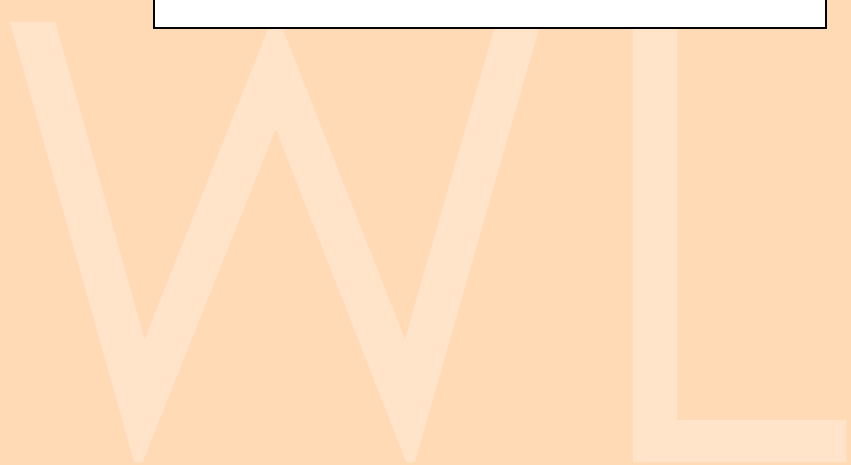




Washington Legal Foundation  
Advocate for freedom and justice®  
2009 Massachusetts Avenue, NW  
Washington, DC 20036  
202.588.0302

**CANADA & PATENTABLE UTILITY:  
NATION'S IP JURISPRUDENCE LAGS  
COMPARED TO U.S. AND EUROPE**

by  
Arvie J. Anderson & Steven P. Caltrider  
*Eli Lilly and Company*



**Washington Legal Foundation**  
CONTEMPORARY LEGAL NOTE Series

Number 70  
March 2012

# TABLE OF CONTENTS

I. BACKGROUND .....	1
II. STATUTORY UTILITY REQUIREMENTS IN THE UNITED STATES, EUROPE, AND CANADA .....	5
A. Proof of Utility in the United States.....	6
B. Proof of Utility in Europe .....	11
C. Proof of Utility in Canada.....	13
III. THE WIDENING GAP IN JUDICIAL APPLICATION OF STATUTORY UTILITY REQUIREMENTS.....	16
IV. THE CANADIAN STANDARD OF UTILITY HAS A DISPARATE IMPACT ON PHARMACEUTICAL AND CHEMICAL PATENTS .....	20
A. The Canadian Approach to Utility Discourages Disclosure .....	24
B. The Canadian Approach to Utility Discourages Innovation .....	26
CONCLUSION.....	28

## **ABOUT WLF'S LEGAL STUDIES DIVISION**

The Washington Legal Foundation (WLF) established its Legal Studies Division to address cutting-edge legal issues by producing and distributing substantive, credible publications targeted at educating policy makers, the media, and other key legal policy outlets.

Washington is full of policy centers of one stripe or another. But WLF's Legal Studies Division has deliberately adopted a unique approach that sets it apart from other organizations.

First, the Division deals almost exclusively with legal policy questions as they relate to the principles of free enterprise, legal and judicial restraint, and America's economic and national security.

Second, its publications focus on a highly select legal policy-making audience. Legal Studies aggressively markets its publications to federal and state judges and their clerks; members of the United States Congress and their legal staffs; government attorneys; business leaders and corporate general counsel; law school professors and students; influential legal journalists; and major print and media commentators.

Third, Legal Studies possesses the flexibility and credibility to involve talented individuals from all walks of life – from law students and professors to sitting federal judges and senior partners in established law firms.

The key to WLF's Legal Studies publications is the timely production of a variety of intelligible but challenging commentaries with a distinctly common-sense viewpoint rarely reflected in academic law reviews or specialized legal trade journals. The publication formats include the provocative COUNSEL'S ADVISORY, topical LEGAL OPINION LETTERS, concise LEGAL BACKGROUNDERS on emerging issues, in-depth WORKING PAPERS, useful and practical CONTEMPORARY LEGAL NOTES, interactive CONVERSATIONS WITH, law review-length MONOGRAPHS, and occasional books.

WLF's LEGAL OPINION LETTERS and LEGAL BACKGROUNDERS appear on the LEXIS/NEXIS® online information service under the filename "WLF" or by visiting the Washington Legal Foundation's website at [www.wlf.org](http://www.wlf.org). All WLF publications are also available to Members of Congress and their staffs through the Library of Congress' SCORPIO system.

To receive information about previous WLF publications, contact Glenn Lammi, Chief Counsel, Legal Studies Division, Washington Legal Foundation, 2009 Massachusetts Avenue, NW, Washington, D.C. 20036, (202) 588-0302.

## **ABOUT THE AUTHORS**

**Arvie J. Anderson** is Assistant General Patent Counsel at Eli Lilly and Company. **Steven P. Caltrider** is Vice President and Deputy General Counsel at Eli Lilly and Company. The authors would like to thank **Paula Davis** for her editorial and helpful comments.

# **CANADA & PATENTABLE UTILITY: NATION'S IP JURISPRUDENCE LAGS COMPARED TO U.S. AND EUROPE**

by  
Arvie J. Anderson & Steven P. Caltrider  
Eli Lilly and Company

An analysis of Canadian decisions by the Federal Court and Federal Court of Appeal highlights the widening gap between the judicial application of the patent utility requirements in Canada and other major jurisdictions including the United States and Europe. While all three jurisdictions find basis for their laws pertaining to patentable utility within their respective statutes and applicable treaty obligations, only Canada looks to the quantum of evidence to establish or “soundly predict” usefulness at the time of filing rather than assessing patentability as usefulness in fact. By doing so, Canada requires a heightened utility standard both as to the necessary disclosure and as to the quantum of proof. This CONTEMPORARY LEGAL NOTE compares and contrasts the requirements for usefulness in Canada, the United States, and Europe, and encourages the Canadians to return the law to its pre-2002 standard of utility-in-fact either through case law or legislative reform.

## **I. BACKGROUND**

In the high risk arena of drug discovery, pharmaceutical innovators use an array of research means to better understand drug effectiveness. *In vitro* (so-called “test tube”) drug studies, when possible, may provide a convenient and in some cases predictable test for activity in a disease model. Given the

complexity of the functional systems of living organisms, *in vivo* studies (also known as animal testing) can generally provide an even better representation of drug effectiveness where the whole animal model is relevant to the targeted disease state.<sup>1</sup> After there have been sufficient *in vitro* and/or *in vivo* studies performed, further investigation in humans is ultimately required before regulatory approval is granted by an agency such as the United States Food and Drug Administration or the European Medicines Agency. In those cases, initiation of a clinical trial in humans may commence only after the drug discoverer has provided a sufficient rationale to the applicable regulatory agency that adequate testing in non-human subjects has been performed to reasonably suggest that studying the safety and efficacy in humans is warranted.<sup>2</sup> Human clinical studies can thus represent the best proof of drug activity available in drug discovery.

Clinical trial results for studies in human patients, however, are somewhat rarely included within patent applications as filed. This is often because clinical trials are arduous, expensive, and time consuming;<sup>3</sup> thus, they may not be completed in a timely fashion for inclusion within an application.

---

<sup>1</sup> The Institute for Laboratory Animal Research of the U.S. National Academy of Arts and Sciences maintains that even sophisticated computers are not able to model interactions between molecules, cells, tissues, organs, organisms and the environment which confirm the need for animal research in many disease states. INST. FOR LAB. ANIMAL RESEARCH, SCIENCE, MEDICINE, AND ANIMALS 2 (Nat'l Research Council of the Nat'l Acads. 2004).

<sup>2</sup> A clinical trial must be approved by a review board and must conform to the appropriate national health authorities in order to be registered. Food and Drug Amendments Act of 2007, Pub. L. No. 110-85, 121 Stat. 823 (2007), available at [http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110\\_cong\\_public\\_laws&docid=f:publ085.110.pdf](http://frwebgate.access.gpo.gov/cgi-bin/getdoc.cgi?dbname=110_cong_public_laws&docid=f:publ085.110.pdf). See also 21 C.F.R. § 312.23(a)(8).

