Foreign Affairs, Trade and Development Canada

Department of Justice

CANADA

Affaires étrangères, Commerce et Développement Canada

Ministère de la Justice

BY EMAIL

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Dear Members of the Arbitral Tribunal,

Re: **Eli Lilly & Company v. Government of Canada (UNCT/14/2)**

We write to provide Canada's comments on the requests to submit *amicus curiae* briefs filed in the above-captioned matter on February 12, 2016. Canada supports openness and transparency in NAFTA Chapter Eleven arbitration proceedings, including through the appropriate participation of *amici curiae*.

An essential attribute of *amici curiae* is independence from the disputing parties. Paragraph 18.1 of Procedural Order No. 1 provides that in exercising its discretion with respect to *amicus curiae* submissions under Article 15 of the *UNCITRAL Arbitration Rules, 1976*, the Tribunal will take into consideration the Statement of the Free Trade Commission on non-disputing party participation (the "FTC Statement"). The FTC

Statement requires applicants to "disclose whether or not the applicant has any affiliation, direct or indirect, with any disputing party".[1] *Amici curiae* must also be able to assist the tribunal by offering a different point of view from that of the disputing parties. Paragraph B.6(a) states that a Tribunal will consider the extent to which the submission would bring "a perspective, particular knowledge or insight that is different from that of the disputing parties".

The FTC Statement also provides that the Tribunal will ensure that "neither disputing party is unduly burdened or unfairly prejudiced" by *amicus curiae* submissions.[2] *Amici curiae* are intended to be friends of the court, not friends of a disputing party.

Canada has serious concerns about the independence of certain *amicus curiae* applicants and their ability to assist the Tribunal by bringing a perspective that differs from Claimant's. Admitting submissions from applicants that are not independent of Claimant would unfairly prejudice Canada. Therefore, on the basis of the information disclosed in their applications and publicly available information, Canada asks that the Tribunal refuse the applications for leave to file *amicus curiae* submissions of: (1) Innovative Medicines Canada ("IMC") and BIOTECanada; and (2) Pharmaceutical Researchers and Manufacturers of America ("PhRMA"), the Mexican Association of the Research Based Pharmaceutical Industry ("AMIIF"), and Biotechnology Innovation Organization ("BIO").

Canada also has concerns regarding the independence from Claimant of (3) the Canadian Chamber of Commerce and (4) the National Association of Manufacturers, but does not have enough information at this time to assess whether these applicants would be appropriate *amici curiae* in this matter.

Canada's comments on each of these applications follow.

(1) Innovative Medicines Canada and BIOTECanada

The disclosure provided by IMC and BIOTECanada significantly understates or leaves undefined the nature and extent of their affiliation with Claimant. Based on this limited disclosure and publicly available information, Canada considers that the applicants lack the requisite independence to serve as *amici curiae*.

The application of IMC and BIOTECanada discloses that Eli Lilly Canada Ltd. ("Lilly Canada"), Claimant's wholly-owned Canadian subsidiary, is a "member company of the associations" and "pays annual membership dues in the normal course in the same manner as any other members of the associations."[3] However, the application does not disclose the magnitude of membership dues paid by Lilly Canada (*i.e.* whether different

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[1] FTC Statement, ¶ B.1.
[2] FTC Statement, ¶ B.7(b).
[3] Application to Submit *Amicus Curiae* Submissions, Submitted by Innovative Medicines Canada and BIOTECanada, *Eli Lilly and Company v. Government of Canada*, Case No. UNCT/14/2, 11 February 2016, ¶ 9, n 13.

members pay different levels of dues), other financial contributions made by Lilly Canada (*i.e.* for specific projects in addition to dues), and the overall significance of these contributions within the annual budgets of IMC and BIOTECanada. It also does not disclose the influence and stature that Claimant has within these organizations. This makes it impossible to assess the financial ties between the applicants and Claimant, and whether they are truly independent of each other.

