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Usefulness Varies by Country: The Utility Requirement of Patent Law in the United States, Europe and Canada

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Abstract
The requirement that an invention have utility is one of the most fundamental of the patent laws. In the United States, for example, the concept of utility is rooted in the Constitution: Article 1, Section 8, gives Congress the power to grant exclusive rights to inventors in order "[t]o promote the progress of Science and *useful* Arts." Other jurisdictions recognize utility in the form of inventions that have "industrial applicability" or are "capable of exploitation in industry," with all of these terms and phrases generally viewed as being synonymous.

Historically, nearly every jurisdiction has excluded some type of invention from patentability as lacking utility. A common and enduring utility-based exclusion is the perpetual motion machine, with the justification being scientific: because perpetual motion is not physically possible, an invention which claims such a feature cannot in fact work and therefore fundamentally lacks utility. Jurisdictions also make exclusions on policy grounds. In Europe, for example, methods of treating human and animal bodies are not patentable, but the justification for doing so, which previously was based on lack of industrial applicability, is now expressly linked to public health policy. In an ever-more global economy, inventions are at the heart of commercial transactions that know no geographic boundaries and are increasingly valued for their job and wealth creation. Obtaining patent protection in multiple jurisdictions therefore is increasingly common. At least to reduce costs and increase efficiency, patent owners, policymakers and practitioners alike have sought increased inter jurisdictional cooperation and patent law harmonization in the patent examination and granting process.

Recent publications, however, have identified a developing trend in Canada in which Canadian courts and the Canadian Intellectual Property Office are interpreting and applying the historically well-settled and generally harmonized utility requirement in a new and different way, in particular with respect to patents for pharmaceutical products. As a result, applicants for Canadian patents must meet conditions and overcome hurdles not required by other major patent offices.

This article will compare Canada's implementation and treatment of the utility requirement with the implementation and treatment practiced in the United States and Europe—two jurisdictions that represent prevailing approaches to utility and also constitute a major share of the world's patenting activity. The article will first examine the statutory and judicial situation in each of the jurisdictions, including a review of the major international treaties and agreements to which each is subject. It will then present a case study that looks at the judicial challenges brought against various members of a single patent family in the United States, Europe, and Canada, and compare the results of those challenges. This analysis, we believe, reveals that the recent shift in Canada's approach to the utility requirement conflicts with international norms and thus presents implications for patentees, patent law harmonization, and international treaty obligations.

Keywords
patent, utility, patentable utility requirement, sound prediction, industrial applicablity

Disciplines
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USEFULNESS VARIES BY COUNTRY: THE UTILITY REQUIREMENT OF PATENT LAW IN THE UNITED STATES, EUROPE AND CANADA[*]

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[*] Patterson Thuente Christensen Pedersen, P.A. (Patterson) represents clients in the pharmaceutical industry, including Eli Lilly & Co., which requested that the firm undertake an independent study of patentable utility requirements. This article is a result of that study.

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I. INTRODUCTION

The requirement that an invention have utility is one of the most fundamental of the patent laws. In the United States, for example, the concept of utility is rooted in the Constitution: Article 1, Section 8, gives Congress the power to grant exclusive rights to inventors in order "[t]o promote the progress of Science and *useful* Arts."[1] Other jurisdictions recognize utility in the form of inventions that have "industrial applicability"[2] or are "capable of exploitation in industry,"[3] with all of these terms and phrases generally viewed as being synonymous.[4]

Historically, nearly every jurisdiction has excluded some type of invention from patentability as lacking utility.[5] A common and enduring utility-based exclusion is the perpetual motion machine, with the justification being scientific: because perpetual motion is not physically possible, an invention which claims such a feature cannot in fact work and therefore fundamentally lacks utility.[6] Jurisdictions also make exclusions on policy grounds. In Europe, for example, methods of treating human and animal bodies are not patentable, but the justification for doing so, which previously was based on lack of industrial applicability,[7] is now expressly linked to public health policy.[8]

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[1] U.S. CONST. art. I, § 8, cl. 8 (emphasis added).

[2] *See* WORLD INTELLECTUAL PROP. ORG., PATENT COOPERATION TREATY INTERNATIONAL SEARCH AND PRELIMINARY EXAMINATION GUIDELINES, § A14.01[1] (Oct. 3, 2011) [hereinafter PCT GUIDELINES], *available at* http://www.wipo.int/pct/en/texts/pdf/ispe.pdf.

[3] *See* EUROPEAN PATENT OFFICE, GUIDELINES FOR EXAMINATION IN THE EUROPEAN PATENT OFFICE, pt. C, ch. II, § 4.12 (Apr. 2010) [hereinafter EPO EXAMINATION GUIDELINES] (referring to French and German texts of the European Patent Convention), *available at* http://documents.epo.org/projects/babylon/eponet.nsf/0/7ffc755ad943703dc12576f00054cacc/$FILE/guidelines_2010_complete_en.pdf.

[4] *See* PCT GUIDELINES, *supra* note 2.

[5] *See* Juicy Whip, Inc. v. Orange Bang, Inc., 185 F.3d 1364, 1367–68 (Fed. Cir. 1999) ("[Y]ears ago courts invalidated patents on gambling devices on the ground that they were immoral, but that is no longer the law . . . . 'Congress never intended that the patent laws should displace the police powers of the States, meaning by that term those powers by which the health, good order, peace and general welfare of the community are promoted.' . . . [W]e find no basis in section 101 to hold that inventions can be ruled unpatentable for lack of utility simply because they have the capacity to fool some members of the public.") (citations omitted); *see also* U.S. PATENT & TRADEMARK OFFICE, U.S. DEP'T COMMERCE, MPEP § 706.03(II) (8th ed. Rev. 8, July 2010) [hereinafter MPEP].

[6] *See* MPEP, *supra* note 5, § 706.03(II) ("A rejection on the ground of lack of utility includes the more specific grounds of inoperativeness, involving perpetual motion."); EPO EXAMINATION GUIDELINES, *supra* note 3, pt. C, ch. II, § 4.11 ("[S]uccessful performance of the invention is inherently impossible because it would be contrary to well-established physical laws – this applies e.g. to a perpetual motion machine.").

[7] European Patent Convention art. 52(4), Oct. 5, 1973, 1065 U.N.T.S. 199 (1973) [hereinafter EPC-1973], *available at* http://www.epo.org/law-practice/legal-texts/html/epc/1973/e/ar52.html

In an ever-more global economy, inventions are at the heart of commercial transactions that know no geographic boundaries and are increasingly valued for their job and wealth creation. Obtaining patent protection in multiple jurisdictions therefore is increasingly common.[9] At least to reduce costs and increase efficiency,[10] patent owners, policymakers and practitioners alike have sought increased interjurisdictional cooperation and patent law harmonization in the patent examination and granting process.[11] Recent publications, however, have

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("Methods for the treatment of the human or animal body by surgery or therapy and diagnostic methods practised on the human or animal body *shall not be regarded as inventions which are susceptible of industrial application* within the meaning of [Article 52(1)]." (emphasis added)).

[8] European Patent Convention art. 53(c), Oct. 5, 1973, 1065 U.N.T.S. 199 (as amended Nov. 29, 2000) [hereinafter EPC-2000], *available at* http://documents.epo.org/projects/babylon/eponet.nsf/0/7bacb229e032863dc12577ec004ada98/$FILE/EPC_14th_edition.pdf; Shamnad Basheer et al., *Patent Exclusions that Promote Public Health Objectives*, *in* AN EXPERT'S STUDY ON EXCLUSIONS FROM PATENTABLE SUBJECT MATTER AND EXCEPTIONS AND LIMITATIONS TO THE RIGHTS Annex IV (2010) *available at* http://www.wipo.int/edocs/mdocs/scp/en/scp_15/scp_15_3-annex4.pdf (last visited Feb. 16, 2012) ("The European Patent Convention (EPC) categorically excludes 'methods of medical and veterinary treatment' from patentability. Such inventions are excluded to ensure that people who carry out medical or veterinary treatments are not inhibited by patents.").

[9] World Intellectual Prop. Org. [WIPO], *World Intellectual Property Indicators* (2011), *available at* http://www.wipo.int/export/sites/www/freepublications/en/intproperty/941/wipo_pub_941_2011.pdf. "The trend in total patent families was stable until 1994 and has followed an upward trend since then . . . . Meanwhile, the number of foreign-oriented patent families more than doubled – from 107,318 in 1985 to 257,321 in 2008 – reflecting the increasing tendency for applicants to file abroad." *Id.* at 56–57. The United States leads all others in foreign-oriented patent family filings (i.e., families for which the first-filed application in a family is foreign) with 22.3% of all foreign-oriented families including a filing at the U.S. Patent & Trademark Office (USPTO), followed by the European Patent Office (EPO) (19.3%), China (52.2%) and Canada (46.9%). *Id.* at 59. With respect to residents, 49.4% of all applications filed in the USPTO in 2010 were filed by U.S. residents, which is similar to the EPO's 49.3%; in Canada, only 12.8% of applications were filed by Canadian residents in 2010. *Id.* at 43.

[10] JAKKRIT KUANPOTH, PATENT RIGHTS IN PHARMACEUTICALS IN DEVELOPING COUNTRIES: MAJOR CHALLENGES FOR THE FUTURE 12 (Edward Elgar Publ'g. Ltd. 2010) ("[A]ttempts have been made to establish regional co-operation regarding patent administration in order to increase efficiency and reduce costs of granting and maintaining patents. In recent years, there has been a drive from certain countries towards the increased harmonization of patent law standards as well as patent granting procedures.").