<sup>3</sup> Steven M. Paul et al., *How to Improve R&D Productivity: The Pharmaceutical Industry's Grand Challenge*, 9 NAT. REVS. DRUG DISCOVERY 203 (2010).

Further, if the applicant were to await the results of a clinical trial which conclusively proves utility before filing a patent application, this waiting period might place the patent application at risk of being found to lack novelty<sup>4</sup> or “obvious” in prosecution or in a later-filed invalidity challenge. Thus, even in cases where clinical trials have been initiated prior to the filing date, patentees rarely await the results before filing or include the results within the application.

It is perhaps in part for these practical reasons that major jurisdictions do not require conclusive proof of an asserted utility within a patent application as filed. Further, except for Canada as described here, the patent laws of all major jurisdictions focus on actual utility (i.e., whether the invention actually works) and allow a patent applicant to submit evidence made available even after the filing date to support utility.<sup>5</sup> Indeed, in the United States, for example, such submissions are not generally required for a claimed invention unless an asserted utility is incredible<sup>6</sup> or inutility is raised as a ground of invalidity.<sup>7</sup> Moreover, the U.S. courts and the United States Patent and Trademark Office (USPTO) recognize that even if the asserted

---

<sup>4</sup> In order to preserve patent eligibility, the subject must be novel. *See, e.g.*, 35 U.S.C. § 102(b). Disclosure of the details of a clinical trial has been argued as a patent-defeating disclosure. *Eli Lilly & Co. v. Teva Canada Ltd.*, [2010] FC 915, 87 CPR (4th) 301, at paragraphs 46 through 48 (*Strattera FC*), where Novopharm argued that two oral conversations that fell outside the one-year grace period rendered the invention anticipated; *see also* *Bayer Schering Pharma AG v. Barr Labs., Inc.*, 2008 U.S. Dist. LEXIS 15917, at \*110-28 (D.N.J.).

<sup>5</sup> *In re Brana*, 51 F.3d 1560, 1567 n.19 (Fed. Cir. 1995).

<sup>6</sup> In the United States, when priority is not an issue and the use is not on its face contrary to generally accepted scientific principles, the law does not require proof of utility in the application. *Eli Lilly and Co. v. Teva Pharms. USA, Inc.*, 619 F.3d 1329, 1343 (Fed. Cir. 2010).

<sup>7</sup> *See, e.g.*, *In re Swartz*, 232 F.3d 862 (Fed. Cir. 2000); *Newman v. Quigg*, 877 F.2d 1575 (Fed. Cir. 1989).

utility has not been demonstrated by a completed clinical trial, the mere initiation of the clinical trial justifies the presumptive utility of the subject of the trial, as clinical trials may commence only after the sponsor has provided a convincing rationale to the U.S. Food and Drug Administration that the investigation may be successful.<sup>8</sup>

Canadian courts are an outlier in their approach to usefulness under patent law. In spite of statutory language that is analogous to the other major jurisdictions, the Canadian Federal Court and the Federal Court of Appeal routinely find patents invalid (or allegations of invalidity found justified under Patented Medicines (Notice of Compliance) Regulations<sup>9</sup>) for inutility even where patentees provide data from human clinical trials as evidence of utility.<sup>10</sup> Paradoxically in Canada, the likelihood of a patent being ruled to possess

---

<sup>8</sup> MANUAL OF PATENT EXAMINING PROCEDURE § 2107.03 (8th ed. Rev. 8 2008); *see also* Eli Lilly & Co. v. Actavis Elizabeth LLC, 435 Fed. Appx. 917, 924 (Fed. Cir. 2011); Eli Lilly & Co. v. Teva Pharms. USA, Inc., 619 F.3d 1329 (Fed. Cir. 2010).

<sup>9</sup> Patented Medicines (Notice of Compliance) Regulations, SOR/93-133 (Can.) as amended [*PM(NOC)*] (*Patent Act* s. 55.2).

<sup>10</sup> Recent Canadian Federal Court and Federal Court of Appeal decisions invalidating pharmaceutical patents for a lack of utility in infringement or revocation proceedings where human clinical data was referenced in the decision in support of utility include the following: Eli Lilly & Co. v. Teva Canada Ltd., [2011] FCA 220, 94 CPR (4th) 95 [*atomoxetine FCA*], affirming 2010 FC 915, 87 CPR (4th) 301 [*Strattera FC*], leave to appeal to SCC dismissed Dec. 8, 2011 (No. 34396); Shire BioChem Inc. v. Canada (Minister of Health), [2008] FC 538, 2008 4 FCR D-2 [*modafinil*]; Ratiopharm Inc. v. Pfizer Ltd., [2009] FC 711, 76 CPR (4th) 241 [*amlodipine besylate*], affirmed 2010 FCA 204, 87 CPR (4th) 185 (FCA does not comment on utility); and Eli Lilly Canada Inc. v. Novopharm Ltd., [2011] FC 1288 [*Olanzapine*]. Decisions where allegations of inutility were found to be justified in PM(NOC) (s. 55.2) hearings include the following: Apotex Inc. v. Pfizer Canada Inc., [2011] FCA 236, 95 CPR (4th) 193 [*latanoprost FCA*]; Eli Lilly Canada Inc. v. Apotex Inc., [2009] FCA 97, 78 CPR (4th) 388 [*raloxifene*], leave to appeal to SCC refused [2009] SCCA No 219 (QL); Pfizer Canada Inc. v. Ratiopharm Inc., [2010] FC 612, 85 C.P.R. (4th) 103 [*sildenafil FC*]; AstraZeneca Canada Inc. v. Apotex Inc., [2010] FC 714, 88 CPR (4th) 28 [*esomeprazole*]; GlaxoSmithKline Inc. v. Pharmascience Inc., [2008] FC 593, 72 CPR (4th) 295 [*valacyclovir*]; Pfizer Canada Inc. v. Apotex Inc., [2007] FC 26, 59 CPR (4th) 183 [*sildenafil*], affirmed 2007 FCA 195, 60 CPR (4th) 177, leave to appeal to SCC refused [2007] SCCA No 371 (QL); and Sanofi-Aventis v. Apotex Inc., [2011] FC 1486 [*clopidogrel*]. Collectively, these products represent billions of dollars of sales lost due to judge-made heightened standards of utility.

utility does not appear to increase as the supporting evidence trends toward positive human clinical results.<sup>11</sup> This is likely due to the judicial gloss on Canada’s statutory utility requirements which require a “sound prediction” that an invention will meet the so-called promise of the patent prior to the filing date of the invention.

## **II. STATUTORY UTILITY REQUIREMENTS IN THE UNITED STATES, EUROPE, AND CANADA**

The patent statutes in the United States, Europe, and Canada all define patentable utility in a remarkably similar manner. In the United States, 35 U.S.C. § 101 of the Patent Act defines what is patentable: “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.”<sup>12</sup> (emphasis added). In Canada, the statutory language is remarkably similar: An invention is “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.”<sup>13</sup> (emphasis added). In Europe, the European Patent Convention (EPC) establishes that inventions which are “*susceptible of industrial application*, which are new and which involve an inventive step” are patentable.<sup>14</sup> (emphasis added). Being “susceptible of

---

<sup>11</sup> See Figure 1, *infra*.

<sup>12</sup> 35 U.S.C. § 101.

<sup>13</sup> Patent Act, R.S.C., § 2 (1985) (Can.); MANUAL OF PATENT OFFICE PRACTICE § 12.02 (Can. Intell. Prop. Off. 2010).

