

AMICUS CURIAE SUBMISSION
Eli LILLY AND COMPANY v. THE GOVERNMENT OF CANADA

I. Introduction

In September 2013, the Claimant Eli Lilly and Company (Lilly) launched a CDN \$ 500 million claim against the Government of Canada under the North American Free Trade Agreement's (NAFTA) investment chapter. The Claimant is challenging Canada's invalidation of secondary patents related to the previously-known and patented active ingredients atomoxetine (Strattera) and olanzapine (Zyprexa), drugs used to treat attention deficit hyperactivity disorder, schizophrenia and bipolar disorder. Lilly argues that this "improper" and "discreditable" invalidation of its patents constitutes a NAFTA-prohibited "indirect expropriation" and a breach of NAFTA's guarantee of a "minimum standard of treatment" for foreign investors.

In essence, Lilly claims that NAFTA country patentability practices must be uniform, largely in conformance with U.S. standards, and that Canada's standards must remain static or change only in the direction of more permissiveness from NAFTA's 1994 signing. Lilly argues that its expectations of continuing monopoly-based profits must be respected at the expense of Canada's sovereignty to establish, clarify, and even adapt its NAFTA compliant standards for granting or invalidating patents. In addition to Canada's arguments, *Amici* here address a number of considerations based on principles of international patent law and practice and the human right of access to affordable medicines that the Government of Canada either did not address or elaborate. The *Amici* collectively are international intellectual property experts around the globe who focus broadly on maximizing permissible use of standards and flexibilities in NAFTA and other trade agreements to ensure access to knowledge, goods, and most particularly medicines. Because the Lilly case against Canada is a case of first impression and the first case pursuing ISDS with respect to intellectual property rights affecting pharmaceuticals, the case has heightened significance.

Generally, under NAFTA and other analogous agreements, including the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS), countries have significant flexibility to set their own standards for patentability as long as basic minimums are maintained. Every patent system has built-in checks and balances that seek to disseminate knowledge and promote access and innovation. A wide range of policy options and flexibilities have been built into patent systems to accommodate diverging national public health interests and objectives. The well-accepted international legal principles discussed in this submission support the premise that the Tribunal should take these principles into account.

II. NAFTA does not impose a uniform standard of patentability criteria and clearly not so with respect to industrial applicability, the criteria at issue in this case.

NAFTA, in parallel with TRIPS¹ requires that patents be granted when prototypical standards for patentability, novelty, inventive step and industrial applicability, are satisfied. NAFTA does not specify how these criteria should be defined and applied. The Claimant claims infringement of patentability standards “enshrined” in NAFTA ‘in a way that contradicts the standard accepted by the NAFTA parties at the time the treaty was negotiated’². It does so as if the definitions in Article 1709(1) were clear and immutable, but they certainly are not. The Article does not provide for a definition of the concepts that it refers to, such as, novelty, inventive step, capable of industrial application. This is a matter which is intentionally left to the Parties to deal within their own legal system and practice. Given the latitude of NAFTA provisions in not providing any definitions, Parties can determine when an invention is deemed to be a capable of industrial application or useful. This view has long standing support; the same terms in TRIPS are viewed as being ones that parties can self-define and policy makers and scholars have in fact recommended parties do so.³

Parties may treat the terms as synonymous, but are not required to do so. Indeed, in patent law and practice the term ‘useful’ is not treated same as industrial application per se. Article 1709(1) clarifies that there is significant flexibility with respect to inventions ‘capable of industrial application’ which may (but need not) be deemed by a Party to be synonymous with the term ‘useful’. Not only are differences in industrial applicability standards widespread, there is substantial variation globally with respect to inventive step.

