the art *and disclose that advance in order to gain the patent monopoly*. Failing to do so, thus invalidating the monopoly, can be in the form of one or more of several matters such as, the "invention" was not new, or the so-called invention was "obvious" or the disclosure was "insufficient" or "what you disclosed doesn't support the monopoly that you claim."[85]

The court then said that

> [t]he question to be asked therefore is whether this "invention" or "discovery" or "breakthrough" was already known, or would have been known to the skilled person or, turning to what the patent discloses, whether the disclosure in the patent was adequate to tell a person skilled in the art how to practice the invention or whether it discloses enough so that a person skilled in the art could "soundly predict" that it would work.[86]

The judge analyzed the specific advance offered by the patent by conducting a detailed review of the history of the prior art and the parallel development of the invention up to filing[87] and determined that, prior to the filing of the patent application, a paper (referred to as the "Jordan article") had already described the use of

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[81] *Ibid*. In fact, the decision states at para 78:

> The basis for the promise of the invention is what is set out in Examples 1 through 5 at pages 36 to 47 of the patent. Thus, having acknowledged that a "known" compound which has previously known uses as a drug and can be made by "known" methods, *the reader is now provided with what is said to be a disclosure as to how the promised invention, a new treatment was made or at least soundly predicted at Examples 1 through 5* (emphasis added).

[82] *Ibid* at para 64.

[83] *Ibid* at paras 69-74.

[84] *Ibid* at para 72.

[85] *Ibid* at para 74.

[86] *Ibid* at para 96.

[87] *Ibid* at para 124.

the drug in treating rats for bone loss, but there was no prior art describing efficacy in humans. Thus the state of the art at the time showed that the contribution of the invention over the art was successful treatment of humans.

The patent disclosed only that "such a study of women is underway and that certain results are 'expected' with a long term study to follow."[88] Because no human studies were disclosed, the patent was held to be invalid.

In reaching this conclusion, the court stated that sound prediction has three requirements: first, a sound basis for prediction; second, an articulable and sound line of reasoning to infer the result; and third, proper disclosure. Notably, a subsequent study in Hong Kong disclosing treatment of post-menopausal women with raloxifene *was* found to be sufficient to turn the prediction into a sound prediction.[89] However, the results of this study were not disclosed in the patent. According to the court, "[a] considered reading of paragraph 70 of the *AZT* decision leads to the conclusion that the disclosure must be in the patent not elsewhere." The third criterion for sound prediction was thus not met:

> The third criterion however is that of disclosure. It is clear that the '356 patent does not disclose the study described in the Hong Kong abstract. The patent does not disclose any more than Jordan did. The person skilled in the art was given, by way of disclosure, *no more than such person already had*. No "hard coinage" had been paid for the claimed monopoly. Thus, for lack of disclosure, there was no sound prediction.[90]

Although it could be argued that this was a high standard, with little regard for tying the disclosure standard to the court's noted promissory language, given the developments in the field, use in humans represented the specific advance in the art and so disclosure of the human studies in the patent itself, in my view, was warranted.

However, *Sanofi-Aventis v Apotex Inc* (*Plavix*®)[91] is a decision in which the court expressly rejected that the promise of the patent should be construed with an eye to its validity. The Federal Court of Appeal reversed a decision in which the trial judge read into the patent a promise of use in humans in "order to validate the patent as a selection patent."[92] No human studies were disclosed and so the trial judge invalidated the selection patent for failure to meet utility requirements. The trial judge construed certain statements concerning dosage ranges of Plavix® (an

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[88] *Ibid* at para 106.

[89] *Ibid* at para 120. An abstract published four months after the Canadian filing date outlines that "a study was conducted on 251 … post-menopausal women who were grouped and fed either a placebo or increasing doses of raloxifene. The investigators measured the level of various biochemical markers of bone metabolism and performed pre- and post-treatment uterine biopsies." The abstract is quoted as stating that raloxifene "shows promise as a skeletal anti-resorptive with hypolipidemic action, but without uterine stimulatory effects."

[90] *Ibid* at para 163 (emphasis added).

[91] *Sanofi-Aventis v Apotex Inc*, 2013 FCA 186 [*Plavix*®].

[92] *Ibid* at para 69.

anti-coagulant drug) and other passages in the description[93] as implying that use was in humans and then concluded that the patent promised such use, despite the fact that there were no explicit statements in the patent that the use was restricted to humans.

However, the Federal Court of Appeal noted that "[c]ourts should not strive to find ways to defeat otherwise valid patents"[94] and held that the patent did not promise use in humans. In this connection, the Federal Court of Appeal stated that the trial judge erred when "he read into the patent a promise of use in humans in order to validate the patent as a selection patent, then used this promise in order to invalidate it for lack of utility."[95] However, the Federal Court of Appeal also pointed out that the selection patent

> described the advantages of the compound … over the compounds of the '875 Patent [the earlier genus patent], and that the inventor was able to demonstrate the existence of those advantages as of the date of the filing of the patent application.[96]

The judge explained that a selection patent describes a compound that has an unexpected advantage over the compounds of the genus patent and that the

> unexpected advantage need not be an improvement on every aspect of the invention described in a genus patent, though it may be. It is sufficient that it is a new and useful improvement on some aspect of the invention.[97]

The Federal Court of Appeal found that sufficient advantages were disclosed in the selection patent over the earlier genus patent, without the need to disclose use in humans:

> The '777 Patent [the patent at issue] described a compound having advantages (including the absence of disadvantages) over the compounds of the '875 patent [the earlier genus patent] *and those advantages were clearly disclosed in the patent specification. The Trial Judge found that those advantages were demonstrated at the time of the patent application*. The Trial Judge erred in construing the patent as specifically promising a result when the invention was used in humans and then assessing the utility of the patent against that specific promise.[98]

By contrast, in *Novopharm Ltd v Eli Lilly* (*Atomoxetine*)[99] the disclosure of clinical use was required to meet the promise of the patent. The patent related to an old

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[93] *Ibid* at paras 56 and 58. Some of the diseases referred to in the patent were clearly human diseases and the invention was described as being a "medicine and 'active medicinal[s]' for therapeutic purposes." According to an expert, a haemotologist would understand from these words that this is a medicine that can be used in humans, referring an expert report.

[94] *Ibid* at para 54.

[95] *Ibid* at para 69.

[96] *Ibid* at para 70.

[97] *Ibid*.

[98] *Ibid* at para 71 (emphasis added).

[99] *Atomoxetine*, *supra* note 69.

drug with a newly discovered use in treating attention deficit hyperactivity disorder (ADHD). In this decision, the issue was whether the results of clinical studies contained in a report referred to as the "MGH Study" needed to be disclosed in the patent to meet the utility requirement. Lilly argued that the patent needed only to show that the drug atomoxetine had a "mere scintilla of utility," requiring only positive experimental results and not a showing of actual clinical usefulness.[100] Although construction of the promise of the patent was not specifically contested by the parties,[101] after a discussion of *Consolboard* and affirmation that the promise of the patent must be met,[102] Barnes J said that "utility is assessed against the inventive promises of the patent."[103] In turn, such "inventive promise" was determined to be "a new use for atomoxetine to effectively treat humans with ADHD."[104]

What is interesting about the decision is that the judge did not focus the analysis on construing specific passages in the description to arrive at the "inventive promise." Rather, it was based on his general understanding of what the invention encapsulated, obtained from his understanding of the claimed subject matter; what the disclosure taught; and expert evidence.[105] In this regard, the judge noted that the patent discussed that the drug was already well known with a "recognized mechanism of activity as a norepinephrine reuptake inhibitor."[106] The judge then pointed to teachings in the patent that the drug is quite free of side effects and that it was effective at low doses and could therefore be administered once per day.[107] The patent was thus seen to offer an "effective treatment for ADHD" and this was "the consideration required of Lilly for the monopoly it claimed."[108] Because ADHD is a chronic disorder requiring sustained treatment, implicit in the promise was that atomoxetine would work in the longer term.[109] Expert evidence also informed the judge's conclusion regarding what the patent promised. An expert was quoted as stating: "If I knew the medicine was going to work tomorrow, but never again, then

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[100] *Ibid* at para 92.

[101] *Ibid* at para 31.

[102] *Ibid* at para 90.

[103] *Ibid* at para 93.

[104] *Ibid* at para 112.

[105] *Ibid* at para 32. In determining the inventive promise, there was no detailed analysis of specific passages in the patent. Paragraphs 33-35 of the decision discuss passages of the patent, but only in the context of gaining an understanding of what the invention encompassed. In that regard, it was stated at para 32 that "[t]here is no dispute about the inventive promise of the '735 Patent. The 16 patent claims involve the use of atomoxetine for treating ADHD in three of its manifestations among all age groups (children, adolescents and adults). The patent does not claim the compound atomoxetine but only its use to treat ADHD. The patent does not assert nor would it have been expected by a person of skill that atomoxetine would work for every person."

[106] *Ibid* at para 34.

[107] *Ibid*.

[108] *Ibid* at para 93.

[109] *Ibid* at para 112.

I would not consider that a good medicine."[110] Because the patent offered no information about the nature or sources of the evidence relied on by the inventors to support atomoxetine's utility to treat ADHD, it was held to be invalid.

Compared to the *Raloxifene*, *Plavix*®, and *Atomoxetine* decisions, the decision of *Pfizer Canada Inc v Mylan Pharmaceuticals ULC* (*Celebrex*®)[111] tended to focus more on promissory language when construing the promise of the patent. Nonetheless, it cannot be overlooked that an examination of the inventive contribution over the art did, at least partially, drive the analysis.

In *Celebrex*®, the judge analyzed passages in the patent containing the word "may" when discussing advantages. At issue was whether "such preferred selectivity [of the drug] *may indicate* an ability to reduce"[112] was a promise of reduced side effects. The judge concluded that it only indicated a "possibility; maybe yes, maybe no."[113]

However, the analysis did not stop there. In discussing expert evidence that Celebrex® was entering a crowded field, and that "there would be no point to it were it not for the promised reduced side effects," the judge stated that "it does not matter how crowded a field may be."[114] This might suggest that the judge rejected the notion that a promise should be construed by taking into consideration the specific advancement over the art. However, the judge went on to state that "[i]f Celebrex® was new, *which it was*, and useful in treating inflammation, *which it is*, then the invention is entitled to letters patent."[115] Thus the judge clearly factored in the inventive concept when construing the promise, but rejected the expert evidence that the promise required reduced side effects. In this instance, it was noted that Celebrex® was new and also exhibited an anti-inflammatory effect, and thus the lower threshold of merely treating inflammation was seen as a sufficient contribution.[116] As in *Atomoxetine*, the court also looked at the claims when construing the promise and noted that there was "not a word of reduced side effects in the claims."[117] The construed promise of "treating inflammation" was thus arrived at by examining not only the language of the description but also the state of the art and the claim language itself.

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110 *Ibid*.

111 *Pfizer Canada Inc v Mylan Pharmaceuticals ULC*, 2014 FC 38 [*Celebrex*®].

112 *Ibid* at para 64 (emphasis added).

113 *Ibid* at para 65.

114 *Ibid* at para 66.

115 *Ibid* (emphasis added).

116 *Ibid*. This is consistent with the judge's earlier statement at para 4 that "[i]t is not in issue that Celebrex® is both new and useful in the treatment of inflammation."

117 *Ibid* at para 67.

