Eli Lilly and Company, Claimant/Investor
and
Canada, Respondent/Party

(Case No. UNCT/14/2)

APPLICATION FOR *AMICUS CURIAE* STATUS

BY THE CANADIAN GENERIC PHARMACEUTICAL ASSOCIATION

INTRODUCTION

1. The Canadian Generic Pharmaceutical Association ('CGPA') hereby applies for leave to file a non-disputing party submission in the North American Free Trade Agreement ('NAFTA') Chapter 11 arbitration between Eli Lilly and Company ('Lilly') and Canada in Case No. UNCT/14/2. The CGPA's application is made pursuant to Procedural Order No. 1 in this arbitration, Article 15 of the UNCITRAL Arbitration Rules (1976), and the recommendation of the North American Free Trade Commission on non-disputing party participation, dated October 7, 2013 ('FTC's Statement on *Amici*').

2. The CGPA is an industry association that represents manufacturers and distributors of finished generic pharmaceutical products and active pharmaceutical chemicals, as well as suppliers of other goods and services to the generic pharmaceutical industry. Over the past two decades, members of the CGPA have been involved in the majority of actions and applications in Canada that have examined the validity of patents. Further, the CGPA itself has been granted leave to appear as an Intervener at the Supreme Court of Canada on six occasions in patent matters.

Public Interest in this Arbitration

3. There is a clear public interest in the subject matter of this arbitration, which involves a consideration of and, potentially, an adjudication upon central and substantive aspects of Canadian patent law. This public interest is more fully elucidated below.

The CGPA and its members represent the public interest

4. The members of the CGPA, as regular litigants before the Federal Courts and the Supreme Court of Canada, rely on the consistency of Canadian patent law in making decisions as to whether to engage in the time-intensive and costly endeavour of challenging the validity of patents.

5. The generic medications marketed by the members of the CGPA are essential to the health of Canadian citizens; having lower-cost versions of drugs means greater

access for all who are prescribed those drugs. Also, due to the substantial difference between the monopoly prices charged by brand name drug manufacturers and the members of the CGPA, many important drugs in Canada are only available as generic versions. For some important drugs, the brand name drug manufacturers have stopped selling them entirely, rather than competing on price with generic manufacturers.

6. To encourage the marketing of generic drugs in Canada, the *Food and Drugs Act* permits a generic drug company to seek regulatory approval for a drug by submitting to Health Canada an abbreviated new drug submission ('ANDS') comparing its drug product to a brand name drug product which has already been approved by Health Canada through the issuance of a Notice of Compliance ('NOC'). By comparing a generic drug with a previously approved brand name drug, the generic drug company avoids the need to undertake costly and time-consuming clinical trials, thereby expediting low-cost generic drug entry into the Canadian market.

The CGPA's members ensure timely access to less expensive medication

7. There is a significant public interest in Canada for timely access to cost-saving generic alternatives to brand name prescription drugs. According to IMS Health data, total expenditures on prescription drugs were $23.3 billion (CAD) in 2014. To help control health-care costs, Canada depends on a steady supply of safe, effective generic prescription medicines. In 2014, generic medicines were dispensed to fill 67.1% of all prescriptions but accounted for only 22.6%, or $5.5 billion, of the total dollar value Canadian prescription drug market. According to 2014 IMS Health data, the average cost of a brand name prescription was $85.11, while the average cost of a generic prescription was $21.34. The availability of generic drugs in Canada has a significant effect on drug expenditures in Canada by public provincial drug plans, private drug insurance plans and the Canadians who pay for their prescriptions out of pocket. If generic drug manufacturers were to be impeded in their efforts to bring new products to market, the cost to governments and Canadian consumers would soar. CGPA estimates that the use of generic drugs saved Canadians nearly $15 billion in 2014.

8. If granted leave to file an *amicus* brief, the CGPA will provide a different perspective from the parties by focusing on the broader issue of maintaining the proper balance and promoting predictability in Canadian patent law and in the Canadian patent system as a whole, for the benefit of all, including the Canadian public, the CGPA, and the CGPA's members. The matter before the Tribunal risks promoting and encouraging changes to longstanding Canadian jurisprudence that the fundamental balance in Canadian patent law, known as the "bargain theory" of patent law, fosters and upholds. Accordingly, there is a risk that the decision on this arbitration will create or at least foster uncertainty and unpredictability in Canadian law, including for generic pharmaceutical manufacturers.