NAFTA does not seek to achieve (nor its implementation likely to produce) harmonization of patent laws throughout North America. NAFTA, like TRIPS, is only intended to impose flexible minimum standards. The lack of harmonization is underscored by the fact that after NAFTA and TRIPS, some parties attempted to create uniform standards of patentability through the World Intellectual Property Organization (WIPO) that failed.⁴

¹ Although NAFTA was signed in 1992, three years before TRIPS, NAFTA Article 1709 (1) on patentability standards is based on the Article 27 of ‘Dunkel Draft’ from the GATT Secretariat which was presented in Geneva in December 1991. The text then became the Final Act of the TRIPS Agreement. Margaret Smith, *Patent Protection for Pharmaceutical Products In Canada - Chronology Of Significant Events*, Law and Government Division (March 30, 2000), available at <http://publications.gc.ca/Collection-R/LoPBdP/BP/prb9946-e.htm>

² Notice of Arbitration dated September 12, 2013, para 68

³ E.g. *Declaration on Patent Protection: Regulatory Sovereignty Under TRIPS*, available at <https://www.mpg.de/8132986/Patent-Declaration.pdf>; UNCTAD-ICSTSD Capacity Building Project on IPRs, *Resource Book on TRIPS and Development: An Authoritative and Practical Guide to the TRIPS Agreement* (2005); Carlos Correa, *Guidelines for the Examination of Pharmaceutical Patents: Developing a Public Health Perspective*, WHO-UNCTAD-ICTSD (2007); World Health Org. et al., *Promoting Access To Medical Technologies And Innovation: Intersections Between Public Health, Intellectual Property And Trade* 57 (2012); Chan Park et al., *Using Law to Accelerate Treatment Access in South Africa: An Analysis of Patent, Competition and Medicines Law* 41–46 (U.N. Development Programme 2013); Carlos M. Correa, *Patent Rights, in Intellectual Property and International Trade: The TRIPS Agreement* 189, 198–200 (2d ed. 1998); Straus, *Implications of the TRIPS Agreement in the Field of Patent Law*, From GATT to TRIPS – The Agreement on TRIPS 187 (Beier & Schriker eds., 1996).

⁴ E.g., Jerome Reichman & Rochelle Dreyfuss, *Harmonization without Consensus: Critical Reflections on Drafting a Substantive Patent Law Treaty*, 57 Duke L J 85, 89-90 (2007).

III. Canada is well within its rights under NAFTA to set an industrial applicability standard requiring adequate disclosure of promised utility of an invention – what Canadian courts identify as the sound prediction doctrine.

Canada is well within its rights under NAFTA to set its own industrial applicability and disclosure requirements. The Claimant is asking the Tribunal to reinterpret this flexible NAFTA standard and require adoption of a lax, U.S.-centric usefulness standard. It further seeks to deprive Canada of its NAFTA compliant flexibility to define its disclosure requirements with respect to patent claims generally and with respect to industrial applicability specifically. The Claimant seeks to gain unchallengeable patent exclusivity without having to satisfy adequate disclosure of its claims of industrial applicability at the time of filing its patent application.

The patent right is a negative right; it confers the right to exclude others doing or making anything that falls within the subject-matter contained in the patent’s claims in exchange for a full and adequate disclosure of the claimed invention sufficient to allow the invention to be worked by persons skilled in the art. Patents do not provide positive privileges. The ultimate goal of the patent system is to promote progress of science and technology through incentives to innovation and dissemination of disclosed⁵ inventions.

Under Canadian law, utility means having industrial or commercial value in a manner that benefits the public. Utility serves two functions: a) it determines general patentability of the invention and b) it signals completion of the invention. In order to offer immediate concrete benefits to the public, sufficient disclosure becomes critical.⁶ In the case of an explicit promise of utility, the utility of a claimed invention is measured against that promise. If a patent specification “promises” a specific result, benefit or use, a patent should do what the specification promises that it will do. This is called the “promise of the patent” or “promise doctrine” in Canada.