<sup>14</sup> EUR. PAT. CONVENTION, art. 52 (1973).

industrial application” is Europe’s form of utility, and an invention is susceptible of industrial application if “it can be made or used in any kind of industry.”<sup>15</sup> “Industry” generally is understood “in its broad sense.”<sup>16</sup> There is no debate whether “susceptible of industrial application” and “useful” carry the same intent and meaning, as TRIPS defines the terms to be synonymous.<sup>17</sup>

Accordingly, all three regions require that an invention be useful as the statutory test for utility. All three regions also provide a separate and distinct requirement that the specification of the patent application describe the manner of making and using the invention so as to enable a person of ordinary skill in the art to which it pertains to make and use the invention.<sup>18</sup> None of the three statutes, however, contain a requirement that the specification contain proof of the accuracy of the utility asserted for the invention. Importantly, none of the three statutes require the patentee to prove operability before the filing date of the invention. Nevertheless, the three regions are far from aligned on the test for utility.

### **A. Proof of Utility in the United States**

It is unsurprising that “useful,” as used in the statute and in the context of the patent acts and treaty obligations, means utility-in-fact. That is, as a question of fact, the issue is properly whether the invention is useful under the

---

<sup>15</sup> *Id.* at art. 57.

<sup>16</sup> GUIDELINES FOR EXAMINATION IN THE EUROPEAN PATENT OFFICE ch. IV, § 5.1 (2010).

<sup>17</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27 n 5, Apr. 15, 1994, 1869 U.N.T.S. 299 [TRIPS].

<sup>18</sup> *Compare* 35 U.S.C. § 112, Patent Act, R.S.C., § 27(3) (Can.) *and* the European Patent Convention arts. 52 and 57 *with* *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] 1 S.C.R. 504.

statute. The framework of the patent act in the United States, which is analogous to other countries, sets patentable utility as a condition precedent. It is one of the conditions that must be met to obtain a patent. The United States Court of Appeal for the Federal Circuit stated it as follows:

It has long been understood that the Patent Act sets out the conditions for patentability in three sections: sections 101, 102, and 103. *See Graham v. John Deere*, 383 U.S. 1, 12, 86 S. Ct. 684, 15 L. Ed. 2d 545 (1966) (“The [1952 Patent] Act sets out the conditions of patentability in three sections. An analysis of the structure of these three sections indicates that patentability is dependent upon three explicit conditions: novelty and utility as articulated and defined in § 101 and § 102, and nonobviousness, the new statutory formulation, as set out in § 103.”). These conditions are included in Chapter 10 of the Patent Act, entitled ‘Patentability of Inventions,’ and the titles of the sections themselves make clear that they relate to fundamental preconditions for obtaining a patent. Section 101, relating to utility and patent eligibility, is entitled ‘Inventions Patentable.’ Likewise, sections 102 and 103, relating to novelty and nonobviousness, respectively, are explicitly entitled ‘[c]onditions for patentability.’

Whereas 35 U.S.C. § 112 defines the requirements for the patent specification in order for a patent to be valid, *viz.*, the patented invention must be enabled by the specification.<sup>19</sup> Accordingly, if an invention has utility—that is, it is operable—then the condition for patentability is met.<sup>20</sup> The only relevant issue remaining is whether the specification adequately teaches how to make and use the invention or is otherwise in compliance with section 112 (assuming novelty and non-obviousness).<sup>21</sup> The Federal Circuit described the test of

---

<sup>19</sup> *Id.* at 662 (“the requirements in section 112 are not conditions for patentability; they are merely requirements for obtaining a valid patent.”).

<sup>20</sup> Section 101 also governs whether subject matter is patent eligible, which is a distinct inquiry from whether an invention is useful. 35 U.S.C. § 101.

<sup>21</sup> 35 U.S.C. § 112, para. 1.

operability as follows:

To meet the utility requirement, the Supreme Court has held that a new product or process must be shown to be ‘operable’—that is, it must be ‘capable of being used to effect the object proposed.’ Our cases have not, however, interpreted this language in *Mitchell* to mean that a patented device must accomplish *all* objectives stated in the specification. On the contrary, ‘[w]hen a properly claimed invention meets at least one stated objective, utility under § 101 is clearly shown.’ The utility requirement, though an essential requisite of patentability, has other limits. An invention need not be the best or the only way to accomplish a certain result, and it need only be useful to some extent and in certain applications: ‘[T]he fact that an invention has only limited utility and is only operable in certain applications is not grounds for finding lack of utility.’ Whether an invention claimed in a patent lacks utility is a question of fact, which we therefore review for clear error.<sup>22</sup>

(citations omitted). In the context of pharmaceutical arts, when a credible allegation of inutility is made, usefulness can be established with reference to preclinical testing. The predecessor to the Federal Circuit noted:

In our opinion, he need do no more to satisfy the requirement of 35 U.S.C. § 101 that the claimed invention be useful. We do not agree with the solicitor that appellant’s immediate aim was to use the compounds to treat human iritis. Even though there appears to be no question that his ultimate purpose was to do this, the lack of proof of the effectiveness of the compounds for this purpose is not determinative of the issues here.

We wish to point out that this court is aware of the common practice of using ‘experimental animals’ in considerable variety for the evaluation of chemical compounds for possible pharmaceutical applications prior to clinical testing on humans. It is also our understanding that a demonstration that a compound has desirable or beneficial properties in the prevention, alleviation, or cure of some disease or manifestation of a disease in experimental animals does not necessarily mean that the compound will have the same

---

<sup>22</sup> *Stiftung v. Renishaw PLC*, 945 F.2d 1173, 1180 (Fed. Cir. 1991).

properties when used with humans. With this information in mind, we hold that when an applicant for a patent has alleged in his patent application that a new and unobvious chemical compound exhibits some useful pharmaceutical property and when this property has been established by statistically significant tests with 'standard experimental animals,' sufficient statutory utility for the compounds has been presented. By 'standard experimental animals,' we mean whatever animal is usually used by those skilled in the art to establish the particular pharmaceutical application in question. These may be mice in one case, rabbits in another, chickens in another, and monkeys in another.<sup>23</sup>

Of course, science has progressed since *Kimmel* in 1961 to the point where genetic markers and cellular and tissue experiments can be as predictive as or more predictive than whole animal studies. Nevertheless, the conclusion remains sound—that an allegation of inutility is answered fully if the invention is shown to be useful by reference to studies showing potential pharmacological activity relevant for a specific use.<sup>24</sup>

In contrast to Canada, where the “sound line of reasoning” must be set out within the patent as discussed below, the United States does not require a patent applicant to provide any rational or scientific principle explaining how the invention works. So long as the principle is not incorporated into the

---

<sup>23</sup> *In re Krimmel*, 292 F.2d 948, 953 (C.C.P.A. 1961).

<sup>24</sup> *See also In re Brana*, 51 F.3d 1560, 1567-68 (Fed. Cir. 1995):

FDA approval, however, is not a prerequisite for finding a compound useful within the meaning of the patent laws. *Scott*, 34 F.3d 1058, 1063, 32 U.S.P.Q.2d 1115, 1120. Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.

claims, it has no bearing on whether an invention is useful even if the hypothesis advanced by the inventor as to how the invention works is shown to be wrong.<sup>25</sup>

Thus, the test for utility in the United States can be summarized as one where a specific and substantial (non-frivolous) credible utility must be disclosed in the patent application. The USPTO must accept the assertion of utility, absent some scientific reason to doubt its credibility. Inutility—whether raised by the patent examiner or subsequently in a patent challenge—must establish that the invention is in fact not useful. The only disclosure requirement under this test is that defined by section 112, that the use be enabled by the disclosure.<sup>26</sup> The specification as filed need not contain proof.<sup>27</sup>

As it pertains to the development of life-saving innovative medicines, U.S. courts and the USPTO have developed practical rules pertaining to patentable utility. U.S. courts and the USPTO recognize that even if an asserted utility has not been demonstrated by completion of a clinical trial, the mere initiation of a clinical trial justifies a presumption of utility of the subject

---

<sup>25</sup> *Process Control Corp. v. HydReclaim Corp.*, 190 F.3d 1350, 1359 (Fed. Cir. 1999):

While an otherwise valid patent covering a meritorious invention should not be struck down simply because of the patentee's misconceptions about scientific principles concerning the invention, [] when "the claimed subject matter is inoperable, the patent may indeed be invalid for failure to meet the utility requirement of § 101 and the enablement requirement of § 112.