IMC and BIOTECanada's application also discloses that Lilly Canada's President and General Manager, Ms. Lisa Matar, sits on IMC's Board of Directors.[4] The application does not clarify whether Ms. Matar recused herself from discussions on the Board of Directors relating to the decision to file an *amicus* submission in this matter or if she played any role in soliciting the *amicus* submissions by IMC and BIOTECanada. This is similarly unclear with respect to other Lilly Canada employees serving on the committees and subcommittees through which the two organizations carry out their work.[5]

Even if there was no involvement by Lilly Canada or its employees in the applicants' decision to file an *amicus* submission in this matter (which is unclear), Lilly Canada may nevertheless have influenced the applicants' position on Canada's utility requirement through previous activities and deliberations within each organization. This *amicus* submission is not the first time that IMC and BIOTECanada have determined and set out their position on Canada's utility requirement.[6] Claimant's involvement in these earlier activities and deliberations has not been disclosed.

Indeed, the lobbying efforts of Lilly Canada, IMC, and BIOTECanada on Canadian patent law issues – including the utility requirement in particular – have been closely intertwined for many years. All registration materials filed by Lilly Canada with the Officer of the Commissioner of Lobbying of Canada since at least December 19, 2005 list both IMC (formerly known as Rx&D) and BIOTECanada as a "beneficiary" of Lilly Canada's lobbying activities.[7] All six of Lilly Canada's registrations filed since October 10, 2012 expressly list the utility requirement as the subject of lobby efforts, and all list IMC

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[4] *Ibid*, ¶ 9.

[5] Canada's Research-Based Pharmaceutical Companies, *2015 Annual Report*, p. 6, available at: <http://innovativemedicines.ca/wp-content/uploads/2015/11/RXD_7097_AR_2015_Short_web.pdf> (setting out the organizational structure of IMC); BIOTECanada, "About BIOTECanada", available at: <http://www.biotecanada.ca/en/who-we-are/overview.aspx> (describing the Advisory Boards and Committees of BIOTECanada, including the "Health Advisory Board" which is "focused on the development of a strong policy, advocacy, and investment environment in Canada" and includes a sub-committee on intellectual property issues).

[6] See the 2014 Canadian court submissions of IMC and BIOTECanada addressing Canada's utility requirement: *Apotex Inc. v. Sanofi-Aventis*, Factum of the Intervener Canada's Research-Based Pharmaceutical Companies, Supreme Court of Canada File No. 35562, 16 September 2014; *Apotex Inc. v. Sanofi-Aventis*, Factum of the Intervener BIOTECanada, Supreme Court of Canada File No. 35562, 16 September 2014.

[7] Office of the Commissioner of Lobbying of Canada, Registration – In-house Corporation, Eli Lilly Canada Inc / Lisa Matar, President and General Manager, Registration Number 865672-6034, available at: <https://lobbycanada.gc.ca/app/secure/ocl/lrs/do/vwRg?cno=6034&regId=854265>.

(Rx&D) and BIOTECanada as beneficiaries.[8] This fact alone should raise serious doubts as to the independence of these organizations from Claimant.

Both IMC and BIOTECanada have previously attempted to come to the assistance of Claimant in domestic litigation in Canada, including with respect to one of the patents at issue in this case. For example, in *Eli Lilly Canada Inc. v. Novopharm*, the Federal Court of Appeal observed that IMC sought "to intervene to support the appellant, Eli Lilly"[9] and BIOTECanada similarly "supports the appellant, Eli Lilly."[10] The proceeding concerned Claimant's patent for the use of olanzapine – one of the two patents at issue in this arbitration. Both applications for leave were denied.[11]

The above considerations regarding the independence of IMC and BIOTECanada equally bear on whether these organizations would assist the Tribunal with a different "perspective, particular knowledge or insight" than Claimant's.[12] The available information indicates that IMC, BIOTECanada and Claimant are closely aligned in each of these respects, and that the applicants would not offer the Tribunal a different perspective. The roughly 50 members of IMC are innovative pharmaceutical companies highly similar in profile to Claimant.[13] Approximately half are also members of BIOTECanada.[14] The members of IMC and BIOTECanada include the Canadian subsidiaries of major multinational innovative pharmaceutical companies, such as AstraZeneca, Bristol-Myers Squibb, Pfizer, and Merck.[15] The role of these organizations is to be the national voice of pharmaceutical companies like Eli Lilly.