Utility should either be demonstrated directly and fully or soundly predicted as of the application filing date. The patent applicant can rely on data or other evidence obtained before filing to demonstrate utility. If the applicant is unable to demonstrate the full utility, he can rely on evidence that is not included in the specification to show that the utility is not based on “mere speculation” – that it is not merely an idea. The Supreme Court of Canada established the “sound prediction” test in *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77. The “sound prediction” test recognizes likely utility when there is not enough evidence to prove it directly. The test creates a guide that increases efficiency in drafting patent applications and reduces litigation over ambiguity. In the meantime, it aims to balance the public interest in early disclosure of new and useful inventions even before the utility has been fully verified by

⁵ See e.g., Mark A. Lemley, *The Myth of the Sole Inventor*, 110 Mich. L. Rev. 709 (2012); Lisa Larrimore Quелlette, *Do Patents Disclose Useful Information?*, 25 Harv. J. L. & Tech. 531 (2012); Alan Devlin, *The Misunderstood Function of Disclosure in Patent Law*, 23 Harv. J. L. & Tech. 401 (2020); Jeanne C. Fromer, *Patent Disclosure*, 94 Iowa L. Rev. 539 (2009); Dan L. Burk & Mark A. Lemley, *Policy Levers in Patent Law*, 89 Va. L. Rev. 1575 (2003).

⁶ Gold R. Shortt M., *The Promise of the Patent in Canada and Around the World*, 30 CIPR 1 (2014) (“the promise of the patent is a key element in ensuring that patentees actually deliver a concrete and tangible benefit to the public in exchange for their 20-year exclusivity”).

tests. However, since the patent applicant is not able to prove immediate utility directly, the applicant has a heightened obligation to disclose underlying facts and line of reasoning in support of the prediction of utility.

IV. The Claimant's two patents are secondary patents claiming new therapeutic uses of previously-known and patented active ingredients; they should only be allowed if there is evidence-based, sound prediction of these new uses.

Most of the pharmaceutical patent applications filed globally are so-called secondary or second generation patents⁷, which are directed to new developments or improvements of the subject matter of the existing patents. Secondary patent filing has become “a key element of any life cycle management strategy is to extend patent protection beyond the basic patent term for as long as possible by filing secondary patents which are effective to keep generics off the market.”⁸ A recent study of Kapczynski, Park & Sampat demonstrated that out of 528 new molecular entities (NMEs) approved by the US Food and Drug Administration from 1988 to 2005, 81% of drugs are patent protected by formulation claims, 83% by method of use claims, and 51% by polymorph, isomer, prodrug, ester, salts (PIPES) claims⁹. A number of countries and policy makers consider this a problematic phenomenon and have laws or proposed laws to minimize such patents.¹⁰

The patents on Lilly's two blockbuster drugs Strattera and Zypexera were both secondary patents. Atomoxetine, Strattera's active ingredient first developed as an antidepressant. In 2002, Lilly filed a second patent for the new use of atomoxetine to treat Attention Deficit Human Disorder (ADHD). The company was unable to conclusively demonstrate the claimed utility at the time filing because clinical trials had not yet been completed. Thus it relied on a short-term study, the “MGH Study,” which involved only 22 patients in a randomized, double-blind, placebo-controlled study lasting only 7 weeks. The Court held that a short-term study of 22 patients was not sufficient to meet the promise of treating a chronic disorder requiring a long-term sustained treatment. The patent was invalidated as the Court reasoned that “the requirement to disclose the basis of the prediction in the patent specification is said to be the quid pro quo the patentee offers in exchange for the patent monopoly.”

The situation was not different for Lilly's other blockbuster drug Zyprexa. Olanzapine, the active ingredient of Zyprexa, was first patented in 1980 as a part of large compounds “atypical” or “second-generation” antipsychotic drugs. In 1991, the company had applied for a second patent on a superior form of olanzapine, claiming “surprising and unexpected properties by comparison with flumezapine and other related compounds”, “marked superiority”, and “a better side effects profile” than prior

⁷ Correa, C.M., *Integrating Public Health Concerns into Patent Legislation in Developing Countries*, South Centre (2000).

⁸ Michael B and Sloper K, *The Art of Using Secondary Patents to Improve Protection*, Vol. 3 International Journal of Medical Marketing (2003).

⁹ Kapczynski A, Park C, Sampat B, *Polymorphs and Prodrugs and Salts (Oh My!): An Empirical Analysis of “Secondary” Pharmaceutical Patents*, PLoS ONE 7(12): e49470 (2012).

