Under the Arbitration Rules of the
United Nations Commission on International Trade Law and
the North American Free Trade Agreement
(Case No. UNCT/14/2)

ELI LILLY AND COMPANY

Claimant,

v.

GOVERNMENT OF CANADA,

Respondent.

MOTION FOR LEAVE TO FILE BRIEF OF PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA (PhRMA), MEXICAN ASSOCIATION OF THE RESEARCH BASED PHARMACEUTICAL INDUSTRY (AMIIF), AND BIOTECHNOLOGY INNOVATION ORGANIZATION (BIO) AS *AMICI CURIAE* IN SUPPORT OF CLAIMANT

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INTRODUCTION

1. The Pharmaceutical Research and Manufacturers of America ("PhRMA"), Mexican Association of the Research Based Pharmaceutical Industry ("AMIIF"), and Biotechnology Innovation Organization ("BIO") (collectively, "Amici") respectfully request leave to file a non-disputing party submission in this matter. Amici are trade associations whose members are adversely affected by Canada's so-called "promise utility doctrine." The submission Amici seek to file explains how the promise utility doctrine disproportionately affects biopharmaceutical companies and negates the business certainty innovators need to undertake the inherently risky and extraordinarily expensive investments involved in developing innovative medicines.

2. Shepherding a new drug from discovery to distribution takes an average of more than 10 years and 2.6 billion dollars (USD). Based on our members' experience, investments of that magnitude are feasible only when innovators have sufficient certainty that, upon development of a safe and effective drug or treatment, their patent claim concerning the underlying discovery will be respected. The promise utility doctrine destroys that assurance. The pressure it imposes to delay filing of a patent application (while data are collected) substantially increases the risk that an innovation will be denied patent protection on novelty or non-obviousness grounds. This risk is particularly acute in the biopharmaceutical industry, because researchers must make myriad disclosures during clinical testing—and in doing so, may defeat the novelty of *their own* innovations. Further, biopharmaceutical companies operate on a global scale, and cannot simply delay filing patent applications (which require disclosures) in other countries while they labor to satisfy Canada's heightened utility standard. Finally, and perhaps most importantly, because Canadian courts apply the promise utility doctrine

inconsistently, it is never clear *what promise* will later need to be fulfilled. As a result, innovators are essentially forced to gamble the huge sums required for biopharmaceutical development on whether their application will survive the promise utility doctrine. Amici respectfully submit that a fuller exposition of this dilemma, as set out in their proposed submission, is worthy of this Tribunal's consideration.

INTERESTS OF THE NON-DISPUTING PARTIES

3. PhRMA is a voluntary, nonprofit association representing the United States' leading innovative pharmaceutical and biotechnology companies, which are devoted to discovering and developing medicines that enable patients to live longer, healthier, and more productive lives. Those efforts produce the cutting-edge medicines, treatments, and vaccines that save, prolong, and improve the quality of the lives of countless individuals around the world every day. PhRMA's members are the primary source of the many new drugs and biologics introduced each year. Since 2000, PhRMA members have spent more than half a trillion dollars (USD) on research and development. PhRMA seeks to advance public policies that foster innovation and encourage its members' investments. To those ends, PhRMA seeks to remove barriers that may arise in a nation's systems, including the patent laws, for protecting the intellectual property of its members.[1]

4. AMIIF has existed for more than 65 years and currently represents 43 pharmaceutical companies with operations in Mexico. AMIIF works very closely with different stakeholders to increase the health system's performance, to demonstrate the relationship between health and productivity, and to illustrate the fact that a better intellectual property system can increase the level of innovation and investment in Mexico.

[1] PhRMA, 2015 Profile: Biopharmaceutical Research Industry 26 (April 2015), *available at* http://phrma.org/sites/default/files/pdf/2015_phrma_profile.pdf.

