

Under the Arbitration Rules of the  
United Nations Commission on International Trade Law and  
Chapter 11 of the North American Free Trade Agreement  
(Case No. UNCT/14/2)

**ELI LILLY AND COMPANY**

*Claimant*

- and -

**GOVERNMENT OF CANADA**

*Respondent*

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**APPLICATION TO SUBMIT  
AMICUS CURIAE SUBMISSIONS**

**Submitted by  
INNOVATIVE MEDICINES CANADA and BIOTECANADA**

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## I. ABOUT INNOVATIVE MEDICINES CANADA AND BIOTECANADA

1. Innovative Medicines Canada (“**IMC**”) is the Canadian national association of research-based pharmaceutical companies, representing over 50 member companies throughout Canada,<sup>1</sup> ranging from start-ups to established enterprises. With more than 500 therapeutic products presently under development in Canada, IMC members invest more than \$1 billion annually into researching and developing new medicines and vaccines for treating and curing illnesses and diseases.<sup>2</sup> The innovative pharmaceutical industry supports 34,000 high-quality, well-paying jobs in Canada, and creates an overall economic impact of more than \$3 billion a year on Canada’s economy.<sup>3</sup>

2. Originally founded in 1914, IMC is a non-profit organization federally incorporated in Canada under the *Canada Non-for-profit Corporations Act* with a head office located in Ottawa Ontario, Canada. IMC has no “parent” organization and is the national voice representing Canada’s innovative pharmaceutical companies. IMC’s mission is to advocate for policies that enable the discovery, development and commercialization of new medicines and vaccines that improve the lives of all Canadians.<sup>4</sup>

3. Pursuant to its mission, IMC actively engages with Canadian federal, provincial, and territorial governments in developing the laws and policies that impact the innovative industry in Canada. This activity includes regular consultations with the Canadian government on issues relating to intellectual property protection for pharmaceuticals, legislative reform, industrial and economic initiatives, and international trade. For example, most recently, IMC was actively involved in consultations relating to intellectual property provisions in the Comprehensive Economic and Trade Agreement and the Trans-Pacific Partnership Agreement. IMC was also granted leave to intervene in *Apotex Inc. et al. v. Sanofi-Aventis et al.*, a 2014 Supreme Court of Canada proceeding involving Canada’s patent law and the “promise utility doctrine”, in which no decision ultimately issued as the case was discontinued by the appellant.<sup>5</sup>

4. In addition to these activities, IMC is also active on the ground in funding health research in Canada. In 1964, IMC founded the Health Research Foundation (“**HRF**”), which is one of Canada’s leading non-profit, private health research foundations. Through the HRF, IMC assists in funding health research in Canadian universities and promotes the benefits of research-driven health innovation in Canada. The HRF and its partners have contributed over \$29 million in funding to 1,700 researchers across Canada, with new investments made annually.<sup>6</sup>

5. BIOTECCanada (“**BTC**”) is the national association of the Canadian biotechnology industry with over 200 members located nationwide, reflecting the diverse nature of Canada’s health, industrial and agricultural biotechnology sectors.<sup>7</sup> The majority of biotech research in Canada is health-based and the health biotech firms create products including therapies and drugs, vaccines and new diagnostic and testing equipment.<sup>8</sup>

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<sup>1</sup> See Schedule “A” to the *amicus curiae* submissions.

<sup>2</sup> Research and Development, online: IMC <<http://innovativemedicines.ca/innovation/research-and-development/>>.

<sup>3</sup> About our Industry, online: IMC <<http://innovativemedicines.ca/about/our-industry/>>.

<sup>4</sup> Innovative Medicines 2015 Annual Report, online: IMC <<http://innovativemedicines.ca/about/2015-annual-report/>>.

<sup>5</sup> *Apotex Inc. et al. v. Sanofi-Aventis et al.* (S.C.C.) Court File No. 35562.

<sup>6</sup> See About Canada’s Health Research Foundation, online: HRF <<http://www.hrf-frs.com/en/about>>.

<sup>7</sup> See About BIOTECCanada, online: BTC <<http://www.biotecanada.ca/en/who-we-are/overview.aspx>>.

<sup>8</sup> See Better Healthcare, online: BTC <<http://www.biotecanada.ca/en/what-biotech-is/health.aspx>>.