¹⁰ E.g., European Commission, *Pharmaceutical Sector Inquiry Preliminary Report* (2008); Harris, T., Nicol, D., Gruen, N., *Pharmaceutical Patents Review Report*, IP Australia (2013); Cynthia Ho, *Should all Drugs be patentable?*, 17 Vand. J Ent & Tech L 295, 313-22 (2015).

known antipsychotics. Zyperaxa's global sales were over 5 billion USD in 2010, which constituted 22% of Lilly's revenues. It was important for the company to extend the patent protection on olanzapine as long as possible. In the Court's words "as the sun began to set on the first patent, it became important to try to extend the patent protection for olanzapine." Therefore, the patent specification was "clearly drafted with a view to justifying a fresh patent". Even though the patent was granted in 1998, it was clear to the court that the claims were all speculative and lacked any factual basis. The company, for instance, relied on studies in which dogs given olanzapine "did not show any rise in cholesterol levels" in order demonstrate the cholesterol effects in human. The Court was not able to conclude from the submitted evidence that Zyperaxa had substantial and special advantages over the previously patented compounds. The patent was invalidated because there was no adequate factual basis to soundly predict pharmaceutical superiority. Lilly was unable to fill its part of patent bargain, to disclose any substantial advantage over the genius compounds at the time of filing. The company appealed both cases up to Supreme Court of Canada but the Court denied leave to hear the cases.

Lilly's practice of filing numerous secondary patent applications with little or no basis for alleged new uses reveals an intention to cordon off broad swaths of pharmaceutical research to prevent competition by others rather than to disclose an already proven or predicted utility. Between 1992 and 2004, Lilly filed patent applications claiming twelve alleged new uses of atomoxetine (Strattera) in the treatment of psoriasis, stuttering, incontinence, hot flashes, anxiety, learning disabilities, cognitive failure, conduct disorder, tic disorders, oppositional defiant disorder, pervasive development disorder and ADHD, with only half of these applications actually referring to any experimental data. Only, the claim for ADHD usage was eventually established, but after-the-fact, not at the time of filing. Similarly excessive patent applications were filed (and later abandoned) for olanzapine (Zyperaxa). Lilly's history of speculative patenting effectively created a "thicket" of low-quality patent applications, which were later abandoned or proven only later – precisely the kind of abusive patenting behavior that Canadian patent law is designed to prevent.

The patent system is not designed to grant monopolies on the basis of hunches, guesses, or hopes. It is also not designed to allow actual verification of the alleged invention after-the-fact.¹¹ Contrary to all of these foundational principles, Lilly has tried to exploit the Canadian patent system with a thicket of patent applications around its prior invention of active pharmaceutical ingredients with spurious, untested, and unproven new-use claims. These claims were designed not to identify actual known or soundly predicted new uses, but rather to build patent fortresses around the two base compounds at issue. Rather than satisfy Canada's well-grounded and well-established "sound prediction" requirement, Lilly filled unsubstantiated new-use claims, including claims of long-lasting therapeutical effects, without the bare-bones minimum of evidentiary support required. It is irrelevant that some of Lilly's guesses proved out after-the-fact and that the new-use was ultimately approved and marketed widely. The Tribunal should confirm Canada's sovereign right to prevent gaming of patent system.

¹¹ *Apotex Inc. v. Wellcome Foundation Ltd.* (2002) 21 C.P.R. (4th) 499, the Supreme Court of Canada established the doctrine of "sound prediction", to "balance the public interest in early disclosure of new and useful inventions, even before their utility has been fully verified by tests, and the public interest in avoiding cluttering the public domain with useless patents and granting monopoly rights in exchange for speculation or misinformation."

V. Patent grants are provisional and subject to potential court review and patent doctrine evolves over time, and the initial granting of a patent does not create a legitimate expectation that the patent will not be overturned, including through evolving judicial interpretation.

