

INTERNATIONAL CENTER FOR SETTLEMENT OF INVESTMENT DISPUTES

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Washington, D.C.

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Re: Eli Lilly and Company v. Government of Canada (ICSID Case No. UNCT/14/2)

SUBMISSION OF AMICUS CURIAE BRIEF ON THE MERITS OF THE DISPUTE

February 12, 2016

Dear Members of the Tribunal,

Amici respectfully request leave from the Tribunal to submit the attached amicus curiae brief, in the above mentioned case, pursuant to Article 37(2) of ICSID's Arbitration Rules. We present this request in good time prior to the hearing on the merits and after having acquired knowledge of the written submissions of the contending parties, so as not to disrupt the arbitral proceedings, in accordance with the terms of cited article 37(2).

Amici are scholars whose research and teaching focus is intellectual property law. *Amici* have particular knowledge of the complex political and legal debates on national and international patent law and practice, intellectual property chapters in trade agreements, investment treaties, and the human right to health, including most especially access to medicines. As active participants of this debate, *amici* are uniquely placed to provide the Tribunal with a different perspective from that of the disputing parties,

particularly one touching on the right to health implications of this dispute. At the same time, *amici* bring a perspective that addresses certain matters within the scope of the dispute and that would allow the Tribunal to better evaluate the dispute.

Firstly, the patent right is a negative right granted upon procedures and laws set forth by a given state. It confers the right to exclude others doing or making anything that falls within the subject-matter contained in the patent's claims. It is not inherently given and does not provide positive privileges. It is given under particular circumstances, only if certain criteria are met, and does not guarantee positive privileges in the marketplace, such as approval by a drug regulatory authority.

The patent system is based on a theory that there is a bargain between a patent owner and society, in which society grants the exclusivity to restrain others from using the invention in exchange for disclosure of the invention. The ultimate goal of the patent system is to promote progress of science and technology through dissemination of knowledge while promoting a balance between the interests of the inventors, the user, and the public-at-large.

Secondly, whether or not a particular invention can be granted a patent depends on jurisprudences and practices under national patent laws. Countries have sovereign rights to adopt various standards on patentability while nonetheless maintaining baseline compliance with the imprecise but minimum standards set forth in the North American Free Trade Agreement's (NAFTA) Chapter 17 on intellectual property and the World Trade Organization's (WTO) Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS). NAFTA members make patents available for inventions that are new, result from an inventive step and are capable of industrial application. They can do so via differing definitions, standards, procedures, legal doctrines and approaches. They can be amended legislatively, and be re-interpreted and re-defined judicially, including through appellate review at the national levels. Patent rules and doctrines are permitted to and have evolved over time in all NAFTA member states respectively to achieve public policy objectives, including health objectives. The same situation is also found among all members of TRIPS.

Thirdly, patents are subject to potential court reviews at national levels. It is common knowledge that a patent law system in compliance with NAFTA requirements does not automatically render a guarantee of patent granting on any applications in all member states in the same manner. Patents can be revoked, according to a NAFTA rule, if grounds exist to justify a refusal. It is not unusual for courts to overturn initial patent grants or uphold the rejection of unmerited applications and to clarify and develop patent standards and doctrines. Hence, Canada has the right to define, reason, modify and implement its own rules and doctrines for patent utility and disclosure, and implement through its judicial procedures, as allowed by NAFTA and TRIPS.

In the present case under dispute, according to Canadian rules on patentability, Eli Lilly and Company should have demonstrated or soundly predicted their inventions' usefulness at the time of patent filing. This is a long standing rule in Canadian jurisprudence, though it has also evolved and been clarified over time, and has been applied continuously and consistently in Canadian judicial practices to different types of parties without prejudice. Eli Lilly has had sufficient access to and received full judicial process,

including appellate review all the way to Canada's highest court. As a result of failing to fulfill the clearly defined and reasoned patentability criteria, Eli Lilly's patents were found to be unworthy and were revoked with soundly justified grounds.

Canada's patentability standards and its judicial applications are consistent with the Chapter 17 requirements of NAFTA. The invalidation of the Claimant's patents is a legitimate judicial practice in compliance with NAFTA. It does not qualify as "indirect expropriation" under Chapter 11 of NAFTA and does not give rise to a violation of minimum standards of treatment.

The Claimant asks the Tribunal to look at the legality under international law, not domestic patent law, of Canada's patent law and its patent jurisprudence. *Amici* also point out that the factor that gives this case particular public interest is that the investment dispute centers on pharmaceutical-related patent law and practice.

The Claimant's claim rather merely appears to reflect the Claimant's dissatisfaction with Canadian patent law and jurisprudence. Meanwhile, 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. Therefore, *amici* argue that the Claimant's claims are unjustified and should be dismissed.

The outcome of this case will be instructive about whether other foreign investors pursue future attacks on substantive policies embedded in national patent systems through the arbitral proceedings challenging differences in patentability standards that frustrate their "expectations".

Therefore, *amici* underline the strong public health and public interest components of this case both for NAFTA countries and other countries as well. The dispute that is currently carried on in this case has far reaching implications for international patent law and practice concerning permissible variability in patent rules and the allowed flexibility of patent law to evolve over time, even if that evolution upsets pharmaceutical companies' expectation of uninterrupted monopoly profits..

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 millions of people and the wider implications of this case 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 patent systems and thereby the public and human rights interests they serve and affect.

In the years since NAFTA and TRIPS were adopted, the global community has made enormous progress toward promoting access to affordable medicines for all. The Doha Declaration on the TRIPS Agreement and Public Health provides one example while international trade law reconciliates the objective of access to medicines for all by affirming the use of flexibility of intellectual property rules by its members. Those developments have greatly supported the scaling up of access to medicines on critical diseases at a global level. Efforts to use flexibilities in intellectual property laws in the face of public health

challenges and pressures, as well as taking innovative approaches to support the use of these flexibilities, are at stake in the current dispute brought by the Claimant in this arbitration. If the Claimant was allowed to use international investment arbitration as a *de facto* appeal procedure for its frustrated “expectations” to national substantive laws, this case will set a critical precedent for other pharmaceutical companies to freely challenge countries’ judicial and regulatory sovereignty over patent laws before or after having exhausted the national due process, and to overthrow the rule of law principles at both national and international levels. Consequently, the space to use flexibilities of intellectual property laws as currently enshrined by both NAFTA and TRIPS rules, would shrink further thus putting access to affordable medicines for all under threat. *Amici* emphasise the importance for the Tribunal to consider the critical public implications of the current dispute as described above.

Amici are academics from the United States, United Kingdom, Switzerland, South Africa and Nepal. None of the *amici* has received any financial or other support from any of the contending parties in relation to the elaboration of this amicus curiae submission.

Kind Regards,

On behalf of *Amici*,

[signed]

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