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Patents in the TPP: Proof of Utility at the Time of Filing[1]

U.S. Proposal Could Undermine Canadian Law; Support Eli Lilly Attacks

Eli Lilly recently sued Canada for $500 million under investor-state dispute mechanisms, due to Canadian court decisions invalidating Lilly's patents. Canada's decisions were based in what is sometimes known as the "promise doctrine." Where a patent applicant promises a certain utility to their invention, their application must demonstrate or soundly predict that utility at the time of filing.

The United States has proposed a rule for the Trans-Pacific Partnership (TPP) negotiations that could undermine Canada's patentability requirements. Whether purposeful or not, this would support the pharmaceutical industry's plans to transform Canadian practice and even, seemingly, some of the goals of Lilly's suit.

Background: Utility

[1] To be patentable, an invention must be useful. The degree of usefulness required varies depending on the jurisdiction. Similarly, how and when usefulness should be measured is a matter of national patent policy.[2]

Article QQ.E.10 of the draft TPP Intellectual Property Chapter published by WikiLeaks[3] includes a proposed definition for utility.[4] The standard is weak and should not be adopted. (Eight countries presently oppose the provision.) This U.S.-led proposal also fails to include a 'timing perspective' on the

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[1] Contact bkilic@citizen.org or pmaybarduk@citizen.org. Thanks to Mi Kyoeng Kim for her excellent research.

[2] *See* Shann Kerner, et al., *Examples Requirements for Patentability of Inventions in U.S. and Foreign Jurisdictions*, Bloomberg Law Report, Vol. 3, No. 36, 2009 (discussing the varying requirements of working examples in different jurisdictions).

[3] Available at http://wikileaks.org/tpp. Further analysis available at: http://citizen.org/access.

[4] TPP IP Art QQ.E.8 (proposed by the United States, Australia, Peru and Vietnam) requires a disclosure that allows the invention to be used by a person skilled in the art, without undue experimentation, as of the filing date. Art.QQ.E.10 would require that a claimed invention be considered useful (US and Australia) or industrially applicable (Mexico) if it meets the lax U.S. standard of specific, substantial and credible utility.

utility requirement. This should be changed. If the flawed proposal were nevertheless adopted, it should, at a minimum, be modified to require that applicants demonstrate utility at the time of filing.

[2] In mechanical and electrical patent applications, utility is predictable and easily ascertainable from the functions asserted. In chemical and pharmaceutical applications, by contrast, a mere description of a compound or a gene does not reveal what specific functions that invention can achieve. Therefore a person skilled in the art cannot easily predict the utility of the compound or the gene. This lack of predictability in the fields of chemistry and biology leads patent offices and courts in many countries including the U.S. to impose a special timing requirement, as well as more rigorous standards for supporting the utility and enablement requirements for applications in those fields.[5]

[3] The U.S. generally requires *de minimis* utility. Utility asserted in a patent application creates a presumption of utility so long as it is credible.[6] However, even in the U.S., chemical and pharmaceutical inventions are subject to a stricter standard, in view of the challenges in predicting their utility.[7] Chemical and pharmaceutical inventions must have some currently available specific substantial use to satisfy the utility requirement. An invention with no currently known use, but only with a potential use, is found practically useless.[8] In *in re Fisher*, the Federal Circuit established that "an invention is useful to the public as disclosed in its current form" as opposed to "proving useful at some future date after future research."[9]

As to when utility should be measured, recent Federal Circuit decisions provide that test results which occurred after the filing date cannot be relied upon to establish therapeutic utility.[10] But it would be premature to say that there is a general rule in the U.S. allowing only experimental data included in the original application. Although non-precedential, the Federal Circuit made a contrasting decision in another case, admitting post-application data to satisfy the enablement and utility requirements. [11] In sum, the current U.S. practice of determining utility relies on fact-specific inquiries, taking into

[5] Manual of Patent Examination Procedure (MPEP), §2164.03 (8th ed. Rev. 8, July 2010), United States Patent and Trademark Office

[6] *Juicy Whip, Inc. v. Orange Bang, Inc.*, 185 F.3d 1364, 1367-68 (Fed. Cir. 1999); MPEP §706.03(a)(II); Jay A. Erstking et al., *Usefulness varies by country: The utility requirement of patent law in the United States, Europe and Canada*, Cybaris® An Intellectual Property Law Review, Vol.3, 2012.