Eli Lilly Canada Inc v Novopharm Limited (*Olanzapine*)[118] is another decision in which the promise of the patent was arrived at by elucidating the inventive contribution over the art. As in *Plavix*®, the patent at issue was a selection patent. While certain language was construed, the analysis factored in the advantages that the selection patent offered over the prior art. Analyzed in this context, the judge noted a statement in the patent that the drug "[o]verall, therefore, in clinical situations … shows marked superiority and a better side effects profile than prior known antipsychotic agents, and has a highly advantageous activity level."[119] In this regard, it was noted that the patent discussed the superiority of olanzapine only in respect of the particular side effects specifically mentioned in the patent, most especially EPS (extra-pyramidal symptoms) and agranulocytosis.[120] Thus, the inventive concept was inextricably linked to the promise of the patent. The judge then measured the disclosure against this standard and arrived at a finding of invalidity.

Bell Helicopter Textron Canada Limitée v Eurocopter[121] is a decision that stands apart from the above-noted decisions in that the technology at issue was mechanical in nature—namely, helicopter landing gear in the shape of a sleigh. Nonetheless, much of the same principles of construction were applied. The decision cited *Consolboard* as authority that the "promise is the standard against which the utility of the invention is measured" and that "[i]f the inventor does not make in the patent an explicit promise of a specific result, the threshold to find utility will be low; if, on the other hand, the inventor makes an explicit promise of a specific result, then utility will be assessed by reference to the terms of the explicit promise."[122] The judge also stated that the utility was assessed against the stated advantages of the patent,[123] which, earlier in the decision, were listed as (1) elevated acceleration factors upon landing; (2) difficult frequency adaptation with respect to ground resonance; and (3) high landing gear weight.[124] However, when determining whether the patent provided a sound prediction of utility, the inventive concept was given a certain amount of weight. In particular, the judge said that "the inventive concept is described in the '787 Patent as a particular geometry (inclined offset front cross piece and an integrated transition zone) which creates a cantilever, allowing the front cross piece to work in both flexion and torsion modes."[125] It was then concluded that it was only the front cross piece that is offset forward (as provided in claim 15), which "has the advantage of allowing the roll operation of the assembly to cause the front piece to work both in torsion and in bending rather than in pure bending."[126]

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[118] *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288, aff'd 2012 FCA 232 [*Olanzapine*].

[119] *Ibid* at para 120.

[120] *Ibid* at para 122.

[121] *Bell Helicopter Textron Canada Limitée v Eurocopter, société par actions simplifiée*, 2013 FCA 219 [*Eurocopter*].

[122] *Ibid* at para 132.

[123] *Ibid* at para 147.

[124] *Ibid* at para 25.

[125] *Ibid* at para 156.

Against this backdrop, claim 15 was held to be valid, but claims directed to an integrated piece of the landing gear offset backward were invalidated because, in contrast to the forward offset, there was no demonstration or explanation in the patent that a backward inclination would improve ground resonance behaviour.[127]

Thus, in the above-noted decisions, promissory passages were only one component of the analysis, and in some instances took a back seat to questions about the inventor's contribution to the existing knowledge and whether there was sufficient disclosure of the patentee's contribution to warrant a monopoly. The approach taken to determine the "promise of the patent" was more along the lines of asking "What is the invention?,"[128] based on reviewing the patent as a whole through the eyes of an expert, as opposed to interpreting and delineating specific passages. Indeed, this is consistent with the principles of construction, as set out in *Whirlpool*:

> [W]here the language of the specification, upon a reasonable view of it, can be so read as to afford the inventor protection for that which he has actually in good faith invented, the court, as a rule, will endeavour to give effect to that construction.[129]

2.3.3.2 More Promise-Centric Cases

It could be argued that the decisions discussed above applied a more holistic-type analysis because construction is a question of law and expert evidence is needed for the judge to understand the words used in a patent "through the eyes and with the common knowledge of a worker of ordinary skill in the field to which the patent relates."[130] It has been argued that the promise of the patent involves construing the patent as a whole to determine the nature of the invention and does not involve scouring the patent for promissory language.[131] However, it cannot be ignored that certain decisions tend to rely more heavily on construction of particular passages of the specification than others to elucidate and set disclosure standards, particularly if a promise is explicit.

Astrazeneca Canada Inc v Mylan Pharmaceuticals ULC (*Anastrozole*)[132] is an example of one such decision. Again citing *Consolboard*[133] that the promise of the patent must be met,[134] the court analyzed the promise in a manner that has been

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126 *Ibid* at para 157.

127 *Ibid* at paras 158-162.

128 Consistent with *Consolboard*, *supra* note 18.

129 *Whirlpool Corp v Camco Inc*, 2000 SCC 67 at para 49, [2000] 2 SCR 1067 [*Whirlpool*].

130 *Ibid* at para 53.

131 *Eli Lilly and Company v Government of Canada*, Expert Report of Ronald E Dimock (4 December 2015) at paras 73-78, online: italaw <http://www.italaw.com/sites/default/files/case-documents/ITA%20LAW%207021.pdf> [Dimock, 2nd expert report].

132 *Astrazeneca Canada Inc v Mylan Pharmaceuticals ULC*, 2011 FC 1023 [*Anastrozole*].

133 *Supra* note 18.

134 *Anastrozole*, *supra* note 132 at para 86.

referred to by commentators as a "linguistic parsing of the text"[135] to construe the promise. Prior to doing so, the court articulated some principles of construing the promise. In particular, the judge said that "[c]onstruction of the promise of the patent is a question of law within the exclusive province of the Court" and that "[c]ourts should be careful in relying on expert evidence to construe the promise of the patent."[136] The judge further reinforced that promises should be construed by looking at the patent specification:

> While I have relied on the expert evidence, the jurisprudence, and the language of similar patents, *the promise must ultimately be grounded in the language of the patent specification*.[137]

This is counter to *Raloxifene*, which looked at other factors as part of this determination, and *Atomoxetine*, which construed the "inventive promise."

Construing the "promise" then became an exercise of differentiating promises from goals or objectives based on particular passages in the specification. In this regard, the judge said that "[g]oals and objectives are by definition forward looking. They refer to potential, possibility or contingent events or consequences."[138] Although in this case an objective did not "rise to the level of a promise," and the promise of the patent was construed simply as "[t]he use of the compound [anastrozole] as an inhibitor of the enzyme aromatase,"[139] *Anastrozole* illustrates how subjective the analysis can be.

A similar approach was taken in a more recent decision, *AstraZeneca Canada v Apotex* (*Esomeprazole*).[140] As in other decisions, the court relied on *Consolboard*[141] as legal authority for determining the promise and meeting it.[142] Although the judge stated that "identifying the promise of the patent requires a consideration of the patent as a whole,"[143] the debate over the promise in the decision was actually centred on a passage from the disclosure. Understandably, both parties advocated for different interpretations of the specific passage.

The drug covered by the patent, esomeprazole, is used in the reduction of gastric acid, reflux esophagitis, and related maladies. At issue was whether the following statement in the patent was a promise:

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135 Bernstein & Bienenstock, *supra* note 77 at 249.

136 *Anastrozole*, *supra* note 132 at para 90.

137 *Ibid* at para 131 (emphasis added).

138 *Ibid* at para 133.

139 *Ibid* at paras 145 and 148.

140 *Esomeprazole*, *supra* note 70.

141 *Supra* note 18.

142 *Esomeprazole*, *supra* note 70 at para 86.

143 *Ibid* at para 87.

> It is desirable to obtain compounds with improved pharmacokinetic and metabolic properties which *will give an improved therapeutic profile such as a lower degree of interindividual variation*. The present invention provides such compounds, which are novel salts of single enantiomers of omeprazole.[144]

Apotex interpreted the emphasized text above to be an explicit promise, while AstraZeneca interpreted the text as a "goal" that fell short of an explicit promise. The judge rejected AstraZeneca's argument that the emphasized passage was a goal.[145] However, in arriving at the conclusion that it was a promise, the judge made some interesting statements regarding goals versus promises:

> Goals merely describe "a hoped-for advantage of the invention" (*Mylan Arimidex*, at para 139). For example, in *Mylan Arimidex*, I found that an object clause, beginning with "it is a particular object of the present invention to," merely described a goal that the patent strived to achieve rather than a promised outcome. Similarly, in *Sanofi-Aventis Plavix*, at paras 55-67, Justice Pelletier found the inference of a promise of therapeutic utility based on indirect references to the use of the drug in humans (e.g. references to human diseases and dosages that potentially correspond to use in humans) was insufficient to substantiate a promise and merely alluded to potential uses. In sum, promises are explicit and define guaranteed or anticipated results from the patent (depending on whether the promise is demonstrated or soundly predicted), whereas goals merely relate to potential uses for the patent.[146]

The judge further stated that "[t]he same cannot be said of 'will.' Will does not convey a low threshold of potential outcomes, but to the contrary, a high threshold of probable or certain outcomes that will occur, which in turn, suggests that such outcomes are promised by the patent."[147]

Thus, as in *Anastrozole*, the construction of the promise became a hair-splitting exercise, delving into an analysis of whether certain words were forward looking or not. Certainly, the original draftsperson of the patent did not intend for the language to be subjected to such meticulous verbal analysis. The inventive concept did not play a central role in the analysis and this construction of the promise was affirmed on appeal.[148]

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144 *Ibid* at para 3 (emphasis added). There were actually three "promises" at issue. The first was the promise of inhibition of a proton pump, the second the lack of enzyme-mediated racemization, and the third an improved therapeutic profile with lower interindividual variation: see discussion at paras 101-112, in which it was concluded that the common ground was the advantage of improved therapeutic profile and, later in the decision, the patentee was held to the proton pump inhibition promise and therapeutic profile.

145 *Ibid* at para 114.

146 *Ibid* at para 117.

147 *Ibid* at para 120.

148 *Ibid*. On appeal AstraZeneca argued that the Federal Court erred by construing the claims as requiring an improved therapeutic profile, which was not supported by the inventive concept. The judge disagreed and stated at para 11 that there is no requirement that "a promise of utility must be

2.3.4 Analysis of Post-AZT Case Law on Utility

Although the above-noted decisions all affirmed in theory that construction of the promise comes before a determination of sufficiency of disclosure, the underlying analysis differed in practice. In *Raloxifene*, *Plavix*®, *Atomoxetine*, *Celebrex*®, *Olanzapine*, and *Eurocopter*, the approach was more holistic, with the "inventive concept" often playing a key role in the analysis. By contrast, in *Anastrozole* and *Esomeprazole*, the interpretation of specific promissory language in the patent specification resided more at the heart of the analysis. In *Esomeprazole*, on appeal, an approach to construction in which the promise is coterminous with the inventive concept was rejected outright.[149]

The more holistic approach provides greater fairness and equity than a more promise-centric analysis of the patent disclosure, even if promissory language is explicit. This approach captures a principle aptly stated by Hughes J that one must "both advance the state of the art and disclose that advance in order to gain the patent monopoly."[150] It also highlights that in some technical fields, simply showing how to make and use an invention is not always adequate to disclose the specific contribution made over the art. For example, patents relating to old drugs with a newly discovered use would add nothing to the state of the art if they simply showed how to make the drug with the disclosure of a speculative use.

Elucidating what the inventive contribution is over the art, and setting the disclosure standard accordingly, ensures that the specific advancement given to the public after patent expiry is properly disclosed. Such an approach is multifaceted because it considers the complexity that often comes into play in determining the inventive concept against the backdrop of the state of the art, which is often in flux for emerging technologies. A more promise-centric approach, while potentially providing a clearer bright-line disclosure test, which focuses on specific passages in the text, is not equipped to factor in these complexities.

