CPUC

Canadian Patent Utility Coalition

February 7, 2014

Mr. Stanford K. McCoy
Assistant U.S. Trade Representative for
Intellectual Property and Innovation
Office of the United States Trade Representative
1724 F Street, N.W.
Washington, DC 20508
http://www.regulations.gov (docket number USTR-2013-0040)

RE: **Office of the United States Trade Representative's 2014 Special 301 Review, Docket No. USTR-2013-0040: Written Submission of the Canadian Patent Utility Coalition**

Dear Mr. McCoy:

The Canadian Patent Utility Coalition (CPUC) appreciates this opportunity to submit comments to the United States Trade Representative (USTR) regarding the serious economic harm and uncertainty caused by Canada's failure to extend to U.S. innovative pharmaceutical and biotechnology companies the full benefit of intellectual property rights to which these companies are entitled in Canada. In particular, CPUC's members, which represent 19 innovative companies,[1] are extremely concerned about the emergence of a heightened and improper patent utility standard in Canada which threatens U.S. jobs, innovation and competitiveness.

Contrary to internationally accepted norms and its own trade obligations, Canada has imposed an unusual and improper patent utility requirement that has led to the revocation of highly valuable patents, which have been upheld in other jurisdictions around the world as useful (i.e., demonstrating utility). Canada's outlier patent utility test is undermining adequate and effective intellectual property rights protection and creating an unequal playing field for U.S.

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[1] CPUC members are: Amgen; Astellas Pharma US; Biogen Idec Inc, BN Immuno-Therapeutics, Bristol-Myers Squibb; Celgene Corporation; Eisai Incorporated; Eli Lilly and Company; F. Hoffmann La Roche, Genentech; Gilead; GlaxoSmithKline USA; Johnson & Johnson; Merck & Company; Novartis US; Oncolytics Biotech Inc., Pfizer; Sanofi US; and Takeda California Inc. For purposes of this submission, we have focused on harm caused to U.S.-based companies.

innovators, particularly those innovators involved in the development of life-saving therapies such as the members of our coalition. We appreciate the serious concerns that USTR raised in last year's Special 301 report about the impact of Canada's heightened patent utility requirements. However, we are dismayed that there has been no meaningful progress or efforts by the Canadian government to address these concerns. Until Canada remedies the problem by bringing its utility requirement into line with international standards and more importantly its own treaty obligations, we request that USTR elevate Canada to the Priority Watch List in its 2014 Special 301 Report.

Background: International and U.S. Patent Standards

Robust intellectual property protections are vital to the biopharmaceutical sector; adequate and effective patent protection, in particular, is what drives innovators to undertake enormous risks by investing in the research, development, and delivery of innovative new therapeutics to patients globally. The WTO Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS) and North American Free Trade Agreement (NAFTA) require patents to be granted for inventions relating to all fields of technology that are new, result from an inventive step, and are "capable of industrial application." "Capable of industrial application" is synonymous with "useful" and is often referred to as the "utility" standard. Thus, TRIPS and NAFTA require signatories to provide patent protection to useful inventions that meet the other requirements for patentability.

The utility standard is by no means intended to be a burdensome requirement. It is designed simply to ensure that patents are not granted for inoperable, fanciful, or purely aesthetic inventions. For example, in applying the patent utility test, the United States Patent and Trademark Office and U.S. courts require simply that an invention's claimed utility be specific and practical. The patent utility test applied in the U.S. is very similar to the tests applied in the European Union and Japan, among most other industrialized nations. When a patent is challenged for a lack of utility under Section 101 of the Patent Act, U.S. courts focus on actual utility and will consider evidence developed and submitted after the filing of the patent application in evaluating an invention's utility. Specific utility can be shown where a pharmaceutical or biotechnology patent discloses a specific disease against which the claimed compounds are useful.

Importantly, U.S. courts have made it abundantly clear that the human testing necessary for U.S. Food and Drug Administration (FDA) approval is not a prerequisite for finding usefulness for a therapeutic under the patent laws. The FDA's focus on human testing to demonstrate the safety and efficacy of a therapeutic before it is sold on the market is distinct from the Patent Act's patentability requirements. At the same time, USPTO and the U.S. courts accept evidence of FDA approval of human clinical trials as creating a strong presumption that the utility standard has been met. The U.S. approach is consistent with the practices of most if not all other WTO members. Canada's approach is the exception, and is inconsistent with international standards.