(citations omitted).

<sup>26</sup> In exceptional circumstances where the alleged utility is incredible or in the context of a patent interference where establishing utility goes to evidence of a reduction to practice, additional evidence may be required. *In re '318 Patent Infringement Litig.*, 583 F.3d 1317 (Fed. Cir. 2009).

<sup>27</sup> *See, e.g., In re Gazave*, 379 F.2d 973, 979 (C.C.P.A. 1967).

of the clinical trial. The presumption is in recognition of the reality that a clinical trial in humans may only commence after the sponsor has provided a convincing rationale to the U.S. Food and Drug Administration that the investigation may be successful.<sup>28</sup> Therefore, since the inception of patent law in the United States, the focus has been on whether or not the utility asserted in the specification is actually useful, and not on whether the evidence confirming the truth of the asserted utility is disclosed in the application as filed.<sup>29</sup>

## **B. Proof of Utility in Europe**

The European Patent Convention provides the framework for patentability. Article 52(1) requires as a condition precedent for patentability that an invention be “new, [and] involve an inventive step and be susceptible of industrial application.”<sup>30</sup> Article 57 further clarifies the concept of “industrial application” by describing that an invention possesses the requisite utility if “it can be made or used in any kind of industry, including agriculture.”<sup>31</sup> The requirements of the patent application are then set out most notably in Article

---

<sup>28</sup> *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 435 Fed. Appx. 917, 924 (Fed. Cir. 2011); *Eli Lilly & Co. v. Teva Pharms. USA, Inc.*, 619 F.3d 1329, 1343 (Fed. Cir. 2010); 21 C.F.R. § 312.23(a) (2011); MANUAL OF PATENT EXAMINING PROCEDURE § 2107.03 (8th ed. rev. 8 2008).

<sup>29</sup> Most of the U.S. case law on utility relate to appeals from a rejection by a patent examiner who doubts the credibility of a stated utility or arise in the circumstance unique to U.S. law of an interference proceeding where establishing utility is a pre-requisite for a reduction to practice. Establishing utility to establish a reduction to practice in the context of an interference is a different analysis than determining compliance with section 101. Allegations of inutility rarely arise in the context of infringement cases as the use is self-evident from the fact that the claim is infringed. *Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 959 (Fed. Cir. 1983) (“A correct finding of infringement of otherwise valid claims mandates as a matter of law a finding of utility under § 101.”).

<sup>30</sup> EUR. PAT. CONVENTION, art. 52 (1973).

<sup>31</sup> *Id.* at art. 57.

83, which provides that “[t]he European patent application shall disclose the invention in a manner sufficiently clear and complete for it to be carried out by a person skilled in the art.”<sup>32</sup>

The technical board of appeal of the European Patent Office (EPO) in *Zymogenetics* provides the most comprehensive statement of the law in relation to Articles 52(1) and 57.<sup>33</sup> *Zymogenetics* establishes that utility is met if the specification, read in the light of the common general knowledge, makes plausible a practical application of the invention. “Plausible” is equated with “reasonably credible.”<sup>34</sup> Accordingly, patent lawyers often refer to the test of utility in Europe as being a “credible and plausible” statement of use. This minimal standard for establishing usefulness to qualify for a patent was affirmed in a recent decision of the U.K. Supreme Court (formerly The House of Lords) in *Human Genome Sciences, Inc. v. Eli Lilly and Company*, [2011] UKSC 51.<sup>35</sup> Notably, if there is a credible and operable statement of utility, compliance with the statutory framework is met. Issues of proof of utility or inoperability do not arise under Articles 52 and 57. Issues of inoperability and the obligation for the patent application to teach how to carry out the invention arise in the context of Article 83.<sup>36</sup> Accordingly, if an invention is wholly or partially inoperable, the issue is whether the specification teaches how to use the invention as claimed. To establish insufficiency, the burden of proof is

---

<sup>32</sup> *Id.* at art. 83.

<sup>33</sup> Eur. Pat. Off. Case No. T 0898/05 – 3.3.08 (Jul. 7, 2006).

<sup>34</sup> *Id.*

<sup>35</sup> *Human Genome Scis., Inc. v. Eli Lilly & Co.*, [2011] UKSC 51, *rev'g* [\[2010\] EWCA Civ 33](#), *aff'g* [\[2008\] EWHC 1903 \(Pat\)](#).

<sup>36</sup> Eur. Pat. Off. Case No. T 0018/96 – 3.2.5 (Jul. 1, 1998).

upon the challenger to establish that a skilled artisan would be unable to carry out the invention.<sup>37</sup> Conversely, if the skilled artisan can carry out the invention—that is, the specification adequately teaches how to use the invention without undue experimentation—then there can be no issue of inutility or inoperability.

Thus, while the terminology varies—“useful” in the United States and “industrial application” in Europe—the approaches of the jurisdictions are both consistent with the respective statutes of both countries. Further, both the United States and European jurisdictions are similar with respect to the level of disclosure required in the application as filed and the deference given to an asserted utility that may be supported by evidence available after the filing date of the patent application. Finally, and importantly, the utility requirements in both jurisdictions are based on utility-in-fact—operability.

### **C. Proof of Utility in Canada**

While the origins of the modern test for utility can be traced back to the 2002 decision *Apotex Ltd. v. Wellcome Foundation Ltd.*,<sup>38</sup> the test is described most succinctly in *Eli Lilly Canada Inc. v. Novopharm Ltd.*<sup>39</sup> In *Eli Lilly*, the court describes the analysis for assessing utility or usefulness under the statute as follows:

Section 2 of the Act requires that the subject matter of a patent be new and useful. The general principle is that, as of the

---

<sup>37</sup> Eur. Pat. Off. Case No. T 0182/89 (Dec. 14, 1989), although with inventions that offend the generally accepted laws of physics, there is some authority to shift the burden to the applicant to demonstrate feasibility. See Eur. Pat. Off. Case No. T 0541/96 – 3.4.1 (Mar. 7, 1996).

<sup>38</sup> *Apotex Ltd. v. Wellcome Foundation Ltd.*, [2002] 4 S.C.R. 153 [hereinafter *Wellcome*].

<sup>39</sup> *Eli Lilly Canada Inc. v. Novopharm Ltd.*, [2010] FCA 197 [hereinafter *Eli Lilly*].

relevant date (the date of filing), there must have been either demonstration of utility of the invention or a sound prediction of the utility. Evidence beyond that set out in the specification can, and normally will, be necessary.<sup>40</sup>

The court then proceeds to distinguish patent applications where no specific result is promised from those where the specification promises a result:

Where the specification does not promise a specific result, no particular level of utility is required; a ‘mere scintilla’ of utility will suffice. However, where the specification sets out an explicit ‘promise,’ utility will be measured against that promise: *Consolboard; Pfizer Canada Inc. v. Canada (Minister of Health)*, [2009] 1 F.C.R. 253, 2008 FCA 108 (*Ranbaxy*). The question is whether the invention does what the patent promises it will do.<sup>41</sup>

Thus, if there is a “promise” of utility in the specification then “the alleged infringer is able to establish that there was insufficient information upon which to base the promise, the patentee may nevertheless have had sufficient information upon which to make a sound prediction of the promise.”<sup>42</sup> The court then sets out the tripartite test for sound prediction:

[T]here must be a factual basis for the prediction; the inventor must have an articulable line of reasoning from which the desired result can be inferred from the factual basis; and there must be proper disclosure of the factual basis and line of reasoning, although it is not necessary to provide a theory as to why the invention works.

So, while Canadian courts acknowledge that evidence of utility outside of the specification can and will be necessary, if the utility issue is assessed as a “sound prediction of utility,” disclosure of the factual basis and articulable line

---

<sup>40</sup> *Id.* at para. 74.

<sup>41</sup> *Id.* at para. 76.

<sup>42</sup> *Id.* at para. 82.

of reasoning is required.