[7] Dowd, Matthew J., *Rasomusson v. Smithkline Beecham Corp.: Distinguishing Between a Hunting License and the Next Generation Invention* (August 18, 2006). Available at SSRN: http://ssm.com/abstract=1895521.

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

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

[10] *Rasmusson v. SmithKline Beecham Corp.*, 413 F.3d 1318 (Fed. Cir. 2005) (involving a priority dispute in the inference proceeding); *Janssen Pharmaceutica N.V. v. Teva pharmaceuticals USA, Inc.*, 583 F.3d 1317 (Fed. Cir. 2009) (the invalidation case involves a method of treating Alzheimer disease).

[11] *Eli Lilly & Co. v. Actavis Elizabeth LLC*, No. 2010-1500 (Fed. Cir. 2010).

consideration the state of the prior art and the level of description of the therapeutic use in the application.

[4] Canada requires utility to be demonstrated or soundly predicted at the time of application. There must be a technical understanding from the specification and the state of art at the filing date. Data obtained and submitted to the patent office after the filing date of the application cannot cure the defect of lack of utility. The modern test for utility traces back to the 2002 decision in *Apotex*.[12] The same position is re-affirmed in a recent decision in *Eli Lilly*.[13] The test requires the applicant to establish utility at the time of application by ether demonstrating or soundly predicting that utility. The application itself must include a factual basis for the sound prediction, and evidence made available after the filing date is not allowed to support utility.[14]

[5] Allowing applicants to prove utility after filing may encourage a premature race to the patent office. Especially under the first-to-file system, if the lax standard is applied in assessing utility, the applicant will be strongly incentivized to file the application earlier to enjoy priority, ignoring the need to determine what function the invention has and later supplementing the utility obtained after the filing. By granting exclusive rights before applicants have successfully demonstrated usefulness, patents under such a rule may prematurely close off lines of productive research.

Additionally, the social benefit of an invention is reduced when the usefulness of that invention is not disclosed in a timely manner. Such patents may not contribute adequately to furthering community scientific knowledge. All patents block further innovation and research to a certain extent. However, society would be more willing to tolerate blocking where the inventor at least has discovered and disclosed some beneficial uses for his invention.

TPP negotiating countries should be aware of these social costs of granting patents to applications with unproven, speculative uses. As famously stated by the U.S. Supreme Court, "a patent is not a hunting license."[15] It is not enough for an applicant "to be able to buttress speculation with post-patent proof, and thereby turn dross into gold."[16] The better policy is to grant patents where utility is apparent at the time of filing.

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[12] *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 S.C.R. 153.
[13] *Eli Lilly Canada, Inc. v. Novopharm Ltd*., [2010] FCA 197.
[14] Arvie J. Anderson & Steven P.Caltrider, *Canada & Patentability: Nation's IP Jurisprudence Lags Compared to U.S. and Europe*, Washington Legal Foundation, Contemporary Legal Note Series, No. 70, 2012.
[15] *Brenner*, 383 U.S. 535-36.
[16] *Apotex*, [2002] 4. S.C.R. 153, para. 46.

The leaked IP proposal dated November 2013

Article QQ.E.10: US/AU/MX propose[17]; SG/CL/MY/VN/PE/BN/NZ/CA oppose: Each Party shall provide that a claimed invention is [US/AU propose: useful] [MX propose: industrially applicable] if it has a specific [MX propose: and], substantial, [MX oppose: and credible] utility.]

The provision proposed by the U.S., Australia and Mexico aims to impose the U.S.-style patentability test of specific, substantial and credible utility (Mexico, amazingly, would not even require credibility, and would compel countries to lower their industrial applicability standards). Any invention that has a practical application and that produces useful and specific results could satisfy utility requirements. The standard enhances the patentability of research tools, such as combinatorial chemistry libraries, cell lines and methods. This enhanced patentability of inventions which have utility on a theoretical and speculative basis could create new barriers to entry for future pharmaceutical research and development.

Moreover, countries would risk losing the freedom to require a demonstration or sound prediction of specific results when a patent contains a promise, as is found in Canadian law.

If, despite these significant concerns, the US/AU/MX proposal is adopted, then the timing of utility proofs should be taken into account. The words "as of the filing date" should be added to Article. 8.12 of the U.S. TPP Proposal for an IP Chapter.

Article 8.12.
Each Party shall provide that a claimed invention is useful if it has a specific, substantial, and credible utility ***[as of the filing date]***.

[17] Negotiators' Note: JP is considering this provision.