The application of IMC and BIOTECanada only proposes to repeat Claimant's arguments without any distinguishing or distinctive perspective appropriate to *amicus curiae* in NAFTA arbitration. The applicants' view that "Canada's 'promise utility doctrine' is a serious impediment to fostering the discovery, development, and commercialization of new medicines and vaccines in Canada"[16] has been extensively

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[8] Office of the Commissioner of Lobbying of Canada, Registration – In-house Corporation, Eli Lilly Canada Inc / Lisa Matar, President and General Manager, Registration Number 865672-6034, available at: <https://lobbycanada.gc.ca/app/secure/ocl/lrs/do/vwRg?cno=6034&regId=854265> ("Subject Matter Details … Patent Act – An Act respecting patents of invention with regard to Intellectual property Protection for pharmaceutical products – federal court decisions that have changed the disclosure requirements regarding the utility of an invention.").

[9] *Eli Lilly Canada Inc. v. Novopharm*, 2007 FCA 329, ¶ 5 (emphasis added).

[10] *Ibid.*, ¶ 4 (emphasis added).

[11] *Ibid.*, ¶ 14.

[12] FTC Statement, ¶ B.6(a)

[13] Innovative Medicines Canada, Member Companies, available at: <http://innovativemedicines.ca/about/member-companies/>.

[14] BIOTECanada, Members, available at: <http://www.biotech.ca/en/who-we-are/members.aspx>; Innovative Medicines Canada, Member Companies, available at: <http://innovativemedicines.ca/about/member-companies/>.

[15] *Ibid*.

[16] Application to Submit *Amicus Curiae* Submissions, Submitted by Innovative Medicines Canada and BIOTECanada, *Eli Lilly and Company v. Government of Canada*, Case No. UNCT/14/2, 11 February 2016, ¶ 14.

argued by Claimant.[17] Claimant, its witnesses, and its experts have already engaged at length on the three issues that IMC and BIOTECanada announce their intention to address:[18] that "pharmaceutical patent rights are not '*conditional*'",[19] "whether or not the 'promise utility doctrine' in Canada is 'new'",[20] and whether the utility requirement "has put Canada in violation of its international trade obligations."[21]

Nor does the applicants' claim to bring an industry-wide perspective distinguish their submission from Claimant's existing submissions. Claimant repeatedly argues based on the experience of "pharmaceutical companies",[22] the "pharmaceutical sector",[23] or the "industry"[24] in general. Large tracts of Claimant's pleadings and expert reports are already devoted to cases involving the patents of pharmaceutical companies other than Claimant.[25] Similarly, Claimant[26] and its expert Professor Levin[27] put forward a sector-wide statistical analysis of the alleged impact of the utility requirement. There is therefore nothing new in the applicants' proposal to address how the "innovative pharmaceutical industry has been

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[17] *See, e.g.,* Claimant's Memorial, ¶ 225 ("The characteristics of the promise utility doctrine thus conflict … with the reality of innovative drug development."); Claimant's Reply, ¶ 11 ("In its Memorial, Lilly demonstrated that the promise utility doctrine places pharmaceutical companies in a Catch-22.").

[18] Application to Submit *Amicus Curiae* Submissions, Submitted by Innovative Medicines Canada and BIOTECanada, *Eli Lilly and Company v. Government of Canada*, Case No. UNCT/14/2, 11 February 2016, ¶ 16.

[19] *Compare, e.g.,* Claimant's Reply, ¶¶ 10, 35-44 ("there is nothing 'conditional' about the legally enforceable rights that a patent conveys immediately upon issuance." (¶ 10)); Expert Report of Andrew Reddon, ¶¶ 25-29 (section entitled "Patent Rights Are Not Considered 'Conditional'").