The heightened disclosure requirement in cases of sound prediction was explained in *Eli Lilly Canada Inc. v. Apotex Inc. (Raloxifene)*.<sup>43</sup> In *Raloxifene*, the patentee had completed studies demonstrating positive preclinical studies on relevant preclinical markers. The patentee had also disclosed the initiation of a 251-person clinical trial, although the results of this study were not disclosed within the patent. In this case, because the patent claimed the drug as a treatment for humans, the Federal Court of Appeal held:

[B]ased on the foregoing, it is clear that the invention was based on a prediction. Although the rat studies were positive, only a prediction could allow for the proposition that raloxifene had the same effect on women, let alone estrogen deficient post-menopausal women who suffered from bone loss. In other words, the claimed utility required for patentability was not demonstrated but predicted based on the formation provided in the '356 patent.<sup>44</sup>

As to whether the underlying results of the clinical trial are required to support a sound prediction, the Federal Court of Appeal recalled the language in *Wellcome* and reasoned:

[A]s was said in that case (para. 70): 'the sound prediction is to some extent the *quid pro quo* the applicant offers in exchange for the patent monopoly'. In sound prediction cases there is a heightened obligation to disclose the underlying facts and the line of reasoning for inventions that comprise the prediction.<sup>45</sup>

Thus, the Canadian test can be summarized as follows:

(1) The court construes the patent specification to determine the patent's "promise," which, in view of the case law, is much more than a statement of

---

<sup>43</sup> *Eli Lilly Canada Inc. v. Apotex Inc.*, [2009] FCA 97 [*Raloxifene*].

<sup>44</sup> *Id.* at para. 10.

<sup>45</sup> *Id.* at para. 14.

use.<sup>46</sup>

(2) The court determines whether the utility (the promise) is demonstrated or whether the inventor is relying on a “sound prediction” of utility. The question of whether utility is demonstrated or based on a prediction varies from court to court, even when the same patent is at issue.<sup>47</sup> It is clear, however, that a demonstration of utility is significantly higher than the showing required in the United States and Europe, as even human clinical studies in patients have fallen short of demonstrating utility in many cases.<sup>48</sup>

(3) Finally, if the utility is not demonstrated, the court determines whether there was (a) a factual basis for the prediction; (b) an articulable line of reasoning supporting the soundness of the prediction; and (c) proper disclosure. Proper disclosure is also much more than the disclosure requirements for the United States and Europe (and also the requirements of international treaties as noted below).

This test places Canada a long way out of bounds of international norms and intellectual property treaties. The Canadian courts have created, in essence, a heightened utility and disclosure standard that has no direct statutory basis and contravenes international norms.

### **III. THE WIDENING GAP IN JUDICIAL APPLICATION OF STATUTORY UTILITY REQUIREMENTS**

United States and Canadian obligations under NAFTA,<sup>49</sup> and the United States, European, and Canadian obligations under TRIPS, require countries to

---

<sup>46</sup> For example, a patent directed to a method of treating disease can be held to implicitly promise treatment over the longer term. *Eli Lilly & Co. v. Teva Canada Ltd.*, [2010] FC 915, at para. 112.

<sup>47</sup> See discussion of latanoprost decisions, *infra*, where two different proceedings of the Federal Court of Appeal construed the “promise” of the same patent differently—one leading to a finding of validity because the promise utility had been demonstrated, and one leading to a finding of invalidity based on a promise that was not soundly predicted. See *Apotex Inc. v. Pfizer Canada Inc.*, [2011] FCA 236, 95 CPR (4th) 193 and *Pharmascience Inc. v. Pfizer Canada Inc.*, [2011] FCA 102.

<sup>48</sup> See Figure 1, *infra*.

<sup>49</sup> North American Free Trade Agreement, U.S.-Can.-Mex., Dec. 17, 1992, 32 I.L.M. 289 (1993) [hereinafter NAFTA], available at <http://www.ustr.gov/trade-agreements/free-trade-agreements/north-american-free-trade-agreement-nafta>. Mexico is the third NAFTA signatory.

provide patent protection to useful inventions that otherwise satisfy the requirements of patentability.<sup>50</sup> The terms “capable of industrial application” and “useful” in the patent law of respective jurisdictions have plain meaning in that they both require that an invention must simply be useful in fact.<sup>51</sup> The shared consensus as to the meaning of these terms at the time TRIPS was negotiated was captured in a submission by Peru during the Uruguay Round negotiations. Echoing the European Patent Convention, Peru proposed that an invention should be “considered capable of industrial application if its object can be manufactured or used in any kind of industry.”<sup>52</sup> This low threshold for utility remains generally applicable today among WTO member countries.<sup>53</sup> Indeed, it still applies in Canada at least to some patents.<sup>54</sup>

At the time that TRIPS was negotiated, international norms required only a minimal showing to satisfy the utility test. The same is true today. In the United States, for example, a patentable invention is useful if it discloses a specific, substantial, and credible utility. An assertion that a compound may

---

<sup>50</sup> See *Understanding the WTO: The Organization, Members and Observers* (WTO 2012), [http://www.wto.org/english/thewto\\_e/whatis\\_e/tif\\_e/org6\\_e.htm](http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm).

<sup>51</sup> Agreement on Trade-Related Aspects of Intellectual Property art. 27.1, Apr. 15, 1994, 1869 U.N.T.S. 299 [hereinafter TRIPS]; NAFTA art. 1709.1. “Capable of industrial application” and “useful” are synonymous in the agreements. Compare TRIPS and NAFTA.

<sup>52</sup> See “Guidelines for Negotiations that Strike a Balance Between Intellectual Property Rights and Development Objectives: Communication from Peru,” Uruguay Round Negotiating Group on Trade-Related Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods, Doc. MTN.GNG/NG11/W/45, at 2 (Oct. 27, 1989).

<sup>53</sup> See CHRISTOPHER WADLOW, *Utility and Industrial Applicability*, in PATENT LAW AND THEORY: A HANDBOOK OF CONTEMPORARY RESEARCH 381 (Edward Elgar 2008) (“Once the flying saucers and the perpetual motion machines have been seen off, and when all due account has been taken of inherent patentability, and the effect of specific exclusions, it is difficult to see that there is really anything of much practical importance left for either utility or industrial applicability to do.”)

<sup>54</sup> For cases demonstrating that a “mere scintilla” of utility suffices elsewhere, see, e.g., *Consolboard Inc. v. MacMillan Bloedel (Sask.) Ltd.*, [1981] 1 SCR 504; *Pfizer Canada Inc. v. Canada (Minister of Health)*, 2008 FCA 108, [2009] 1 FC 253 [*Ranbaxy*].

be useful in treating *unspecified* disorders would lack specificity, and a drug with *no real-world use* would lack substantial or practical utility. Notably, so long as the stated utility is credible, an attack of inutility is valid only when the invention is inoperable. In the pharmaceutical arts, there is no need to demonstrate in the patent application that a compound is safe or effective. Indeed, as U.S. courts have stated, “FDA approval . . . is not a prerequisite for finding a compound useful within the meaning of the patent laws,” because if such testing were required, “the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.”<sup>55</sup> Regulatory approval is not required in any of the jurisdictions in order for a patent to possess patentable utility.

The language of TRIPS itself and the pattern of practice in WTO Member countries—both at the time TRIPS was negotiated and today—demonstrate that usefulness is a basic patentability requirement that is easily met, as long as an invention is useful in fact. The same analysis applies under the NAFTA text. Further, TRIPS and NAFTA are consistent in their policies of providing a unified procedure for obtaining patent protection in member states. Both NAFTA and TRIPS expressly provide that “useful” and “industrial applicability” are synonymous. Article 27.1 of TRIPS and also Article 1709.1 of NAFTA mandate that signatory nations such as Canada “shall” provide patent

---

<sup>55</sup> See, e.g., *In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995).

protection to inventions which are “new, [and] involve an inventive step and are capable of industrial application.”<sup>56</sup> Under generally accepted rules for interpretation of international treaties, Canada is not allowed to contravene a clear commitment to grant patents which it made as a signatory to the TRIPS Agreement or NAFTA.