Raloxifene is illustrative. In *Raloxifene*, the state of the art was developing rapidly, and at the time of filing, a paper referred to as the "Jordan article," which itself built on prior work, was already published. Added to this, there were conflicting opinions about the teachings of this scientific article. Thus expert opinion was needed to gain an appreciation of the patentee's contribution over this specific piece of art.[151]

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construed to be virtually coterminous with the inventive concept." This was cited with approval in *Leo Pharma Inc v Teva Canada Limited*, 2015 FC 1237 at paras 164 and 166. Teva argued that the inventive concept did not include stability of the composition; however, the judge stated at para 166 that "[b]e that as it may, there is no dispute that the utility of the invention concerns the stability and efficacy of the claimed composition."

149 *Ibid*.

150 *Raloxifene*, *supra* note 78 at para 74.

151 *Ibid* at paras 102-113. Lilly's witnesses did not think the Jordan article conclusively showed efficacy of the drug in rats, although at para 110 one witness had admitted in a Food and Drug Administration submission that the Jordan reference was "very, very good at predicting the actions of pharmacological agents on the skeleton at least regarding estrogen deficiency induced bone loss."

At a broader level, the above-noted cases illuminate how the courts have addressed the difficulties inherent in striking a proper balance between the interests of patentees on the one hand and the public on the other.[152] Achieving a proper level of disclosure in a patent by determining the proper yardstick against which it is measured lies at the heart of striking this delicate balance.

Of course, patent holders' interests lie in filing early to secure patent rights before their competitors, and before public disclosure of their invention, to prevent the disclosure from being citable for novelty and obviousness.[153] This is a particular concern in the pharmaceutical industry because clinical trial data or publications from collaborators may become available to the public. Thus, waiting until clinical trials or other studies are completed may preclude a patentee from securing patent protection. The interests of patentees also reside in curtailing disclosure because fleshing out an invention to meet the requirements for patentability can sometimes exhaust significant resources and time that could be dedicated to other endeavours that increase a company's bottom line for its shareholders.[154] In contrast, the public interest lies in the patentee providing a detailed enough disclosure of the inventive contribution over the art so that the advance in the art can be practised and reproduced after the monopoly is over without having to fill in gaps by extensive experimentation to determine whether the invention has utility. These competing interests are particularly pronounced in emerging technologies, which involve new and often complex technical issues with a unique relationship with the state of the art as it develops over time. Elucidating the right level of disclosure that promotes fairness and equity for all stakeholders is not always an easy task.

Interestingly, Canada was not the first to grapple with the difficulties of striking a balance between the patentee's interest in filing early and curtailing disclosure and the public's interest in obtaining a full and detailed disclosure in the context of emerging technologies. The United States, which notably has statutory provisions almost identical to section 2 and section 27(3) of the *Patent Act*, dealt with the identical issue. To address this, as discussed below, the US laws around adequate disclosure evolved through the years to take on a separate and distinct requirement, referred to as the "written description requirement," which mandates that, depending on the facts, a patent disclosure may need to go beyond showing simply how to

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The judge then concluded at para 113 that the Jordan article "was viewed as a good piece of scientific work which demonstrates that, in rat studies, both tamoxifen and raloxifene … showed selective action in living tissue, limiting bone loss with little effect on sex tissues."

152 Consistent with the utilitarian theory for the justification for intellectual property rights; for a more comprehensive discussion of this theory, see Fisher, *supra* note 19.

153 Or within one year of filing the patent application for those countries with a grace period for inventor-derived disclosures—e.g. Canada, the United States, and Brazil, and the laws vary between the countries.

154 Often the details of pharmaceutical inventions need to be fleshed out to meet regulatory approval. For other types of inventions, data often need to be generated to meet patent disclosure standards, but may not necessarily be required to commercialize and market the specific commercial embodiment of the invention.

make and use an invention by additionally showing "possession of the invention." Although widely criticized as being extra-statutory, judge-made law, this additional requirement in US law has emerged to address adequate disclosure for those inventions in which merely showing how to make and use an invention is not always sufficient to satisfy the patent *quid pro quo*.

3.0 ANALOGOUS UNITED STATES LAW

The following discussion provides an overview of US provisions analogous to section 2 and section 27(3) and how the jurisprudence in the United States has evolved under these provisions to address the challenges of achieving a level of disclosure that is fair to both patent holders and the public.

3.1 35 USC Section 101 Is Similar to Section 2

As mentioned, the US definition of "invention," embodied in 35 USC § 101 of the US statute, formed the basis of section 2 of the Canadian *Patent Act*.[155] The two provisions are similar in substance. Section 101 of the US provision reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

By comparison, section 2 of the Canadian *Patent Act* is as follows:

> *invention* means any new and useful art, process, machine, manufacture or composition of matter or any new and useful improvement in any art, process, machine, manufacture or composition of matter.

Despite the marked similarities, the interpretation of these two provisions with regard to the meaning of "useful" has evolved to take on two divergent utility standards in each respective country.

3.1.1 35 USC Section 101 Mandates Only a "Specific, Substantial and Credible Use"

Similar to the requirements of section 2 in Canada, 35 USC § 101 mandates that the subject matter of a patent cannot be directed to a disembodied idea. As set out in *Bilski v Kappos*:

> The §101 patent-eligibility inquiry is only a threshold test. Even if an invention qualifies as a process, machine, manufacture, or composition of matter, in order to receive the *Patent Act*'s protection the claimed invention must also satisfy "the conditions and requirements of this title." §101. Those requirements include that the invention be novel, see §102, nonobvious, see §103, and fully and particularly described, see §112.[156]

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[155] *Supra* note 5.

[156] 561 US 593, 130 S Ct 3218 at 3225 (2010).

Thus 35 USC § 101 also represents a first-threshold test to establish patentability. If subject matter meets this first hurdle, it nonetheless must meet the other requirements of the US statute.

While a utility standard does come into play under 35 USC § 101, unlike section 2 in Canada, the bar for meeting its requirements is set considerably lower. The United States does not impose a utility standard above and beyond showing that there has to be some "specific, substantial and credible use in industry."[157] Moreover, utility can generally be buttressed by post-filing evidence.

The US courts grappled with what constitutes a "specific, substantial and credible" use in the context of emerging technologies, specifically in connection with patenting DNA sequences. When the human genome and the DNA of microbes and other life forms were first being sequenced, patent applications were filed for short segments of DNA known as expressed sequence tags (ESTs). These sequences had not yet been characterized—that is, their specific biological function had not yet been determined, much less their chemical makeup. Nonetheless, patentees postulated that they could be used as tools in research, referred to in the industry as "probes." Such probes could be used to discover what genes were expressed in a particular cell by using the DNA in a process referred to as "hybridization."[158] Thus, at the time, these sequences did not have an identified use beyond their predicted function as tools for conducting research.

This issue of whether an EST with no ascribed function had utility under § 101 was specifically examined in the decision of *In re Fisher*.[159] The claims were directed to novel EST sequences encoding proteins and protein fragments in maize plants. The patentee had identified several potential uses for the claimed ESTs as tools in research. The Federal Circuit held that the subject matter did not meet utility requirements because there was no "significant and presently available benefit to the public."[160]

Shortly before the time of the decision, the United States Patent and Trademark Office (USPTO), prompted by a deluge of patent applications covering novel biological sequences with no ascribed function, published utility guidelines.[161] The court relied on these guidelines, in particular that "[u]tilities that require or constitute carrying out further research to identify or reasonably confirm a 'real world'

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157 See *Manual of Patent Examining Procedure*, 9th ed (United States Patent and Trademark Office, March 2014), § 2107, II [MPEP].

158 Hybridization is an experimental technique in which the DNA is allowed to contact and associate with a complementary DNA sequence through a weak interaction based on charge, thereby providing a measure of similarity between two sequences.

159 *In re Fisher*, 421 F (3d) 1365, 76 USPQ (2d) 1225 (Fed Cir 2005).

160 *Ibid* at 1371.

161 *Utility Examination Guidelines*, 66 Fed Reg 1092, 1093 (5 January 2001).

context of use are not substantial utility."[162] In arriving at its decision, the court stated: "The claimed ESTs themselves are not an end of Fisher's research effort, but only tools to be used along the way in the search for a practical utility."[163]

Because the patentee did not identify the function for the underlying protein-encoding genes, it was held that the "claimed ESTs [had] not been researched and understood to the point of providing an immediate, well defined, real world benefit to the public meeting the grant of a patent."[164]

Further, the court stated that *In re Fisher* did not present any evidence showing that agricultural companies had purchased or even expressed any interest in the claimed ESTs.[165] The court went on to state that while commercial success could have been used to support utility, the patentee had not done so in this case.[166]

Although the patent was invalidated for lack of utility, *In re Fisher* did not set a particularly high bar for establishing utility. All that was required to satisfy § 101 was to establish a "well-defined, real world benefit to the public."[167] Further, if commercial success had later been established, this could have been used to support utility after the filing date.

Providing post-filing evidence to support utility is well established in US patent law.[168] According to the MPEP, the federal courts have consistently reversed rejections by the USPTO, asserting a lack of utility for patents claiming a pharmacological or therapeutic utility where an "applicant has provided evidence that reasonably supports such a utility."[169] According to USPTO practice, evidence of pharmacological or other biological activity of a compound will be relevant to an asserted therapeutic use if there is a reasonable correlation between the activity in question and the asserted utility.[170] An applicant can establish this reasonable correlation by relying on statistically relevant data documenting the activity of a compound or composition, arguments or reasoning, documentary evidence—for example, articles in scientific journals—or a combination of these.[171]

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[162] *In re Fisher*, *supra* note 159 at 1372, citing MPEP, *supra* note 157, § 2107.01.

[163] *In re Fisher*, *supra* note 159 at 1376.

[164] *Ibid*.

[165] *Ibid* at 1377.

[166] *Ibid* at 1377-78.

[167] *Ibid* at 1376.

[168] MPEP, *supra* note 157, § 2107, II.

[169] *Ibid*, § 2107.03.

[170] *Ibid*, § 2107.03, I, citing *Cross v Iizuka*, 753 F (2d) 1040, 224 USPQ 739 (Fed Cir 1985); *In re Jolles*, 628 F (2d) 1322, 206 USPQ 885 (CCPA 1980); and *Nelson v Bowler*, 626 F (2d) 853, 206 USPQ 881 (CCPA 1980).

[171] *Ibid*.

The US courts also have a rule that a patent infringer is estopped from asserting invalidity of the patent by failing to satisfy utility requirements.[172] Consequently, much of the case law on lack of utility is directed to interference proceedings and appeals from the Patent Office in rejecting patent applications for failing to comply with 35 USC § 101.[173]

Another significant difference between Canada's section 2 and 35 USC § 101 is that there is no or very little interplay between the definition of invention requiring that the invention be "useful" and disclosure requirements. Insofar as there is an interplay, if no utility is met under 35 USC § 101, it follows that disclosure requirements cannot be met.[174] This makes sense because if a patent applicant cannot meet the relatively low bar set for utility—namely, a specific, substantial, and credible use—it follows that there cannot be adequate disclosure.

Moreover, despite US reliance on the prosecution history to interpret claims, it is not required that a particular characteristic set forth in the prosecution history be achieved in order to satisfy § 101.[175] Indeed, the USPTO's guidance to examiners is that "[i]n most cases, an applicant's assertion of utility creates a presumption of utility that will be sufficient to satisfy the utility requirement of 35 U.S.C. §101."[176] Thus, the USPTO's policy is to not challenge statements by the patentee that are akin to promissory language in Canada.