[20] *Compare, e.g.,* Claimant's Reply, ¶¶ 69-209 (section entitled "Canada's Promise Utility Doctrine Represented a Dramatic and Fundamental Change in Canadian Patent Law…"); Second Expert Report of Norman Siebrasse, ¶¶ 13-70 (section entitled "Canada's Traditional Patent Utility Test Changed Dramatically After *AZT*").

[21] *Compare, e.g.,* Claimant's Memorial, ¶¶ 166-295 (section entitled "Canada's Termination of Lilly's Patent Rights with Regard to Zyprexa and Strattera is Inconsistent with NAFTA Chapter 11"); Claimant's Reply, ¶¶ 225-368.

[22] *See, e.g.,* Claimant's Reply, ¶ 11 ("In its Memorial, Lilly demonstrated that the promise utility doctrine places pharmaceutical companies in a Catch-22.), ¶ 202 ("But Lilly, like other pharmaceutical companies, receives substantially fewer patents per dollar of research than companies in any other industry.").

[23] *See, e.g.,* Claimant's Memorial, ¶ 26 ("In most industries, a product is ready to be sold … as soon as patent protection is granted. Not so in the pharmaceutical sector."), ¶ 71 ("In the pharmaceutical sector, the impact of this doctrinal reversal excluding post-filing evidence has been substantial."); Claimant's Reply, ¶ 4 ("Canada cannot explain … the discriminatory impact of those determinations on the pharmaceutical sector.").

[24] *See, e.g.,* Claimant's Reply, ¶ 203 ("But there is nothing strange or unusual about these patent practices. Filing multiple new use patents on a particular compound … is standard practice across the industry.").

[25] *See, e.g.*, Claimant's Memorial, ¶ 226 ("In all 23 inutility decisions under the promise utility doctrine, the patents were initially granted to innovative pharmaceutical companies headquartered outside of Canada …"); Claimant's Reply, ¶ 176 (discussing litigation concerning the compounds latanoprost, memantine, and esamaprozole), ¶ 73 n 124 (discussing cases involving "AstraZeneca's drug Nexium" and "Pfizer's drug Revatio"); Expert Report of Andrew Reddon, ¶¶ 15-18 (opining on litigation involving Pfizer's latanoprost patent); First Expert Report of Norman Siebrasse, ¶ 69 (opining on "the *Rosiglitazone* case …").

[26] Claimant's Memorial, ¶¶ 219-226; Claimant's Reply, ¶¶ 291-300.

[27] Expert Report of Bruce Levin.

disproportionately affected" by Canada's utility requirement.[28] Nor would the applicants' planned submission on "the economic and commercial reality of pharmaceutical research and development"[29] go beyond what Claimant and its witnesses have already presented at length.[30] In sum, the applicants purport to offer no additional insight beyond what Claimant has already presented.

The perspective offered by IMC and BIOTECanada also does not materially differ from that provided in the application for *amicus curiae* submissions from PhRMA, AMIIF, and BIO. Nearly half of IMC's members are affiliated with members of PhRMA, over one-third with members of AMIIF, and roughly half with members of BIO.[31] This similarity in constitution raises serious questions as to the distinct perspective these organizations offer, one from the other.

(2) Pharmaceutical Research and Manufacturers of America (PhRMA), Mexican Association of the Research Based Pharmaceutical Industry (AMIIF), and Biotechnology Innovation Organization (BIO)

The application submitted by PhRMA, AMIIF and BIO similarly raises several questions about both the independence of their views, and the distinct perspective that they would bring to the Tribunal in this proceeding. Most obviously, these amicus applicants entitled their submission: "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 *Amicus Curiae* in Support of Claimant."[32] As Canada noted above, the role of *amici* in international arbitration proceedings such as these is to assist the Tribunal, not to support a disputing party.

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[28] Application to Submit *Amicus Curiae* Submissions, Submitted by Innovative Medicines Canada and BIOTECanada, *Eli Lilly and Company v. Government of Canada*, Case No. UNCT/14/2, 11 February 2016, ¶16(c).