Similarly, under the Patent Cooperation Treaty (PCT), applicants may seek patent protection in some or all of the 141 member countries by filing a single international application. The PCT and international norms require that a claimed invention be industrially applicable, which as discussed above is satisfied if the invention can be made or used in any kind of industry.<sup>57</sup> So, for example, like the European approach if the invention is alleged to have a “credible or plausible” utility, so long as the invention does not operate in a manner contrary to well-established physical laws, then the invention will be patentable as possessing industrial applicability.<sup>58</sup> Similarly, like the U.S. approach, supporting submissions are required only in circumstances where the USPTO provides evidence that the stated specific and substantial utility is incredible.<sup>59</sup> Thus “useful” and “industrial applicability” are synonymous with the PCT and practically both the EU and United States have approached the issue in the same manner. Further, while the PCT sufficiency requirements provide that the applicant disclose the invention in a manner sufficiently clear

---

<sup>56</sup> NAFTA *supra* note 49 and TRIPS *supra* note 51.

<sup>57</sup> Patent Cooperation Treaty art. 33(4), Jun. 19, 1970, 1160 U.N.T.S. 231.

<sup>58</sup> Patent Cooperation Treaty International Search and Preliminary Examination Guidelines ch. 14; *see also* Human Genome Scis., Inc v Eli Lilly & Co., [\[2011\] UKSC 51](#), *rev'g* [\[2010\] EWCA Civ 33](#), *aff'g* [\[2008\] EWHC 1903 \(Pat\)](#).

<sup>59</sup> *See* Eli Lilly & Co. v. Actavis Elizabeth LLC, 435 Fed. Appx. 917, 924 (Fed. Cir. 2011).

and complete for the utility of the invention to be carried out by a person of ordinary skill in the art, it does not require that proof of utility be contained within the application as filed.<sup>60</sup> Article 27 of the PCT specifies that no national law can require more than this.<sup>61</sup> These provisions make it very clear that if the description is clear enough for one of ordinary skill to carry it out, no national office can require more information in the specification as filed, though they certainly could require more information to establish inventive step, utility, or other support during prosecution.

#### **IV. THE CANADIAN STANDARD OF UTILITY HAS A DISPARATE IMPACT ON PHARMACEUTICAL AND CHEMICAL PATENTS**

As noted, the modern test for utility in Canada can be traced to the *Wellcome* decision in 2002, where the Supreme Court of Canada laid the foundation for a heightened interpretation of the Patent Act's utility requirement, one at odds with past Canadian practice and the practice of other WTO Members.<sup>62</sup> This new test is now explicitly incorporated into Section 12.08.04 of Canada's Manual of Patent Office Practice.

In *Wellcome*, the Court observed that the doctrine of "sound prediction" should not be abused by inventors or "diluted to include a lucky guess or mere speculation." As it happens, the doctrine—as interpreted in *Wellcome*—has

---

<sup>60</sup> Patent Cooperation Treaty art. 5, Jun. 19, 1970, 1160 U.N.T.S. 231.

<sup>61</sup> Article 27 of the PCT notes as follows: "(1) No national law shall require compliance with requirements relating to the form and contents of the international application different from or additional to those which are provided for in this Treaty and the Regulations." Patent Cooperation Treaty art. 27, Jun. 19, 1970, 1160 U.N.T.S. 231.

<sup>62</sup> Prior to 2002, utility in Canada like other jurisdictions turned on evidence of actual inutility. *See, e.g., Hoechst Pharmaceuticals of Canada Ltd. v. Gilbert & Co.*, [1966] S.C.R. 189, 50 C.P.R. 26.

since been invoked not by applicants to satisfy the utility requirement, but by companies seeking to invalidate existing patents. Alleging lack of sound prediction, challengers have invalidated patents in Canada at an unprecedented rate, effectively undermining Canada's commitment to provide patent protection to all pharmaceutical products that are new, non-obvious, and useful.

A closer look at the results in decisions involving patentable utility decided since the *Wellcome* decision in 2002 highlights the disparity in comparison to other jurisdictions and the degree to which the standards have impacted pharmaceutical patentees. Figure 1 illustrates the results of an analysis of every Federal Court and Federal Court of Appeals case which was decided based on the issue of utility since the *Wellcome* decision.<sup>63</sup> Each was analyzed to determine whether the patentee relied on *in vitro* data<sup>64</sup>, *in vivo*

---

<sup>63</sup> Process or formulation cases which were decided on the basis of over breadth rather than the quality of utility evidence were excluded. (Thus, *Abbott Labs. v. Canada (Minister of Health)*, 2005 FC 1095, [2006] 3 F.C.R. D-71 (clarithromycin); *Pfizer Canada Inc. v. Apotex Inc.*, [2005] FC 1421 (azithromycin); *Abbott Labs. v. Canada (Minister of Health)*, [2005] FC 1332 (clarithromycin); *Schering-Plough Canada Inc. v. Pharmascience Inc.*, [2009] FC 1128 (desloratadine) and *Sanofi-Aventis Canada Inc. v. Ratiopharm Inc.*, [2010] FC 230 (irbesartan) were excluded). Cases which may have referenced to "promise" but were actually decided on the basis of sufficiency were also excluded. (Thus, *Eli Lilly Canada Inc. v. Novopharm Ltd.*, [2007] FC 596 (olanzapine); *Pfizer Canada Inc. v. Canada (Minister of Health)*, [2008] FCA 108 (atorvastatin); *Ratiopharm Inc. v. Pfizer Ltd.*, [2009] FC 711 (amlodipine); and *Pfizer Ltd. v. Ratiopharm Inc.*, [2010] FCA 204 (amlodipine) were excluded). Also, *Novo Nordisk Canada Inc. v. Cobalt Pharms. Inc.*, [2010] FC 746 (repaglinide), where the utility issue was not decided, was excluded.

<sup>64</sup> Cases which referenced *in vitro* data in support of utility were *Apotex Inc. v. Wellcome Foundation Ltd.*, 21 CPR (4th) 499 (AZT); *Pfizer Canada Inc. v. Canada (Minister of Health)*, [2008] FC 500 (amlodipine); *Labs. Servier v. Apotex Inc.*, [2009] FCA 222 (perindopril); *Eli Lilly & Co. v. Apotex Inc.*, [2009] FC 991 (cefaclor) and *Eli Lilly Canada Inc. v. Apotex Inc.*, [2010] FCA 240 (cefaclor).

data,<sup>65</sup> or both<sup>66</sup> in support of a patentee's assertion of utility. The cases were also analyzed for references to human clinical data by the patentee in support of utility. Cases where parties referenced *in vitro* data alone, *in vivo* data alone or both types of data were held valid on the basis of utility 100%, 61.5%, and 66.7% of the time, respectively. Patents which may have also referenced human clinical trial results were held to possess utility 50% of the time.<sup>67</sup> In