The CGPA has no conflict in this arbitration

9. The CGPA is self-funding its participation in this arbitration and has no direct affiliation with any disputing party. The CGPA has not received any support, financial or otherwise, in the course of the preparation of this application and the attached submissions. The CGPA's application is supported by the International Generic and Biosimilar Medicines Association ('IGBA'), and by its member organizations from the United States and Mexico, namely the Generic Pharmaceutical Association ('GPhA') and Mexican Association of Generic Medicines ('AMEGI'). A copy of a letter dated January 21, 2016 from the IGBA is attached as Appendix 'A' to this application.

10. As mentioned above, the CGPA is an industry association and its members are generic pharmaceutical manufacturers, some of whom engage in litigation with brand name pharmaceutical manufacturers, including Lilly. Although members of the CGPA have been involved in litigation with Lilly, the litigation that underlies this arbitration is exhausted. Moreover, the CGPA was not itself involved in litigation with Lilly and therefore the CGPA submits it has no direct or indirect affiliation with either party to the arbitration.

11. Counsel for the CGPA was counsel in the proceedings that led to the invalidation of Lilly's patents for atomoxetine (Strattera) and olanzapine (Zyprexa) in Canada, as well as in the CGPA's most recent three interventions at the Supreme Court of Canada. Counsel was retained on the basis of expertise and familiarity with the complex subject matter of this arbitration and recent experience working with the CGPA.

ISSUES OF FACT AND LAW RAISED BY CGPA

12. The CGPA makes no submissions on the facts in dispute in the present arbitration.

13. The CGPA makes submissions regarding patent law in Canada, including:

a. The CGPA's perspective;

b. Substantive Canadian patent law issues:

i. There is no so-called "promise doctrine";

ii. The doctrine of sound prediction is well-defined in Canadian law;

iii. The disclosure requirements of the doctrine of sound prediction are fully compatible with Canada's international treaty obligations;

c. The potential impact of the Tribunal's decision on the:

i. Canadian patent law;

ii. Canadian public; and

iii. CGPA's members.

14. The CGPA's perspective on the issues raised on this arbitration is discussed below.

CGPA'S SUBMISSIONS SHOULD BE ACCEPTED BY THE TRIBUNAL

15. Pursuant to paragraph 2(h) of the FTC's Statement on *Amici*, the CGPA is to explain, with reference to the four factors set out in paragraph 6, why the CGPA's submissions will assist the Tribunal and should therefore be accepted for submission in this arbitration.

The CGPA's submissions will 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

16. The CGPA's submissions will assist the Tribunal in several ways, particularly with respect to the long-standing existence of the doctrine of sound prediction, on which the Supreme Court of Canada's, as well as the Canadian Federal Court's and Federal Court of Appeal's, views regarding the necessity of proper disclosure is fundamental.

The CGPA's submissions address matters within the scope of the dispute

17. The CGPA's submissions relate to the matters at issue between the parties to the arbitration. No external evidence is submitted with the CGPA's submissions. The submissions rely on materials already submitted by the parties and provide additional jurisprudence released by the Canadian courts since the arbitration commenced. This new jurisprudence may be relevant to the Tribunal's determination in this arbitration. Nothing in the CGPA's submissions exceeds the ambit of the arbitration, as defined by the parties' own submissions.

The CGPA has a significant interest in the arbitration

18. The CGPA represents generic pharmaceutical manufacturers in Canada, and in so doing, is well-positioned to speak to the public interest in timely access to generic medicine. That timely access is dependent upon a predictable and well-defined patent law in Canada. The impact of this arbitration may potentially affect the substantive content of Canadian patent law in a way that adversely affects the interests of the CGPA's member companies and the public interest in timely access to generic medicine.

There is a public interest in the subject matter of the arbitration

19. Should the Tribunal accept the argument that there has in recent years been a radical shift in Canadian patent law, that outcome may lead to or encourage the amendment of Canadian patent legislation or a shift in patent jurisprudence, such that it may become more difficult for generic manufacturers to obtain timely and predictable regulatory approval of their generic drug products. Increased

unpredictability and costs associated with patent litigation would lead to increased expense and likely higher pricing by the CGPA's members. The Canadian public, which depends on timely access to less expensive generic medications for maintaining quality of life, treating chronic or acute disease, or preserving life, may suffer by diminished or delayed access to generic alternatives to expensive brand name medications.