[11] *See, e.g.*, David Kappos,Under Sec'y for Commerce for Intellectual Prop. & Dir. of the U.S. Patent & Trademark Office, Remarks as prepared for delivery at the WIPO Symposium – Promoting Innovation & Creativity: The America Invents Act and a Global Call for Harmonization, (Sept. 22, 2011) (transcript available at http://www.uspto.gov/news/speeches/2011/kappos_wipo.jsp) ("I'll make the case for the urgency of harmonization, a mandate to better manage the collective challenges our global IP system faces in a 21st century economy. The public *must* have confidence that the patent system is striking the

identified a developing trend in Canada in which Canadian courts and the Canadian Intellectual Property Office are interpreting and applying the historically well-settled and generally harmonized utility requirement in a new and different way, in particular with respect to patents for pharmaceutical products.[12] As a result, applicants for Canadian patents must meet conditions and overcome hurdles not required by other major patent offices.

This article will compare Canada's implementation and treatment of the utility requirement with the implementation and treatment practiced in the United States and Europe—two jurisdictions that represent prevailing approaches to utility and also constitute a major share of the world's patenting activity. The article will first examine the statutory and judicial situation in each of the jurisdictions, including a review of the major international treaties and agreements to which each is subject. It will then present a case study that looks at the judicial challenges brought against various members of a single patent family in the United States, Europe, and Canada, and compare the results of those challenges. This analysis, we believe, reveals that the recent shift in Canada's approach to the utility requirement conflicts with international norms and thus presents implications for patentees, patent law harmonization, and international treaty obligations.

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right balance between incentives to innovate and access to those new innovations. Through global synergy and collaboration, we have a unique opportunity, right away, to meet these challenges – and I believe it is imperative we do that, and act by moving towards a more standardized global patent system."); Dongwook Chun, *Patent Law Harmonization in the Age of Globalization: The Necessity and Strategy for Pragmatic Outcome*, 93 J. PAT. & TRADEMARK OFF. SOC'Y 127, 138 (2011) ("The majority of the international patent community is and has been supportive of the idea of uniformity, recognizing the value of creating a uniform patent law on a global scale."); Dennis Crouch, *Some Hope for the Patent Reforms*, PATENTLY-O (Sept. 7, 2011), http://www.patentlyo.com/patent/2011/09/by-dennis-crouch-at-this-point-it-appears-very-likely-that-the-leahy-smith-america-invents-act-hr-1249-will-become-law-a.html ("Many patent applications are independently and redundantly examined in patent offices around the world. That scenario appears ripe for some level of cooperation and coordination that could seemingly reduce delay and costs while improving quality.").

[12] *See, e.g.*, Charles E. Lipsey & L. Scott Burwell, *Useful in the United States, But Not in Canada: Divergent Applications of the Statutory Utility Requirements*, BLOOMBERG LAW REPORTS, Oct. 3, 2011, available at http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=59ab301b-1d14-441d-85db-67b67f9243ed; Arvie Anderson & Lawrence Welch, *The Canadian Patent Promise: A Concern for Pharmaceutical Innovators?*, IPO COMMITTEE NEWSL. (Intellectual Prop, Owner's Assoc., Washington, D.C.), Dec. 2011, *available at* http://www.morganlewis.com/pubs/IP_IPOIsolatedDNASequences_dec2011.pdf. This selective application is significant because, in 2009 alone, 62,122 pharmaceutical patent applications were filed worldwide; from 2005 to 2009, 5,584 were filed in Canada. *World Intellectual Property Indicators*, *supra* note 9, at 76–77.

II. AN OVERVIEW OF UTILITY IN THE UNITED STATES, EUROPE & CANADA

Utility requirements for patent applications are one of the most basic and fundamental. In general, a common theme exists across jurisdictions about what might be "useful."[13] It is agreed that some level of utility (or "industrial applicability," as it is known in Europe[14]) must be shown, but the question is how much or to what degree. Following the 2002 decision by the Supreme Court of Canada in *Apotex Inc. v. Wellcome Foundation Ltd.*,[15] as expanded by the Canadian Court of Appeal in *Eli Lilly Canada Inc. v. Apotex Inc.*,[16] Canada began requiring that patent applicants do more to prove utility prior to filing than is required by other jurisdictions and international agreements. To begin to put this assertion into context, this section discusses the respective statutory laws, patent office administrative rules, and jurisprudence of the United States, Europe, and Canada.

A. United States

In the United States, § 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."[17] To satisfy § 101, an applicant must claim an invention that falls within one of the categories of statutory subject matter and show that that claimed invention is useful.[18]

The Manual of Patent Examination Procedure (MPEP) administered by the United States Patent & Trademark Office (USPTO) provides examination

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[13] *See, e.g.*, Brenner v. Manson, 383 U.S. 519, 536 (1966) ("But a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion. '[A] patent system must be related to the world of commerce . . . .'" (quoting Application of Ruschig, 343 F.2d 965, 970 (C.C.P.A. 1965)); PCT GUIDELINES, *supra* note 2.

[14] *See infra* Part II.B.

[15] [2002] 4 S.C.R. 153 (Can.).

[16] [2009] F.C.A. 97, para. 18 (Can.) (The Court expressly required that a patent specification *must* include "a disclosure such that a person skilled in the art, given that disclosure, could have as the inventors did, *soundly predicted* that the invention would work once reduced to practice." (emphasis added)).

[17] 35 U.S.C. § 101 (2006) (emphasis added); *see also* MPEP, *supra* note 5, § 2107.01. Section 101 was not amended by the recent America Invents Act. *See* Leahy-Smith America Invents Act of 2011, Pub. L. No. 112-29, 125 Stat. 284.

[18] MPEP, *supra* note 5, § 2107.01 ("As interpreted by the Federal courts, 35 U.S.C. 101 has two purposes. First, 35 U.S.C. 101 defines which categories of inventions are eligible for patent protection. An invention that is not a machine, an article of manufacture, a composition or a process cannot be patented. Second, 35 U.S.C. § 101 serves to ensure that patents are granted on only those inventions that are 'useful.'" (citations omitted)).

guidelines for the utility requirement of § 101.[19] To demonstrate that an invention is useful, an applicant must show that the invention has "specific and substantial utility" or discloses sufficient information about the invention such that its utility is immediately apparent to those familiar with the technological field, so-called "well-established utility."[20]

Specific utility must be specific to the subject matter of the claimed invention and not merely generally applicable to the "broad class of the invention."[21] For example, a statement that an invention is useful to diagnose disease without disclosing a particular disease or condition would lack specific utility, whereas one that discloses a biological activity and "reasonably correlates that activity to a disease condition" would establish sufficient specific utility.[22]

Substantial utility can be equated to showing a "real world" use.[23] To establish substantial utility, an applicant must show that an invention is useful as disclosed in its current form, rather than at some time in the future pending additional research.[24] "Utilities that require or constitute carrying out further research to identify or reasonably confirm a 'real world' context of use are not substantial utilities."[25] The MPEP is careful to qualify, however, that "in its

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[19] *Id.* § 2107.01. The MPEP further provides that inventions in various different technological fields are each subject to the same legal requirements with respect to utility, there being "no basis in the statutes or decisions for requiring any more conclusive evidence of operativeness in one type of case than another." *Id.* § 2107.01(III) (citing *In re* Chilkowsky, 229 F.2d 457, 461–62 (C.C.P.A. 1956)). "Courts have repeatedly found that the mere *identification* of a pharmacological activity of a compound that is relevant to an asserted pharmacological use provides an 'immediate benefit to the public' and thus satisfies the utility requirement." MPEP, *supra* note 6, § 2107.01(III).

[20] MPEP, *supra* note 5, § 2107.01 (citing Brenner v. Manson, 383 U.S. 519, 148 U.S.P.Q. 689 (1966); *In re* Fisher, 421 F.3d 1365, 76 U.S.P.Q.2d 1225 (Fed. Cir. 2005); *In* re Ziegler, 992 F.2d 1197, 26 U.S.P.Q.2d 1600 (Fed. Cir. 1993)). *See also* MPEP, *supra* note 5, § 2107.02(II) ("An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristics of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible.").

[21] MPEP, *supra* note 5, § 2107.01(I)(A). Many of the examples of specific vs. general utility provided in the MPEP are related to pharmacological and biotech inventions. "[I]ndicating that a compound may be useful in treating unspecified disorders, or that the compound has 'useful biological' properties, would not be sufficient to define a specific utility for the compound." *Id.*

[22] *Id.* "Assertions that fall in the former category are insufficient to define a specific utility for the invention, especially if the assertion takes the form of a general statement that makes it clear that a 'useful' invention *may* arise from what has been disclosed by the applicant." *Id.*

[23] MPEP, *supra* note 5, § 2107.01(I)(B).

[24] *Id.* (citing *In re Fisher*, 421 F.3d at 1371).

[25] MPEP, *supra* note 5, § 2107.01(I)(B) ("For example, both a therapeutic method of treating a known or newly discovered disease and an assay method for identifying compounds that themselves have a 'substantial utility' define a 'real world' context of use. An assay that measures

current form" is not intended to mean that a claimed invention must be "currently available," but rather that any reasonable use that is identified by the applicant and can be seen to provide a public benefit is sufficient to establish substantial utility.[26]

A deficiency under § 101 generally leads to a deficiency under § 112 , the first paragraph of which provides that the specification of a patent application:

> [S]hall 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, and shall set forth the best mode contemplated by the inventor of carrying out his invention.[27]

Section 112 therefore has been interpreted to set forth three separate requirements: written description, enablement, and best mode.[28] The interrelationship between §§ 101 and 112 stems from the reasoning that if an invention lacks utility, an application for that invention cannot enable one to use it.[29] Therefore, rejections for lack of utility typically implicate both §§ 101 and 112.[30]

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the presence of a material which has a stated correlation to a predisposition to the onset of a particular disease condition would also define a 'real world' context of use in identifying potential candidates for preventive measures or further monitoring. On the other hand, the following are examples of situations that require or constitute carrying out further research to identify or reasonably confirm a 'real world' context of use and, therefore, do not define 'substantial utilities': (A) Basic research such as studying the properties of the claimed product itself or the mechanisms in which the material is involved; (B) A method of treating an *unspecified* disease or condition; (C) A method of assaying for or identifying a material that itself has no specific and/or substantial utility; (D) A method of making a material that itself has no specific, substantial, and credible utility; and (E) A claim to an intermediate product for use in making a final product that has no specific, substantial and credible utility.")