The Problem: Canada's Outlier Patent Utility Standard

When TRIPS and NAFTA entered into force in the mid-1990s, Canada's utility requirement was consistent with international norms. Courts in Canada have since departed from that standard, creating a burdensome and improper test known as the "promise utility doctrine," vastly eroding the patent rights of innovative companies. Canada's outlier utility test also has been explicitly incorporated into Canada's Manual of Patent Office Practice,[2] which is followed by the Canadian Intellectual Property Office (CIPO) to determine whether or not to grant a patent.

This new doctrine essentially includes three steps:

- First, the court or CIPO subjectively construes the "promise of the patent" from the patent specification, sometimes going beyond a mere statement of use and also beyond that which is specifically claimed in the patent application. There is no similar concept under U.S. law or practice.

- Second, the court or CIPO, using a heightened evidentiary standard of proof, determines whether utility is demonstrated by reference to the promise of the patent. Even completed human clinical trials have been found inadequate to demonstrate utility in Canada where the courts have questioned the size or duration of the trials. This stands in sharp contrast to U.S. practice, as noted above, where data from human clinical trials (even those trials conducted after filing of the patent application) create a presumption of usefulness.

- Finally, if utility is not demonstrated, the court or CIPO determines whether, at the time of the filing, there was a "sound prediction of utility." This last prong creates heightened disclosure requirements inconsistent with U.S. practice, which does not require evidence of utility to be found within the specification as of the filing date.

The Consequences of Canada's Application of its Outlier Patent Utility Standard

Canada's unique and improper utility requirement impedes fair access to the Canadian market and harms U.S. innovators' competitiveness. In sharp contrast to the common practice of other countries, Canada has revoked valuable patents for useful medicines in 20 cases over the past nine years because the patents fail to satisfy Canada's uniquely heightened utility standards.[3] Every pharmaceutical patent revoked on this basis was obviously capable of

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[2] *See* Canada Manual of Patent Office Practice, § 12.08.

[3] Decisions invalidating pharmaceutical patents for a lack of utility in infringement or revocation proceedings include: *Eli Lilly Canada Inc. v. Novopharm Ltd.*, [2011] 100 C.P.R. 4th 269 (Can. Fed. Ct.), affirmed 2012 F.C.A. 232, leave to appeal refused 2013 CanLII 26762 (S.C.C.) (regarding Zyprexa); *Sanofi-Aventis Canada Inc. v. Apotex Inc.*, [2011] 97 C.P.R. 4th 415 (Can. F.C.A.), leave to appeal (continued...)

industrial application since the relevant drug was in fact industrially applied, approved by Health Canada as safe and effective, and used by hundreds of thousands – even millions – of patients. The absurdity of such a result has been highlighted by Canada's *Globe and Mail,* which editorialized that competitors "sometimes challenge the usefulness of a patented drug - paradoxically, because they want to sell the useful drug themselves."[4] It has also earned Canada's utility doctrine the dubious honor of being included on the Information Technology & Innovation Foundation's list of "The 10 Worst Innovation Mercantilist Policies of 2013".[5]

Since the "promise" of the patent is construed by the court years after the filing date, the promise doctrine leads to great uncertainty among innovators as it is now unclear how much information is required at the time of filing to meet these new, onerous requirements. Moreover, this judicially-created utility doctrine applies a shifting standard that places applicants and patentees in an untenable "Catch-22" predicament: To be patentable, useful inventions must also be novel and inventive over all prior art available at the patent filing date. If an applicant aims to meet Canada's enhanced test for proof of utility, which may include carrying out long-term clinical trials prior to filing a patent application, the applicant would have to delay patent filings in Canada and other countries such as the United States. Such delays would increase the risk of patent refusal and patent invalidity in numerous countries on the basis of prior art published during the long-term clinical trials.

Canada's approach to utility is inconsistent with the patent laws of similarly-situated economies[6] and impedes ongoing efforts to achieve patent harmonization internationally. The

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refused [2012] S.C.C.A. No. 19 (QL) (regarding Altace); *Eli Lilly & Co. v. Teva Canada Ltd.*, [2011] 94 C.P.R. 4th 95 (Can. F.C.A.), leave to appeal refused [2011] S.C.C.A. No. 362 (QL) (regarding Strattera). Decisions where allegations of inutility were found to be justified in proceedings under the Patented Medicines (Notice of Compliance) Regulations include: *Pfizer Canada Inc. v. Pharmascience Inc.*, [2013] F.C. 120 (Can. Fed. Ct.) (regarding Lyrica); *Apotex Inc. v. Pfizer Canada Inc.*, [2011] 95 CPR 4th 193 (Can. F.C.A.), leave to appeal refused [2011] S.C.C.A. No. 458 (QL) (regarding Xalatan); *AstraZeneca Canada Inc. v. Apotex Inc.*, [2010] 88 C.P.R. 4th 28 (Can. Fed. Ct.) (regarding Nexium); *Eli Lilly Canada Inc. v. Apotex Inc.*, [2009] 78 C.P.R. 4th 388 (Can. F.C.A.), leave to appeal refused [2009] S.C.C.A. No. 219 (QL) (regarding Evista); *GlaxoSmithKline Inc. v. Pharmascience Inc.*, [2008] 72 C.P.R. 4th 295 (Can. Fed. Ct.) (regarding Valtrex).