6. Established in 1987, BTC is a federally incorporated in Canada under the *Canada Non-profit Corporations Act* with a head office located in Ottawa Ontario, Canada. Its operations include, among others, addressing regulatory and intellectual property issues that affect the entire biotech health-sector from start-up to multi-national, and to ensure innovative life-saving biotech treatments are developed in Canada and are available to Canadian citizens.<sup>9</sup>

7. Two thirds of BTC's members are small and emerging companies that are pre-commercial and do not have a positive revenue stream. These members invest heavily in research, requiring investment from third parties, which makes access to capital the number one priority. The primary means of attracting investment from such third parties is the company's patent portfolio. As such, Canadian biotech industry relies heavily on the patents for its survival and to compete international for investment capital. BTC works to increase access to financing by encouraging regulatory and legislative changes that create incentives for investors to put their money into this innovative sector.<sup>10</sup> In order to achieve these goals, BTC has actively engaged in matters relating to the Canadian patent system, such as participating as an intervener in *Apotex Inc. et al. v. Sanofi-Aventis et al.*

8. IMC and BTC therefore understand very well the importance of securing and enforcing intellectual property rights in Canada, based on a uniquely broad and industry-wide perspective that is rooted in both commercial reality and public policy.

## II. RELATIONSHIP BETWEEN THE DISPUTING PARTIES AND IMC AND BTC

9. Eli Lilly Canada Inc. ("**Lilly Canada**"), the indirectly owned and controlled Canadian subsidiary of the Claimant, Eli Lilly and Company ("**Lilly**"),<sup>11</sup> is a member company of the IMC and BTC. The President and General Manager of Lilly Canada sits on IMC's Board of Directors, along with 11 other individuals from other member companies. Lilly Canada therefore neither controls nor makes decisions on IMC or BTC's behalf and the content of IMC and BTC's submissions in this arbitration was determined by IMC and BTC alone.<sup>12</sup>

10. As with any other industry association, IMC and BTC routinely advocate on behalf of the wider member companies and industry, including by acting as *amicus curiae* and intervener in both domestic court proceedings and international arbitrations. Given the size and breadth of IMC and BTC's memberships, nearly every dispute of interest to IMC and BTC will directly involve at

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<sup>9</sup> See About BIOTECCanada, online: BTC <<http://www.biotecanada.ca/en/who-we-are/overview.aspx>>.

<sup>10</sup> See Financing, online: BTC <<http://www.biotecanada.ca/en/policy-matters/financing.aspx>>.

<sup>11</sup> See Eli Lilly's Notice of Arbitration at para 16.

<sup>12</sup> In this regard, IMC notes that the NAFTA Chapter 11 Tribunal in *United Parcel Service of America Inc. v. Canada* granted the US Chamber of Commerce leave to participate as a non-disputing party, where the claimant in the case, UPS, was a member of the US Chamber. See Award on Merits, May 24, 2007 at para 3, and the leave application of the US Chamber of Commerce, October 20, 2005 at para 9. See also *AES Summit Generation Limited and AEX-Tisza Eronmu Kft v. Republic of Hungary*, ICSID Case No. ARB/07/22, where the tribunal accepted an *amicus curiae* brief by the European Community under ICSID Rule 37(2) notwithstanding the status of Hungary as an EU Member State. ICSID Rule 37(2) includes factors regarding the acceptance of non-disputing party submissions similar to those provided under subsections B.6(a), (b) and (c) of the Statement of the Free Trade Commission on Non-Disputing Party Participation (see Award, September 23, 2010 at para 8.2). See also *Ioan Micula, Viorel Micula, S.C. European Food S.A., S.C. Starmill S.R.L. and S.C. Multipack S.R.L. v. Romania*, ICSID Case No. ARB/05/20, where the tribunal similarly allowed the participation of the European Community notwithstanding Romania's status as an EU Member State (see Award, December 11, 2013 at para 27), and *Philip Morris Brand Sarl (Switzerland), Philip Morris Products S.A. (Switzerland) and Abal Hermanos S.A. (Uruguay) v. Oriental Republic of Uruguay*, ICSIC Case No. ARB/10/7, where the tribunal allowed an *amicus curiae* brief from the World Health Organization and Pan American Health Organization notwithstanding Uruguay's membership in those organizations. (See Procedural Order No. 3 at para 1-3 and Procedural Order No. 4 at para 1-3, respectively.)

least one of their respective members. IMC and BTC's contributions, however, are not member-specific, but reflect the associations' views based on its broader industry and commercial experience. IMC and BTC are free to provide input that may differ from the interests of any given member directly affected by the outcome of a proceeding in which the associations participate.