[26] *Id.*

[27] 35 U.S.C. § 112 (2006).

[28] *See, e.g.*, University of Rochester v. G.D. Searle & Co., 358 F.3d 916, 921 (Fed. Cir. 2004). Best mode will be affected by the recently enacted America Invents Act in that it will no longer be available as an invalidity defense in litigation, but the requirement of § 112 will remain as a requirement of patentability. Leahy-Smith America Invents Act of 2011, *supra* note 17, § 15.

[29] *See In re* Ziegler, 992 F.2d 1197, 1200–01 (Fed. Cir. 1993); *see also* MPEP, *supra* note 5, § 2107.01(IV).

[30] MPEP, *supra* note 5, § 2107.01(IV) ("The fact that an applicant has disclosed a specific utility for an invention and provided a credible basis supporting that specific utility does not provide a basis for concluding that the claims comply with all the requirements of 35 U.S.C. 112, first paragraph. For example, if an applicant has claimed a process of treating a certain disease

An asserted utility, that is, a statement in the patent application that the claimed invention is useful for some purpose, creates a presumption of utility.[31] If the asserted utility is "credible," rejection for lack of utility is inappropriate.[32] Examiners will treat an assertion as credible unless: (1) the logic underlying the assertion is seriously flawed; or (2) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion.[33] The standard for overcoming the presumption of utility is that it is more likely than not that one of ordinary skill in the art would doubt or question the truth of the statement of utility.[34] In some situations, an examiner may request additional information from an applicant to support an asserted utility, for example, if an asserted utility is one that would seem unlikely to one of ordinary skill in the art.[35] Such requests, however, should be imposed "rarely, and only if necessary to support the scientific credibility of the asserted utility."[36]

Fundamentally, the MPEP states that "[t]here is no predetermined amount or character of evidence that must be provided by an applicant to support an asserted utility, therapeutic or otherwise. Rather, the character and amount of evidence needed to support an asserted utility will vary depending on what is claimed."[37] The MPEP specifically addresses "special considerations" related to therapeutic and pharmacologic utilities, providing that in those areas, too, "all that is required

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condition with a certain compound and provided a credible basis for asserting that the compound is useful in that regard, but to actually practice the invention as claimed a person skilled in the relevant art would have to engage in an undue amount of experimentation, the claim may be defective under 35 U.S.C. 112, but not 35 U.S.C. 101.")

[31] *See, e.g.*, *In re* Langer, 503 F.2d 1380, 1391 (C.C.P.A. 1974); *see also* MPEP, *supra* note 5, § 2107.02(III)(A). The asserted utility, however, must be commensurate in scope with the claimed subject matter. *Id.*

[32] *Id.*

[33] MPEP, *supra* note 5, § 2107.02(III)(B). Note that "[s]pecial care should be taken when assessing the credibility of an asserted therapeutic utility for a claimed invention. In such cases, a previous lack of success in treating a disease or condition, or the absence of a proven animal model for testing the effectiveness of drugs for treating a disorder in humans, should not, standing alone, serve as a basis for challenging the asserted utility under 35 U.S.C. 101." *Id.*

[34] *See In re Langer*, 503 F.2d at 1391; *see also* MPEP, *supra* note 5, § 2107.02(III)(A). U.S. courts generally are reluctant to uphold § 101 rejections "solely on the basis that the applicant's opinion as to the nature of the specific and substantial utility was inaccurate." *Id.* § 2107.01(I); *see also* Nelson v. Bowler, 626 F.2d 853, 856 (C.C.P.A. 1980) (finding that proof of any pharmacological activity of a drug was sufficient to find "practical utility").

[35] MPEP, *supra* note 5, § 2107.02(V) (citing *In re* Pottier, 376 F.2d 328, 330 (C.C.P.A. 1967)).

[36] *Id.*

[37] MPEP, *supra* note 6, § 2107.02(VII).

is a reasonable correlation between the activity and the asserted use."[38] Furthermore, courts in the United States generally are not receptive to rejections under § 101 for lack of utility, with the MPEP noting that it is "striking" that § 101 rejections were almost always overturned where a reasonable evidentiary showing supporting an asserted therapeutic utility was made by the applicant.[39] The MPEP also reminds examiners that, with respect to therapeutic and pharmacologic inventions, the role of the USPTO is to examine patent applications with respect to the patent laws, not determine whether, e.g., a drug is safe for sale, use or distribution.[40]

In re Fisher, a 2005 decision of the United States Court of Appeals for the Federal Circuit, illustrates the approach to the utility requirement adopted in the United States.[41] In *Fisher*, the patentee sought to patent certain "expressed sequence tags," or "ESTs," but was rejected for failing to express a specific utility for the ESTs, as the disclosed genes for which the ESTs corresponded had no

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[38] MPEP, *supra* note 5, § 2107.03(I) ("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 (e.g., articles in scientific journals), or any combination thereof. The applicant does not have to prove that a correlation exists between a particular activity and an asserted therapeutic use of a compound as a matter of statistical certainty, nor does he or she have to provide actual evidence of success in treating humans where such a utility is asserted." (citing Nelson v. Bowler, 626 F.2d 853, 857 (C.C.P.A. 1980)).

[39] MPEP, *supra* note 5, § 2107.03(III). "In no case has a Federal court required an applicant to support an asserted utility with data from human clinical trials." *Id.* Regarding human clinical trials, the USPTO:

> [S]hould not impose on applicants the unnecessary burden of providing evidence from human clinical trials. There is no decisional law that requires an applicant to provide data from human clinical trials to establish utility for an invention related to treatment of human disorders . . . . Before a drug can *enter* human clinical trials, the sponsor, often the applicant, must provide a convincing rationale to those *especially* skilled in the art (e.g., the Food and Drug Administration) that the investigation may be successful. Such a rationale would provide a basis for the sponsor's expectation that the investigation may be successful. In order to determine a protocol for phase I testing, the first phase of clinical investigation, some credible rationale of how the drug might be effective or could be effective would be necessary. *Thus, as a general rule, if an applicant has initiated human clinical trials for a therapeutic product or process, Office personnel should presume that the applicant has established that the subject matter of that trial is reasonably predictive of having the asserted therapeutic utility.*

MPEP, *supra* note 5, § 2107.03(IV).

[40] *Id.* § 2107.03(V).

[41] *In re* Fisher, 421 F.3d 1365 (Fed. Cir. 2005).

known function at the time.[42] On appeal, Fisher asserted that the Board of Patent Appeals and Interferences (BPAI) incorrectly applied a heightened utility standard.[43] The Federal Circuit rejected the argument holding that the proposed utility failed to meet the ordinary utility standard.[44] The court reasoned that a claimed invention whose only stated utility was use with genes that have no known use cannot be reasonably found to meet the utility standard.[45] *Fisher* exemplifies the United States approach to the utility requirement, namely that the requirement is met so long as the specified utility is reasonable and not an attempt to create a utility where none exists.

B. Europe

Although Europe[46] uses a different term to describe the standard, its approach to the utility requirement is remarkably similar to that of the United States. The European Patent Convention (EPC) establishes that inventions which are new, involve an inventive step, and are susceptible of industrial application are patentable.[47] Being "susceptible of 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."[48] Rule 42 of the Implementing Regulations of the EPC deals with the content of the description that must be provided in a European patent application and states that the description shall "indicate explicitly, when it is not obvious from the description or nature of the invention, the way in which the invention is industrially applicable."[49]

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[42] *Id.* at 1368–69.

[43] *Id.* at 1369–70.

[44] *Id.* at 1374.

[45] *Id.*

[46] Here "Europe" refers to the European Patent Organisation, an intergovernmental organization established in 1977 on the basis of the European Patent Convention. *See infra* notes 47–61 and accompanying text. The European Patent Organisation has two bodies, the European Patent Office (EPO) and the Administrative Council. *The Administrative Council of the European Patent Organisation*, EUROPEAN PAT. OFF., http://www.epo.org/about-us/organisation/administrative-council.html (last updated Feb. 2, 2011). See *infra* note 61 and accompanying text for a discussion regarding the national laws of the European countries.

[47] EPC-2000, *supra* note 8, art. 52. Discoveries, scientific theories and mathematical methods; aesthetic creations; schemes, rules and methods for performing mental acts, playing games or doing business, and programs for computers; and presentations of information are all specifically excluded from patentability. *Id.*

[48] *Id.* art. 57. "Industry" generally is understood to mean "in its broadest sense." *See* EPO EXAMINATION GUIDELINES, *supra* note 3, pt. C, ch. IV, § 5.1; WIPO, STANDING COMMITTEE ON THE LAW OF PATENTS, "*Industrial Applicability" and "Utility" Requirements: Commonalities and Differences*, SCP/9/5 ¶¶ 4, 12 (Mar. 17, 2003), *available at* http://www.wipo.int/edocs/mdocs/scp/en/scp_9/scp_9_5.pdf.

[49] EPC-2000, *supra* note 8, at R. 42(1)(f).