Thus, to the extent that there is a utility requirement in the United States under § 101, it is a relatively toothless doctrine compared with Canada's. However, in terms of substantiating a patent with proper disclosure, the heavy lifting occurs under 35 USC § 112(a). Disclosure requirements and the debate that ensued over the creation of a separate and distinct requirement for a showing of "possession of the invention" under 35 USC § 112 are discussed below.

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172 Gold & Shortt, *supra* note 4 at 62-63.

173 See the MPEP, *supra* note 157, § 2107 and cases cited therein.

174 *In re Fisher*, *supra* note 159. The United States Patent and Trademark Office (USPTO) argued at 1378 that the application cannot be enabled because "the claimed ESTs were not disclosed as having a specific and substantial utility." The court agreed with the government. In this regard, the court cited *Ziegler*, 992 F (2d) at 1200-1, which stated "[i]f the application fails as a matter of fact to satisfy 35 USC §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 USC §112" at 1378.

175 *Tol-O-Matic, Inc v Proma Produkt-Und Mktg Gesellschaft mbh*, 945 F (2d) 1546 (Fed Cir 1991) [*Tol-O-Matic*]; see also MPEP, *supra* note 157, § 2107.02, I.

176 MPEP, *supra* note 157, § 2107.02, III.A, citing e.g. *In re Jolles*, 628 F (2d) 1322, 206 USPQ 885 (CCPA 1980); *In re Irons*, 340 F (2d) 974, 144 USPQ 351 (CCPA 1965); *In re Langer*, 503 F (2d) 1380, 183 USPQ 288 (CCPA 1974); and *In re Sichert*, 566 F (2d) 1154, 1159, 196 USPQ 209, 212-13 (CCPA 1977).

3.2 35 USC Section 112(a) of the Statute Imposes the Disclosure Standard

Section 112(a) of the post-*America Invents Act* (AIA)[177] sets forth the disclosure standard. The relevant part of the statute reads:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.

The Canadian statute had its roots in the US statute of 1836.[178] Both 35 USC § 112 and section 27(3) of Canada's *Patent Act* require a showing of how to make and use the invention. Section 112(a) requires that the specification describe the invention

> in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same.

The analogous language of section 27(3) of the Canadian *Patent Act*, while much lengthier, is in substance the same:

> 27(3) The specification of an invention must …
>
> (b) set out clearly the various steps in a process, or the method of constructing, making, compounding or using a machine, manufacture or composition of matter, in such full, clear, concise and exact terms as to enable any person skilled in the art or science to which it pertains, or with which it is most closely connected, to make, construct, compound or use it.

It is clear from the plain and ordinary meaning of the respective statutory provisions and settled law in both countries that the description must be sufficiently complete to allow a person of skill in the art to construct or use the invention when the period of monopoly has expired.[179] In the United States, this is referred to as the "enablement requirement."[180]

While the concluding language of each quoted portion requires that a patent specification enable another to make and use the invention, the former part of each provision refers to a description requirement. The US provision requires that the "specification shall contain a written *description* of the invention" (emphasis added), and the Canadian provision requires that the "specification of an invention must (a) correctly and *fully describe* the invention and its operation or use as contemplated by the inventor" (emphasis added).

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[177] *Leahy-Smith America Invents Act*, Pub L No 112-29 (16 September 2011), previously US *Patent Act*, 35 USC § 112 (pre-AIA) [AIA].

[178] *Consolboard*, *supra* note 18 at 518.

[179] *Ibid* at 517; *CFMT, Inc v Yieldup Int'l Corp*, 349 F (3d) 1333 at 1338 (Fed Cir 2003).

[180] See Margaret Sampson, "The Evolution of the Enablement and Written Description Requirements Under 35 USC 112 in the Area of Biotechnology" (2000) 15:3 BTLJ 1234 [Sampson]; MPEP, *supra* note 157, § 2164.

In the United States, the former part of the provision, referred to as the "written description requirement," is an additional requirement above and beyond showing how to make and use an invention.[181] US laws have developed over the years to take on this additional function to police claim overbreadth. Before claims were required in a patent application, the written description requirement served a public notice function of putting the patentee in "possession" of the boundaries of the invention.[182] Claims now supplant this function.[183] In modern patent law, however, after the advent of claims, the written description requirement remained and evolved to take on a role of preventing an inventor from claiming more than he or she was entitled to.

The separate written description requirement after the development of claims had its genesis in the 1967 decision of *In re Ruschig*.[184] In this decision, the court separated the written description requirement from enablement by requiring the former to show that the inventor was in possession of the invention at the priority date.[185]

Although in *Ruschig* the written description requirement was invoked to police priority, its application subsequently evolved beyond the priority context.[186] Its distinct role outside the enforcement of priority was the subject of much debate in the 1980s and through the early 2000s, which saw a sharp increase of patent filings in biotechnology relating to newly discovered biologic material. In this emerging field of technology, patentees filed, and were sometimes issued, patents on DNA and other biological sequences characterized in terms of their function rather than their chemical structure. (Contrast this with ESTs, in which the function had not yet even been determined.) DNA is a biological molecule composed of a chain of repeating units of molecules. At the time, the biological function of the DNA had been elucidated, but the repeating chemical units within the chain (nucleic acids) were unknown at the time of filing. The written description requirement was invoked to prevent patentees from claim overreach when claiming newly discovered DNA sequences before the precise chemical makeup of the sequences had been determined.

A decision that was particularly criticized for its application of the written description requirement outside the priority context was *Regents of the University of California v Eli Lilly and Co*.[187] In 1990 the University of California sued Eli Lilly for the use of a human insulin DNA sequence to make human insulin. The infringe-

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181 *Ariad Pharmaceuticals, Inc v Eli Lilly and Company*, 598 F (3d) 1336 (Fed Cir 2010) (rehearing en banc of 560 F (3d) 1366 (Fed Cir 2009)) [*Ariad*].

182 *Evans v Eaton* 20 US (7 Wheat) 356 (1822).

183 Janice M Mueller, "The Evolving Application of the Written Description Requirement to Biotechnological Inventions" (1998) 13 BTLJ 615 at 620 [Mueller].

184 *In re Ruschig*, 379 F (2d) 990 (CCPA 1967) [*Ruschig*]; see also the discussion in Mueller, *supra* note 183 at 620, and Sampson, *supra* note 180 at 1252.

185 Sampson, *supra* note 180 at 1252.

186 See e.g. *Enzo Biochem, Inc v Gen-Probe Inc*, 323 F (3d) 956 (Fed Cir 2002) [*Enzo*].

187 *Regents of the University of California v Eli Lilly and Co*, 119 F (3d) 1559 (Fed Cir 1997) [*Lilly*].

ment suit was based on a claim for a DNA sequence encoding for human insulin.[188] However, the patentee had not actually disclosed the cDNA sequence of human insulin at the 1977 filing date. Rather, the patentee relied on DNA isolated and sequenced from rats to substantiate its claims. However, there was a "prophetic" example in the patent detailing a method that could be used to obtain the human insulin encoding cDNA, as well as the human insulin protein that could be produced from the cDNA. Thus, the production of human insulin from cDNA was enabled by following the teachings of the example. Nevertheless, the actual isolated human cDNA sequence was not obtained until two years after the 1977 filing date.[189]

Lilly challenged the validity of the patent on the basis that it did not contain a written description of the human insulin cDNA because, as of the filing date, the patentee did not provide adequate written description of the cDNA. Eli Lilly was successful. In reaching its decision, the court said:

> A written description of an invention involving a chemical genus, like a description of a chemical species, "requires a precise definition, such as by structure, formula, [or] chemical name" of the claimed subject matter sufficient to distinguish it from other materials.[190]

This decision is informative in that it established that (1) an invention can be enabled, but not sufficiently disclosed to demonstrate possession of an invention; and (2) written description can be applied outside the priority context.

Lilly was highly criticized for applying the written description to claims as originally filed in the application rather than to police whether claims presented after the original filing date have written description support.[191] The decision was also described as imposing a "super-enablement" standard for biotechnology inventions extending beyond the role first envisioned by *Ruschig* to police priority.[192] Patents most prone to invalidity for failure to meet written description requirements are those in the unpredictable arts.[193] Indeed, the written description requirement, as applied to biotechnology, has been regarded as running counter to technological neutrality, which requires that all technologies be assessed for patentability on an equal footing. Notably, it has been criticized as being contrary to obligations under TRIPS,[194] which requires that "patents should be available for any inventions … in

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[188] The DNA sequence was a "cDNA," which is an artificially created sequence that does not contain short segments of DNA sequence called "introns," present in its naturally occurring counterpart. A cDNA serves as a template for making a protein, which in this case was insulin; see also the discussion in Mueller, *supra* note 183 at 628.

[189] Mueller, *supra* note 183 at 629.

[190] *Lilly*, *supra* note 187 at 1658, citing *Fiers v Revel*, 984 F (2d) 1171 (Fed Cir 1993).

[191] Mueller, *supra* note 183 at 633-52.

[192] *Ibid* at 633.

[193] *Ibid*.

[194] *Agreement on Trade-Related Aspects of Intellectual Property Rights*, 15 April 1994 [TRIPS].

all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application."[195]

But despite criticisms, written description is here to stay. It is now essentially settled law in the United States after the 2010 en banc decision of *Ariad Pharmaceuticals Inc v Eli Lilly and Company*.[196]

Until *Ariad*, the Federal Circuit had refused numerous petitions to rehear decisions en banc in which the written description was applied as a requirement separate from enablement under § 112, paragraph 1.[197] In light of the controversy surrounding the distinctness and proper role of the written description requirement, the court in this instance decided to grant the petition for rehearing.

Ariad's patent related to a method for reducing the release in the body of certain chemicals called cytokines. Cytokines are naturally produced to combat infection, but they can be harmful if produced in excess. The patent specifically related to a method for reducing excessive production of cytokines by reducing the activity of a protein called NK-κF, which is responsible for their production. The inventors had unravelled the mechanism by which the NK-κF protein is activated by certain external stimuli caused by bacterial components.[198] In its inactive state, the NK-κF protein is bound to another protein, forming an inactive complex, but external stimuli causes the NK-κF protein to be released from this complex, which causes the released NK-κF protein to bind DNA, which in turn causes the production of genes that encode cytokines.

Although only the mechanism had been elucidated, the claims broadly covered a method for reducing cytokine production encompassing the use of all substances that achieved the desired result of reducing the binding of NF-κB to NF-κB binding sites on DNA (thereby reducing cytokine production). The patent merely hypothesized that three broad classes of compounds could reduce the binding of NF-κB to DNA. Lilly argued that the claims were broadly directed to an intended result and thus failed to comply with the written description requirement. Ariad, on the other hand, argued that the claims were enabled, which, in its view, was all that was required to satisfy 35 USC § 112, paragraph 1.

The court agreed with Lilly and reaffirmed in a 9-2 decision that the written description requirement is separate and distinct from the enablement requirement. In

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195 Harold C Wegner, "The Disclosure Requirements of the 1952 Patent Act: Looking Back and a New Statute for the Next Fifty Years" (2004) 37 Akron L Rev 243 at 259 [Wegner], citing TRIPS, *supra* note 194.

196 *Ariad*, *supra* note 181.

197 *LizardTech, Inc v Earth Res Mapping, Inc*, 433 F (3d) 1373 (Fed Cir 2005) [*LizardTech*]; *Univ of Rochester v GD Searle & Co, Inc*, 375 F (3d) 1303 (Fed Cir 2004); and *Enzo*, *supra* note 186 were all denied rehearing en banc.