11. Finally, as noted above, while IMC and BTC regularly consult with all levels of government on important legal and public policy issues impacting the innovative pharmaceutical industry and biotechnology industry, the Government of Canada has had no involvement in IMC and BTC's submissions in this arbitration. Neither IMC nor BTC is otherwise affiliated, directly or indirectly, with either disputing party in this proceeding.<sup>13</sup>

### III. NATURE OF IMC AND BTC'S INTEREST IN THE ARBITRATION

12. IMC and BTC have a direct and significant interest in this arbitration. Specifically, the outcome of this arbitration will have a significant impact on the laws and policies that affect the broader innovative pharmaceutical industry and biotechnology industry in Canada.

13. As described above, it is IMC's mission to improve the lives of all Canadians through advocacy of policies for enabling the discovery, development and commercialization of new medicines and vaccines. Likewise, BTC works to ensure innovative life-saving biotech treatments are developed in Canada and are available to Canadian citizens. As discussed in detail in the *amicus curiae* submissions, it is IMC and BTC's position that Canada's "promise utility doctrine" is a serious impediment to fostering the discovery, development, and commercialization of new medicines and vaccines in Canada. This explains why, for example, IMC and BTC have previously intervened in a domestic court proceeding involving the "promise utility doctrine."<sup>14</sup>

14. IMC and BTC's interest in this arbitration is both significant and direct because the outcome goes to the heart of the mission and objectives of IMC and BTC and will have immediate implications for the operations of its large and varied membership. As discussed above, IMC represents many innovative pharmaceutical companies operating throughout Canada. Each of the 25 cases in Canada since 2005 involving patent invalidations under the new "promise utility doctrine" concerned patents belonging to an IMC member or a company affiliated with an IMC member.<sup>15</sup> In addition, the survival of the health biotech companies that BTC represents -- especially the pre-commercial emerging firms with no positive revenue stream which represent two thirds of BTC's membership -- is heavily dependent on a sound and adequate patent system, given that biotech firms' patent portfolio is the primary means of attracting investment from third parties. As described in more detail in IMC and BTC's *amicus curiae* submissions, the development of an innovative drug is a long-term venture that involves significant risk and cost. The viability of any project for the discovery, development, and commercialization of a new medicine or vaccine depends heavily on the patent system. The "promise utility doctrine" is the basis for the invalidation of tremendously valuable patents in Canada. For that reason, the "promise utility doctrine" is directly detrimental to IMC and BTC's member company operations in Canada. The "promise utility doctrine" has also had a significant adverse impact on the attractiveness of

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<sup>13</sup> Nor have IMC and BTC received any financial or other assistance from either of the disputing party in preparing these submissions. As a member company of the associations, Lilly Canada pays annual membership dues in the normal course in the same manner as any other members of the associations.

<sup>14</sup> *Apotex Inc. et al. v. Sanofi-Aventis et al.* (S.C.C.) Court File No. 35562.

<sup>15</sup> See Expert Report of Bruce Levin dated September 7, 2015 in Case No. UNCT/14/2, Appendix C, para. 1 (the number has since increased from 25 to 27 cases invalidating pharmaceutical patents for lack of utility, including: *Gilead Sciences, Inc. v. Idenix Pharmaceuticals, Inc.*, 2015 FC 1156 and *Eli Lilly Canada Inc. v. Hospira Healthcare Corporation*, 2016 FC 47).

Canada as a destination for further and future research and development investment. It is difficult, therefore, to understate the importance of this matter to IMC and BTC and their wider memberships.