Examiners follow the Guidelines for Examination in the European Patent Office (EPO Examination Guidelines) to examine patent applications.[50] The EPO Examination Guidelines begin by defining, in accordance with the EPC, that there are four basic requirements for patentability in Europe: (1) there must be an invention, belonging to any field of technology; (2) the invention must be susceptible of industrial application; (3) the invention must be new; and (4) the invention must involve an inventive step.[51]

With respect to industrial application, the EPO Examination Guidelines state that "[t]he description should indicate explicitly the way in which the invention is capable of exploitation in industry."[52] The EPC hypothesizes that:

> [I]n most cases, the way in which the invention can be exploited in industry will be self-evident, so that no more explicit description on this point will be required; but there may be a few instances, e.g., in relation to methods of testing, where the manner of industrial exploitation is not apparent and must therefore be explicitly indicated.[53]

In one case, the EPO Technical Board of Appeal considered an appeal of a refusal of claims as being not susceptible of industrial application under EPC Article 57.[54] Claim 1 of the application at issue was directed to a method of improving the bodily appearance of a non-opiate-addicted mammal by orally administering naltrexone or a pharmaceutically effective salt thereof in order to reduce appetite, and repeating the dosage until a "cosmetically" beneficial loss of body weight occurred.[55] The specific ground for refusing the claims was that the subject matter was directed to a cosmetic process not susceptible of industrial application.[56]

In its appeal, Appellant E.I. Du Pont De Nemours & Co. argued that "the claims need not necessarily be restricted to industrial application" and that "[t]he

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[50] *See* EPO EXAMINATION GUIDELINES, *supra* note 3.

[51] *Id.* pt. C, ch. IV, § 1.1. Also, with respect to gene sequences specifically, "The invention claimed must have such a sound and concrete technical basis that the skilled person can recognise that its contribution to the art could lead to practical exploitation in industry." *Id.* § 5.4.

[52] *Id.* pt. C, ch. II, § 4.12.

[53] *Id.*

[54] Case T-144/83, E.I. du Pont de Nemours & Co., 1986 O.J. E.P.O. 301, *available at* http://archive.epo.org/epo/pubs/oj1986/p295_336.pdf.

[55] *Id.* at 302.

[56] *Id.* ("The treatment of a human being with such a drug was essentially biological in nature and therefore the administration of the same could not be regarded as susceptible to industrial application.").

word 'industry' should be given a broad interpretation . . . ."[57] The Board of Appeals agreed, finding the subject matter of the claims was patentable under former EPC Article 52(4).[58]

> According to the provision of [EPC Article 52(4)] methods for treatment of the human or animal body by therapy shall not be regarded as susceptible to industrial application. Such exclusions from patentability must be construed narrowly and should not apply to treatments which are not therapeutic in character . . . . [Claim 1] clearly covers a method of cosmetic use and is unrelated to the therapy of human or animal body in the ordinary sense.[59]

The invention was also found to comply with EPC Article 57 (Industrial Application) because the invention "can be used by enterprises whose object is to beautify the human or animal body," and such enterprises in the cosmetic field are part of industry since "'industry' implies that an activity is carried out continuously, independently and for financial gain."[60]

Thus, while the terminology varies ("utility" in the United States but "susceptible of industrial application" in Europe), the approaches of the jurisdictions are very similar with respect to the level of disclosure required and the deference given to asserted utility. The same approach has been adopted by the individual countries of Europe, the national laws of which tend to reflect the EPC and therefore will not be discussed individually herein.[61]

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[57] *Id.* at 303.

[58] *Id.* at 304; Act Revising the Convention on the Grant of European Patents, June 28, 2001, 2007 O.J. E.P.O. SPEC. ED. 1 (repealing Article 52(4), but a provision containing the same wording was added in Article 53(c)), *available at* http://archive.epo.org/epo/pubs/oj007/01_07/special_edition_1_epc_2000.pdf.

[59] *E.I. du Pont de Nemours & Co.*, 1986 O.J. E.P.O. at 304 ("The fact that a chemical product has both a cosmetic and therapeutic effect when used to treat the human or animal body does not render the cosmetic treatment unpatentable.").

[60] *Id.* at 305.

[61] *See, e.g.*, Patents Act, 1977, c. 37 § 4 (U.K.) ("[A]n invention shall be taken to be capable of industrial application if it can be made or used in any kind of industry, including agriculture."), *available at* http://www.legislation.gov.uk/ukpga/1977/37/pdfs/ukpga_19770037_en.pdf; UNITED KINGDOM INTELLECTUAL PROP. OFFICE, EXAMINATION GUIDELINES § 4(1) (July 2011), *available at* http://www.ipo.gov.uk/practice-sec-004.pdf; Basheer et al., *supra* note 8, at n.82 ("Illustratively, Section 4A of the 1977 Act in the UK mirrors Article 53(c) of the EPC."); *see also* Press Summary, Supreme Court of the U.K., *Human Genome Sciences Inc.* (Appellant) *v. Eli Lilly and Company Limited* (Respondent) [2011] UKSC 51, (Nov. 2, 2011) *available at* http://www.eplawpatentblog.com/2011/November/2011.11.02%20HGS%20v%20Eli%20Lilly%20-%20Press%20Summary.pdf ("There is very little UK authority on the topic of industrial applicability, particularly as regards biological material and the applicable principles are really to

C. Canada

The Canadian requirement of utility differs from that of the rest of the world by making it effectively impossible to maintain patents in which no actual working embodiments existed as of the filing date. The reason for this distinction is the doctrine of sound prediction. Understanding the Canadian requirement therefore requires an understanding of the role that the doctrine of sound prediction plays in it.

In Canada, 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."[62] In light of this statutory basis, the Canadian Intellectual Property Office (CIPO) provides in its Manual of Patent Office Practice (MOPOP) that utility "is an essential aspect of an invention" and "can be considered as a requirement for an invention to be operable, controllable and reproducible."[63] Thus, an invention is operable if it works for its intended purpose.[64]

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be found in the jurisprudence of the EPO and the Board . While the reasoning in each decision of the Board is not binding upon national courts, the courts should normally follow the jurisprudence of the EPO, particularly where the Board has adopted a consistent approach to an issue in a number of decisions as is the case with regard to the application of Article 57 to patents for biological material." (citations omitted)). On the issue of industrial applicability, the court in *Human Genome Sciences* allowed the appeal, finding that the lower court failed to follow the principles of the law by:

> [L]ooking for a description that showed a particular use for the product [that] had actually been demonstrated, rather than that the product had plausibly been shown to be usable for the purposes of research work which the Board must have taken to have regarded as an industrial activity in itself.

Id. (citations omitted).

[62] Canadian Patent Act, R.S.C. 1985, ch. P-4, § 2, *available at* http://laws-lois.justice.gc.ca/PDF/P-4.pdf; CANADIAN INTELLECTUAL PROP. OFFICE, PATENT OFFICE, MANUAL OF PATENT OFFICE PRACTICE § 12.02 (1998 ed., rev. Dec. 2010) [hereinafter MOPOP], *available at* http://www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/h_wr00720.html.

[63] MOPOP, *supra* note 62, § 12.08 (which also provides that "[t]he utility of [a particular] invention must be specific . . . practical . . . and credible.").

[64] *Id.* § 12.08.01 ("Where the utility of an invention is self-evident to the person skilled in the art, and no particular promise has been made in regard to any advantages of the invention (e.g. if the invention was to simplify a known invention), the self-evident utility is sufficient to meet the required standard. Where, however, the inventors promise that their invention will provide particular advantages (e.g. will do something better or more efficiently or will be useful for a previously unrecognized purpose) it is this utility that the invention must in fact have. Although an invention need only have one use in order to be patentable, where several uses are promised the applicant must be in a position to establish each of them. For example, if a composition is

In its interpretation of the statute, the Supreme Court of Canada has held that utility does not exist if "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"[65] but that "[i]f when used in accordance with the directions contained in the specification the promised results are obtained, the invention is useful in the sense in which that term is used in patent law."[66] An invention also must be controllable and reproducible such that "the desired result must inevitably follow when the invention is put into practice."[67] Inventions that are merely "arrived at by chance" and "cannot be reliably reproduced" therefore lack utility.[68]

Utility must be established as of the time a patent is applied for and cannot be supported by evidence occurring after the filing date.[69] To show utility, an applicant can: (1) disclose embodiments of the invention that actually work; or (2) disclose soundly predicted embodiments.[70] The latter factor is referred to as the doctrine of sound prediction.

The doctrine of sound prediction was invoked by the Canadian Supreme Court in *Apotex Inc. v. Wellcome Foundation Ltd.*, which held that applicants must demonstrate that a claimed invention's promised utility, or "promise of the

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promised to be useful as a drug, the applicant must be in a position to show that it is useful in the therapy of at least one disease. If, however, it is promised to be useful as a drug for treating many diseases, the applicant must be in a position to establish its utility [see 12.08.03 & 12.08.05] in treating each of the diseases.").

[65] Consolboard, Inc. v. MacMillan Bloedel (Sask.), Ltd., [1981] 1 S.C.R. 504, 525 (Can.); *see also* MOPOP, *supra* note 62, § 12.08.01.

[66] *Consolboard, Inc*. [1981] 1 S.C.R. 504, at 526; *see also* Unifloc Regents, Ld. v. Newstead Colliery, Ld. [1943] 60 R.P.C. 165, 184 (Can.).

[67] MOPOP, *supra* note 62, § 12.08.02. The MOPOP notes "that the idea that the 'desired result must inevitably follow' can refer to an accepted degree of success of a particular repetitive mass production method," and the accepted degree of success can vary with particular arts. *Id.*

[68] *Id.*

[69] Apotex, Inc. v. Wellcome Found. Ltd., [2002] 4 S.C.R. 153, para. 46 (Can.) (It is not enough for an applicant "to be able to buttress speculation with post-patent proof, and thereby to turn dross into gold."); *see also* MOPOP, *supra* note 62, § 12.08.05. If the application claims priority to an earlier application, the claims are only valid insofar as the priority document establishes the utility of invention described in the claims. *Id.*; *cf. In re* Brana, 51 F.3d 1560 (Fed. Cir. 1995) (establishing utility by using a declaration prepared and submitted during the prosecution of the application showing a person of ordinary skilled in the art would not have doubted the asserted utility).

