Useful in the United States, But Not in Canada: Divergent Applications of the Statutory Utility Requirements

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Recent decisions by appellate courts in Canada and the United States highlight the sharp conflict in judicial application of the statutory "utility" requirements under the patent laws of those countries. The decisions involved a U.S. patent and its Canadian counterpart claiming the method of using a known compound for the treatment of attention-deficit/hyperactivity disorder ("ADHD"). In parallel litigations, generic drug manufacturers alleged that the patents were invalid for failure to disclose experimental data demonstrating the effectiveness of the claimed treatment. While the U.S. court rejected the challenge and held the U.S. patent valid,[1] the Canadian court reached the opposite result and held the Canadian counterpart invalid.[2] The outcome in Canada is a result of a unique interpretation of the statutory requirement that patented inventions be "useful," recently adopted by intermediate appellate courts. That interpretation is out of step with international norms for the disclosure of utility, has significant negative ramifications for pharmaceutical development, and warrants the intervention of the Supreme Court of Canada.

Background

The patents at issue in the U.S. and Canadian litigations are directed to the use of a drug called "atomoxetine" to treat ADHD. Atomoxetine is approved by U.S. and Canadian regulatory authorities for this indication and is marketed by Eli Lilly and Company under the brand name STRATTERA. The patents contain identical disclosures, and include a specific description of how to use atomoxetine to treat ADHD, the criteria for identifying the relevant patient population, the preferred routes of administration, and the preferred daily doses.

However, the patents contain no data proving that atomoxetine is effective to treat ADHD. Because there is no in vitro or animal model of ADHD, such proof can be obtained only from clinical trials of the drug on human patients having the disease. A clinical trial of atomoxetine to treat ADHD had begun but was not completed before the U.S. patent application was filed. That trial ultimately proved successful before the filing one year later of the Canadian application.

The U.S. Court of Appeals for the Federal Circuit rejected the generic manufacturers' validity challenge, holding that the specification of the patent disclosed as a matter of fact a practical utility for the invention—the treatment of ADHD—and that the asserted utility was not so incredible as to require the provision of additional information to the United States Patent and Trademark Office during examination of the patent application. The court rejected the defendants' argument that experimental data proving the truth of the asserted utility was required to be included in the specification.

The Canadian Federal Court of Appeal, however, reached the opposite result. That court held that the Canadian patent did not comply with a recently-imposed judicial gloss on Canada's statutory utility requirement, now said to require a "basis of sound prediction" that the invention will work. Specifically, the Canadian court required that the patent disclose the factual basis from which utility of the claimed invention can be soundly predicted and that the absence from the disclosure of any discussion of the clinical trial rendered the patent invalid.

The Statutory Utility Requirements

The patent statutes in the United States and Canada treat the concept of "utility" in a remarkably similar manner. The patent statutes in both countries require that an invention be "useful" to be patentable.[3] Similarly, both countries require that the specification of the patent application describe the manner of making and using the invention so as to enable a person skilled in the art to which it pertains to make and use it.[4] Neither statute, however, contains a requirement that the specification contain proof of the accuracy of the utility asserted for the invention. As is evident from the outcomes of the atomoxetine cases, despite the common statutory language, the courts in the United States and Canada have interpreted the utility requirement quite differently.

Divergent Judicial Application of the Utility Requirements

The U.S. Approach

The U.S. courts have interpreted the utility requirement under 35 U.S.C.[5]

It is, of course, necessary in the United States that the assertion of utility in fact be true. The patent application need not, however, contain *proof* that the asserted utility is correct. The longstanding rule in the United States is that an invention is presumed operable as disclosed without the need for further evidence. Accordingly, additional submissions supporting the assertion of utility are required only in certain circumstances where the USPTO provides evidence that the assertion is incredible. Such submissions are generally required only where the assertion of utility is contrary to generally accepted scientific principles, such as for inventions pertaining to cold fusion or perpetual motion.[6]

Should the USPTO identify such evidence of incredibility, the applicant may then submit evidence demonstrating the correctness of the assertion of utility. Those submissions can be based, if necessary, on experiments conducted after the filing of the application that demonstrate that the invention actually works as described.[7] Moreover, the U.S. courts and the USPTO recognize that even if the asserted utility has not been demonstrated by a completed clinical trial, the mere initiation of the clinical trial justifies the presumptive utility of the subject of the trial, as clinical trials may commence only after the sponsor has provided a convincing rationale to the U.S. Food and Drug Administration that the investigation may be successful.[8]

In the United States, the focus for more than four decades has been on whether or not the utility asserted in the specification is *in fact* true, and not on whether evidence confirming the truth of the asserted utility is disclosed in the application as filed. Accordingly, in this case, the U.S. court held that the patent on the method of using atomoxetine to treat ADHD was not invalid for lack of utility. The court held that the U.S. patent described and enabled the utility of atomoxetine to treat ADHD, and that such disclosure was not on its face contrary to generally accepted scientific principles. The court also noted that even if the USPTO had questioned the asserted utility, experimental verification of the utility had been subsequently obtained.

