Biotechnology Industry Organization

United States Trade Representative

Executive Office of the President

**Re: Request for Comments on Negotiating Objectives with Respect to Canada's Participation in the Proposed Trans-Pacific Partnership Trade Agreement**

Submitted electronically via http://regulations.gov Docket ID: USTR-2012-0015

The Biotechnology Industry Organization (BIO) is a non-profit organization with a membership of more than 1,100 biotechnology companies, academic institutions, state biotechnology centers, and related organizations in all 50 States and a number of foreign countries. BIO's members are involved in the research and development of health care, agricultural, industrial, and environmental biotechnology products. The U.S. life sciences industry, fueled by the strength of the U.S. patent system, supports more than 7.5 million jobs in the United States, and has generated hundreds of drug products, medical diagnostic tests, biotech crops, and other environmentally-beneficial products such as renewable fuels and bio-based plastics. These products are literally helping to feed, fuel and heal the world.

The majority of BIO's members are small companies that currently do not have products on the market. As such, BIO's members rely heavily on the strength and scope of their patents, both domestically and internationally, to recoup the investment necessary to sustain their long product development cycle. On average, it takes more than 10 years to develop a biotech medicine or a plant improved through agricultural biotechnology from its inception to regulatory approval and finally to market launch. The average, fully capitalized cost of developing a new medicine has been estimated at $1.2 billion and a new biotechnology derived plant product at $133 million.

To fully understand what is needed to level the playing field for the biotechnology sector in international markets, one must understand the intellectual property (IP) needs of the biotechnology sector. Biotechnology innovation requires predictable and effective IP protection throughout the research, development and commercialization process, including upstream (early stage) and downstream (product) IP protection. Biotechnology innovation generally starts with an early laboratory discovery, and thus upstream protection helps to generate investment and interest in the further, applied research and development of the invention. Upstream protection includes broad patent eligibility for biotech innovations, consistent patent term, flexible licensing practices, and effective patent enforcement.

Downstream protection is just as important. As mentioned above, the research and development of a biological product can take decades and cost more than a billion dollars to complete. A significant portion of this time and money goes towards developing the regulatory data package that is required by the FDA, USDA, or similar foreign regulatory offices to approve the biotech product. Therefore, downstream

1201 Maryland Avenue SW
Suite 900
Washington DC 20024

202.962.9200 P
202.488.6301 F
bio.org

protection for biotech products must include sufficient protection against foreign and domestic competitors relying on the innovator's data package to secure abbreviated approval of competitive products in such markets.

## I. Agricultural and Animal Biotechnology

The Government of Canada has long been a trusted ally to the United States on agricultural biotechnology. Canada has been a like minded partner in various international fora, including joining the United States government in a successful World Trade Organization (WTO)challenge of the European Union's moratorium on product approvals; coordinating in global environmental negotiations such as the negotiations of the Cartagena Protocol on Biosafety, and has recently emerged as a leader on establishing low-level presence policies to facilitate trade of products derived from agricultural biotechnology. To further the utilization of technology and lessen any potential trade barriers in animal production, the Canadian government should complete and publish its risk-assessment for animal cloning. We encourage the United States government to utilize the TPP as an opportunity to reduce barriers to trade of agricultural biotechnology products, and to do so in partnership with the Government of Canada.

## II. Transparency in Pricing and Reimbursement of Pharmaceuticals

BIO supports USTR's TPP proposal to include specific commitments on transparency in the purchase and reimbursement of pharmaceutical and related products by government bodies. It is important that such processes are transparent, follow clear criteria and timelines, that reasons are given for decisions, and that some form of external appeal to such decisions is possible. BIO will be interested to provide further input on how these transparency disciplines should apply in Canada.

## III. IP Protections in Canada

Canada continues to present challenges to the intellectual property rights of BIO's members. Patentability requirements applied in Canada involving the "promise of the patent" and "sound prediction" are a concern for BIO member companies. Further, lack of an equitable right of appeal, lack of patent term restoration and lack of data package exclusivity for drugs not marketed in Canada are also challenges which have led BIO to request that these issues be raised during negotiations of the Trans Pacific Partnership Agreement (the TPP Agreement). It is important that the TPP Agreement address these deficiencies and incorporate obligations to assure that U.S. innovators are not inappropriately deprived of patent protection in a way that is contrary to international norms and Canada's trade obligations.