[70] *Apotex*, [2002] 4 S.C.R. 153; *see also* MOPOP, *supra* note 62, § 12.08.03 (stating that disclosure of soundly predicted embodiments can be shown in applications "for which an appropriate basis exists upon which this utility can be predicted.").

patent" as it is known in Canada,[71] is "soundly predicted" as of the filing or priority date if no actual working embodiment exists.[72] In doing so, the Supreme Court departed from the "patent friendly" origins of the doctrine of sound prediction that accepted the promise of the patent unless there was evidence of a lack of utility.[73] The Supreme Court was seeking to prevent applicants from "buttress[ing] speculation with post-patent proof," thereby allowing applicants to be rewarded for patenting what was effectively a guess.[74] Although the Commissioner is required "by law" to reject a patent application where the invention is merely "arrived at by chance" and "cannot be reliably reproduced,"[75] the Court reasoned that the burden should be placed on the applicant to first establish utility before requiring the attacker to prove invalidity.[76] Following *Apotex*, CIPO amended the MOPOP to incorporate the doctrine of sound prediction into the examination procedure.[77]

Despite being referred to commonly as a "utility requirement," the doctrine of sound prediction is unconcerned with whether the claimed invention can actually perform the promise of the patent.[78] Instead, the doctrine looks solely at whether the applicant could have reasonably inferred that the claimed invention was suitable for the promise of the patent based on the evidence available at the filing or priority date.[79] According to *Apotex*, the doctrine of sound prediction has three

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[71] Since "promise of the patent" is the accepted Canadian term for promised utility, we will use it here.

[72] MOPOP, *supra* note 62, § 12.08.05. If the application claims priority to an earlier application, the claims are only valid insofar as the priority document establishes the utility of invention described in the claims. *Id.* It is not enough for an applicant "to be able to buttress speculation with post-patent proof, and thereby to turn dross into gold." *Id.* (quoting *Apotex*, [2002] 4 S.C.R. 153, para. 46 (Binnie, J.).

[73] *See, e.g.*, Monsanto Co. v. Comm'r of Patents [1979] 2 S.C.R. 1108, 1121–22 (Can.) ("In my opinion the Commissioner cannot refuse a patent because the inventor has not fully tested and proved it in all its claimed applications. This is what he has done in this case by refusing to allow claims 9 and 16 unless restricted to what had been tested and proved before the application was filed. If the inventors have claimed more than what they have invented and included substances which are devoid of utility, their claims will be open to attack. But in order to succeed, such attack will have to be supported by evidence of lack of utility. At present there is no such evidence and there is no evidence that the prediction of utility for every compound named is not sound and reasonable.").

[74] *Id.* at 1127.

[75] *Apotex*, [2002] 4 S.C.R. 153 (citing the Canadian Patent Act, *supra* note 62, § 40; *see also* MOPOP, *supra* note 62, § 12.08.02).

[76] *Id.*

[77] MOPOP, *supra* note 62, § 12.08.02. The MOPOP notes "that the idea that the 'desired result must inevitably follow' can refer to an accepted degree of success of a particular repetitive mass production method," and the accepted degree of success can vary with particular arts. *Id.*

[78] *Apotex*, [2002] 4 S.C.R. 153.

[79] *Id.*

prongs, requiring: (i) a factual basis, (ii) a line of sound reasoning based on the factual basis that leads to the desired result, and (iii) the provision of sufficient disclosure in the specification.[80]

The factual basis prong can be established by examples of what could be found in "scientifically accepted laws or principles, in data forming part of the state of the art and which is referred to in the description, or in information forming part of the common general knowledge of the person skilled in the art."[81] The factual basis must be established by evidence linked to a date that predates the filing date or earliest priority date.[82] As such, according to *Lilly*, if an applicant neglects to include disclosure within the specification and cannot otherwise establish a factual basis preceding the filing date, any application in Canada claiming priority to an earlier priority application may be invalidated even if that earlier application arose in a jurisdiction that does not require the provision of a factual basis.[83]

The general test for the sound reasoning prong of the doctrine of sound prediction is whether a person of ordinary skill in the art would accept the logic presented in the line of reasoning and derive from the prediction that the invention will provide the promise of the patent.[84]

> Although no inventor is required to understand why their invention works, this does not dilute the requirements for a sound prediction. If an inventor cannot articulate a line of reasoning to soundly connect their factual support (e.g. their examples) to the remaining matter of their claims, they are not entitled to the full breadth of their claims.[85]

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[80] *Id.*

[81] MOPOP, *supra* note 62, at § 12.08.04a.

[82] G.D. Searle & Co. v. Novopharm Ltd. [2007] F.C. 81, para. 97 (Can.). The United States and other jurisdictions do not have comparable requirements. *See supra* note 69.

[83] Eli Lilly Can. Inc. v. Apotex Inc., [2009] F.C.A. 97 (Can.).

[84] *Apotex*, [2002] 4 S.C.R. 153; *see also* MOPOP, *supra* note 62, § 12.08.04b ("Since a sound line of reasoning is directed to a person skilled in the art, those elements of the sound line of reasoning that would be self-evident to the person skilled in the art in view of their common general knowledge do not need to be explicitly disclosed in the application . . . . It is not possible to provide exhaustive guidance on the types of reasoning which may be found to be 'sound.' If brief, however, the soundness of a line of reasoning can be effectively assessed by asking whether the person skilled in the art (represented during examination by the examiner) would accept the logic presented in the line of reasoning and derive from the sound prediction as a whole an expectation that the invention will provide the promised utility.").

[85] MOPOP, *supra* note 62, § 12.08.04b; *see also* Monsanto Co. v. Comm'r of Patents, [1979] 2 S.C.R. 1108 (Can.).

The result is that the court or a patent examiner must subjectively evaluate the scientific thought process of the applicant.

For example, Canadian Patent No. 2, 225,626 was at issue in the post-*Apotex* case of *Allergan, Inc. v. Minister of Health*, and claimed a new use for a brimonidine compound as a topically applied neuro-protectant for the optic nerve and retina of humans from damage from glaucoma or ocular hypertension.[86] In response to an action for infringement, the defendant asserted that the patent lacked utility since the tests disclosed in the specification upon which the patent applicant relied to illustrate utility were only *in vivo* tests in rats rather than topical testing in humans.[87] To evaluate utility under the doctrine of sound prediction, the court was required to determine whether the results of the rat testing provided sufficient basis for a sound prediction that the claimed compound could provide the stated utility in treating humans.[88] In other words, the court, as the legal fact-finder, must judge the scientific reasonableness of the applicant's thought process regarding the chosen test procedure.[89]

According to the Canadian Court of Appeal in *Lilly*, the disclosure prong of the *Apotex* sound doctrine analysis requires that "the patent must provide a disclosure such that a person skilled in the art, given that disclosure, could have as the inventors did, soundly predicted that the invention would work once reduced to practice."[90] The doctrine of sound prediction therefore places an additional

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[86] Allergan, Inc. v. Minister of Health [2011] F.C. 1316, para. 24 (Can.).

[87] *Id.* para. 211. Because the tests were not performed on humans, "the utility of that subject matter could not be soundly predicted as of the priority date . . . ." *Id.* para. 193.

[88] "The doctrine of sound prediction has three components, namely: [that] . . . the inventor must have had an articulable . . . and sound line of reasoning from which the desired result can be inferred from the factual basis . . . ." *Id.* para. 216. "Therefore, the key question that remains is whether the '626 Patent disclosed the factual basis on which a POSITA could soundly predict in June 1996 that the topical administration of brimonidine would have a neuroprotective effect in humans, once the invention was reduced to practice." *Id.* para. 220 (citing Merck & Co. v. Apotex Inc., [2010] F.C. 1265, para. 521 (Can.)).

[89] Allergan, Inc. [2011] F.C. 1316, para. 220. The Court ultimately found that the patent did not lack utility as: (1) the in vivo drug administration would have allowed the drug to navigate to the eye, (2) the included results demonstrated that the drug produced the proposed effect despite in vivo administration, and (3) expert testimony that the results would suggest to a POSITA that drugs would have a similar effect in humans. *Id.* para. 223.

[90] Eli Lilly Can. Inc. v. Apotex Inc., [2009] F.C.A. 97, para. 18 (Can.). "The requirement for proper disclosure means that the person skilled in the art has to, through the specification [alone] . . . be provided with sufficient information to understand the basis of the sound prediction and to practice the entire scope of the claimed invention." MOPOP, *supra* note 62, § 17.03.02c (citing Eli Lilly Can. Inc. v. Apotex Inc. [2008] F.C. 142, para. 164). While elements of the factual basis and/or the sound line of reasoning that form part of the common general knowledge need not be disclosed, elements known only to the applicant must be included in the description.

burden on applicants not only to assert utility but also to explain a basis for the assertion.[91]

This outcome is a departure from pre-*Lilly* jurisprudence in Canada.[92] In *Consolboard Inc. v. MacMillan Bloedel (SASK)*, the Supreme Court of Canada previously had held that the "new and useful" requirement is distinct from the requirement of what the specification must disclose in a patent application.[93] Specifically, the Supreme Court reasoned that the "new and useful" requirement imposes a condition precedent, from which the disclosure requirement is independent.[94] The Supreme Court held, however, that the inventor was not obligated, as part of the "new and useful" requirement, to describe in the specification why the invention is useful so long as the specification describes the invention in sufficient detail such that it can be practiced.[95] The current sound prediction disclosure requirement as incorporated within the MOPOP following *Lilly*, however, obligates applicants to describe a basis of a sound prediction of utility "through the specification alone."[96]

Thus, according to the doctrine of sound prediction, an examiner or court must first construe the promise of the patent of the claimed invention before evaluating whether the specification provides a sound line of reasoning linking the construed promise of the patent to the factual basis thereof. If the utility of the claimed invention is misconstrued, a proper determination of whether a sound prediction exists cannot be made. Further, because applicants are not required to explicitly identify the utility in the specification, the utility of a claimed invention can be misconstrued by fact finders such that the sound prediction analysis may not be targeted properly to that which the applicant intended. The result can be conflicting conclusions as to the promise of the patent.