The Canadian Approach

A 1981 decision of the Supreme Court of Canada interpreted the Canadian utility requirement in a manner similar to the interpretations of the U.S. courts, requiring only that the invention be useful in fact.[9] The Supreme Court of Canada has never held that the factual basis underlying the asserted utility must be disclosed in the application. Indeed, the *Consolboard* case specifically

held that the utility requirement was distinct from the disclosure requirement.

In a 2002 case, the Supreme Court of Canada held that if the asserted utility for a new use of a known compound has not been actually demonstrated, there must be evident a sound prediction of the utility based on the information and expertise then available.[10] The court identified three components of the "sound prediction" doctrine: (i) there must be a factual basis for the prediction, (ii) the inventor must have at the filing date of the application an articulable and "sound" line of reasoning from which the desired result can be inferred from the factual basis, and (iii) there must be "proper disclosure." With respect to "proper disclosure," the court explained that it is normally sufficient if the specification provides a full, clear, and exact description of the nature of the invention and the manner in which it can be practiced, but that it is generally not necessary for the inventor to provide a theory of why the invention works. Notably, the court did *not* hold that the basis for the sound prediction must be set forth within the application itself.

Subsequent decisions of the Canadian Federal Court of Appeal, however, have further engrafted upon the statute the requirement that the basis for the sound prediction indeed must be disclosed in the application, effectively imposing a heightened disclosure requirement not provided for by the statute or by the Supreme Court of Canada's decision in *Apotex*. For example, in a 2008 decision regarding another Lilly patent, the court held that the absence from the disclosure of data supporting the sound prediction of utility for the use of the drug raloxifene to treat osteoporosis rendered the patent invalid.[11] In that case, the court acknowledged that the basis for a sound prediction of the invention's utility existed in the form of published data from a clinical trial demonstrating the effectiveness of the drug. Nonetheless, the court held the patent invalid, as the data was not included in the specification. Thus, even if the basis for the sound prediction is available to those in the field as of the Canadian filing date, absence of the basis from the disclosure of the patent will render the patent invalid. As was the case with the atomoxetine decision, this outcome was the opposite of that reached in the parallel U.S. litigation involving the counterpart U.S. patents, in which the U.S. court rejected the defendant's similar challenge to validity.[12]

As discussed above, in the atomoxetine case the Federal Court of Appeal followed the same approach as it did in the raloxifene case, holding that the absence from the patent of any reference to the clinical trial of atomoxetine in patients with ADHD rendered the patent invalid. And again last month, the Federal Court of Appeal invalidated a patent on the use of Pfizer's drug latanoprost to treat glaucoma, in view of the absence from the disclosure of data from experiments concerning long term use of the drug.[13]

The Canadian courts have attempted to justify the heightened disclosure requirement by stating that disclosure of such information is the "hard coinage" that an inventor must pay for the patent monopoly and goes to the "essence of the bargain with the public" underlying patentability.[14] It is noteworthy, however, that in each of the raloxifene, atomoxetine, and latanoprost cases, the patents contained specific disclosures identifying an asserted utility for the drug and explaining how the drug should be used to treat the disease. Indeed, the Canadian regulatory authorities have approved all three drugs for treatment of the disease as specified in the respective patents, and the very reason the patents were challenged was because those treatments work and generic drug manufacturers sought approval to sell generic copies of the drugs. Clearly, the utility in fact of the drugs cannot be disputed. Yet notwithstanding the specific disclosure in those patents of how to use the drugs to treat the indications for which regulatory approval was ultimately granted, the Canadian Federal Court of Appeal struck down the patents for want of evidence that the drugs could be predicted to work.

The Canadian Approach Is Out of Step with International Norms

As discussed above, the Canadian requirement that a patent disclose the basis of sound prediction for the asserted utility is in conflict with the U.S. requirement that the patent simply contain an assertion of a specific, substantial utility and that the utility is in fact true. The Canadian approach is similarly out of step with the practice in Europe. There, as in the United States, the focus is on utility in fact. Accordingly, an invention may not be patentable if it is alleged to operate in a manner clearly contrary to well-

established physical laws, such as a perpetual motion machine.[15] While European practice requires that the patent disclose the "industrial applicability" of the invention—i.e., the way in which the invention is capable of exploitation in industry—it does not require the patent to contain proof of the operability of the invention.[16]

The heightened disclosure requirements imposed by the Canadian courts are also at odds with international treaties such as the Patent Cooperation Treaty ("PCT"), which provides a unified procedure for obtaining patent protection in member states. The PCT requires that a claimed invention be industrially applicable, a requirement that is satisfied if, according to its nature, the invention can be made or used in any kind of industry.[17] Like the U.S. and European approaches to utility, if the invention is alleged to operate in a manner clearly contrary to well-established physical laws and thus cannot be carried out by a person skilled in the art, the invention will be unpatentable for lack of industrial applicability.[18] While the PCT requires that the application shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art, it does not require that proof of the asserted utility of the invention must be contained in the application.[19]