**Patent Utility Requirements**

Canada's rules and requirements for establishing the usefulness (more commonly called "utility") for a patentable invention are burdensome and inconsistent with international norms and Canada's existing trade obligations. The unique utility test currently applied by the Canadian Intellectual Property Office (CIPO) and its courts also exceed Canadian statutory authority, and are contrary to longstanding Canadian case law. Concerns over the new Canadian utility requirements are as follows**:**

1. Canadian rules include the requirement that the description in a patent application *as filed* provide whatever explanation is necessary to supplement the common general knowledge of the person skilled in the art so as to permit a person skilled in the art to *soundly predict* that an invention will have a promised utility. This is more burdensome than the international norm and the Canadian Patent Act, which simply requires the inventor to correctly and fully describe the invention, its operation and its use as contemplated, and requires the inventor to describe the invention in such full, clear, concise and exact terms as to enable a person skilled in the art to make or use the invention.

2. This new "sound prediction" requirement is nearly impossible for BIO innovator pharmaceutical companies to meet based on the necessity to timely file their patent applications prior to completion of phase III clinical trials, and as such has become a primary means for the invalidation of patents owned by innovative pharmaceutical companies – patents that protect significant research and development investments and that regularly withstand corresponding patent challenges worldwide. The proper test is that the "use" or utility requirement requires only the disclosure of how to use the invention. It does not require evidence to support the utility of the invention in the patent application as filed. Canada now applies a more burdensome utility test out of line with international norms. Under Canada's unique patentability requirements, an inventor also may not submit evidence to support an invention's usefulness or utility after the filing date of the patent, despite it being well-understood that most clinical trials take place after the patent application has been filed.[1]

Particularly within the last several years, as a result of Canada's burdensome standard, inutility has been disproportionately alleged as a basis for invalidity against BIO member patents. As a result, several patents from BIO member companies have been rendered unenforceable for lack of utility within the courts, even while those same patents have been upheld in other jurisdictions, including the United States[2]. In many cases,

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[1] See MOPOP Chapter 9.04.01*b*, fourth paragraph.

[2] Compare the result in *Eli Lilly and Co. v. Actavis Elizabeth LLC*, No. 2010-1500, 2011 BL 197400 (Fed. Cir. July 29, 2011) with the result in *Novopharm Ltd. v. Eli Lilly and Co.*, 2011 FCA 220. See also: *Useful in the United States, but Not in Canada: Divergent Applications of the Statutory Utility Requirements*, Bloomberg Law Reports (Contributed by Charles E. Lipsey and L. Scott Burwell), October 3, 2011, available online at: <http://www.finnegan.com/resources/articles/articlesdetail.aspx?news=59ab301b-1d14-441d-85db-

Canada's burdensome patent utility requirement leads to perverse results, with patents for pharmaceuticals that have been approved as safe and effective and used by patients across Canada being invalidated for lack of utility or usefulness.

These burdensome standards have led to the invalidation for inutility or finding allegations of inutility for at least eleven (11) BIO member patents [3] where the pharmaceutical is plainly useful. There is substantial uncertainty as to how much work must be performed and disclosed when a patent application is filed due to the arbitrary application of Canada's burdensome standard. Canadian policies, which require the "promised" utility or usefulness to be demonstrated or "soundly predicted" at the time of filing, are an *ultra vires* hurdle for patents directed to pharmaceuticals. If an innovator must delay filing a patent application until after the data is obtained, it may result in loss of IP rights for lack of novelty due to obligations to disclose planned and ongoing clinical trial information.