198 Specifically, bacterial lipopolysaccharides.

arriving at the decision, the court rejected that written description is only applicable to police priority:

> Ariad provides no principled basis for restricting that requirement to establishing priority. Certainly nothing in the language of §112 supports such a restriction; the statute does not say "The specification shall contain a written description of the invention for purposes of determining priority." And although the issue arises primarily in cases involving priority, Congress has not so limited the statute, and neither will we.[199]

The court also stated that written description cannot be satisfied by looking outside the specification:

> [W]e have repeatedly stated that actual "possession" or reduction to practice outside of the specification is not enough. Rather … it is the specification itself that must demonstrate possession.[200]

Thus, written description cannot be buttressed by post-filing evidence.

Rader J wrote a strong dissent saying "the separate written description requirement that the court petrifies today has no statutory support."[201] In his view, the language of the provision unambiguously supports only an enablement requirement and the written description requirement should be applied only within that context.[202]

Rader J also stated that "the opinion fails to set the boundaries for compliance with its separate written description test."[203] In that regard, he stated:

> Commentators have noted our use of variable and confusing vocabulary to delineate the test: that the specification demonstrate "possession," that the inventor "invented what is claimed," or that a person of ordinary skill be able to "visualize or recognize" the claimed subject matter.[204]

However, as attractive as a bright-line test is in that it provides greater certainty and predictability, it needs to be balanced against promoting fairness to patentees. Judging each invention based on its own unique contribution over the public domain adds fairness and equity in emerging technologies where, because of the complexity of the technology at issue, one size does not fit all. As a technical field evolves over time due to knowledge gained and added to the state of the art, so too must the written description requirement evolve. The court in *Ariad* recognized this requirement, aptly stating:

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199 *Ariad*, *supra* note 181 at 1349.

200 *Ibid* at 1352.

201 *Ibid* at 1362.

202 *Ibid*. Rader J stated that "the written descriptions of the invention and of the manner and process of making and using the invention are both judged by whether they are in such full, clear, concise, and exact terms as to enable a person skilled in the art to make and use the invention."

203 *Ibid* at 1368.

204 *Ibid*.

> The law must be applied to each invention at the time it enters the patent process, for each patented advance has a novel relationship with the state of the art from which it emerges.[205]

An earlier decision, *Capon v Eshhar*,[206] cited with approval by *Ariad*, underscored that the inquiry is highly fact-dependent and must be analyzed in view of the state of the art. In *Capon v Eshhar*, the patent described combining two known segments of DNA to produce an artificial "chimeric gene," encoding a protein with novel therapeutic properties to treat cancer. One segment of DNA encoded an antigen-binding domain of an antibody and the other a receptor for certain cells of the immune system called "lymphocytes." The chimeric gene produced a protein having an antibody-binding-domain and a lymphocyte receptor protein. At issue was whether the chimeric gene described and claimed in the patent without any sequence data met the written description requirement. Notably, enablement was not at issue.

The board[207] rejected the patent application based on failure to comply with the written description requirement because the structure of the chimeric gene was not disclosed.[208] The board stated that " 'controlling precedent' required inclusion in the specification of the complete nucleotide sequence of 'at least one' chimeric gene."[209]

However, expert evidence established that, at the time of the invention, methods for forming chimeric genes were described in the literature. Likewise, the segments of DNA making up the chimeric gene were known and published as early as 1991. Accordingly, the Federal Circuit found that the written description requirement was met.

In arriving at its decision, the Federal Circuit said that the written description requirement

> does not state that every invention must be described in the same way. As each field evolves, the balance also evolves between what is known and what is added by each inventive contribution.[210]

The court then articulated that the application of the written description requirement is dictated by the state of the art at the time of the invention and its predictability:

> Since the law is applied to each invention in view of the state of relevant knowledge, its application will vary with differences in the state of knowledge in the field and differences in the predictability of the science.[211]

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[205] *Ibid* at 1351.

[206] *Capon v Eshhar*, 418 F (3d) 1349 (Fed Cir 2005).

[207] Board of Appeals and Interferences of the United States Patent and Trademark Office.

[208] *Capon v Eshhar*, *supra* note 206 at 1354.

[209] *Ibid* at 1355.

[210] *Ibid* at 1357.

[211] *Ibid*.

The court enumerated factors that should be taken into consideration when determining whether the written description is met for generic claims. These included (1) existing knowledge in the particular field, (2) the extent and content of the prior art, (3) the maturity of the science or technology, (4) the predictability of the aspect at issue, and (5) other considerations appropriate to the subject matter.[212]

Thus, despite being directed to DNA segments whose sequences—that is, their precise chemical makeup—were not disclosed, it was held that such precise disclosure was not required to satisfy the written description requirement. The court arrived at this conclusion by weighing all the facts.

Although some still argue that written description is not a separate requirement,[213] as evidenced by the strong dissent from Rader J on the *Ariad* panel, since *Lilly* in 1990 and subsequent cases in which written description was applied outside the priority context, it would be very difficult to conclude that this doctrine has not now become well entrenched and indeed is settled law in the United States. Although many of the cases litigated concerned generic claims for biological material, the doctrine has even been applied beyond the unpredictable arts to cases involving more predictable technology.[214]

Indeed, the court in *Ariad* provided guidance that could be broadly applied to all technology fields, not just to claims directed to a genus of biological material. Avoiding an attempt to "predict and adjudicate all the factual scenarios to which the written description requirement could be applied,"[215] the court in *Ariad* stated that the test requires that the specification "describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed."[216] The court also stated that the description must "clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."[217] Other statements made by the Federal Circuit further clarify the requirement, but articulate it slightly differently. More recently, the Federal Circuit has said that "requiring a written description of the invention plays a vital role in curtailing claims … that have not been invented, and thus cannot be described,"[218] and in *Ariad* it was stated that "[c]laims define and circumscribe, the written description discloses and teaches."[219]

In essence, the written description requirement boils down to determining what the invention is, followed by determining whether the inventor has disclosed

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212 *Ibid* at 1359.

213 See Rader and Linn JJ in dissent in *Ariad*, *supra* note 181.

214 See e.g. *LizardTech*, *supra* note 197.

215 *Ariad*, *supra* note 181 at 1351.

216 *Ibid* at 1366.

217 *Ibid* at 1351, citing *In re Gosteli*, 872 F (2d) 1008 at 1012 (Fed Cir 1989).

218 *Abbvie Deutschland GMGH & Co v Janssen Biotech Inc*, 759 F (3d) 1285 at 1299 (Fed Cir 2014).

219 *Ariad*, *supra* note 181 at 1347.

enough in his patent to show that he invented the invention claimed. This simple test, at least at a conceptual level, works surprisingly well. Take, for example, *Lilly*, where the inventors claimed a previously unknown human insulin DNA sequence. They did not show possession of that sequence data in the disclosure of their patent because they had not even isolated the gene. So how could they assert that they invented it and advanced the state of the art sufficiently to justify a monopoly?

4.0 COMPARISON OF DISCLOSURE REQUIREMENTS BETWEEN THE UNITED STATES AND CANADA

Equipped with an understanding of how the US and Canadian patent laws police claim overreach, a proper comparison and contrast of the laws operating in each country can be made between the two countries.

4.1 Differences Between 35 USC Section 101 and Canadian Patent Act Section 2

As discussed, section 2 of the Canadian *Patent Act* and 35 USC § 101 contain similar language, but have notable differences in their judicial construction. A primary function of each provision is defining the threshold for subject matter eligibility. Both provisions also mandate a utility requirement, but this requirement differs markedly in each country. In the United States, the threshold needed to meet utility requirements under 35 USC § 101 is quite low; a patentee need only establish some "specific, substantial and credible" use.[220] Further, if the utility disclosed is not demonstrated at filing, it can later be buttressed by actual commercial success. Moreover, in the United States, a patent infringer is estopped from asserting invalidity of the patent by failing to satisfy utility requirements.

In Canada, by contrast, utility requirements under section 2 need to be met at filing. As set out in *AZT*, the policy rationale underlying this requirement is to prevent shotgun patenting.[221] In addition, a third party is clearly not estopped from invalidating a patent based on lack of utility. Thus, compared with Canada's, the utility requirement under 35 USC § 101 is a relatively toothless doctrine.

When viewing the laws of utility in each country through this lens, it is easy to see why certain commentators assert that "utility requirements" in Canada are out of line with the requirements in the United States and that establishing utility should require only a showing of how to make and use the invention, which can be established at a later date with post-filing data. However, delving deeper into US case law, it becomes apparent that the requirement to provide adequate disclosure to support utility is primarily policed in the United States under provisions addressing disclosure requirements.

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[220] See MPEP, *supra* note 157, § 2107, II.

[221] *AZT*, *supra* note 21 at para 80.

4.2 Canada's Functional Equivalent Can Be Found in 35 USC Section 112 Written Description Requirements

The additional disclosure requirement under § 112(a) to show "possession of invention" has many functional similarities to Canada's utility requirements. Similar to Canada's utility requirement, under 35 USC § 112(a), disclosure requirements cannot be supported later by post-filing data. The court in *Ariad* expressly rejected the notion that possession can be shown by "producing records documenting a written description of a claimed invention,"[222] stating that it is the specification itself that must demonstrate possession.[223] *Ariad* went as far as to state that the "hallmark of written description is disclosure." Similarly, in Canada, the Supreme Court in *AZT*[224] rejected the notion that an inventor can demonstrate utility or a sound prediction at the time a patent is attacked—it must be shown at filing.

Courts in both countries also emphasize that proper disclosure is needed to satisfy the *quid pro quo*. In the United States, 35 USC § 112(a) serves this function. The Federal Circuit has stated that the written description requirement "serves a teaching function, as a '*quid pro quo*' in which the public is given 'meaningful disclosure in exchange for being excluded from practicing the invention for a limited period of time.'"[225] In Canada, Binnie J stated that sound prediction under section 2 is the *quid pro quo* "the applicant offers in exchange for the patent monopoly."[226]

Another striking similarity is the debate that has ensued in each country over whether simply showing how to make and use an invention is all that is needed to substantiate a patented invention. Most of the debate centres around the supposed creation of an "extra-statutory requirement" to police claim overreach. In the United States, the debate is in the context of the separate § 112(a) written description requirement; in Canada, the requirement to demonstrate or predict utility is based on the interplay between sections 2 and 27(3). Although the final say in the *Ariad* decision is that showing how to make and use an invention alone will not suffice to meet disclosure requirements, Rader J wrote a strong dissent stating that the written description requirement has no statutory basis,[227] the *Eli Lilly* decision is new law,[228] and the enablement requirement is sufficient in that it "identifies the invention and tells a person of ordinary skill what to make and use."[229] As mentioned above, US commentators have argued that the requirement unfairly prejudices inventions

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222 *Ariad*, *supra* note 181 at 1351.

223 *Ibid*, stating that the "hallmark of written description is disclosure."

224 *AZT*, *supra* note 21 at paras 79 and 80.

225 *University of Rochester v GD Searle & Co*, 358 F (3d) 916 at 922 (Fed Cir 2004), citing *Enzo*, *supra* note 186.

226 *AZT*, *supra* note 21 at para 70.

227 *Ariad*, *supra* note 181 at 1362.

228 *Ibid* at 1364, stating that written description is a "new creation."