NAFTA must be interpreted to recognize that patent law is not static and that it is permitted to change over time, both in regard to its substantive elements and the way in which it is interpreted and applied. NAFTA parties have sovereign rights not only to adopt varying patentability standards but to change and reinterpret them without thereby violating any legitimate, NAFTA-protected investor expectations or rights. Patent standards and procedures can be amended legislatively and interpreted judicially, including through appellate review. Simply put, nothing in NAFTA prohibits the domestic patent law from evolving over time.¹²

Despite the passage of NAFTA, which described patentability standards in the broadest of terms, Canada and other parties retained freedom to amend or interpret patentability and disclosure requirements so long as basic minimums are retained. It is simply untenable to conclude that patent rules and their interpretation can never be altered without interference by disgruntled IP right holders who wish that a different rule or interpretation, more advantageous to them, were maintained.

Likewise, it is not unusual for Courts to overturn initial patent grants. The decision of the patent office to grant or reject a patent is always subject to review by the Courts. Courts interpret and reinterpret patent rules all the time, including in the U.S. For example, the *Myriad* case decided by the Supreme Court hugely upset the expectations and wishes of the biotech industry with respect to patentability of genes and other biological isolates, but it was fully within the Court's mandate to fairly adjudicate its understanding and application of U.S. patent law.¹³ Indeed, although patents have been invalidated, interested companies have not claimed that this is impermissible.

In addition, the investor expectation should not be subjective and not all expectation of investor is legitimate. Moreover, the arguments put forwarded by Lilly directly come in conflict with Canada's sovereign right to regulate its domestic intellectual property regime. Lilly completely ignores that patents are conditional rights. Patents are at most presumed valid; however, Courts can and do decide its validity. Similarly, once rights are acquired, it cannot be absolute; it is subject to changes on several grounds, which can also be found in TRIPS Agreement. In practice, fair and equitable treatment or legitimate expectations are not absolute; there are limitations. *Parkerings- Compagniet AS v. Lithuania*¹⁴ analyzes that the state's sovereign power to regulate lies on higher foot than claims of fair and equitable treatment. Tribunal states;

¹² *Eli Lilly and Company v. Government of Canada*, Counter-Memorial of Canada at ¶ 81.

¹³ *Assoc. for Molecular Pathology v. Myriad Genetics, Inc.* 569 U.S. (2013); Robini Feldman, *Gene Patenting After the U.S. Supreme Court Decision – Does Myriad Matter?*, 26 Stan. L. & Pol'y Rev. 16 (2014).

¹⁴ *Parkerings-Compagniet AS v. Republic of Lithuania*, ICSID Case No. ARB/05/08, Decision on award.

“It is each state’s undeniable right and privilege to exercise its sovereign legislative power. A state has the right to enact, modify or cancel a law at its own discretion. Save for the existence of an agreement, in the form of a stabilization clause or otherwise, there is nothing objectionable about the amendment brought to the regulatory framework existing at the time an investor made its investment. As a matter of fact, any businessman or investor knows that law will evolve over time. What is prohibited however is for a State to act unfairly, unreasonably or inequitably in the exercise of its legislative power.”

It is an established principle, that ‘fair and equitable’ treatment must be seen in light of an agreement and must not be unjust or in an arbitrary manner to a level unaccepted in international practice¹⁵, but when it comes to conflict with regulatory right of state, the tribunal generally weighs claimants’ legitimate and reasonable expectation on the one hand and the respondent’s legitimate regulatory interest on the other¹⁶. Similarly, tribunal decisions highlight that the host state may take public policy measures even if they affect investment, but the host country must have implemented the policies bona fide. And such conduct does not noticeably violate the requirements of consistency, transparency, even-handedness and non-discrimination. The tribunal in *Waste Management II* interpreted NAFTA and established a test;

“ the minimum standard of treatment to the claimant if the conduct is arbitrary, grossly unfair, unjust, idiosyncratic, is discriminatory and exposes the claimant to sectional or racial prejudice, or involves a lack of due process leading to an outcome which offends judicial propriety-as might be the case with a manifest failure of natural justice in judicial proceedings or a complete lack of transparency and candor in an administrative process.”

NAFTA requires that patents be granted when prototypical standards for patentability, novelty, inventive step and industrial applicability, are satisfied. It does not define these terms. Furthermore, Canadian Supreme Court decision does not represent an unfair and unjust ruling.