20. Maintaining a patent system that respects the balance between patent protection (to encourage innovation) and timely access to generic medications (to ensure quality of life) is a matter of significant public interest. A unanimous Supreme Court of Canada expressly acknowledged the need for balance over fifteen years ago, where it stated "There is a high economic cost attached to uncertainty and it is the proper policy of patent law to keep it to a minimum."[1] These economic costs will be borne by the Canadian public and the CGPA's members.

CONCLUSION

21. The CGPA would be a suitable and appropriate *amicus curiae* in the present arbitration. The CGPA is specially positioned to speak to the significant public interest in the outcome of this arbitration and the risk of high economic costs to the Canadian patent system as an *amicus* before this honourable Tribunal. The CGPA's submissions will focus on Canadian patent law, and in so doing, provide support for the Tribunal's eventual findings of fact and law in this arbitration.

The above Application and the attached Submissions are respectfully submitted by the Canadian Generic Pharmaceutical Association, this 12th day of February, 2016, by counsel for the Canadian Generic Pharmaceutical Association:

[signed]

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[1] *Free World Trust v. Electro Santé Inc.*, 2000 SCC 66 at para 42 (C-189).

Appendix ‘A’

INTERNATIONAL GENERIC AND BIOSIMILAR MEDICINES ASSOCIATION

January 21, 2016

By E-Mail

Jim Keon
President
Canadian Generic Pharmaceutical Association
Suite 409
4120 Yonge Street,
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Re: CGPA application for *amicus curiae* status in NAFTA Case No. UNCT/14/2 (*Eli Lilly and Company v. Canada*)

Dear Mr. Keon:

The International Generic and Biosimilar Medicines Association ('IGBA') supports the Canadian Generic Pharmaceutical Association's ('CGPA') application for *amicus curiae* status in Case No. UNCT/14/2. The CGPA's application and its proposed submissions are supported by the IGBA, itself, and by its member organizations from the United States and Mexico, namely the Generic Pharmaceutical Association ('GPhA') and Mexican Association of Generic Medicines ('AMEGI').

The IGBA was founded in March 1997 as an international network of generic medicine associations. The IGBA includes member organizations from Canada, the United States, Mexico, Europe, Japan, Jordan, South Africa, Taiwan, Australia and Brazil. Its mandate is to address issues important to the generic pharmaceutical industry by maintaining dialogue with the World Health Organization, the World Trade Organization, the World Intellectual Property Organization, the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use and other international organizations. Important aspects of the IGBA's role include encouraging access to affordable quality medicines, ensuring timely access for patients, promoting the harmonization of global regulations relating to quality of drugs, and improving regulatory and legal expertise relating to the manufacture of high quality generic medicines.

The IGBA believes that the CGPA's submissions will provide insight that is different from the positions advanced by the disputing parties. As the IGBA member organization from Canada, the

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CGPA has specific knowledge of Canadian patent law and the generic pharmaceutical industry in Canada. Accordingly, the CGPA is particularly well situated to address the public interest aspect of this arbitration.

The IGBA agrees with the CGPA's view that permitting a party to an arbitration under NAFTA Chapter 11 (or any other international treaty or trade agreement) to revisit extensive legal arguments that have been resolved before domestic courts has the very real potential to undermine the legal rights of generic pharmaceutical manufacturers that are members of the IGBA's member associations in the United States, Mexico and elsewhere, and to create a climate of uncertainty harmful to the generic pharmaceutical industries in those jurisdictions. This impact is all the more probable where, as here, the party purporting to challenge the domestic legal decisions expressly disavows any denial of natural justice or procedural fairness by the domestic courts.

Generic pharmaceutical companies (including members of the IGBA and its member associations) rely on predictable domestic patent laws and on the finality of patent law decisions rendered by domestic courts. These fundamental principles are threatened by any supra-national measures or any decisions of arbitral bodies that might call into question the principles of domestic patent laws and/or the finality of domestic legal decisions on patent matters.

Yours sincerely,

Mr. Vivian Frittelli
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