[29] Application to Submit *Amicus Curiae* Submissions, Submitted by Innovative Medicines Canada and BIOTECanada, *Eli Lilly and Company v. Government of Canada*, Case No. UNCT/14/2, 11 February 2016, ¶16(a).

[30] *See, e.g.,* Claimant's Memorial, ¶¶ 25-35 (section entitled "Patent Protection is the Cornerstone of Lilly's Innovative Pharmaceutical Products"); Claimant's Reply, ¶¶ 23-28 (section entitled "Lilly Filed its Patent Applications on Zyprexa and Strattera to Secure the Economic Foundation Necessary to Bring the Drugs to Market."); Witness Statement of Robert A. Armitage, ¶ 4 ("Patents today are the lifeblood of Lilly as well as of the research-based biopharma industry as a whole.").

[31] Innovative Medicines Canada, Member Companies, available at: <http://innovativemedicines.ca/about/member-companies/>; PhRMA, Member Companies, available at: <http://www.phrma.org/about/member-companies>; AMIIF, Asociados, available at: <http://www.amiif.org/asociados.html>; Biotechnology Innovation Organization, BIO Members and Web Site Links, available at: <http://www.bio.org/articles/bio-members-web-site-links>.

[32] 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 *Amicus Curiae* in Support of Claimant, 12 February 2016, p. 1 [emphasis added].

The disclosure provided by these organizations also significantly understates or leaves insufficiently defined the nature and extent of their relationship with Claimant. The application states that: "Eli Lilly is a member of each of the three associations," that Eli Lilly pays "general membership dues," and that Eli Lilly did not participate in the decision to file or assist in the preparation of the submission, financially or otherwise.[33]

However, the application does not disclose the extent of financial contributions Claimant offers to each organization. For example, while the application discloses that "approximately 90% of BIO's corporate members have annual revenues under $25 million,"[34] it does not note that those members pay significantly less in membership dues than those members with greater annual revenues. The highest-contributing member with annual revenues under $25 million contributes $51,000 per annum, while a company with Claimant's annual revenue is likely to pay $430,000 or more per annum.[35] Indeed, BIO appears to have two special levels of contributors, "Double Helix Sponsors" and "Helix Sponsors." Eli Lilly is listed as one of only six "Helix Sponsors."[36] It is also unclear whether Claimant's "sponsorship" includes financial contributions in addition to its annual membership dues.

Nor does the application disclose the role that Claimant and its subsidiaries play in developing the policy positions of each organization. For example, the application does not disclose the fact that senior Eli Lilly officials hold high-level positions in each organization:

- Dr. John C. Lechleiter, the Chairman, President & CEO of Eli Lilly is a PhRMA Board Member.[37] Dr. Lechleiter has acted as Chair of that Board within the last five years.[38] As recently as November 2014, he was Chair of the PhRMA Board's Intellectual Property Committee.[39] He was previously Board Treasurer.[40]

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[33] 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 *Amicus Curiae* in Support of Claimant, 12 February 2016, ¶ 6.
[34] 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 *Amicus Curiae* in Support of Claimant, 12 February 2016, ¶ 5.
[35] BIO, Dues Schedule & Fees, available at: <https://www.bio.org/node/3415>.
[36] BIO, Areas of Work: Intellectual Property, available at: <https://www.bio.org/category/intellectual-property>.
[37] PhRMA Board Leadership, Members and Senior Executive Team, available at: <http://phrma.org/about/leadership>.
[38] PhRMA, "Lilly's John Lechleiter Becomes PhRMA Board Chairman", April 13, 2012, available at: <http://www.phrma.org/media/releases/lillys-john-lechleiter-becomes-phrma-board-chairman>.
[39] Appendix A, Letter from Dr. John C. Lechleiter to Prime Minister Stephen Harper, 20 November 2015 (writing "As Chair of the PhRMA Board's Intellectual Property Committee, I welcome the opportunity to meet with you and some of my CEO colleagues on this matter in the context of the broad innovation climate in Canada.").
[40] PhRMA, "Pfizer's Jeffrey Kindler Becomes PhRMA Board Chairman; Christopher Viehbacher, John Lechleiter Assume New Posts", 18 March 2010, available at:

- Mr. Alex M. Azar, President of Lilly USA, sits on BIO's Health Governing Board, which "develops policy positions" and "recommends members to sit on the Board of Directors."[41]

- Mr. Carlos Baños, Director General of Eli Lilly Mexico, was President of AMIIF's Intellectual Property Committee.[42] He previously served as Vice President.[43]

Such prominent leadership roles suggest that Claimant has had a significant role in shaping each organization's policy positions. Indeed, Claimant's President and CEO, Dr. Lechleiter, wrote a letter to Prime Minister Stephen Harper in November 2014 – well after the commencement of this arbitration – with the sole purpose of conveying "our industry's concerns" about Canada's utility requirement.[44] Dr. Lechleiter described himself as "Chair of the PhRMA Board's Intellectual Property Committee" and sought to arrange a discussion on the utility requirement between the Prime Minister "and some of my CEO colleagues".[45] This plainly demonstrates the lack of independence and lack of differing perspective between the applicant and Claimant.

The material the applicants propose to address in their submission further supports the view that they lack a distinguishing or distinctive perspective appropriate to *amicus curiae* in NAFTA arbitration. Specifically, the applicants seek to address the impact of the so-called promise utility doctrine on the pharmaceutical industry "as a whole", in particular "the discriminatory effects on the biopharmaceutical industry".[46] As noted above, Claimant has addressed the significance of this issue for the industry.[47] Claimant

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<http://www.phrma.org/media/releases/pfizer%E2%80%99s-jeffrey-kindler-becomes-phrma-board-chairman-christopher-viehbacher-john-lec>.

[41] BIO, Executive Committee & Governing Boards, Health Section Governing Board, available at: <https://www.bio.org/node/3853>.

[42] Consejo para el Fomento de la Ética Médica, Dispensación y Uso Racional de Medicamentos (COFEMEDIR), Consejo Directivo, available at: <http://www.cofemedir.org.mx/?page_id=2436> (describing Mr. Baños' affiliations and involvement in the Mexican pharmaceutical industry); Forbes Mexico, Profile of Mr. Carlos Baños, available at: <http://www.forbes.com.mx/author/carlos-banos/>.

[43] *Ibid*.

[44] Appendix A, Letter from Dr. John C. Lechleiter to Prime Minister Stephen Harper, 20 November 2015, pp. 1-2 ("As promised, I am writing to provide more information regarding our industry's concerns about one particular aspect of Canada's intellectual property (IP) environment: Canada's "promise utility" doctrine. … As Chair of the PhRMA Board's Intellectual Property Committee, I welcome the opportunity to meet with you and some of my CEO colleagues on this matter in the context of the broad innovation climate in Canada.").

[45] *Ibid*.

[46] 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 *Amicus Curiae* in Support of Claimant, 12 February 2016, ¶¶ 8-9.

[47] *See, e.g.,* Claimant's Memorial, ¶¶ 17, 213-226, 291 (including the following statements: "Canada's Federal Courts have applied the promise utility doctrine in a manner that has had disproportionate effects on pharmaceutical inventions, as compared with inventions in other technological fields" (¶ 215); "… the doctrine has had disproportionate consequences on innovative pharmaceutical companies, as compared with patent holders in other fields of technology" (¶ 219)). *See also* Claimant's Reply, ¶¶ 21 ("As for discrimination, the promise utility discriminates not just against innovative pharmaceutical companies as

addresses, in detail, other patent cases in which utility was in issue.[48] The applicants have failed to explain why their membership's interests diverge from those of Claimant such that their further submissions on these issues will assist the Tribunal in deciding the dispute.

All of these connections seriously call into question the independence of this *amicus* application. In reality, the applicant organizations exist for the purpose of promulgating pharmaceutical companies' (and Claimant's) interests.