5. BIO is the world's largest trade association representing the biotechnology industry in all fifty U.S. states and abroad. BIO has more than 1,100 members, including businesses, biotechnology centers, and academic institutions. BIO members undertake research and development of biotechnological health care, agricultural, environmental, and industrial products, including life-saving drugs. BIO's members range from Fortune 500 companies to research universities and small start-up companies. Approximately 90% of BIO's corporate members have annual revenues under $25 million.[2]

6. Both PhRMA and BIO are persons of the United States, and both have a significant presence in the territory of the United States. AMIIF is a person of Mexico, and has a significant presence in Mexico's territory. Eli Lilly is a member of each of the three associations, but Eli Lilly did not participate in the decision to file or otherwise assist in the preparation of this submission. Other than payment of its general membership dues, Eli Lilly did not provide direct financial assistance with this submission. No other government, person, or organization other than amici or their counsel has provided any financial or other assistance in preparing this motion or the non-party submission discussed herein.

REASONS TO ACCEPT THE SUBMISSION

7. "In determining whether to grant leave to file a non-disputing party submission," this "Tribunal will consider … the extent to which": (i) "the non-disputing party submission would assist the Tribunal in the determination of a factual or legal issue related to the arbitration by bringing a perspective, particular knowledge or insight that is different from that of the disputing parties"; (ii) "the non-disputing party submission would address matters within the scope of the dispute"; (iii) "the non-disputing party has a significant interest in the arbitration";

[2] Biotechnology Innovation Organization, About BIO, *available at* http://www.bio.org/articles/about-bio.

and (iv) "there is a public interest in the subject-matter of the arbitration." STATEMENT OF THE FREE TRADE COMMISSION ON NON-DISPUTING PARTY PARTICIPATION ("STATEMENT"), Part B ¶ 6. Each of those factors counsels in favor of accepting Amici's submission.

8. Amici's submission would provide this Tribunal with knowledge and a perspective not fully presented by any of the disputing parties. Eli Lilly's submission ably explains the impermissible shift in Canadian patent law embodied in the promise utility doctrine, as well as why that shift is unlawful under NAFTA and in tension with the PCT. *See, e.g.*, Notice of Arbitration at 25–27; *see also* STATEMENT, Part B ¶ 2(g) (requiring identification of the issues of law raised by the applicant). But Eli Lilly's focus is, understandably, on the particulars of the invalidations of its Zyprexa® and Strattera® patents—not the broader significance of this issue for the entire biopharmaceutical industry. Amici are uniquely well-positioned to reflect the views of the industry as a whole and to provide this Tribunal with valuable information concerning the application of the promise utility doctrine in Canada and the context in which the promise utility doctrine will reverberate.

9. The proposed submission addresses matters squarely within the scope of this dispute: the unique nature of and burdens imposed by the promise utility doctrine, including its discriminatory effects on the biopharmaceutical industry. In particular, it stresses why the doctrine's application to biopharmaceutical patents is dangerous and unsustainable.

10. Amici have a significant interest in the arbitration, because of the adverse effect the promise utility doctrine has on their members' research efforts and business plans. As noted, the cost of developing a safe and effective, marketable drug is extraordinary. Invalidation of even a single patent thus can be an economically catastrophic event. The threat of invalidation not only looms over existing patents, it also weighs against members' future investment. The

scale of the investments at stake is substantial; PhRMA estimates that in 2014, for example, its members spent more than $51 billion (USD) on research and development of new medicines.

11. The risk of discouraged investment in biopharmaceutical innovation obviously affects Amici's members. And it means, just as certainly, that there is a public interest in the subject-matter of the arbitration. Innovative biopharmaceutical research is not only the lifeblood of the organizations that conduct that research; it is also, in many instances, critical for the health and well-being of individuals suffering from illness and disease. The public's interest in this arbitration is beyond dispute.

CONCLUSION

12. For the foregoing reasons, the Tribunal should grant Amici leave to file a non-disputing party submission in this matter.

Date: February 12, 2016

Respectfully submitted,

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