[4] *See*, Globe Editorial, *Drug patents and the paradoxes of 'utility'*, The Globe and Mail, Feb. 17, 2013, *available at* http://www.theglobeandmail.com/globe-debate/editorials/drug-patents-and-the-paradoxes-of-utility/article8766751/.

[5] Information Technology & Innovation Foundation, *The 10 Worst Innovation Mercantilist Policies of 2013*, *available at* http://www2.itif.org/2014-ten-worst-innovation-mercantilist-policies.pdf.

[6] *See, e.g.* Global Intellectual Property Center, *Charting the Course: GIPC International IP Index*, Jan. 2014, *available at* http://dev.theglobalipcenter.com/wp-content/themes/gipc/map-index/assets/pdf/Index_Map_Index_2ndEdition.pdf, which, in a survey of the adequacy of the intellectual property protection and enforcement systems in 25 countries, ranks Canada well below its high income counterparts, particularly on patentability requirements.

Canadian approach is strikingly out of step with the first-to-file rule of the America Invents Act, which encourages early filing. It also compromises the ability of innovators to file patents in Canada using an international application under the Patent Cooperation Treaty (PCT), which has less onerous disclosure obligations. Moreover, the results in Canadian cases contradict those in the United States and Europe: pharmaceutical patents found to lack utility by Canadian courts have been upheld as having utility in U.S. and European proceedings, if utility is challenged at all.

Canada's promise doctrine, in practice, has discriminated against a particular area of technology - the biopharmaceutical sector. Since 2005, all patent revocations based on utility in Canada have involved pharmaceutical patents.[7] Given the disproportionate impact of the promise doctrine on the biopharmaceutical sector, Canada is failing to meet its international obligation to apply patent standards in a non-discriminatory manner across different technologies.

Damages Estimate

The consequences of Canada's heightened standards for U.S. companies are substantial: unpredictability and unfairness in the patenting process, forfeiture of intellectual property rights granted in similarly-situated economies around the world, and billions of dollars in lost sales when patent rights are prematurely terminated by Canadian courts or denied by CIPO. To date, based on court actions alone, U.S. companies have suffered damages of more than $730 million from the premature loss of patent protection based solely on Canada's outlier patent utility standard. This is a conservative estimate and does not include additional damages paid to competitors as a result of Canadian decisions applying the promise doctrine, CIPO denials of patent applications based on the faulty Canadian utility standard, and cases currently before the Canadian courts. While it is difficult to quantify future damages from the denial or delay of new patents, the potential future lost sales will be substantial if Canada does not bring its patent law into compliance with its international obligations.

[BUSINESS CONFIDENTIAL INFORMATION REDACTED]

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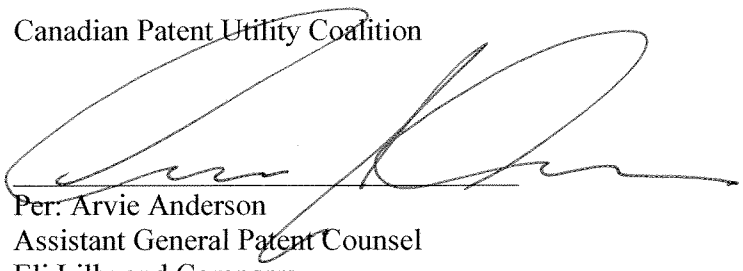
[7] In only one case outside the pharmaceutical sector have any challenged claims been found to lack utility; a distinct claim under the same patent was upheld as useful, such that the patent remained valid. *See Bell Helicopter Textron Canada Limitée v. Eurocopter*, 2013 FCA 219.

Members of CPUC appreciate the ongoing efforts of USTR to improve the protection of intellectual property rights in Canada and around the world. We hope that this submission provides helpful information to U.S. officials and to the public regarding Canada's outlier approach to patent utility. We urge your continued attention to this important enforcement matter through elevation of Canada to the Priority Watch List for 2014. If you would like to receive additional information, please do not hesitate to contact us.

Sincerely,

Canadian Patent Utility Coalition



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