229 *Ibid* at 1363.

in the unpredictable arts, and one commentator has gone as far as to say that the US written description requirement is out of line with TRIPS.[230]

The parallels in Canada are uncanny. Analogous arguments by Lilly are embodied in the Second Notice of Intent filed against the government of Canada.[231] In this instance, however, Lilly is on the other side of the battle line.[232] In the Second Notice of Intent, Lilly characterizes Canada's utility requirements as "onerous and non-statutory disclosure obligations imposed by Canada's Federal Courts."[233] Lilly also argues that "Canada … is responsible for measures inconsistent with its commitments under *NAFTA* Chapter Eleven, including … Canada's incorporation of the Judge-made law on utility into Canadian law."[234] Specifically, Lilly urges that Canada has obligations under NAFTA[235] and TRIPS[236] "to make patents available and to enforce patent rights without discrimination as to field of technology," and that the judicial decisions on utility "discriminate against pharmaceutical and biopharmaceutical patents."[237] Further, Lilly argues that showing how to make and use an invention is sufficient disclosure. In this connection, Lilly states that the "imposition of the non-statutory disclosure obligations is that patents are invalidated on the basis of insufficient disclosure … even though the patent specification met PCT requirements by clearly teaching *how to make and use the invention*."[238] Lilly further urges that Canada has a "heightened evidentiary standard for proof of utility, which requires that the promised utility either be 'demonstrated' or be based on a 'sound prediction' of utility as of the date the patent application was filed."[239] One decision on utility was even characterized by Lilly as "absurd and shocking."[240]

On the other hand, the government of Canada argues that the laws of each country are functionally equivalent. Commentators have argued that the utility requirement in the United States is not commonly invoked for strategic reasons, but is nonetheless not a "toothless doctrine" and that there is overlap between enablement, together with the written description requirement, and Canada's laws on sufficiency of description.[241]

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230 Wegner, *supra* note 195.

231 *Supra* note 1.

232 Compare with *Lilly*, *supra* note 187.

233 Second Notice of Intent, *supra* note 1 at para 61.

234 *Ibid* at para 99.

235 *North American Free Trade Agreement*, 32 ILM 289 and 605 (1993) [NAFTA].

236 *Supra* note 194.

237 Second Notice of Intent, *supra* note 1 at para 104.

238 *Ibid* at para 65 (emphasis added).

239 Notice of Arbitration, *supra* note 1 at para 10.

240 Second Notice of Intent, *supra* note 1 at para 96, referring to the decision *Eli Lilly Canada Inc v Novopharm Limited*, 2011 FC 1288.

241 Gold & Shortt, *supra* note 4 at 62-64.

Although the Canadian government sees essentially no discrepancies between the two patent regimes at a functional level, I suggest that there are important differences between the laws of the two countries that are simply more granulated. Where Canada differs is in those cases where construing promissory language in the patent specification is central to the analysis. The US determination of whether written description is satisfied is a fact-based inquiry, and the backdrop against which the analysis is conducted involves looking at the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, and the predictability of the aspect at issue.[242] While this approach is similar to the line of Canadian cases discussed above, in which a more holistic, evidentiary-based approach is taken to determine the threshold for disclosure, it departs markedly from those cases in which analyzing promissory language resides more at the centre of the analysis for determining the standard for disclosure.

In the United States, statements about utility in the patent specification or prosecution history do not play a central role in setting a disclosure standard. Such statements were specifically examined in the Federal Circuit decision of *Tol-O-Matic*.[243] The case was an appeal taken from the US District Court in which the jury had previously found certain claims invalid for failure to meet the utility requirement of 35 USC § 101, but the judgment of invalidity due to non-utility was reversed. The invention related to a rodless piston cylinder, and tests conducted by the technical experts tended to show that the device did not work precisely as the patentee had argued during patent prosecution when distinguishing the invention over prior art, though the invention described was still clearly operative. While the decision did not turn on language in the patent specification itself, the decision is still informative because prosecution history weighs heavily in claim interpretation in the United States, often on equal footing with the patent specification.

In arriving at its decision, the court explained that 35 USC § 101 excludes things such as "scientific theories, pure mathematics and laws of nature" or inventions deemed to be "immoral … or scientifically impossible, such as perpetual motion machines."[244] The court then said that even though the device did not work as argued in distinguishing over the prior art, "this is not an issue of lack of utility."[245] The court also stated that a "reasonable jury could not have found the 'total incapacity' that is required to prevail on a lack of utility defense under §101."[246] In other words, lack of utility is not predicated on statements made on file by the patentee, but rather is invoked when the claimed invention is completely inoperable. While this is similar to *X v Commissioner of Patents*[247] for the death ray that was found to be inopera-

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242 *Ariad*, *supra* note 181 at 1351.

243 *Tol-O-Matic*, *supra* note 175.

244 *Ibid* at 1552.

245 *Ibid* at 1553.

246 *Ibid*.

247 *Supra* note 17.

ble, it is out of line with the promise doctrine. This is consistent with the USPTO's guidance that instructs examiners to presume that utility under § 101 is met.[248]

Understanding how the two patent regimes function to police claim overreach can also explain why each country has arrived at different conclusions regarding the validity of Eli Lilly's patent for the drug atomoxetine to treat ADHD. As discussed, in Canada the patent for atomoxetine was invalidated for failure to meet the promise of clinical efficacy because clinical data from a study (the MGH study) was not included in the patent specification.[249] By contrast, in the United States the atomoxetine patent was not invalidated, even though it was challenged on the identical ground.[250]

However, in the corresponding US decision, the validity of the atomoxetine patent was attacked under § 101 for lack of utility and enablement under § 112, paragraph 1, in what was referred to as an "enablement/utility" standard.[251] The District Court held that utility was not established because experimental data showing the results of treatment of ADHD were not included in the specification. The Federal Circuit arrived at a different conclusion. The outcome of the decision turned on whether, during examination of the patent application, data should have been submitted to support utility under § 101 and enablement under § 112, paragraph 1. It was found that the "utility of tomoxetine [atomoxetine] was accurately stated in the specification" and that "the patent examiner did not require the presentation of additional data" to support utility.[252] In this connection, the court cited *In re Brana*,[253] in which it was stated:

> A specification disclosure which contains a teaching of the manner and process of making and using the invention in terms which correspond to those used in describing and defining the subject matter sought to be patented must be taken as in compliance with the enabling requirement of the first paragraph of §112 unless there is reason to doubt the objective truth of the statements contained therein which must be relied on for enabling support.[254]

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[248] MPEP, *supra* note 157, § 2107.02, III.A, citing e.g. *In re Jolles*, 628 F (2d) 1322, 206 USPQ 885 (CCPA 1980); *In re Irons*, 340 F (2d) 974, 144 USPQ 351 (CCPA 1965); *In re Langer*, 503 F (2d) 1380, 183 USPQ 288 (CCPA 1974); and *In re Sichert*, 566 F (2d) 1154 at 1159, 196 USPQ 209 at 212-13 (CCPA 1977).

[249] *Atomoxetine*, *supra* note 69.

[250] *Eli Lilly & Co v Actavis Elizabeth LLC*, 435 Fed Appx 917 (Fed Cir 2011) (issued on a non-precedential basis), *slip op*, rehearing en banc denied 18 October 2011 [*Eli Lilly v Actavis Elizabeth*]. Claim 1 of the patent at issue (US Patent No 5,658,590) reads: "A method of treating attention-deficit/hyperactivity disorder comprising administering to a patient in need of such treatment an effective amount of tomoxetine [atomoxetine]."

[251] *Ibid* at 11, *slip op*.

[252] *Ibid* at 16, *slip op*.

[253] *In re Brana*, 51 F (3d) 1560 (Fed Cir 1995) [*Brana*].

[254] *Eli Lilly v Actavis Elizabeth*, *supra* note 250 at 15, *slip op*.

Accordingly, the patent was not invalidated for lack of enabling disclosure under § 112, paragraph 1—namely, failure to describe how to make and use the invention.

Although enablement under § 112, paragraph 1 was clearly at issue, the more stringent written description standard requiring a showing of "possession of the invention" in the description of the patent was not. The court stated[255] that the "utility of tomoxetine is accurately stated in the specification," and cited *In re Marzocchi*,[256] as explaining that

> [t]he only relevant concern of the Patent Office under these circumstances should be over the truth of any such assertion. *The first paragraph of §112 requires nothing more than objective enablement.* How such a teaching is set forth, either by the use of illustrative examples or by broad terminology, is of no importance.[257]

However, *Ariad* is now the law on § 112, paragraph 1.[258] As discussed, *Ariad* unequivocally mandates an additional component to the US disclosure requirement above and beyond showing how to make and use an invention—namely, a showing of possession of the invention.

5.0 EUROPEAN "UTILITY" STANDARDS

Most of the foregoing historical and comparative analysis focuses on the United States because the United States is Canada's largest trading partner and much of the criticism of Canada's utility requirements originates from that country.[259] However, Europe also has many analogies with the US and Canadian laws on claim overreach, which warrant brief mention.

Similar to Canada and the United States, the European Patent Convention (EPC) provides general requirements for subject matter eligibility. This is set forth in article 52(1) of the EPC, which states, in part, that European patents must be "susceptible of industrial application," and article 57, which states that this requirement is fulfilled if the invention "can be made or used in any kind of industry, including agriculture." That the invention needs to be "susceptible of industrial application" has parallels with Canada and the United States under provisions requiring an invention to be "useful" in an economic sense. An invention has to have a plausible, practical use to satisfy these requirements and not be directed to "an interesting research result which *per se* does not yet allow a practical industrial application to be identified."[260] This

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255 *Ibid* at 16.

256 *In re Marzocchi*, 439 F (2d) 220 (CCPA 1971).

257 *Eli Lilly v Actavis Elizabeth*, *supra* note 250 at 16-17, *slip op* (emphasis added).

258 Section 112(a) post-AIA.

259 See Michael BG Froman, *2015 Special 301 Report* (Executive Office of the President of the United States, United States Trade Representative, April 2015) at 66, online: United States Trade Representative <https://ustr.gov/sites/default/files/2015-Special-301-Report-FINAL.pdf>, stating that Canada is on the 2015 watch list because the United States has "serious concerns about the lack of clarity and the impact of the heightened utility requirements for patents that Canadian courts have applied recently," among other things; see also note 1 above.

260 See T 0870/04 (BDP1 Phosphatase/MAX-PLANCK) at para 6.

is a rather low bar in that it simply precludes inventors from filing patent applications on research discoveries with no plausible use in industry.

Nonetheless, similar to the United States, most of the heavy lifting in terms of adequacy of disclosure is dealt with under disclosure requirements—namely, article 83 of the EPC, which requires that the invention be disclosed "in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art." Under article 83, board decisions have found that the description must disclose sufficient detail to render it apparent to the skilled person how to put the invention into practice without undue burden; this requirement is also referred to as "sufficiency of disclosure."[261]

However, the disclosure requirements depend on the factual background of each case. This includes predictability of the technical area,[262] common general knowledge possessed by the skilled person,[263] adequate teaching in the specification,[264] and the teachings in the state of the art.[265] Similar to the United States, sufficiency of disclosure in Europe is assessed on the basis of the application as a whole, including the description and claims, and not of the claims alone.[266] This fact-based approach has notable analogies with the US written requirement under § 112, although post-filing data can be used in Europe to establish sufficiency of disclosure.[267] Europe also balances the "actual technical contribution to the state of the art by said invention, and … the terms in which it is claimed, so that, if patent protection is granted, its scope is fair and adequate."[268]

A commentator who has compared US and European laws on disclosure requirements opines that there is no separate written description requirement in Europe per se, but it is examined instead in the context of enablement.[269] Nonetheless, the functional equivalents cannot be ignored, including the fact-intensive inquiry when determining whether the disclosure is adequate.