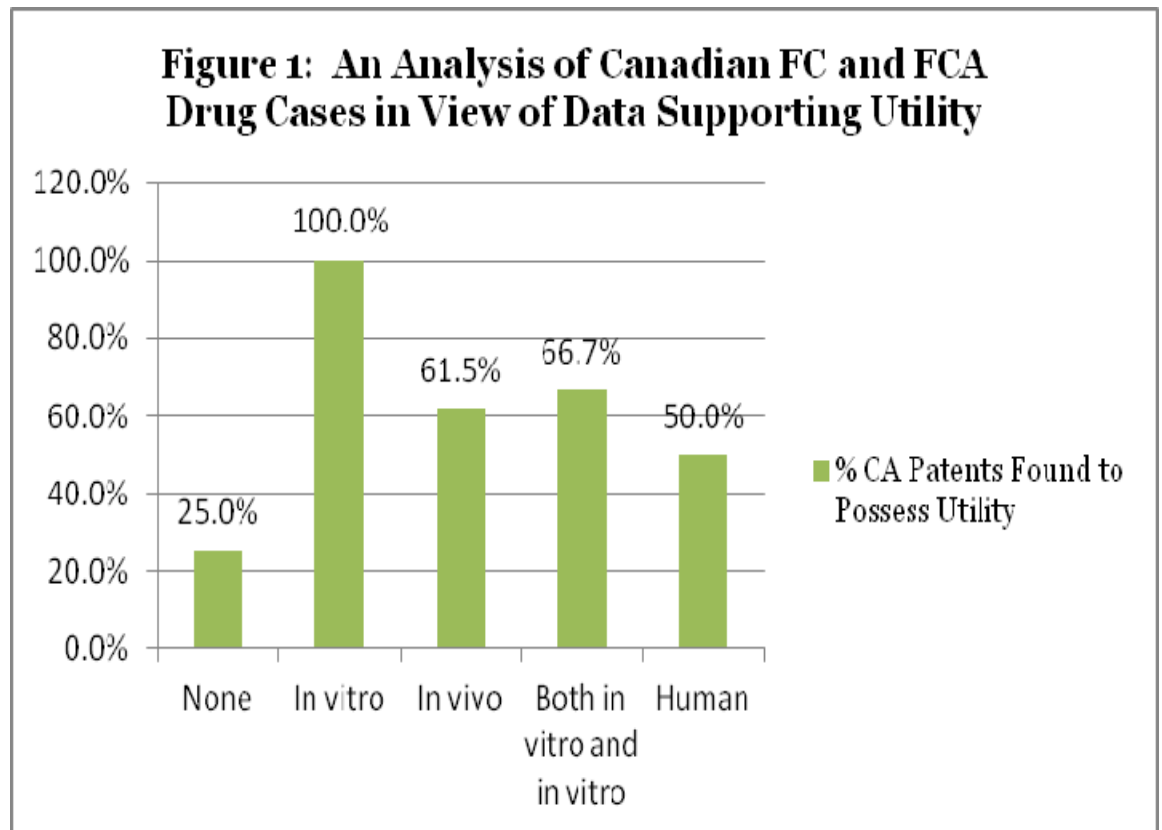
---

<sup>65</sup> Cases which referenced *in vivo* data in support of utility were Apotex Inc. v. Pfizer Canada Inc., [2011] FCA 236 (latanoprost); Pfizer Canada Inc. v. Canada (Minister of Health), [2010] FC 447 (latanoprost); Pfizer Canada Inc. v. Pharmascience Inc., [2011] FCA 102 (latanoprost); Pfizer Canada Inc. v. Pharmascience Inc., [2009] FC 1294 (latanoprost); GlaxoSmithKline Inc. v. Pharmascience Inc., [2011] FC 239 (rosiglitazone); Pfizer Canada Inc. v. Ratiopharm Inc., [2010] FC 612 (sildenafil); Sandoz Canada Inc. v. Abbott Labs., [2010] FCA 168 (clarithromycin); Abbott Labs. v. Canada (Minister of Health), [2009] FC 648 (clarithromycin); Apotex Inc. v. Lundbeck Canada Inc., [2010] FCA 320 (escitalopram); Lundbeck Canada Inc. v. Canada (Minister of Health), [2009] FC 146 (escitalopram); GlaxoSmithKline Inc. v. Pharmascience Inc., [2008] FC 593 (valacyclovir); Shire Biochem Inc. v. Canada (Minister of Health), [2008] FC 538 (modafinil); and Merck & Co. Inc. v. Apotex Inc., [2005] FC 755 (alendronate).

<sup>66</sup> Cases which referenced both *in vivo* and *in vitro* data included G.D. Searle & Co. v. Novopharm Ltd., [2007] FC 81 (celecoxib); G.D. Searle & Co. v. Novopharm Ltd., [2007] FCA 173 (celecoxib); Pfizer Canada Inc. v. Canada (Minister of Health), [2008] FC 13 (atorvastatin); Eli Lilly Canada Inc. v. Apotex Inc., [2008] FC 142 (raloxifene); Eli Lilly Canada Inc. v. Apotex Inc., [2009] FCA 97 (raloxifene); Janssen-Ortho Inc. v. Apotex Inc., [2008] FC 744 (lenoxacin); Eli Lilly Canada Inc. v. Novopharm Ltd., [2009] FC 235 (raloxifene); Purdue Pharma v. Pharmascience Inc., [2009] FC 726 (oxycodone); Lundbeck Canada Inc. v. Ratiopharm Inc., [2009] FC 1102 (memantine—'453 patent); Pfizer Canada Inc. v. Novopharm Ltd., [2009] FC 638 (sildenafil); Novopharm Inc. v. Pfizer Canada Inc., [2010] FCA 242 (sildenafil); Merck & Co. Inc. v. Apotex Inc., [2010] FC 1265 (lovastatin); Pfizer Canada Inc. v. Mylan Pharms ULC, [2011] FC 547 (donepezil); Hoffmann-La Roche Ltd. v. Apotex Inc., [2011] FC 875 (mycophenolate); AstraZeneca Canada Inc. v. Mylan Pharms ULC, [2011] FC 1023 (anastrozole); Eli Lilly Canada Inc. v. Novopharm Ltd., [2011] FC 1288 (olanzapine); Allergan Inc. v. Canada (Minister of Health), [2011] FC 1316 (brimonidine tartrate and timolol maleate); and Apotex Inc. v. Sanofi-Aventis, [2011] FC 1486 (clopidogrel).

<sup>67</sup> Cases which referenced human studies included Eli Lilly Canada Inc. v. Apotex Inc., [2008] FC 142 (raloxifene); Eli Lilly Canada Inc. v. Apotex Inc., [2009] FCA 97 (raloxifene); Shire Biochem Inc. v. Canada (Minister of Health), [2008] FC 538 (modafinil); Abbott Labs. v. Canada (Minister of Health), [2009] FC 648 (clarithromycin); Sandoz Canada Inc. v. Abbott Labs., [2010] FCA 168 (clarithromycin); Purdue Pharma v. Pharmascience Inc., [2009] FC 726 (oxycodone); Pfizer Canada Inc. v. Ratiopharm Inc., [2010] FC 612 (sildenafil); Pfizer Canada Inc. v. Novopharm Ltd., [2009] FC 638 (sildenafil); Novopharm Inc. v. Pfizer Canada Inc., [2010] FCA 242 (sildenafil); Pfizer Canada Inc. v. Pharmascience Inc., [2009] FC 1294 (latanoprost); Pfizer Canada Inc. v. Pharmascience Inc., [2011] FCA 102 (latanoprost); Novopharm Ltd. v. Eli Lilly & Co., [2010] FC 915 (atomoxetine); Eli Lilly & Co. v. Teva

decisions in which no studies were referenced in the case in support of utility, patents were held to possess utility only 25% of the time.<sup>68</sup>



The results are paradoxical in that one would expect that the likelihood of a patent being declared to possess utility would increase as the supporting

---

Canada Ltd., [2011] FCA 220 (atomoxetine); Pfizer Canada Inc. v. Canada (Minister of Health), [2010] FC 447 (latanoprost); Apotex Inc. v. Pfizer Canada Inc., [2011] FCA 236 (latanoprost); Eli Lilly Canada Inc. v. Novopharm Ltd., [2011] FC 1288 (olanzapine); Allergan Inc. v. Canada (Minister of Health), [2011] FC 1316 (brimonidine tartrate and timolol maleate); and Apotex Inc. v. Sanofi-Aventis, [2011] FC 1486 (clopidogrel).

<sup>68</sup> Cases which referenced no data in their disclosure were Aventis Pharma Inc. v. Apotex Inc., [2006] FCA 64 (ramipril); Aventis Pharma Inc. v. Apotex Inc., [2005] FC 1283 (ramipril); Pfizer Canada Inc. v. Apotex Inc., [2007] FC 26 (sildenafil); Pfizer Canada Inc. v. Apotex Inc., [2007] FCA 195 (sildenafil); Sanofi-Aventis Inc. v. Lab. Riva Inc., 58 CPR (4th) 109 (ramipril); Pfizer Canada Inc. v. Canada (Minister of Health), [2005] FC 1205 (quinapril); Pfizer Canada Inc. v. Canada (Minister of Health), [2007] FCA 209 (quinapril); Sanofi-Aventis Canada Inc. v. Apotex Inc., [2011] FCA 300 (ramipril); Novopharm Ltd. v. Eli Lilly & Co., [2010] FC 915 (atomoxetine); Eli Lilly & Co. v. Teva Canada Ltd., [2011] FCA 220 (atomoxetine); Lundbeck Canada Inc. v. Ratiopharm Inc., [2009] FC 1102 (memantine—'453 patent); and AstraZeneca Canada Inc. v. Canada (Minister of Health), [2010] FC 714 (esomeprazole).

evidence trends closer toward human clinical trial data. The analysis suggests otherwise. Further one would not infer the results in Figure 1, particularly given that the availability of human clinical trial results establish a presumption of utility on this basis alone in the U.S. The type of data relied upon by the patentee in support of utility has no correlation to a positive decision on patent utility by the Canadian Federal Courts.

