

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

**CLAIMANT'S COMMENTS ON APPLICATIONS
FOR LEAVE TO FILE *AMICUS* SUBMISSIONS**

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19 February 2016

1. This arbitration has attracted a significant number of potential *amici*. As explained further below, Claimant Eli Lilly and Company (“Lilly”) believes that several of the *amicus* submissions reflect valuable perspectives that merit the Tribunal’s attention. At the same time, “in the interest[] of fairness and the orderly conduct of arbitrations under Chapter 11,”¹ *amici* participation should comport with the principles established by Article 15 of the UNCITRAL Arbitration Rules and the NAFTA Free Trade Commission in its Statement on Non-Disputing Party Participation (the “FTC Statement”).² In particular, pursuant to the FTC Statement, applicants for leave to file *amicus* submissions should demonstrate that they:

- are “person[s] of a [NAFTA] Party, or . . . [have] a significant presence in the territory of a Party” in accordance with paragraph B.1 of the FTC Statement ; and
- “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”;
- “would address matters within the scope of the dispute”; and
- “ha[ve] a significant interest in the arbitration” in accordance with paragraph B.6 of the FTC Statement.³

With these principles in mind, Lilly offers the following comments on the *amicus* applications pending before the Tribunal.⁴

¹ *Statement of the Free Trade Commission on Non-Disputing Party Participation* (NAFTA Free Trade Commission, October 7, 2003) [hereinafter FTC Statement].

² *Pope & Talbot Inc. v. Canada*, Canada’s Letter to the Tribunal of 1 October 2001, at 1 (CL-178); see also *Merrill & Ring Forestry L.P. v. Canada*, NAFTA/UNCITRAL, Respondent’s Observations on Amicus Petition (16 July 2008), at 3 (“The FTC Statement Provides Appropriate Guidelines for Accepting Non-Disputing party Briefs in this Case”) (CL-179).

³ See FTC Statement, at ¶¶ B.1, B.6 (“Any non-disputing party *that is a person of a Party, or that has a significant presence in the territory of a Party*, that wishes to file a written submission with the Tribunal (the ‘applicant’) will apply for leave from the Tribunal to file such a submission.”) (emphasis added).

⁴ Claimant makes this submission pursuant to Paragraph 18.2 of Procedural Order No. 1 and Paragraph 5 of Procedural Order No. 3.

I. Trade Associations

2. The Tribunal has received *amicus* applications from three groups of innovative and generic pharmaceutical trade associations based in Canada, the United States, and Mexico: Innovative Medicines Canada and BIOTECanada (“IMC/BIOTECanada”); Pharmaceutical Research and Manufacturers of America, the Mexican Association of the Research Based Pharmaceutical Industry, and the Biotechnology Innovation Organization (“PhRMA, AMIIF and BIO”); and the Canadian Generic Pharmaceutical Association (“CGPA”). In addition, two broader North American trade associations whose members include both pharmaceutical and non-pharmaceutical companies with an interest in, and experience with, Canada’s intellectual property practices – the Canadian Chamber of Commerce and the National Association of Manufacturers – have also sought leave to make *amicus* submissions. All of these associations are persons of a NAFTA Party, consistent with the nationality provisions of paragraph B.1 of the FTC statement.

3. Further, these associations are comprised of members that have a significant interest in the stability and reasonableness of Canadian patent law, particularly as applied to pharmaceutical patents.⁵ As set out in their applications, IMC, BIOTECanada, PhRMA, AMIIF, BIO, and CGPA represent firms of vastly different sizes that play different roles in the pharmaceutical industry – from the “small and emerging . . . pre-commercial” research companies represented by BIOTECanada⁶ to the “manufacturers and distributors of finished generic pharmaceutical products” represented by CGPA.⁷ The Canadian Chamber of Commerce and the National Association of Manufacturers also represent the views of firms in other industries that rely on intellectual property rights.

4. Lilly notes that CGPA’s submission is drafted by Jonathan Stainsby, who acted as counsel for generic manufacturer Teva Novopharm Ltd. (now Teva Canada Ltd.) in the domestic Zyprexa and Strattera cases – *i.e.*, in the cases revoking the very patents at

⁵ Cf. *United Parcel Service of America Inc. v. Government of Canada*, NAFTA/UNCITRAL, Award on the Merits (24 May 2007), at ¶ 3 (“the Chamber of Commerce of the United States of America applied for leave to file” an *amicus* submission; “Canada did not object to the application”) (CL-177).

⁶ Application for Leave to File Amicus Submissions by IMC/BIOTECanada (12 Feb. 2016), at 1.

⁷ Application for Leave to File Amicus Submissions by CGPA (12 Feb. 2016), at 1.

issue in this dispute. Lilly takes issue both with CGPA's gross mischaracterizations of the domestic litigation and with CGPA's spurious attempt to question Lilly's good faith in bringing this arbitration – arguments that Lilly will respond to in its substantive filing of 22 April 2016. For present purposes, however, given that CGPA's members include the vast majority of the generic pharmaceutical companies that have benefitted from the invalidation of a patent under the promise utility doctrine and thus CGPA has a significant interest in the outcome of this dispute, Lilly does not oppose CGPA's application should the Tribunal determine that the criteria for admission are met.

