IN THE MATTER OF AN ARBITRATION UNDER CHAPTER ELEVEN OF THE NORTH AMERICAN FREE TRADE AGREEMENT AND THE UNCITRAL ARBITRATION RULES (1976)

BETWEEN:

ELI LILLY AND COMPANY

Claimant/Investor

AND:

GOVERNMENT OF CANADA

Respondent/Party

(Case No. UNCT/14/2)

APPLICATION FOR LEAVE TO FILE A NON-DISPUTING PARTY *AMICUS CURIAE* SUBMISSION BY INTELLECTUAL PROPERTY LAW PROFESSORS 12 FEBRUARY 2016

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I. Introduction

The group of intellectual property law professors described below (collectively "Applicants") applies for the status of *amicus curiae* on critical legal issues of public concern before this Tribunal in the arbitration between Eli Lilly and Company ("Lilly") and the Government of Canada ("Canada") and the United States of America. Applicants make this Application pursuant to the Statement on Non-disputing Party Participation adopted by the NAFTA Free Trade Commission on October 7, 2003.

II. Description of the Applicants

The Applicants are a group of seven law professors who teach, research, and write on patent law and international intellectual property law and policy, and who are thus concerned with the integrity of the legal systems that secure innovation to its creators and to the companies that commercialize it in the marketplace.

The group is comprised of Gregory Dolin (University of Baltimore School of Law); Christopher Holman (University of Missouri-Kansas City School of Law); Jay Kesan (University of Illinois School of Law); Erika Lietzan (University of Missouri-Columbia School of Law); Adam Mossoff (George Mason University School of Law); Kristen Osenga (University of Richmond School of Law); and Mark Schultz (Southern Illinois University School of Law) who together seek to submit the attached brief as *amici curiae*.

The group is an ad hoc group that has come together for purposes of offering an *amicus curiae* submission in this action. Such efforts are common in the legal academic community to serve the public interest, and many of the professors in this group have participated in other such efforts before many tribunals. No member of the group has any affiliation, direct or indirect, with any disputing party. Applicants have received strictly *pro bono* legal support from its counsel Simon J. Elliott and Foley & Lardner LLP. No other government, person or organization, besides the Applicants, has provided any financial or other assistance in preparing the submission.

III. Interest of the Applicants

The named Applicants are professors possessing an interest and professional background in intellectual property law generally and especially as it relates to heath care and patented drugs. These professors have a strong interest in ensuring that patent law and the legal precedent applying it do not serve to undermine patent rights or to reduce innovation with regard to patented products, most especially with regard to drugs.

The Applicants are concerned that Canada's "promise utility doctrine" is inconsistent with global norms regarding patentability requirements and with the function and goals of the patent system. The standard essentially demands that inventors delay their patent application until they have developed the invention sufficiently to soundly predict its efficacy as a marketable product. This puts patenting much later on the path from lab to market than the global norm. The delay risks interfering with inventors' ability to secure investment to commercialize their inventions and interferes with their ability to obtain patents globally. This result is particularly harsh for innovation in new drugs and treatments for disease.

In seeking *amicus* standing, the Applicants seek to inform the tribunal regarding global norms regarding industrial applicability and how Canada's departure from these norms clashes with the goals and functions of the patent system.

IV. Issues of Fact and Law Raised by Applicants

In the attached submissions, Applicants submit:

1. Canada's promise utility doctrine departs greatly from global norms regarding the industrial application requirement. The submission summarizes the standards for industrial applicability in the major-patent granting jurisdictions of Europe, Japan and the USA, as well as the United Kingdom. Outside of Canada, the standard for industrial application or utility as interpreted and applied is liberal, focusing on concepts such as "plausibility" or "credibility."

2. The long-standing and clear trend outside Canada is toward convergence on more liberal requirements for industrial application, making Canada's recent increasing stringency a notable departure in the opposite direction. This trend is particularly notable among the top patent-granting countries, which have converged on liberal standards of utility or industrial application.

3. The promise utility doctrine's departure from global norms is further illustrated by its incompatibility with the functions and institutions of the patent system. An overly strict utility standard requires extensive further research and potentially even clinical trials to show that the new product does what it claims before a patent may be obtained. This demand impractically pushes the time of patenting further down the path of commercialization—the very path that a patent is supposed to open. The delay in getting a property right makes it less likely an inventor can secure the necessary funding to satisfy the more stringent standard.

4. The promise doctrine is also incompatible with the patent system's incentives toward early disclosure of inventions. The patent system contains many incentives for early disclosure, including first to file priority and bars for disclosure, public use, or commercialization of the invention before filing. Contrary to all of these other incentives, the promise utility doctrine strongly urges an inventor to wait to further develop its invention before filing.

5. The promise doctrine also conflates the role of the patent office – an agency that determines eligibility for property rights – with the role of a health regulator, which determines the efficacy of medicines. For the reasons explained in the submission, patent offices are not well-suited to this role.

For these reasons, Applicants believe that the promise utility doctrine contravenes NAFTA Article 1709, a point that ultimately supports Eli Lilly & Company's claim against the Government of Canada under NAFTA Chapter 11.

V. Reasons For Accepting The Submissions By Applicants

Pursuant to paragraph 2(h) of the procedures set forth by the Free Trade Commission in its October 7, 2003 Statement on Non-disputing Party Participation, the Applicants refer to the four factors to support this Application:

1. *Applicants' submission would assist the Tribunal in the determination of a factual or legal issue.* The issue of whether the promise utility doctrine contravenes NAFTA Article 1709 is clearly raised by the arbitration. The submission explains global norms regarding the

application of the industrial application requirement, as well as how industrial application should function within the context of the patent system.

2. *Applicants' submission would address matters within the scope of the dispute.* Whether the promise utility doctrine contravenes NAFTA Article 1709, and more broadly the question of global norms concerning the industrial application requirement, are key to the ultimate determination as to whether Lilly is entitled to the relief requested pursuant to Chapter 11.

3. *Applicants have significant interest in the arbitration.* As set out in part III above, Applicants have a significant interest and expertise in patent and international intellectual property law issues. This Arbitration raises these matters.

4. *Public interest in the arbitration.* The functioning of the global patent system, particularly with respect to innovation in the biopharmaceutical sector is key to public health, and thus involves the public interest.

For the foregoing reasons, Applicants request amicus standing, pursuant to the rules and procedures adopted by the NAFTA Free Trade Commission on October 7, 2003.

Respectfully submitted,

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