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261 Case Law of the Boards of Appeal of the European Patent Office, 7th ed, section II, "Patent Applications and Amendments" (September 2013) at 321, online: European Patent Office <http://www.epo.org/case-law> [Case Law of the Boards of Appeal].

262 *Ibid* at 321, citing T 187/93.

263 *Ibid* at 306, citing e.g. T 206/83, T 32/85, T 51/87, T 212/88 and T 772/89, and 321, citing T 617/07.

264 *Ibid* at 320, citing T 1466/05.

265 *Ibid* at 307, citing T 267/91 and T 611/89, stating: "An invention is sufficiently disclosed if reference is made to another document in the patent specification and the original description, and the skilled person can obtain from this cross-reference the information required to reproduce the invention but not disclosed in so many words in the description itself."

266 *Ibid* at 306.

267 *Ibid* at 323, citing T 609/02.

268 *Ibid* at 318, citing T 694/92. However, sufficiency of disclosure is not described per se as satisfying a *quid pro quo* consistent with utilitarian justification for intellectual property rights as in Canada and the United States.

269 Martina I Schuster, "Sufficient Disclosure in Europe: Is There a Separate Written Description Doctrine Under the European Patent Convention?" (2007) 76 UMKC L Rev 491 at 502 [Schuster].

Thus, in Europe, as in the United States, disclosure requirements form the heart of analyzing whether disclosure is adequate, not laws dealing with general requirements for patentability—namely, article 52 in Europe and § 101 in the United States. Further, while the specification and claims are analyzed to determine whether disclosure requirements are met, there is no specific focus per se on statements of utility to set a disclosure standard.

Accordingly, Canada is clearly out of step with both the United States and Europe by strictly enforcing statements of utility, or "promises" as they are characterized in Canada. However, the government of Canada argues that "Canadian courts have long held that the utility requirement under the *Patent Act* is a contextual consideration dependent on the language of the patent specification itself" and that "[i]f the patent is silent on the issue of utility, then the invention simply needs to have a 'scintilla of utility.'"[270] The government of Canada also argues that "[h]olding patentees to promises of utility serves important policy objectives at the heart of the Canadian patent system."[271] This sets the stage for yet another debate in Canada—namely, whether a promise-centric approach is an appropriate yardstick to determine whether a patent's disclosure is adequate. This is examined further below.

6.0 IS IT GOOD LAW TO HOLD A PATENTEE TO PROMISSORY LANGUAGE?

Now that we have delineated the real or practical differences of disclosure requirements required to support utility between Canada and other countries, we can next ask whether the differences in Canada are good law and sound policy. Does this extra dimension to our laws that requires elucidating the promise of the patent unfairly prejudice patent applicants, or is it the necessary consideration for the grant of a patent?

In addition to having a shaky basis in the jurisprudence, construction of promises presents numerous practical problems. The use of promissory language in other countries is generally acceptable practice with essentially no legal ramifications. As discussed above, US case law does not mandate an analysis in which promises are construed in order to set disclosure standards, and statements concerning utility made during US prosecution are not factored into the analysis. In Europe, statements about the potential utility of the patent are often made to support industrial applicability standards, but similarly are not the primary focus of an analysis concerning sufficiency of disclosure. However, in Canada, such supposedly innocuous statements have the potential to become self-inflicted wounds.

By contrast, claims are carefully drafted. The principle that an unnecessary claim limitation becomes a self-inflicted wound in the context of claim construction

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[270] *Counter Memorial*, *supra* note 2 at para 90.

[271] *Ibid* at para 100.

makes good sense.[272] A claim forms the monopoly sought, and is thoughtfully amended during prosecution of the patent application to ultimately obtain allowance. However, the balance of the specification serves a more primary role of teaching how the invention can be made and used, as well as fleshing out the full breadth of the claims, and thus should not be held to such rigorous standards. The description "was never meant to be parsed in this way."[273] Even in the context of claim construction, it has been stated that the inquiry should avoid "the kind of meticulous verbal analysis in which lawyers are too often tempted by their training to indulge."[274]

It might be argued that the trap of promissory language can be dealt with by avoiding these statements altogether. However, this is not always a practical solution. Focusing on promissory language in the specification can unfairly prejudice patent applicants with fewer financial resources. Those patentees who are most sophisticated are more likely to obtain patents with no statements "promising" what the invention provides because of better access to the legal system and, consequently, better legal advice. Moreover, Canadian practitioners often have limited control over the content of foreign patent applications filed in Canada. Yet patent applications arising from foreign jurisdictions form the majority of Canadian applications filed at the Canadian Intellectual Property Office.[275] It is a reality that fewer patent applications originate from Canada where practitioners are cognizant of these standards.

Further, statements of advantage are often needed to secure issuance outside Canada, a task that has become increasingly difficult in recent years, especially at the United States Patent and Trademark Office, where issue rates are currently reported at only 55.8 percent.[276] Without some statements speaking to the advantages of the invention, prosecuting a patent application can be an uphill battle. Thus, from a patent prosecution perspective, some discussion of the advantages ascribed to an invention is necessary. Although other avenues are available to secure issuance, such as declarations,[277] this is often not a realistic option for clients with limited resources because of the high legal cost for preparing argumentation in this type of

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272 *Free World Trust v Électro Santé Inc*, 2000 SCC 66 at para 51, [2000] 2 SCR 1024, stating that "if the inventor has misspoken or otherwise created an unnecessary or troublesome limitation in the claims, it is a self-inflicted wound."

273 Bernstein & Bienenstock, *supra* note 77 at 257.

274 *Whirlpool*, *supra* note 129 at para 48.

275 World Intellectual Property Organization, Economics and Statistics Division, *World Intellectual Property Indicators, Economics and Statistics Series 2015* at 62-65, online: World Intellectual Property Office <http://www.wipo.int/edocs/pubdocs/en/wipo_pub_941_2015.pdf>. In 2014, 4,198 resident patent applications and 31,283 non-resident applications were filed at the Canadian Intellectual Property Office. Compare with the United States, in which 285,096 resident patent applications and 293,706 non-resident patent applications were filed at the United States Patent and Trademark Office: WIPO statistic database, 2015.

276 Michael Carley, Deepak Hegde & Alan Marco, "What Is the Probability of Receiving a US Patent?" (2015) 17 Yale JL & Tech 203, online: USPTO <http://www.uspto.gov/ip/officechiefecon/publications.jsp#heading-3> at 9.

277 E.g. a 37 CFR 1.132 declaration: see MPEP, *supra* note 157, § 716.

format. This puts smaller concerns at a marked disadvantage in obtaining patent rights that are valid and enforceable.

Further, there are uncertainties in defining what a promise is, which, as seen above, can become a slippery slope of construction. Are goals or descriptions of advantages promises? What rises to the level of a promise can potentially become a subjective exercise that unfairly prejudices a patentee. Whether or not a statement rises to the level of a "promise" can be highly dependent on an agent's particular drafting style. But if it does rise to this level, and the patent's promise is not met, the consequence is that a claim of the patent may be rendered invalid. This is a harsh result.

At the other extreme end of the spectrum are patents that contain no promissory language whatsoever. In those cases, only a scintilla standard need be met. This is a low threshold, requiring only a showing of how to make and use an invention as required by section 27(3).[278] This is out of step with the US disclosure standard, which requires more than a showing of how to make and use an invention.

As noted previously, like Canada, the United States, under § 112, paragraph 1,[279] requires a description of how to make and use an invention, referred to in the jurisprudence as the "enablement requirement." For many years the law was unsettled as to whether a separate and distinct written description standard under §112, paragraph 1 could be applied outside the priority context. Many felt that written description requirements were subsumed by enablement requirements—that is, the written description requirement required a patentee only to provide a description of how to make and use the invention and should not be applied outside the priority context. After denying numerous petitions for rehearing en banc, a petition was finally granted to Ariad Pharmaceuticals by the Federal Circuit. In *Ariad*, the panel was asked to answer whether 35 USC § 112, paragraph 1 "contains a written description requirement separate from an enablement requirement."[280] Here is what the court said:

> Since its inception, this court has consistently held that §112, first paragraph, contains a written description requirement separate from enablement, and we have articulated a "fairly uniform standard," which we now affirm. *Vas-Cath Inc. v. Mahurkar*, 935 F.2d 1555, 1562-63 (Fed. Cir. 1991). Specifically, the description must "clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed." Id. At 1563 (citing *In re Gosteli*, 872 F.2d 1008, 1012 (Fed. Cir. 1989)). In other words, the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date. …
>
> [T]he test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the

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278 *Pfizer*, *supra* note 20 (although *Pfizer* also requires that one must particularly point out the invention).

279 Now § 112(a) post-AIA.

280 *Ariad*, *supra* note 181 at 1342.

> specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.
>
> This inquiry, as we have long held, is a question of fact. *Ralston Purina*, 772 F.2d at 1575. Thus, we have recognized that determining whether a patent complies with the written description requirement will necessarily vary depending on the context. *Capon v. Eshhar*, 418 F.3d 1349, 1357-58 (Fed. Cir. 2005). Specifically, the level of detail required to satisfy the written description requirement varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology. Id. For generic claims, we have set forth a number of factors for evaluating the adequacy of the disclosure, including "the existing knowledge in the particular field, the extent and content of the prior art, the maturity of the science or technology, [and] the predictability of the aspect at issue." Id. at 1359.
>
> The law must be applied to each invention at the time it enters the patent process, for each patented advance has a novel relationship with the state of the art from which it emerges. Thus, we do not try here to predict and adjudicate all the factual scenarios to which the written description requirement could be applied.[281]

It thus bears repetition that the United States not only requires a patentee to describe how to make and use an invention under § 112(a),[282] but additionally to demonstrate possession of the invention within the confines of the "four corners of the specification." As is evident from the above-quoted passages from *Ariad*, it is a highly fact-dependent analysis.[283] This might beg the question: Are written description and sound prediction tests the same? Certainly, both are fact-based analyses. I am not suggesting that the tests are in every aspect identical, and a rigorous comparative analysis is beyond the scope of this article. The court in *Ariad* refused to provide a governing test as to whether written description requirements are satisfied, stating that "each patented advance has a novel relationship with the state of the art from which it emerges,"[284] and refused to "predict and adjudicate all the factual scenarios to which the written description requirement could be applied."[285] Nonetheless, it is clear that the United States does not embark on a preliminary exercise of construing promises in the description in order to set disclosure standards prior to determining whether those standards are met.

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[281] *Ibid* at 1351.

[282] Section 112, paragraph 1 under pre-AIA laws.

[283] In *Capon v Eshhar*, *supra* note 206, which was cited with approval by *Ariad*, no data were required to meet the written descripton standard, in spite of the fact that the invention was in the unpredictable arts—that is, novel biological material. However, the invention in *Capon v Eshhar* involved creating a fusion protein made up of two known and well-characterized proteins and the art had advanced to the point whereby the techniques to make fusion proteins had become standard. Thus, showing how to make and use the invention (enablement) sufficed. On the other hand, as discussed above, the patent in *Ariad*, which related to undisclosed compounds that reduced cytokine production, was rendered invalid due to failure to demonstrate possession of invention. In this case, the chemical structures of the compounds had not been disclosed and were characterized only in terms of their function (reducing binding of NF-κB to DNA).

[284] *Ariad*, *supra* note 181 at 1351.

[285] *Ibid*.