II. Academic Submissions

A. Drs. Ruse-Khan, Liddell, and Waibel

5. Lilly opposes the application of Drs. Henning Gross Ruse-Khan, Kathleen Liddell and Michael Waibel, who do not meet the nationality test under the FTC Statement. These three prospective *amici* do not claim to be persons of a NAFTA Party, nor do they claim to be persons with a significant presence in North America. Rather, on the face of their submissions, they appear to be European residents,⁸ employed by a European university,⁹ whose *amicus* submission is funded by a grant issued by “a UK government-funded research and training agency.”¹⁰ The prospective *amici* do not address paragraph B.1 of the FTC Statement, and thus do not offer any exceptional circumstances or considerations that might justify departing from the nationality provisions of that paragraph.

B. Dr. Hu, Prof. Ho, Dr. McDonagh, Mr. Upreti, and Mr. Heled

6. Lilly also opposes the *amicus* participation of the three non-NAFTA persons – Dr. Hu Yuanqiong, Dr. Luke McDonagh and Mr. Pratyush Upreti – who filed a leave application together with two U.S.-based academics. As with Drs. Ruse-Khan, Liddell and Waibel, these three non-NAFTA persons, who are based in the United Kingdom and

⁸ Application for Leave to File Amicus Submissions by Dr. Henning Gross Ruse-Khan, Dr. Kathleen Liddell, and Dr. Michael Waibel (12 Feb. 2016), at 1, 5.

⁹ *Id.* at 1.

¹⁰ *Id.* at 5, n. 10.

Nepal,¹¹ do not meet the nationality requirement of the FTC Statement. The applicants do not make reference to FTC Statement’s paragraph B.1 in their application for leave, and they offer no explanation why Dr. Yuanqiong, Dr. McDonagh, and Mr. Upreti should be allowed to participate as *amici* even though they are not persons of a NAFTA Party.

7. At the same time, Lilly observes that both Professor Cynthia Ho and Mr. Yaniv Heled state that they are affiliated with universities (Loyola University of Chicago and Georgia State University) that have a significant presence in the territory of a NAFTA Party (the United States). To the extent the Tribunal determines that applicants’ submission meets the other criteria set out in the FTC Statement, Lilly does not oppose granting leave to Professor Ho and Mr. Heled. Dr. Hu Yuanqiong, Dr. Luke McDonagh and Mr. Pratyush Upreti should be rejected as *amici* since they are not persons of a NAFTA Party.

C. Remaining Academic Submissions

8. The remaining academic submissions by the Canadian Internet Policy & Public Interest Clinic and the Centre for Intellectual Property Policy (“CIPPIC/CIPP”) and the group of seven IP scholars (Profs. Dolin, Holman, Kesan, Lietzan, Mossoff, Osenga, and Schultz) meet the nationality criterion in paragraph B.1 of the FTC Statement.¹² Both sets of prospective *amici* consist of persons of a NAFTA Party. In addition, the seven IP scholars have established their ability to put forward an experienced, independent perspective on two core issues in dispute: “Canada’s departure from [global] norms” regarding patent utility, and the absence of a rational policy justification for this departure.¹³ Lilly, therefore, supports admission of these seven scholars as *amici*.

* * *

¹¹ Application for Leave to File Amicus Submissions by Dr. Hu Yuanqiong, Dr. Cynthia Ho, Dr. Luke McDonagh, Mr. Pratyush Upreti and Mr. Yaniv Heled (12 Feb. 2016), at 4, 5. Dr. Yuanqiong is affiliated with the University of London, but lists an address in Switzerland.

¹² In reviewing the seven IP scholars’ Leave Application, Covington & Burling LLP learned that a former Covington partner, Erika Lietzan, has joined that submission as *amicus*. For avoidance of doubt, Covington confirms that Professor Lietzan had no involvement in Covington’s representation of Lilly in this arbitration.

¹³ Application for Leave to File Amicus Submissions by Profs. Dolin, Holman, Kesan, Lietzan, Mossoff, Osenga, and Schultz 12 Feb. 2016), at 2-3.

9. In sum, Lilly believes it is appropriate to grant leave to IMC/BIOTECanada, PhRMA, AMIIF, and BIO; the Canadian Chamber of Commerce; the National Association of Manufacturers; and the seven IP scholars. To the extent that the Tribunal considers they have met the criteria for admission, Lilly does not oppose the admission of CGPA, CIPPIC/CIPP, and Professor Ho and Mr. Heled. While Lilly has substantial concerns with respect to the content of the proposed submissions by CGPA, CIPPIC/CIPP, and Professor Ho and Mr. Heled, Lilly is prepared to respond to these submissions on the merits should the Tribunal grant the relevant applications for leave.

10. Lilly does, however, oppose the *amicus* applications of Drs. Ruse-Khan, Liddell, and Waibel, and Dr. Hu Yuanqiong, Dr. Luke McDonagh, and Mr. Pratyush Upreti. These applicants have failed to demonstrate compliance with the basic criteria set forth in the FTC Statement.

11. Consistent with the Tribunal's Procedural Orders,¹⁴ Lilly reserves its comments on the substance of all *amicus* submissions that are granted leave by the Tribunal.

Respectfully submitted,

[signed]

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¹⁴ Procedural Order No. 1, ¶ 18.2; Procedural Order No. 3, ¶ 5.