15. The outcome of this arbitration is also of direct and significant public interest in Canada. Canadians have benefitted for decades from access to new and ground-breaking medicines and vaccines for treatment of a wide-variety of conditions, including long-term and acute diseases. The “promise utility doctrine” and its impact on patent rights are of particular concern, as innovative companies in Canada face the challenge of an expensive and lengthy process for developing new pharmaceuticals without reasonable assurance that they will be able to recoup those investments under Canada’s patent system. Specifically, Canada’s new “promise utility doctrine” creates considerable uncertainty as to whether or not pharmaceutical patents for products approved and sold in Canada will be declared invalid. The public interest in this arbitration is therefore clear and it certainly extends as far as similar public interests raised in the context of other investment arbitrations.<sup>16</sup>

#### **IV. ISSUES TO BE ADDRESSED BY IMC AND BTC**

16. In its *amicus* submissions, IMC and BTC provide the following perspective, particular knowledge, and insight that is different from that of the disputing parties on the following issues:

- (a) As a matter of Canadian law, pharmaceutical patent rights are not “conditional.” Given IMC and BTC’s substantial and long-term experience with the Canadian patent system and with marketing products in Canada, based on their longstanding and large and varied memberships, IMC and BTC can provide the Tribunal with a unique and important perspective on Canada’s claim that “the grant of a patent by the Patent Office is only presumptively valid and always subject to final determination by the Federal Court based on the evidence presented to the court,”<sup>17</sup> which is in dispute in the application of Articles 1105 and 1110 to the facts in this arbitration. Important facts relating to the legal and business environment in Canada in which the wider innovative pharmaceutical industry operates, including the economic and commercial reality of pharmaceutical research and development, will assist the Tribunal in assessing Canada’s claim that pharmaceutical patent rights in Canada are “conditional.”
- (b) Another issue in dispute in this arbitration is whether or not the “promise utility doctrine” in Canada is “new.” Here again, given IMC and BTC’s substantial and long-term experience in pharmaceutical patent matters from their commercial and public policy perspective, IMC and BTC can provide the Tribunal with a unique and important perspective on the timing and degree of change in the law brought about by the “promise utility doctrine.” This will assist the Tribunal in assessing Canada’s denial of any such

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<sup>16</sup> See *Methanex Corporation v. United States of America*, Decision of the Tribunal on Petitions from Third Persons to Intervene as “*Amici Curiae*”, January 15, 2001 at para 49 cited in *Philip Morris Brand Sarl (Switzerland), Philip Morris Products S.A. (Switzerland) and Abal Hermanos S.A. (Uruguay) v. Oriental Republic of Uruguay*, ICSIC Case No. ARB/10/7, Procedural Order No. 3 at para 26, and *Biwater Gauff (Tanzania) Ltd. v. United Republic of Tanzania*, ICSID Case No. ARB/05/22, Procedural Order No. 5 at para 51. See also *Agua Argentinas, S.A., Suez, Sociedad General de Aguas de Barcelona, S.A. and Vivendi Universal, S.A. v. Argentina*, ICSID ARB/03/19, where the tribunal dealt with issues involving the water distribution and sewage systems of the City of Buenos Aires and surrounding municipalities, and found that “this case does involve matters of public interest of such a nature that have traditionally led courts and other tribunals to receive *amicus* submissions.” (See Order in Response to a Petition for Transparency and Participation as *Amicus Curiae*, May 19, 2005 at paras 19-21.)

<sup>17</sup> See, e.g., Government of Canada Counter-Memorial dated January 27, 2015 in Case No. UNCT/14/2s at para. 294.

change and that the innovative pharmaceutical industry has been disproportionately affected by this change.

- (c) Finally, it is also disputed whether Canada's "promise utility doctrine" has put Canada in violation of its international trade obligations. On this point, IMC and BTC can provide the Tribunal with a broader perspective and better industry-wide intelligence than either of the disputing party on how Canada's patent system is perceived by foreign investors and foreign governments around the world and the implications these perceptions have on Canada's ability to attract foreign investment into the Canadian innovative pharmaceutical sector.

## V. CONCLUSION

17. IMC and BTC request that the Tribunal accept their submissions as being timely and within the scope of the dispute. The IMC and BTC's submissions are based on a perspective, and on particular knowledge and insight, that is different from that of either disputing party. IMC and BTC also have a direct interest in the outcome of this dispute. As such, their submissions are fully consistent with criteria set forth in the Statement of the Free Trade Commission on Non-Disputing Party Participation in Chapter 11 Disputes and timely filed pursuant to the Tribunal's Procedural Orders No. 1 and No. 3.

**Respectfully submitted on behalf of Innovative Medicines Canada and BIOTECanada this 11<sup>th</sup> day February, 2016.**

[signed]

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