Additionally, as noted above, there is a large degree of overlap between the membership of PhRMA, AMIIF and BIO, on one hand, and IMC and BIOTECanada on the other. Canada also notes that BIOETECanada is itself a member of BIO. These overlaps raise serious questions as to whether these organizations offer distinct perspectives.

Canada also notes that Counsel for the applicant, Akin Gump Strauss Hauer & Feld LLP ("Akin Gump"), is a registered lobbyist for the Coalition for 21st Century Patent Reform,[49] a coalition of companies that features Claimant on its Steering Committee.[50] The coalition has reportedly paid Akin Gump $2.84 million for its lobbying activities in the last three years.[51] Counsel for Claimant in this arbitration, Covington & Burling LLP, is also a registered lobbyist for PhRMA.[52]

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a field of technology, it also has the effect of favoring a prominent domestic industry (generic manufacturers) at the expense of foreign patent holders."), ¶¶ 291-300, 324, 365-368; Expert Report of Bruce Levin.

[48] *See, e.g.*, Claimant's Memorial, ¶ 226 ("In all 23 inutility decisions under the promise utility doctrine, the patents were initially granted to innovative pharmaceutical companies headquartered outside of Canada …"); Claimant's Reply, ¶ 176 (discussing litigation concerning the compounds latanoprost, memantine, and esamaprozole), ¶ 73 n 124 (discussing cases involving "AstraZeneca's drug Nexium" and "Pfizer's drug Revatio"); Expert Report of Andrew Reddon, ¶¶ 15-18 (opining on litigation involving Pfizer's latanoprost patent); First Expert Report of Norman Siebrasse ¶ 69 (opining on "the *Rosiglitazone* case …").

[49] United States Senate, Query the Lobbying Disclosure Act Database (search criteria: Registrant Name = "Akin Gump Strauss Hauer & Feld" + Client Name = "Coalition for 21st Century Patent Reform"), available at: <http://soprweb.senate.gov/index.cfm?event=selectfields>. *See also* Center for Responsive Politics, Lobbyists representing Cltn for 21st Century Patent Reform, 2015, available at: <https://www.opensecrets.org/lobby/clientlbs.php?id=D000049343&year=2015>.

[50] The Coalition for 21st Century Patent Reform, Who We Are, available at: <http://www.patentsmatter.com/about/who_we_are.php>; Akin Gump Strauss Hauer & Feld LLP, Professionals – Joel Jankowsky, Partner, profile available at: <https://www.akingump.com/en/lawyers-advisors/joel-jankowsky.html>.

[51] *See* United States Senate, Query the Lobbying Disclosure Act Database (search criteria: Registrant Name = "Akin Gump Strauss Hauer & Feld" + Client Name = "Coalition for 21st Century Patent Reform"), available at: <http://soprweb.senate.gov/index.cfm?event=selectfields>. *See also* Center for Responsive Politics, Lobbyists representing Cltn for 21st Century Patent Reform, 2015, available at: <https://www.opensecrets.org/lobby/clientlbs.php?id=D000049343&year=2015>.

[52] United States Senate, Query the Lobbying Disclosure Act Database (search criteria: Registrant Name = "Covington & Burling LLP" + Client Name = "Pharmaceutical Research"), available at: <http://soprweb.senate.gov/index.cfm?event=selectfields>. *See also* Center for Responsive Politics,

(3) The Canadian Chamber of Commerce

The disclosure provided by the Canadian Chamber of Commerce leaves undefined the nature and extent of the relationship between the applicant and Claimant. While its application discloses that Claimant "is a member in good standing of the Canadian Chamber of Commerce,"[53] it does not disclose the extent of financial contributions made by Claimant to the organization. Nor does it disclose the role that Claimant plays in developing and informing Canadian Chamber of Commerce policy positions for the organization's "active[] and consistent[] engage[ment] with government and the media on issues related to international trade and intellectual property."[54]

Furthermore, the application does not disclose that Claimant is currently sponsoring a Canadian Chamber of Commerce policy project on regulatory barriers to trade. The project, which will result in a report that "draw[s] on input from members, sponsors and regulatory experts," purports to answer questions like: "How can we make sure our trade agreements result in real regulatory harmonization and mutual recognition?"[55] The project's co-sponsors include Claimant, IMC (formerly Rx&D, and another applicant for amicus status in this proceeding), and another life sciences organization of which counsel for Claimant, Gowlings, is a member.[56] These facts should concern the Tribunal as to whether the applicant and Claimant are truly independent and whether they have a unique perspective that would assist the Tribunal.