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[91] We have considered whether the proper disclosure prong effectively creates a new written description requirement, or whether it merely shifts the statutory basis with respect to an existing written description requirement, but found this to be beyond the scope of this article. In the future we would like to explore whether *Apotex* effectively creates a new written description requirement by the third prong of the doctrine of sound prediction, given that the doctrine arises under § 2 of the Patent Act rather than § 27(3), which governs all other Canadian written description requirements.

[92] The shift in the doctrine of sound prediction began with the Supreme Court decision *Apotex*, and was expanded with the Federal Court of Appeal's decision in *Lilly*. *See supra* notes 15–16.

[93] Consolboard, Inc. v. MacMillan Bloedel (Sask.), Ltd., [1981] 1 S.C.R. 504 (Can.) *see also* Canadian Patent Act § 27(3) (1996).

[94] *Consolboard, Inc.*, [1981] 1 S.C.R. 504 at 527 (the court distinguished the new and useful requirement from the disclosure requirement: "The first is a condition precedent to an invention, and the second is a disclosure requirement, independent of the first.").

[95] *See id.*

[96] Eli Lilly Can. Inc. v. Apotex Inc., [2009] F.C.A. 97 (Can.); MOPOP, *supra* note 62, § 12.08.04c.

Illustrating the risks associated with this approach, in 2011 the Federal Court of Appeal rendered two decisions pertaining to the same patent and reached opposite conclusions as to utility. In *Pfizer Canada Inc. v. Canada*, the Federal Court of Appeal upheld a finding that Canadian Patent No. 1,339,132 (the '132 Patent) was not lacking in utility based on the test results disclosed in the specification.[97] However, in the subsequent case of *Apotex Inc. v. Pfizer Canada Inc.*, which dealt with the same '132 Patent, the Federal Court of Appeal held that the patent was invalid for lacking utility.[98] In the latter case, the Federal Court of Appeal found that the judge had incorrectly construed the utility of the claimed invention, and it held that had the judge correctly construed the utility requirement, the judge would have found that the patent was invalid for lack of utility.[99]

Canadian patent law therefore significantly departs from that of the United States and Europe via the doctrine of sound prediction, which requires applicants to provide, at the time of filing, the factual basis and line of reasoning for a prediction of the promise of the patent. It is also a departure from existing international patent agreements to which Canada is a party.

III. TREATIES AND OTHER INTERNATIONAL AGREEMENTS

Many of the similarities in the requirements for patentability among the United States, Europe, and Canada may be attributed to treaty obligations, and to the general trend toward harmonization that has resulted from our increasingly interconnected global economy. A fundamental goal of each of the agreements discussed below, whether the agreement is specifically directed to patents and intellectual property or is a broader agreement that includes patent and intellectual property provisions, is harmonization and the creation of international norms to permit the equal treatment of inventions and inventors across borders. The doctrine of sound prediction and the heightened utility requirement that it creates arguably serve to defeat that goal.

A. Paris Convention

The United States, the countries of Europe, and Canada are among the contracting states of the Paris Convention for the Protection of Industrial Property (Paris Convention).[100] The Paris Convention is administered by the World

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[97] *See* Pfizer Can., Inc. v. Canada, [2011] F.C.J. 406, para. 37 (Can.).

[98] Apotex Inc. v. Pfizer Can. Inc., [2011] F.C.A. 236, para. 32 (Can.).

[99] *Id.* para. 52–53.

[100] *Contracting Parties*, WIPO, http://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=2 (last visited Feb. 17, 2012). The Paris Convention has a total of 174 contracting parties. *Id.*

Intellectual Property Organization (WIPO), which also administers the Patent Cooperation Treaty (PCT) and the Patent Law Treaty (PLT), discussed *infra*, both of which are Special Agreements under Article 19 of the Paris Convention.[101]

A bedrock principle of the Paris Convention is national treatment, which requires each contracting state to grant the same protection to nationals of the other contracting states as it grants to its own nationals.[102] The doctrine of sound prediction, however, tends to disadvantage foreign nationals and thus arguably impinges on the principle of national treatment. By insisting that applications disclose supporting evidence at a level of proof not required by foreign applicants' own national jurisdictions (and therefore not of the type that foreign applicants typically disclose in their priority applications), the doctrine of sound prediction renders applications filed by foreign nationals and their ensuing patents especially subject to invalidation for lack of utility.

B. PCT

The Patent Cooperation Treaty (PCT) entered into force in 1978 and was created to provide applicants with a user-friendly, cost-effective, and efficient system for filing international patent applications.[103] Under the PCT, an applicant may seek patent protection in some or all of the 144 member countries simultaneously by filing a single international application.[104] Canada, the United States, and all of the European countries have ratified the PCT and are PCT contracting states.[105]

The PCT and the Regulations under the PCT set forth harmonizing requirements for the international application. Moreover, according to Article 11 of the treaty, an international application has the same legal effect as a national application in each member country in which an applicant chooses to pursue

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[101] *See WIPO-Administered Treaties*, WIPO, http://www.wipo.int/treaties/en/index.jsp (last visited Feb. 17, 2012). WIPO administers a total of 24 treaties, including those that prescribe norms of intellectual property protection (for example, the PLT), those that establish global protection systems (for example, the PCT), and those that create intellectual property classification systems. *Id.*

[102] Paris Convention for the Protection of Industrial Property art. 2, Mar. 20, 1883, 21 U.S.T. 1583 [hereinafter Paris Convention] (as amended Sept. 28, 1979), *available at* http://www.wipo.int/treaties/en/ip/paris/pdf/trtdocs_wo020.pdf.

[103] *See* Patent Cooperation Treaty pmbl., June 19, 1970, 28 U.S.T. 7645 [hereinafter PCT], *available at* http://www.wipo.int/pct/en/texts/pdf/pct.pdf.

[104] *See id.* art. 1, 3; WIPO, *PCT Applicant's Guide - International Phase*, Annex A [hereinafter PCT Applicant's Guide], http://www.wipo.int/pct/guide/en/gdvol1/pdf/gdvol1.pdf.

[105] *See* PCT Applicant's Guide, *supra* note 104.

patent protection.[106] The international application, when undergoing national phase examination in a member country, is then subject to the same national laws and requirements as a national application filed in that member country.[107]

Chapter 14 of the PCT International Search and Preliminary Examination Guidelines (PCT Guidelines) addresses industrial applicability, which is deemed to be synonymous with utility.[108] The PCT Guidelines consider an invention to be industrially applicable if it has specific, substantial, and credible utility.[109] The methodology for assessing industrial applicability under the PCT Guidelines is to: (1) determine what the applicant has claimed;[110] and (2) determine whether a person skilled in the art would recognize the claimed invention to have industrial applicability.[111] Identical to the EPO Examination Guidelines, the PCT Guidelines provide that "[i]n most cases, industrial applicability will be self-evident and no more explicit description on this point will be required."[112]

Article 27(1) of the PCT addresses the national requirements that member countries may impose on international applications: "No national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this Treaty and the Regulations."[113] In accordance with Article 27(1), member countries therefore should not implement form or content requirements that exceed or differ from those of the PCT, as such requirements work against the international filing concept and violate the terms of the PCT.[114] The Post-Conference Documents contained in the Records of the Washington Diplomatic Conference on the PCT, which include a chronological account of the main

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[106] *See About the Patent Cooperation Treaty*, WIPO, http://www.wipo.int/pct/en/treaty/about.html (last visited Feb. 17, 2012); WIPO, PROTECTING YOUR INVENTIONS ABROAD: FREQUENTLY ASKED QUESTIONS ABOUT THE PATENT COOPERATION TREATY (PCT) 3–4 (Apr. 2006) [hereinafter PROTECTING YOUR INVENTIONS ABROAD], http://www.wipo.int/export/sites/www/pct/en/basic_facts/faqs_about_the_pct.pdf (last visited Feb. 17, 2012).

[107] *See* PROTECTING YOUR INVENTIONS ABROAD, *supra* note 106, at 14–15

[108] PCT GUIDELINES, *supra* note 2, § 14.01.

[109] *Id.* § A14.01[1]. The PCT Guidelines provide alternative guidelines for utility and industrial applicability, such that "[a]n International Authority may rely upon either." *Id.* § A14.01. Both utility and industrial applicability should be familiar from the discussion *supra* Part II. Much of the language and many of the examples given in the Appendix to Chapter 14 are the same as or very similar to that which appears in the MPEP, EPO Examination Guidelines and MOPOP; accordingly, the discussion will not be repeated here.

[110] PCT GUIDELINES, *supra* note 2, § 14.04.

[111] *Id.*

[112] *Id.* § 14.05; *cf.* EPO EXAMINATION GUIDELINES, *supra* note 3 and accompanying text.

[113] PCT, *supra* note 103, art. 27(1).

[114] *See id.*

decisions and consultations leading to the adoption of the PCT and its Regulations,[115] state that "[f]orm and contents mean not only the physical requirements and the identification data but also the form and manner of describing and claiming."[116]

Rule 5.1 of the Regulations under the PCT is directed to the manner of the description and provides that the description in an international application should:

> [I]ndicate explicitly, when it is not obvious from the description or nature of the invention, the way in which the invention is capable of exploitation in industry and the way in which it can be made and used, or, if it can only be used, the way in which it can be used.[117]

An international application therefore must demonstrate, either explicitly or implicitly, the way in which the invention is capable of being exploited and used, i.e., the invention's utility. However, the PCT in Rule 5.1 contemplates variations in the manner in which an invention will be described based upon the nature of the invention, and it therefore abstains from dictating the particular manner in which utility must be substantiated.[118] The sole exception is expressly set forth in Rule 5.2 for nucleotide and/or amino acid sequence disclosures, for which the PCT requires a sequence listing.[119] In all other cases, if a member country requires evidence in a particular form in respect of utility, it may only oblige the applicant to furnish such evidence during prosecution in the national phase.