BIO member companies must file their patent applications early in the development process and in many cases before conclusive clinical data or even models exist which more conclusively prove utility. As such, construction of the "promise" of a Canadian patent can be a bar to patentability for any drug claimed as useful for treatment of a chronic condition and therefore is in effect discriminatory toward pharmaceutical patents relative to other types of subject matter.[4]

The Canadian "promise of the patent" approach also interjects a high level of uncertainty into the patenting process as it is unclear how much information is required to meet the utility standard before filing. The promise of the patent may be misconstrued such that the identified promise may not be what the patentee intended. If the promise is construed too high then evidence of utility may be considered an inadequate

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67b67f9243ed>. This was notwithstanding that the Canadian patent was filed one year after the U.S. patent, by which date, positive results of a human clinical trial had been received.

[3] Decisions invalidating pharmaceutical patents for a lack of utility in infringement or revocation proceedings include the following: *Novopharm Ltd. v. Eli Lilly and Co.,* 2011 FCA 220, 94 CPR (4th) 95 [*Strattera FCA*], leave to appeal to SCC refused [2011] SCCA No 362 (QL); *Sanofi-Aventis Canada Inc. v. Apotex Inc.*, 2011 FCA 300, [*Ramipril FCA*]; *Ratiopharm Inc. v. Pfizer Ltd.*, 2009 FC 711, 76 CPR (4th) 241 [*Amlodipine besylate*], affirmed 2010 FCA 204, 87 CPR (4th) 185 (FCA does not comment on utility), and *Eli Lilly Inc. v. Novopharm*, 2011 FC 1288, 100 CPR (4th) 269 [*Olanzapine]* and *Sanofi-Aventis v. Apotex*, 2011 FC 12782; 2011 FC 1486 [*Plavix*].. Decisions where allegations of inutility were found to be justified in *PM(NOC)* (s. 55.2) hearings include the following: *Apotex Inc. v. Pfizer Canada Inc.*, 2011 FCA 236, 95 CPR (4th) 193 [*Latanoprost FCA*]; *Eli Lilly Canada Inc. v. Apotex Inc.*, 2009 FCA 97, 78 CPR (4th) 388, leave to appeal to SCC refused [2009] SCCA No 219 (QL) [*Evista]*; *Pfizer Canada Inc. v. Ratiopharm Inc.*, 2010 FC 612 [*Revatio FC*]; *AstraZeneca Canada Inc. v. Apotex Inc.*, 2010 FC 714, 88 CPR (4th) 28 [*Esomeprazole*] ; *GlaxoSmithKline Inc. v. Pharmascience Inc.*, 2008 FC 593, 72 CPR (4th) 295 [*Valacyclovir*]; and *Pfizer Canada Inc. v. Apotex Inc.*, 2007 FC 26, 59 CPR (4th) 183 [*Viagra*], affirmed 2007 FCA 195, 60 CPR (4th) 177, leave to appeal to SCC refused [2007] SCCA No 371 (QL). Collectively these products represent billions of dollars of sales lost due to judge-made heightened standards of utility.

[4] The courts acknowledge that utility only requires a scintilla of utility where there is no promise of a pharmaceutical use. See *Consolboard*, [1981] 1 SCR 504; *Pfizer Canada Inc. v. Canada* (*Minister of Health*), 2008 FCA 108, [2009] 1 FC 253 [*Ranbaxy*]. A scintilla of utility as the test for "utility" for ***any*** invention -- a pharmaceutical use or otherwise -- is a standard analogous to the European, credible or plausible test for industrial applicability, or the U.S. specific and substantial (non-trivial) test for useful.

demonstration of usefulness. Similarly, since "sound prediction" relies in part on disclosure of utility evidence, biopharmaceutical patents are at an increased risk of invalidity due to the lack of clarity in the standard.

**Canadian Patentability Requirements are Out of Step with US Practice, International Norms, and Recent FTAs.**

The U.S. has routinely sought to incorporate U.S. patentability standards, which follow widely-accepted international norms, into various free trade agreements (FTAs). TRIPS Article 27.1, the Patent Cooperation Treaty Article 33(4) and NAFTA Article 1709.1 all include analogous obligations to ensure that "patents shall be available for any inventions, whether products or processes, in all fields of technology," if they are "new," include "an inventive step," and are "capable of industrial application." The term "capable of industrial application" is synonymous with "useful" in these agreements. The same patentability obligation is incorporated into U.S. trade agreements with Australia, Korea, and Peru among others. The Australia, Korea, and Peru agreements require the parties to provide that a claimed invention is "useful" (or "industrially applicable") according to the U.S. "specific, substantial, and credible" test.