The Canadian Approach Punishes Meritorious Inventors and Discourages Innovation

While the Canadian courts refer to the requirement that the basis of the "sound prediction" be disclosed in the patent as the "hard coinage" the inventor must pay for the patent monopoly, an accurate disclosure of a new utility places useful information in the hands of the public that it did not otherwise have. Concern that the U.S. approach rewards "lucky guesses" ignores that some meritorious inventions are the result of insight or intuition rather than experimental observation. The Canadian doctrine thus serves only to punish the meritorious inventor, as patents on inoperable inventions would be invalid under the existing statutory utility requirement.

The Canadian approach also places the insightful pharmaceutical inventor on the horns of an insoluble patent law dilemma. In many cases, the only way the utility requirement can be satisfied without a completed clinical trial is by conceding that the operability of the new treatment could have been "soundly predicted" from the public literature, whereby it will be contended, and likely found, that the invention is unpatentable for "obviousness" or "lack of inventive step" under Canadian and other patent laws.[20] Indeed, at least one U.S. court has come to precisely that conclusion in such circumstances.[21] The sad reality is that the current Canadian approach discourages pharmaceutical innovation, particularly in situations where there is no preclinical model of a disease. The vast majority of pharmaceutical patent applications are filed before confirmatory clinical trial data becomes available for a very practical reason—clinical trials are hugely expensive and normally would not be undertaken without assurance of patent protection for a successful result. Delaying submission of the patent application until completion of the trials results in delayed public disclosure of the invention, risks that the patent will be held invalid in some countries for a prior public use, and greatly increases patent procurement costs.[22] Indeed, the net effect of the Canadian approach will be to discourage pharmaceutical development in areas where pre-clinical disease models are unavailable, which includes some of the most challenging problems in modern medicine. Unfortunately, it appears that this practice will continue in Canada unless and until the Supreme Court of Canada intervenes.

Endnotes

[1] *Eli Lilly and Co. v. Actavis Elizabeth LLC*, No. 10-01500, 2011 BL 197400 (Fed. Cir. July 29, 2011).

[2] *Eli Lilly and Co. v. Teva Canada Ltd*., 2011 FCA 220.

[3] *Compare* 35 U.S.C. § 101 *with* Section 2, Canadian Patent Act.

[4] *Compare* 35 U.S.C. § 112, ¶ 1 *with* Section 27, ¶ 3, Canadian Patent Act.

[5] *Brenner v. Manson*, 383 U.S. 519 (1966).

[6] *See, e.g., In re Swartz*, 232 F.3d 862 (Fed. Cir. 2000); *Newman v. Quigg*, 877 F.2d 1575 (Fed. Cir. 1989).

[7] *In re Brana*, 51 F.3d 1560, 1567 n.19 (Fed. Cir. 1995).

[8] *Lilly v. Actavis*, 2011 BL 197400 at 13-14; *Eli Lilly and Co. v. Teva Pharms. USA, Inc*., 619 F.3d 1329, 1343 (Fed. Cir. 2010); Manual of Patent Examining Procedure § 2107.03 (2008).

[9] *Consolboard Inc. v. MacMillen Bloedel Ltd*., [1981] 1 S.C.R. 504.

[10] *Apotex Inc. v. Wellcome Found. Ltd*., [2002] 4 S.C.R. 153.

[11] *Eli Lilly Canada Inc., et al. v. Apotex Inc*., 2009 FCA 97.

[12] *Eli Lilly & Co. v. Teva Pharms. USA, Inc*., 657 F. Supp. 2d 967 (S.D. Ind. 2009), *aff'd* 619 F.3d 1329 (Fed. Cir. 2010).

[13] *Apotex Inc. v. Pfizer Canada Inc*., 2011 FCA 236.

[14] *Eli Lilly Canada Inc., et al. v. Apotex Inc.*, 2008 FC 142 at [163]; *Lilly v. Teva Canada*, 2011 FCA 220 at [51].

[15] Guidelines for Examination in the European Patent Office, Part C – Chapter IV, Section 5.1.

[16] European Patent Convention, Articles 52 and 57.

[17] Patent Cooperation Treaty, Article 33(4).

[18] Patent Cooperation Treaty International Search and Preliminary Examination Guidelines, Chapter 14.

[19] Patent Cooperation Treaty, Article 5.

[20] *See* Section 28.3, Canadian Patent Act; 35 U.S.C. § 103; Patent Cooperation Treaty, Article 33(3).

[21] *In re '318 Patent Infringement Litig*., 583 F.3d 1317 (Fed. Cir. 2009).

[22] *See, e.g., In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995).