### **A. The Canadian Approach to Utility Discourages Disclosure**

Based on an objective view of the results from the analysis of Canadian cases shown in Figure 1, patentees cannot reliably predict the odds of having their patent declared useful upon challenge based on the type of utility evidence contained within the patent. Secondly, in any event, a patentee cannot know in advance of filing exactly how an examiner or court will identify or infer the promised utility before evaluating the link between the factual basis and sound line of reasoning in the patent. Since applicants are not required to specifically identify the factual basis and sound line of reasoning in the specification, the fact finder can easily misconstrue the promise. This may lead to misconstruction of the factual basis and sound line of reasoning as well. Thus, the less an applicant discloses, the lower the odds of having the promise of their patent misconstrued.

Two decisions by the Canadian Federal Court of Appeal illustrate how the subjective construction of a patent's promise can lead to unpredictable results and discourage disclosure by applicants. In *Pharmascience Inc. v.*

*Pfizer Canada Inc. et al. (Latanoprost I)*, the Federal Court of Appeals affirmed the lower court’s construction of the promise of the patent—that Latanoprost is a therapeutically more useful compound than known intraocular pressure-lowering prostaglandins. The Court of Appeal also agreed with the lower court’s view that utility had been demonstrated based on test results disclosed in the application.<sup>69</sup> In a subsequent case during the same year as *Apotex Inc. v. Pfizer Canada Inc. (Latanoprost II)*, however, a different panel on the Federal Court of Appeals held that the ’132 patent was invalid for lack of sound prediction.<sup>70</sup> The Federal Court of Appeals in *Latanoprost II* overturned a lower court ruling by finding that the judge had incorrectly construed the promise of the claimed invention:

[24] For the Applications Judge, Apotex’s position that the promise of the patent is chronic use of the compound amounted to a ‘mistaken premise’ upon which Apotex wrongly relied for its case. At paragraph 192 of her reasons, she held that Apotex ‘was unable to show that its basic premise was sound’ and dismissed the argument. I agree with Apotex that, in so doing, the Applications Judge overlooked Pfizer’s own evidence that glaucoma, at the time of filing, would have been known by the POSITA to be a chronic condition that required chronic treatment.

[27] ... I see it as an error to construe the promise of the ’132 patent without consideration as to the nature of the disease it purports to treat effectively.<sup>71</sup>

The conflicting decisions in *Latanoprost I* and *Latanoprost II*, as well as the misconstruction by the lower court discussed in *Latanoprost II* which led to a

---

<sup>69</sup> *Pharmascience Inc. v. Pfizer Canada Inc. et al.*, [2011] FCA 102 (*Latanoprost I*); the Applications judge found that “the ’132 Patent offers the public a useful choice from what was offered as the state of the art at the time of filing the patent application.” *Id.* at para. [148].

<sup>70</sup> *Apotex, Inc. v. Pfizer Canada Inc.*, [2011] FCA 236, at para. 14 (*Latanoprost II*).

<sup>71</sup> *Id.* at paras. 24 and 27.

different decision on utility by the Court of Appeal, discourage patentees from extolling their invention lest they be in some way held to an implicit or explicit promise of the patent.<sup>72</sup> Discouraging disclosure is counter to the policy of the *Patent Act* and analogous statutes in the other major jurisdictions which encourage disclosure in exchange for patent protection for an invention.

## **B. The Canadian Approach to Utility Discourages Innovation**

The Canadian approach creates significant uncertainty for pharmaceutical innovators which discourages innovation. Perhaps the only way the utility requirement may be satisfied confidently is with a conclusive and completed human clinical trial performed before the application filing date and even then, based on the analysis of recent cases above, patentees cannot reliably predict that a patent application will be found to meet the Canadian utility requirements. The Canadian approach also discourages pharmaceutical innovation, particularly in situations where there is no preclinical model of the disease. For the reasons discussed earlier in this paper, the vast majority of drug patent applications are filed before confirmatory clinical trial information becomes available. The practical reality, given the tremendous expense involved in conducting confirmatory human clinical trials, is that innovators cannot undertake the risks without some reasonable assurance of patent protection. Further, delaying submission of an application until completion of human clinical trials places the applicant in an impossible “catch-22” situation, given the risk that the patent may be held invalid for lack of novelty or obviousness arising

---

<sup>72</sup> See Arvie Anderson & Lawrence Welch, “The Canadian Patent Promise: A Concern for Pharmaceutical Innovators?” IPO COMMITTEE NEWSLETTER (Dec. 2011) available at <http://www.ipo.org/AM/Template.cfm?Section=Patents&Template=/MembersOnly.cfm&ContentID=32110&FusePreview=False>. at p. 29 [IPO membership required].

from disclosures during large scale clinical use. In other words, a patentee who might seek to establish utility for a drug which treats a chronic condition by conducting longer term clinical studies suggested by the Federal Court of Appeal in *Latanoprost II* before filing their patent application would likely be exposed to an allegation of invalidity based on anticipation.<sup>73</sup> Given the current trends it appears that unless the Supreme Court of Canada intervenes, the country will remain an outlier as compared with other major jurisdictions and outside its treaty obligations.

The volume of ongoing appellate litigation in Canada involving cases wherein patentable utility is a key issue illustrates the growing challenge for pharmaceutical patentees. In each case under appeal, the innovative drugs are plainly useful, commercially successful, and have helped many patients. (See Table 1 below).

**Table 1: Drugs for Which Patents Are Currently Under Appeal in the Courts**

<b><u>Innovator</u></b>	<b><u>Drug</u></b>	<b><u>Citation</u></b>
Pfizer	Latanoprost	2011 FCA 236 <sup>74</sup>
Eli Lilly	Olanzapine	2011 FC 1288
Astrazeneca	Anastrozole	2011 FC 1023
Roche	Mycophenolate	2011 FC 875
Pfizer	Donepezil	2011 FC 547
Sanofi-Aventis	Clopidogrel	2011 FC 1486
Merck	Lovastatin	2010 FC 1265
Pfizer	Sildenafil	2010 FCA 242

<sup>73</sup> See *Eli Lilly & Co. v. Teva Canada Ltd.*, [2010] FC 915, 87 CPR (4th) 301, at paras. 46-48, where Novopharm argued that two oral conversations that fell outside the one-year grace period rendered the invention anticipated.

<sup>74</sup> Leave to appeal to the Supreme Court of Canada recently denied. *Latanoprost FCA*, [2011] FCA 236, 95 CPR (4th) 193, leave to appeal to SCC dismissed Feb. 2, 2012 (No. 34497); as the decision was reached under Canada's Patent Medicines Notice of Compliance (PMNOC) regime, a type of litigation wherein an innovator has no right of appeal under the Regulations, it is presumed that the only remedy available a patent infringement action will be filed.

## **CONCLUSION**

Canada is an outlier in its approach to patentable utility as compared with other major jurisdictions including the United States and Europe. The doctrine of sound prediction also places Canada in contravention of its treaty obligations under TRIPS, NAFTA, and the PCT. Analysis of the results of Canadian cases decided on the issue of utility illustrates that applicants cannot reliably predict what information will suffice to establish utility in Canada. The requirements therefore create uncertainty for patent applicants which discourages both disclosure and future innovation. The requirements warrant a return to the pre-2002 standard of utility-in-fact either through case law or legislative reform.