Henning Grosse Ruse-Kahn argues that patents do not provide the right holder with a legitimate expectation that measures interfering with the use of these rights in the host state will not occur.¹⁷ A

¹⁵ *S.D. Myers, Inc. v. Government of Canada*, Decision on Partial Award at 268.

¹⁶ *Saluka Investments BV (The Netherlands) v. The Czech Republic*, Decision on Partial Award, UNCITRAL (March 17, 2006) at para 306.

¹⁷ Henning Grosse Ruse-Kahn, *Litigating Intellectual Property Rights in Investor State Arbitration: From Plain Packaging to Patent Revocation*, University of Cambridge Legal Students Research Paper Series, Paper No. 52/2014 (2014), available at http://papers.ssrn.com/sol3/papers.cfm?abstract_id=2463711###; See also, Ruth L. Okediji, *Is Intellectual Property “investment”?* *Eli Lilly v. Canada and the International Intellectual Property System*, 35 U. Pa. J. Int’l L. 1121 (2014) (arguing that IPRs should not automatically be considered investments for ISDS purposes and that when they are ISDS claims can be highly disruptive of the desired policy space needed for rational IP systems); Cynthia M. Ho, *Sovereignty Under Siege: Corporate Challenges to Domestic Intellectual Property Decisions*, 30 Berkeley Tech. L.J. 213 (2015) (arguing as well that IPR invalidations should not be and are not covered by investment chapter rules and that Eli Lilly had no legitimate expectation that common law interpretation of Canada’s patent law might not change).

patent is a domestic statutory creation, granted upon the fulfillment of certain conditions, and if one of those conditions is not met, the grant can be revoked as easily as it was given. Ruse-Khan summarizes his position as follows:

“In all cases, the grant of the patent certainly does not and cannot create any legitimate expectation that the exclusivity it confers is absolute and will remain without interference from accepted checks and balances inherent in the IP system. Instead, the expectations of the patent holding investor are a priori limited by the regulatory tools the domestic IP law of the host state foresees. Even in case a host state newly introduces such tools, or changes its policy of using existing ones after the investor has obtained his patent, the general acceptance and widespread state practice vis-à-vis these measures would strongly side against findings of interference with legitimate expectations. ... Also a change in how the Canadian courts apply patentability standards such as utility or the disclosure obligation as such does not affect legitimate investor expectations: No expectation for a stable and predictable business environment can go so far that the circumstances prevailing at the time the investment is made must remain unchanged. Any resort to familiar and commonly used mechanisms to limit IP exclusivity ... should never be considered as a breach of [fair and equitable treatment standards].”¹⁸

Furthermore, Ruse-Khan argues that the negative, rather than positive, character of IP rights – which allow the right holder to prevent others from utilizing the protected subject matter but do not confer a positive right to exploit that matter – naturally permits national governments to impose further limitations on the use of the protected subject matter, in the form of regulatory controls.¹⁹ The WTO Panel in *EC-Geographical Indications* confirmed “the TRIPS Agreement does not generally provide for the grant of positive rights to exploit or use certain subject matter, but rather provides for the grant of negative rights to prevent certain acts. This fundamental feature of intellectual property protection inherently grants Members freedom to pursue legitimate public policy objectives since many measures to attain those public policy objectives lie outside the scope of intellectual property rights and do not require an exception under the TRIPS Agreement.”²⁰

Amici are particularly concerned that NAFTA parties maintain freedom to adopt stricter standards of patentability and to use NAFTA compliant exceptions and limitations particularly to help ensure a proper balance between the interests of inventors and users and to promote public health and other public interest objectives. The right to health is entitled to substantial weight in defining, adapting, and modifying patent rights so that exclusive rights do not needlessly interfere with access to medicines.

VI. *Lilly’s initiation of an arbitration claim has not been made in ‘good-faith’, it abuses the arbitral process*

¹⁸ *Id.* at 27.

¹⁹ *Id.* at 27-29.

²⁰ *European Communities – Protection of Trademarks and Geographical Indications for Agricultural Products and Foodstuffs*, WT/DS174/R, Report of the Panel (March 15, 2005), at para 7.210, available at https://www.wto.org/english/tratop_e/dispu_e/174r_e.pdf.