Canada's patent utility (or "usefulness") requirement is inconsistent with international norms and the standard set forth in U.S. FTAs. In contrast to the established practice in the United States and elsewhere where a relatively liberal "usefulness" test is applied, Canada's utility standard is burdensome and leads to absurd results. In recent years, Canadian courts have found in several cases that a pharmaceutical patents lack utility (are not "useful") despite approval of the product by Health Canada and widespread use in Canada. The Canadian courts have taken it upon themselves to impose a utility test that goes far beyond a specific assertion that an invention is useful for any particular practical purpose,[5] and the CIPO also has adopted this problematic approach.

Application of Canada's unreasonably burdensome utility test also has been applied against pharmaceutical patents in manner that inappropriately discriminates against pharmaceuticals as a field of technology. The burdens of Canada's utility requirement are overwhelmingly concentrated on the pharmaceutical sector. Since 2002, the vast majority of inutility findings (lack of usefulness) have involved pharmaceutical patents. As such, Canada fails to meet its international obligation to apply patentability standards in a non-discriminatory manner.

It is a well-established norm that a patentable invention must be "useful." At the same time, this "usefulness" requirement is not a high bar: under U.S. law, one must merely assert that "the claimed invention is useful for any particular practical purpose (i.e., it has a 'specific and substantial utility') and the assertion would be considered credible by a person of ordinary skill in the art[.]"[6] The U.S. standard is sufficiently liberal that

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[5] *See* U.S. MPEP, § 2107(II)(B)(1).
[6] U.S. Manual of Patent Examining Procedure ("U.S. MPEP"), Guidelines for the Examination of Applications for Compliance with the Utility Requirement, § 2107(II)(B)(1).

pharmaceutical innovations generally satisfy the usefulness test. The TPP should embrace widely-accepted international standards for patent utility which are embodied in U.S. law and prior FTAs, and all TPP partners, including Canada, should accept these norms.

**Lack of an Equitable Right of Appeal, Patent Term Restoration (PTR) and Data Package Exclusivity for Drugs not Marketed in Canada**

The lack of an equitable right of appeal also remains an enforcement challenge in Canada. The Patent Medicines (Notice of Compliance) (PMNOC) regulations create a process and a forum to resolve patent infringement issues and validity between generic and brand companies. However, practically, the regulations provide unequal appeal rights in favor of the generic company. Once a Notice of Compliance has been issued, a patent holder has no right to appeal the Notice as the appeal will be dismissed due to mootness. However, a generic company can appeal the decision in a Notice of Compliance proceeding. Even with a patent infringement action, complete redress remains illusory.

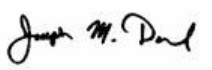
Further, Canada is one of the only developed nations providing no form of PTR to compensate for lost effective patent life due to obtaining regulatory approval for medicines. This problem is compounded by Canada having longer average regulatory approval process times than the European Union and the USA.

As it was an important step in improving Canada's intellectual property regime, BIO appreciates Canada's 2006 implementation of eight years of data package exclusivity to prevent unauthorized parties from gaining unfair commercial benefit during the period of exclusivity. However, BIO continues to have concerns about the potential loss of data protection under the October 2006 regulations if the innovative biopharmaceutical drug is not being marketed in Canada. These restrictions on the scope of protection find no basis in applicable FTAs such as Article 39.3 of the TRIPS Agreement or Article 1711 of the NAFTA. BIO would urge Canada to take steps to ensure that the data of BIO member companies in this respect is otherwise protected against unfair commercial use.

**Conclusion**

Eligibility and enforcement challenges related to patent utility, lack of an equitable right of appeal, lack of patent term restoration and lack of data package exclusivity for drugs not marketed in Canada have led BIO to request that these issues be raised by the U.S. during negotiations of the TPP Agreement. Canada needs to adhere to international norms in this area and commit through the TPP process to providing full patent protections for pharmaceuticals.

Sincerely,



Joseph Damond
Senior Vice President, International Affairs
Biotechnology Industry Organization