Despite Rule 5, the Canadian Court of Appeal has ruled, as for example in the *Lilly* case, that there is an additional requirement that applicants filing Canadian patent applications through the PCT must face where the invention is based on a sound prediction.[120] In such cases, applicants must not only disclose the factual basis and line of reasoning for their sound prediction, but they must also provide the disclosure in the patent specification as filed.[121] An additional requirement of

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[115] WIPO, POST-CONFERENCE DOCUMENTS: RECORDS OF THE WASHINGTON DIPLOMATIC CONFERENCE, 741, ¶ 1 (1970), *available at* http://www.wipo.int/export/sites/www/pct/en/texts/pdf/washington_p739_to_764.pdf.

[116] *Id.* at 751, ¶ 57.

[117] Regulations Under the PCT, R. 5.1(a)(vi) (July 1, 2011), *available at* http://www.wipo.int/pct/en/texts/rules/r5.htm. The Rule continues: "[T]he term 'industry' is to be understood in its broadest sense as in the Paris Convention for the Protection of Industrial Property." *Id.*; *see supra* note 48.

[118] *Id.*

[119] *Id.* at R. 5.2.

[120] Eli Lilly Can. Inc. v. Apotex Inc., [2009] F.C.A. 97, para. 14 (Can.).

[121] *Id.*

this sort concerning the contents of an application is contrary to, and indeed defeats the purpose of, the PCT.[122]

C. PLT

The Patent Law Treaty (PLT),[123] the scope of which covers both national and regional applications, is also directed toward procedural standards of patent protection to be provided by member states.[124] The PLT aims "to harmonize and streamline formal procedures in respect of national and regional patent applications and patents."[125]

The United States and Canada each signed the PLT but have not yet ratified it. Among the European Patent Organisation member countries, the following are PLT member states: Albania, Denmark, Estonia, Finland, France, Hungary, Latvia, Lithuania, Macedonia, Montenegro,[126] the Netherlands, Romania, Serbia, Slovakia, Slovenia, Sweden, Switzerland, and the United Kingdom.[127]

Article 6(1) of the PLT extends the form and contents requirements of the PCT to all patent applications, not just international ones, by prohibiting member countries from demanding compliance with any requirement relating to form and contents other than those provided for in the PCT.[128] Moreover, Article 6(6) of the

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[122] *See supra* note 113. Surprisingly, in reaching its decision in the *Lilly* case, the Court of Appeal relied upon PCT Article 27(5), which provides in part that "[n]othing in this Treaty and the Regulations is intended to be construed as prescribing anything that would limit the freedom of each Contracting State to prescribe such substantive conditions of patentability as it desires." Substantive conditions of patentability, however, do not include the contents of the application, but rather relate to novelty, inventive step, and utility. Moreover, the article expressly provides that the freedom to prescribe does not extend to conditions of patentability "constituting requirements as to the form and contents of applications." PCT, *supra* note 103, art. 27(5); *Lilly*, [2009] F.C.A. 97, para. 19.

[123] *Treaties, Laws, and Practices: Patent-Related Treaties Administered by WIPO*, WIPO, http://www.wipo.int/patent-law/en/treaties.html (last visited Feb. 16, 2012).

[124] *Summary of the Patent Law Treaty (2000)*, WIPO, http://www.wipo.int/treaties/en/ip/plt/summary_plt.html (last visited Feb. 16, 2012).

[125] *Id.*

[126] Montenegro is an EPO extension state. *Extension States*, EUROPEAN PAT. OFF., http://www.epo.org/about-us/organisation/member-states/extension-states.html (last visited Feb. 16, 2012).

[127] *Compare Member States of the European Patent Organisation*, EUROPEAN PAT. OFF., http://www.epo.org/about-us/organisation/member-states.html (last visited Feb. 16, 2012), *with Contracting Parties: Patent Law Treaty*, WIPO, http://www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=4 (last visited Feb. 16, 2012).

[128] Patent Law Treaty art. 6(1), June 1, 2000, U.N.T.S. Reg. No. I-41939 ("[*Form or Contents of Application*] Except where otherwise provided for by this Treaty, no Contracting Party shall require compliance with any requirement relating to the form or contents of an application

treaty limits a patent office's authority to require applicants to file evidence "in the course of the processing of the application only where that Office may reasonably doubt the veracity of that matter."[129] The regulations under the PLT require the patent office to state its reason for doubting that veracity.[130]

D. TRIPS and NAFTA

The Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) is another treaty to which the United States, European countries, and Canada are obligated.[131] Canada and the United States are also signatories to the North American Free Trade Agreement (NAFTA),[132] which, like TRIPS, provides that "patents shall be available for any inventions, whether products or processes, in all fields of technology, provided they are new, involve an inventive step and are capable of industrial application."[133] TRIPS "establishes minimum levels of protection that each government has to give to the intellectual property of fellow [World Trade Organization] members."[134] Non-discrimination is a core goal, not only as between nationals and foreigners, but also as to the technological field of an invention, the place of its creation, and whether it was imported or locally produced.[135] TRIPS has another important principle: "[I]ntellectual property protection should contribute to technical innovation and the transfer of

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different from or additional to: (i) the requirements relating to form or contents which are provided for in respect of international applications under the Patent Cooperation Treaty . . . .").

[129] *Id.* art. 6(6).

[130] *Regulations Under the Patent Law Treaty*, R. 5, WIPO (Jan. 1, 2006), http://www.wipo.int/treaties/en/ip/plt/trtdocs_wo039.html.

[131] *See Members and Observers, Understanding the WTO: The Organization*, WORLD TRADE ORG., http://www.wto.org/english/thewto_e/whatis_e/tif_e/org6_e.htm (last visited Feb. 16, 2012).

[132] 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. *Id.*

[133] Agreement on Trade-Related Aspects of Intellectual Property Rights art. 27.1, April 15, 1994, 1869 U.N.T.S. 299 [hereinafter TRIPs], *available at* http://www.wto.org/english/res_e/booksp_e/analytic_index_e/trips_02_e.htm#article27; NAFTA art. 1709.1. "Capable of industrial application" and "useful" are synonymous in the agreements. *Compare* TRIPS, *supra*, *with* NAFTA, *supra* note 132.

[134] *Understanding the WTO: The Agreements, Intellectual Property: Protection and Enforcement*, WORLD TRADE ORG., http://www.wto.org/english/thewto_e/whatis_e/tif_e/agrm7_e.htm (last visited Feb. 16, 2012).

[135] *See Overview: The TRIPS Agreement*, WORLD TRADE ORG., http://www.wto.org/english/tratop_e/trips_e/intel2_e.htm (last visited Feb. 16, 2012).

technology. *Both* producers and users should benefit, and economic and social welfare should be enhanced."[136]

In an effort to strike a balance between the objective of providing incentives for pharmaceutical invention and the demands of providing access to public health, the TRIPS Agreement has paid special attention to the patenting of pharmaceutical products. For example, the TRIPS Agreement permits member countries to benefit from important flexibilities, including the adoption of compulsory licensing provisions to help ensure the adequate supply of pharmaceuticals, but it stops short of permitting differential treatment in the examination of pharmaceutical patent applications.[137]

A country that has ratified the Paris Convention, the PCT and/or the PLT has agreed to treat all patent applications filed in that country uniformly, regardless of whether the applications are filed under one of those conventions or the national laws of the country. Imposing national form and contents requirements beyond those of the harmonizing international treaties undermines a fundamental purpose of the agreements: uniform treatment of domestic and foreign-origin applications, irrespective of the convention under which the foreign-origin application is filed. A country that has ratified the TRIPS Agreement, moreover, has agreed not to single out applications in particular areas of technology for discriminatory treatment. The body of treaties and agreements thus forms part of an international patent law framework within which patent applicants operate. This framework is increasingly valued as patent applicants pursue global families of patent applications and patents.[138]

IV. AN INTERJURISDICTIONAL CASE STUDY

Given the frequency with which owners of technology seek protection for their inventions in multiple countries,[139] it is not infrequent for patent or patent application members of a single patent family to be the object of similar litigation in several jurisdictions simultaneously. The following case study involves judicial (courts in Canada and the United States) and administrative (EPO Technical Board of Appeal in Europe) treatment of a patent family owned by the

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[136] *Understanding the WTO: The Agreements, Intellectual Property: Protection and Enforcement*, *supra* note 134 (emphasis added). "The [TRIPS] Agreement covers five broad issues: how basic principles of the trading system and other international intellectual property agreements should be applied; how to give adequate protection to intellectual property rights[;] how countries should enforce those rights adequately in their own territories[;] how to settle disputes on intellectual property between members of the WTO[; and] special transitional arrangements during the period when the new system is being introduced." *Id.*

[137] *Id.*

[138] *See supra* note 9 and accompanying text.

[139] *See supra* note 9 and accompanying text.

pharmaceutical company AstraZeneca. The patent family originated with a Swedish patent application[140] filed on May 28, 1993 that was generally directed to optically pure salts of omeprazole,[141] which have a superior therapeutic profile to omeprazole salts having mixed enantiomers.[142] On May 27, 1994, the applicant filed European and PCT applications claiming priority to the Swedish parent application.[143] The applicant subsequently filed Canadian, United States, and other national phase applications based on the PCT application, with priority being claimed back to the Swedish application.[144]

The Canadian patent, No. 2,139,653 ('653 patent), was challenged in 2010 in *AstraZeneca Canada Inc. v. Apotex Inc*., in which Apotex alleged that the '653 patent was invalid for lack of utility.[145] The patent describes omeprazole as a gastric acid secretion inhibitor "*useful* as [an] antiulcer agent[s]," but can have two possible enantiomers.[146] As such, the patent describes and claims the present invention as a series of omeprazole salts having a single enantiomer (esomeprazole) and a process for making single enantiomer compounds having improved pharmacokinetic and metabolic properties.[147] Instead of looking to the stated utility of the claimed compounds, the court reasoned that the utility of the claimed invention was an "improved therapeutic profile" made possible by the single enantiomer salts.[148] In response to this court-constructed utility, AstraZeneca presented evidence that prior to the priority date of the Canadian patent, AstraZenca researchers had found that pure salts of enantiomers, including esomeprazole, could provide improved therapeutic results. The court nevertheless rejected the evidence because the report detailing the information was not

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[140] S.E. Application No. 19931830A (filed May 28, 1993); PCT Application No. PCT/SE94/00830 (filed May 27, 1994).