(4) National Association of Manufacturers ("NAM")

The application submitted by the NAM similarly raises questions about the independence and distinct perspective of the organization from Claimant. While the application discloses that Claimant is a member of the NAM,[57] it does not disclose the extent of financial contributions Claimant makes to the organization. Similarly, while it states that Claimant "provided no financial or other assistance with the preparation of this brief and was not part of the decision-making process for filing this submission,"[58] the

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Lobbyists representing Pharmaceutical Rsrch & Mfrs of America, 2015, available at: <https://www.opensecrets.org/lobby/clientlbs.php?id=D000000504&year=2015>.

[53] Canadian Chamber of Commerce Application of non-disputing parties for leave to file a written submission, 12 February 2016, p. 2.

[54] Canadian Chamber of Commerce Application of non-disputing parties for leave to file a written submission, 12 February 2016, p. 2.

[55] Canadian Chamber of Commerce, 2015 Policy Projects: Contribution Prospectus, p. 2, available at: <http://www.chamber.ca/advocacy/sponsorship-opportunities/2015_Policy_Project_Contribution_Prospectus.pdf>.

[56] Canadian Chamber of Commerce, Annual Report 2015, p. 33, available at: <http://www.chamber.ca/download.aspx?t=0&pid=6dc6a01d-e3b3-e511-bb93-005056a00b05>.

[57] Application for Leave to File *Amicus Curiae* Submission by the National Association of Manufacturers, 12 February 2016, ¶ 14.

[58] Application for Leave to File *Amicus Curiae* Submission by the National Association of Manufacturers, 12 February 2016, ¶ 14.

application does not disclose the role Claimant plays in shaping the organization's policy positions. Instead, the application describes that the NAM's "formal policy positions, approved by the NAM Board of Directors, specifically identify international intellectual property protection as a top issue."[59] It does not disclose that Mr. Enrique Conterno, one of Claimant's Senior Vice Presidents, sits on the NAM Board.[60] As with the Canadian Chamber of Commerce, these facts should be of concern to the Tribunal.

* * *

For the foregoing reasons, Canada asks that the Tribunal refuse the requests to submit *amicus curiae* briefs of (1) IMC and BIOTECanada and (2) PhRMA, AMIIF, and BIO. Allowing their admission would cause serious prejudice to Canada and unfairly permit Claimant to, in essence, exponentially expand its legal team and its legal submissions.

Canada also draws the Tribunal's attention to the above-noted concerns regarding the independence of (3) the Canadian Chamber of Commerce and (4) the National Association of Manufacturers, but does not have enough information at this time to assess whether they are sufficiently independent of Claimant to avoid prejudice to Canada and assist the Tribunal as *amici curiae*.

Yours sincerely,

[signed]

Mark A. Luz
Senior Counsel
Trade Law Bureau

encl: Appendix A, Letter from Dr. John C. Lechleiter to Prime Minister Stephen Harper

cc: Marney Cheek, John Veroneau, James M. Smith, Alexander A. Berengaut
Richard Dearden and Wendy Wagner, counsel to Claimant
Lindsay Gastrell, ICSID, Tribunal Secretary

[59] Application for Leave to File *Amicus Curiae* Submission by the National Association of Manufacturers, 12 February 2016, ¶ 5 [emphasis added].
[60] National Association of Manufacturers, About, Board of Directors, available at: <http://www.nam.org/About-Us/Board-of-Directors/Landing-Page.aspx>.