Amici argue that Lilly's use of this arbitration proceeding is abusive because it seeks to leverage the proceedings to influence the Canadian Parliament to change the law and limit the interpretation of the utility requirement by judges.

As has been clearly established in the case law, tribunals must be vigilant "to prevent an abuse of the system of international investment protection . . . [by] ensuring that only investments that . . . do not attempt to misuse the system are protected."²¹

In *Phoenix Action Ltd v Czech Republic*, the Tribunal noted that:

"The principle of good faith has long been recognized in public international law, as it is also in all national legal systems. This principle requires parties 'to deal honestly and fairly with each other, to represent their motives and purposes truthfully, and to refrain from taking unfair advantage . . .' This principle governs the relations between States, but also the legal rights and duties of those seeking to assert an international claim under a treaty. Nobody shall abuse the rights granted by treaties, and more generally, every rule of law includes an implied clause that it should not be abused."

Lilly seeks to place undue pressure on the Canadian parliament by bringing this case to the arbitration process. This purpose is confirmed by the chief patent counsel of the Claimant "[t]he Parliament could have stepped in and fixed Canada's patent statutes, . . . [but] [t]o date they have looked the other way."²²

The Claimant's efforts to put pressure on Canadian parliament are not limited to this arbitration. The Claimant appears to use this case to bring U.S. political pressure to bear against Canada to seek changes to Canada's patent rules.²³ Therefore, *amici* argue that the Tribunal should defend against the Claimant's use of arbitration process as a lobbying strategy.

VII. This case could have an adverse chilling effect on efforts to enhance access to medicines globally

Amici highlight the far reaching implications of this case for international patent law and practice. The decision has the potential, directly or indirectly, to affect countries and people beyond those immediately involved as parties in the case. This case will consider the legality under international law, not domestic patent law, of various rules and jurisprudence.

²¹ *Phoenix Action, Ltd. v. Czech Republic*, ICSID Case No. ARB/06/5, Award (Apr. 15, 2009) at ¶ 113.

²² See Adam Behsudi, *Eli Lilly Sues Canada on Drug Patents*, POLITICO, available at <http://www.politico.com/story/2013/09/eli-lillysues-canada-over-drug-patents-96743.html> (quoting Doug Norman, Eli Lilly's chief patent counsel, in an interview with POLITICO).

²³ See Ed Silverman, *Eli Lilly vs. Canada: The Patent War Moves to Washington*, The Wall Street Journal, available at <http://blogs.wsj.com/corporate-intelligence/2014/04/14/eli-lilly-vs-canada-the-patent-war-moves-to-washington/>.

The outcome of this case will be instructive about whether other parties pursue future challenges to attack other patent systems for differences in patentability standards which frustrate their “expectations”. According to the Claimant, its investment expectation is the best deal on IP achieved anywhere else, e.g. the US. Lilly can apparently only tolerate movement on IP policy in only one direction—upward, which would mean reduced access to affordable medicines for many people. Every patent system has built-in checks and balances that seek to disseminate knowledge and promote access and innovation. A wide range of policy options and flexibilities have been built into patent systems to accommodate diverging national public health interests and objectives. Key flexibilities in the field of patent law improve access to medicines for hundreds of thousands of people and as a result may raise a variety of complex public and international law questions, including human rights considerations. Any decision rendered in this case, whether in favor of the Claimants or the Respondent, has the potential to affect the operation of those systems and thereby the public they serve.

In the years since TRIPS and NAFTA were adopted, the global community has made enormous progress toward promoting access to affordable medicines for all. The determined efforts to use TRIPS flexibilities by developing countries in the face of challenges and pressures, as well as taking innovative approaches to support the use of these flexibilities are at stake in this arbitration. If the Claimant is allowed to use international investment arbitration as a de facto appeal procedure for its frustrated “expectations”, this case will set a critical precedent for other pharmaceutical companies to challenge countries judicial and regulatory sovereignty over patent laws. Consequently, the shrinking policy space for countries will be at risk of shrinking even further, which would threaten access to affordable medicines for many people.

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