It has been argued that meeting promises as articulated in the patent is required for consideration in exchange for the monopoly.[286] However, when viewed through the lens of the utilitarian justification for intellectual property rights, one needs to ask whether promissory language justifies a patent grant or, more fundamentally, the full disclosure of a new and useful invention shown to advance the arts. As discussed above, the latter inquiry is what drives the *quid pro quo* as mandated by *Consolboard*[287] and affirmed recently by *Pfizer*[288]—that is, the actual disclosure of a new and useful invention provides the necessary consideration for the patent monopoly. This serves the important policy function of ensuring that the public will be able "to make the same successful use *of the invention* as the inventor could at the time of his application."[289] Although promises might form an important component in delineating what the invention is, they are only a means to an end—they should not reside at its heart.

If one accepts that promissory language in the patent specification should not be the focus of the analysis, what, then, should the test require? Clearly, some guidance is needed based on the specification to set the standard for disclosure.

One option might be to focus entirely on the claims. The claims define the monopoly and reflect what the inventor thought the inventive contribution was, so there is some logic to this approach. However, as attractive as this approach is in that it potentially provides a bright-line rule and consequently increased certainty, statements of the invention's utility are usually not included in claims—in fact, such practice is generally frowned on among patent agents. Claims generally define the components of a product or the steps of a process or method, not usually the end result achieved. An exception is claims directed to a new use for an old compound. In such cases, the utility is necessarily recited because it is the gravamen of the invention. Clearly, however, one should not impose a higher standard for disclosure on this subset of inventions.

Another option is to police adequate disclosure under a heightened "enablement standard," which requires a patentee to show how to make and use an invention. In the United States, Rader J suggested in his dissent in *Ariad*[290] that the court should "strengthen its enablement jurisprudence instead of making new rules [that is, the new written description doctrine]."[291] Indeed, in Canada, the enablement standard has become strenghtened in view of *Pfizer*,[292] which held that more than a showing

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[286] See the discussion in Gold & Shortt, *supra* note 4 at 38-40, articulating their views on the policy justification for meeting promises.

[287] *Supra* note 18.

[288] *Supra* note 20.

[289] *Ibid* at para 50, citing *Consolboard*, *supra* note 18, which in turn cites *Minerals Separation North America Corporation v Noranda Mines, Limited*, [1947] Ex CR 306 (emphasis added).

[290] *Supra* note 181.

[291] *Ibid* at 1367.

[292] *Supra* note 20.

of how to make and use was needed in that one must particularly point out the invention.[293] This would be consistent with the approach taken in Europe in which disclosure requirements are assessed under enablement.[294] This approach makes good sense. However, *Pfizer* expressly rejected that utility needs to be established under section 27(3).[295] LeBel J stated that there should be limits placed on the ambit of section 27(3) beyond showing how to make, use, and particularly point out the invention. Accordingly, this is not a solution either. Given the drawbacks discussed above of meeting the promise of the patent and alternative approaches to determine what a patent should disclose, a fairer and more equitable standard is desirable.

A more multifaceted approach to defining the standard set for disclosure offers solutions to overcome some of the legal and practical shortcomings of the promise of the patent outlined above. Such an analysis is consistent with some of the "holistic cases" discussed above. Further, also as discussed above, this approach has some similarities to US written description requirements, at least to the extent that the legal standard that must be met to show possession of invention is a question of fact and "the level of detail required to satisfy [it] … varies depending on the nature and scope of the claims and on the complexity and predictability of the relevant technology."[296] Further, the written description standard acknowledges that the "law must be applied to each invention at the time it enters the patent process, for each patented advance has a novel relationship with the state of the art from which it emerges."[297]

Shifting the focus from promissory language in the patent specification to the inventive contribution can also avoid a bifurcated approach to the utility analysis—namely, one in which a patent is invalidated if a patentee has made a "promise" in the specification but has not provided evidence in the patent to meet a high standard of disclosure that might be imposed by that promise, and where no promise has been made and the patentee needs to show only a "scintilla of utility." In the former situation, a patentee stands an increased chance of his or her patent being invalidated than in the latter situation, where only a scintilla of utility needs to be established. Taking the focus off construction of the "promise" to set the disclosure standard can serve to temper these two extreme outcomes.

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[293] Although outside the scope of this article, this has some functional equivalence to a line of "trail-blazing cases" in the United States under written description laws: see Joseph M Manak, "The Law of Written Description in Pharmaceutical and Biotechnology Patents" (2004) 23 Biotech L Rep 30 at 35-41, discussing a line of "trail-blazing cases" in which patentees sought to patent "laundry lists" or "shotgun disclosures" of chemical compounds, and later relied on generic language to support filed claims for particular chemical compounds encompassed within the generic language. This approach was rejected as failing to satisfy the written description requirement.

[294] See Case Law of the Boards of Appeal, *supra* note 261; see also Schuster, *supra* note 269 at 502, stating that "the written patent description is merely examined in the context of enablement" when referring to European sufficiency of disclosure.

[295] *Pfizer*, *supra* note 20 at para 40, stating "there is no requirement *whatsoever* in s. 27(3) to disclose the utility of the invention" (emphasis added).

[296] *Ariad*, *supra* note 181 at 1351.

[297] *Ibid*.

Some might argue that lack of predictability is a potential drawback with a holistic analysis. In the United States, the written description standard has faced just such criticism because of its fact-based nature.[298] However, given the vast differences in subject matter eligible for patent protection, a one-size-fits-all test is not fair or equitable. Each invention has its own unique relationship with the state of the art. Further, it is easier to predict the utility of some inventions than of others. Taking this variation into account when conducting the analysis is necessary in the pursuit of promoting fairness across the full gamut of inventions for which patent protection can be sought. Despite the attractiveness of a bright-line test, it must be balanced with equity and fairness.

In addition to being supported by promise cases that adopt a more holistic approach to construction of the promise, a holistic analysis is also consistent with views expressed by certain commentators in Canada.[299] These commentators have said that a less promise-centric analysis will actually add more certainty to the law.[300] Promises can potentially be construed as part of a hair-splitting exercise, which the commentators refer to as "lawyerly parsing of text"[301] and also as an "unchaperoned romp through the disclosure."[302] They then suggest that focusing on the inventive concept "will take much-needed emphasis away from discerning the promise through reading the patent specification."[303] I am not suggesting that elucidating the inventive concept in order to set the disclosure standard should be dispositive in all instances. Some inventions are approached from many sides and their relationship with what has gone before is not always easily circumscribed. A holistic analysis by its very nature is multifaceted and thus takes this into consideration. US jurisprudence acknowledges this. As noted in *Ariad*, "[t]he law must be applied to each invention at the time it enters the patent process, for each patented advance has a novel relationship with the state of the art from which it emerges."[304]

Nevertheless, many of the drug patents that are challenged for lack of utility have a fairly definable contribution over the art. For example, in *Plavix*® and *Olanzapine*, the patents at issue were selection patents that offered specific advantages over the earlier respective genus patents. In *Raloxifene*, human studies needed to be provided in the patent itself because the closest prior art already disclosed successful treatment in animal models. Thus, in many instances, ensuring that the disclosure standard is consistent with the contribution over the art makes good sense—this is the consideration offered by the patent in exchange for the monopoly.

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298 *Ibid*; see Rader J in dissent at 1361-67.

299 Bernstein & Bienenstock, *supra* note 77.

300 *Ibid* at 249, stating that "there is no real test, nor any standard approach that courts follow to ensure that [a] promise is determined in a consistent and predictable manner."

301 *Ibid* at 249.

302 *Ibid*.

303 *Ibid* at 258.

304 *Ariad*, *supra* note 181 at 1351.

7.0 POLICY CONSIDERATIONS

More generally speaking, the debate in Canada and the United States as to whether a separate disclosure standard should exist when policing claim overreach reflects the necessity of laws to adapt to challenges posed by emerging technology and the resistance to such changes by certain stakeholders. Clearly, such an additional dimension to the analysis is warranted to keep pace with technological developments. The *Patent Act* is not static; it must be applied in ways that recognize changes in technology.[305] It is likely intentional that the statutory provisions in the United States and Canada defining what constitutes patentable subject matter were broadly written to encompass the evolution of technology unforeseen at the date of enactment. Disclosure requirements are written in a similarly broad manner. Given that there is so much room for interpretation, it is not surprising that in each country the judiciary has construed the statutory provisions so differently. But, despite having different statutory bases for disclosure requirements, fundamentally each country agrees on the fact that an additional disclosure standard for certain inventions beyond showing how to make and use an invention is needed, particularly in the emerging arts, which are often unpredictable in nature.

An examination of the analogies between US and Canadian law also illuminates a more general tension between striking a balance between a patentee's interests in modest disclosure and the public interest in advancing the industrial arts by mandating a full and detailed disclosure of the invention. Striking this balance in emerging technologies is particularly challenging due to the complexity of the subject matter at issue. For instance, in pharmacology, changing even a single atom in a drug can drastically change the drug's metabolism by the body, which in turn can change the efficacy of the therapy. The state of the art is an important component to analyze what the inventive contribution is over what was previously known. Yet this is also complicated, since experts can disagree on the teaching of a particular piece of prior art.[306] The level of predictability in the art also provides room for debate. A patentee arguing adequate disclosure will assert that a patented technology is predictable and that disclosure in the patent is adequate. On the other hand, in an effort to raise the bar for disclosure standards, a party challenging a patent may argue that the field of technology is unpredictable. In reality, the truth probably lies somewhere in the middle. A holistic approach is equipped to deal with these complexities.

The complicating factors involved in elucidating what the inventive contribution is over the art and the level of disclosure needed to substantiate that contribution is a reality of modern-day patent law. It is necessary to deal with all the variables at play on a case-by-case analysis, rather than focusing on particular passages in the patent specification. By applying the holistic approach, factoring in promissory language is just one part of the analysis in determining what has been invented. By unravelling what has been invented through a multifaceted inquiry, one can then ask

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[305] *Amazon*, *supra* note 14 at para 54.

[306] See discussion of *Raloxifene*, *supra* note 78, and the "Jordan article," note 151 above.

whether the invention is sufficiently disclosed to meet the *quid pro quo*, which lies at the heart of advancing the technical arts in line with the utilitarian justification for patent rights.

8.0 CONCLUSION

Although each country is justified in having its own laws dictating adequate disclosure within the confines of international treaties, the criticism of the Canadian utility requirements as being out of line with other countries warranted a historical and comparative analysis focusing on the US patent regime. The foregoing analysis has revealed that Canada is not significantly out of step with US laws on disclosure requirements.

This is not to say that there are no differences between the two jurisdictions. Canadian law takes on an additional role of construing promises in order to set disclosure standards, a requirement that clearly has no parallels under US law. Further, two landmark Supreme Court decisions in Canada dealing with disclosure requirements do not specifically mandate construction of promises in order to set disclosure requirements. Thus, construction of promissory language has a weak legal basis. Further, recent case law in which promises are construed is unsettled. Certain cases are promise-centric—that is, promises take on the central role of disclosure standards—and other cases adopt a more holistic approach to setting disclosure standards.

A holistic approach to setting the disclosure standard is better law—it takes into account that each invention has its own unique set of factors which must be considered when determining its contribution over the art and whether the disclosure satisfies that objective to meet the *quid pro quo*. Indeed, case law on utility seems to be evolving in this direction and is consistent with a tenet of construction:

> If the language of the specification, upon a reasonable view of it, can be so read as to afford the inventor protection for that which he has actually in good faith invented, the court, as a rule, will endeavour to give effect to that construction.[307]

Nonetheless, given the tensions felt at present between stakeholders in the pharmaceutical industry, a Supreme Court decision would greatly help clarify this issue.

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[307] *Whirlpool*, *supra* note 129 at para 49.