[141] Omeprazole is a chemical compound that acts as a proton pump inhibitor for treating gastric disorders. *Omeprazole*, DRUGBANK, http://www.drugbank.ca/drugs/DB00338#pharmacology (last updated Feb. 14, 2012).

[142] Enantiomers are different configurations of substituents on a tetrahedral carbon or other atom. GEORGE ODIAN, PRINCIPLES OF POLYMERIZATION 621 (4th ed. 2004).

[143] E.P. Application No. 1 020 460A (filed May 27, 1994) (now issued as E.P. Patent No. 1 020 460B); PCT Application No. PCT/SE94/00830 (filed May 27, 1994).

[144] C.A. Application No. 2139653A (filed December 08, 1994) (now issued as C.A. Patent No. 2139653B); U.S. Patent Application No. 08/376,512 (filed January 23, 1995) (now issued as U.S. Patent 5,714,504).

[145] AstraZeneca Can. Inc. v. Apotex Inc., [2010] F.C. 714 (Can.).

[146] C.A. Patent No. 2139653B p. 1, ll. 12–22.

[147] *Id.*

[148] *AstraZeneca Can. Inc.*, [2010] F.C. 714, para. 82–84. The court's reasoning seems to deviate from that of other countries since the nature of "improved" is not a concern for utility but rather for obviousness. Under Canadian law, patents are awarded for inventions which are not devoid of utility, and the measure of an invention's improvement over the art should be a separate concern.

presented until after the filing date of the Canadian application and was not mentioned in the specification.[149] Consequently, the Court invalidated the claims at issue as lacking a sound prediction, because the applicant failed to show that as of the priority date the inventors had a factual basis for a prediction that an esomeprazole salt of a particular purity would have the utility indicated in the patent.

In contrast, in *Astrazeneca AB v. Hanmi USA, Inc.*, Hanmi alleged that U.S. Patent 5,714,504 ('504 patent), an equivalent application to the Canadian '653 patent, was invalid for lack of enablement, written description, and other theories, but it did not even assert that the patent was invalid for lack of utility, although the Canadian '653 patent had already been invalidated on that ground.[150] Although the defendant argued that the specification of the '504 patent was lacking in virtually every way, the defendant did not raise lack of utility, no doubt because the stated utility of the compounds as gastric acid secretion inhibitors, which was expressly taught in the patent specification, would be considered sufficient to meet the utility requirement under the U.S. law.[151]

The European counterpart to the Canadian '653 patent and the United States '504 patent was European Patent No. 0652872 ('872 patent). Its fate was addressed in an EPO opposition proceeding.[152] The decision of the EPO Technical Board of Appeal in that case was to revoke certain claims of the '872 patent, and in reaching its decision, the Board relied upon the "use" constructed by the Canadian Court to invalidate the '653 Patent.[153] As with the Canadian court, the Board based its decision to revoke the patent on the "improved therapeutic profile." However, unlike the Canadian counterpart case, the Board did not invalidate the patent for lack of utility, but instead held that the "improved therapeutic profile" from single enantiomer salts was obvious to a person of skill in the art.[154] As in the United States counterpart case, the Board accepted the proposed use, and even relied upon the proposed use, without questioning its validity.

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[149] *Id.* para. 86–90.

[150] AstraZeneca AB v. Hanmi USA, Inc., No.11–760(JAP), 2011 WL 5526009, at *6 (D.N.J. Nov. 14, 2011).

[151] Though this litigation remains pending, utility remains unchallenged. *Id.*

[152] Case No. T 0401/04, Boards of Appeal of the EPO (December 19, 2006), *available at* http://www.epo.org/law-practice/case-law-appeals/pdf/t040401eu1.pdf.

[153] *Id.*

[154] *Id.*

V. PRACTICAL IMPLICATIONS OF CANADA'S DOCTRINE OF SOUND PREDICTION

The doctrine of sound prediction effectively imposes a heightened utility requirement on patent applicants in Canada and has broad implications, both nationally and internationally. First, the heightened utility requirement may create a new, potentially unintended class of unpatentable subject matter unique to Canada if selectively used to target a particular type of invention. Second, it exceeds existing international utility standards, raising questions with respect to Canada's obligations under international treaties and potentially leading to disparate treatment of domestic and foreign-origin applications within Canada. Finally, it could present a significant hurdle to increased global patent law harmonization going forward.

With respect to policy, others have noted that utility challenges to Canadian patent applications have been almost exclusively directed at pharmaceutical patents.[155] Therefore, the doctrine of sound prediction, or at least its focused application, may be an attempt to implement a policy change in Canada with respect to certain classes of inventions, namely pharmaceutical. Canada has been accused in the past of "treating patent holders in the field of pharmaceutical inventions . . . less favorably than inventions in all other fields of technology," which resulted in a complaint being filed against Canada under the WTO TRIPS Dispute Resolution procedures.[156] The patent system, however, should not be manipulated to implement such a policy change. Rather, policy issues should be addressed transparently if it is desired, on some level, to promote a new course.

Turning to the international agreements, as a signatory to the Paris Convention, PLT, PCT, TRIPS, and NAFTA, Canada has agreed to treat all patent applications filed in its patent office uniformly, regardless of whether the applications are filed under one of the international conventions (e.g., the Paris Convention, PLT and PCT) or the national law of Canada.[157] Imposing national form and content requirements beyond those of the harmonizing international

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[155] *See supra* note 12 and accompanying text.

[156] Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, WT/DS114/R (Mar. 17, 2000). This treatment was alleged to violate Canada's obligations under Article 27.1 of TRIPS. *Id.*; *see generally supra* Part III.D. Canada was also accused of violating Articles 28.1 and 33 of TRIPS. *Id.* Ultimately, Canada was found to be in compliance with Articles 27.1 and 28.1 (with respect to § 55.2(1) of the Canadian Patent Act) but in violation of Article 28.1 (with respect to § 52.2(2) of the Canadian Patent Act). *Id.* at 174. Article 28.1 of TRIPS addresses rights conferred on patent owners. TRIPS, *supra* note 133, art. 28.1. Following the Report of the Panel, Canada announced it would implement the Panel's findings, and in October 2000 revoked the necessary regulations. KRISTEN DOUGLAS & CELIA JUTRAS, CANADIAN PARLIAMENTARY INFO. AND RESEARCH SERV., PRB 99-46E, PATENT PROTECTION FOR PHARMACEUTICAL PRODUCTS IN CANADA – CHRONOLOGY OF SIGNIFICANT EVENTS, (Rev'd Oct. 6, 2008).

[157] *See supra* Part III.

treaties, which is an effect of Canada's doctrine of sound prediction, undermines uniform treatment of domestic and foreign-origin applications, irrespective of the convention under which the foreign-origin application is filed.

Furthermore, the doctrine of sound prediction creates potential traps that can ensnare foreign[158] applicants. As discussed *supra*, United States patent law is similar to that of Canada and requires that an invention must be useful in order to be patentable.[159] Specifically, a specific, substantial, and credible use for the invention must be disclosed in the specification of a United States patent application.[160] Unlike the Canadian doctrine of sound prediction, under United States law, the applicant is not required to provide evidence that the connection between the proposed use and the claimed invention is well-reasoned.[161] While Europe uses the phrase "industrial applicability," it is analogous to the utility requirements of United States and Canadian law, as discussed *supra*.[162] An invention has industrial applicability if the invention "can be made or used in any kind of industry."[163] Like in United States law, Europe simply requires that the industrial applicability of the invention be identified and does not require a showing that the identified industrial applicability be selected as a result of sound prediction based on the disclosure in the patent.[164] As a result, Canadian patent applications and patents arising from foreign applications or patents, including United States and European applications or patents, are particularly vulnerable to invalidation for lacking utility, because United States and European law only require that the utility be specified, while Canadian law invokes the heightened evidentiary standard.[165] Because other jurisdictions do not require the same evidentiary standard, foreign-origin specifications likely will not include the supporting evidence required by Canada alone. Therefore, Canadian patents based on foreign applications drafted under conventional international utility requirements, including those of the PCT to which Canada is a signatory party, are vulnerable to the shifting evidentiary requirements associated with complying with the doctrine of sound prediction. In imposing on patent applicants heightened standards that go beyond the letter and intent of the various international agreements to which Canada is party, Canada has ignored its international obligations.

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[158] "Foreign" is used here with respect to Canada (*i.e.*, non-Canadian).
[159] U.S. CONST. art. 1, § 8, cl. 8.
[160] 35 U.S.C. §§ 101, 112 (2006); *see also* MPEP, *supra* note 5, § 2164.07.
[161] *See id.*
[162] *See supra* Part II.
[163] *Id.*
[164] *See supra* Part II.
[165] *See supra* Part II.

Finally, Canada's heightened utility requirements present a barrier to increased global patent law harmonization. Increased harmonization will be difficult if nations do not abide by current obligations, never mind anticipated and future ones intended to harmonize national laws. Given the increasingly global economy in which innovators operate, jurisdictions that are unwilling or unable to commit to broadly supported harmonization goals may be left behind, presenting ever higher hurdles to their innovators and economies.