

**In the Arbitration under Chapter 11 of the
North American Free Trade Agreement and
the UNCITRAL Arbitration Rules**

BETWEEN:

Eli Lilly and Company

CLAIMANT/INVESTOR

- and -

Government of Canada

RESPONDENT/PARTY

APPLICATION FOR *AMICUS CURIAE* STATUS

**SAMUELSON-GLUSHKO CANADIAN INTERNET POLICY
& PUBLIC INTEREST CLINIC
&
CENTRE FOR INTELLECTUAL PROPERTY POLICY**

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INTRODUCTION

1. The Canadian Internet Policy & Public Interest Clinic (“CIPPIC”) and the Centre for Intellectual Property Policy (“CIPP”) apply for the status of *amicus curiae* on critical legal issues of public concern before this Tribunal in the arbitration between Eli Lilly and Company and the Government of Canada.

DESCRIPTION OF THE APPLICANTS

2. **Samuelson-Glushko Canadian Internet Policy & Public Interest Clinic (CIPPIC)** - CIPPIC is a public interest technology law clinic founded by the University of Ottawa, Faculty of Law. CIPPIC’s mandate is to ensure balance in policy and legal decision-making on issues raised at the intersection of law and technology by participating in public and legal debates on those issues. CIPPIC advocacy includes interventions in various levels of court, expert testimony before parliamentary committees, involvement in Internet governance related matters before various quasi-judicial tribunals, and the publication of academic and advocacy reports on Internet law related issues. CIPPIC has intervened in the Supreme Court of Canada on numerous occasions to address legal and policy issues arising at the intersection of law and technology, including in intellectual property cases. Notably, CIPPIC, partnered with CIPP, was granted leave to intervene at the Supreme Court of Canada to address the synergistic relationship between the substantive Canadian requirements for patentability and the appropriate basis for comparing Canadian patent law to that of other jurisdictions (*Apotex v Sanofi-Aventis*, 2014 SCC Court File No 35562).
3. **Centre for Intellectual Property Policy (CIPP)** - The CIPP is an internationally recognized, independent, not-for-profit think tank sitting within McGill University’s Faculty of Law. Its mission is to ensure that Canada’s patent laws further innovation by adequately protecting inventors while facilitating continual innovation of goods and services that are made available to Canadians. Possessing over a decade of intensive work on patent law and policy, CIPP brings the latest knowledge about patent law and innovation to those engaged in legal and policy development.

4. It is central to the CIPP's mission to intervene in litigation in which the balance of patent law is at stake. Two internationally peer-reviewed, large-scale projects directly support these efforts. The first, VALGEN (Value Addition through Genomics and GE3LS), a project sponsored by the Government of Canada through Genome Canada, Genome Prairie, and Genome Quebec, mandates the translation of academic and policy studies in the field of agricultural biotechnology into tangible policies and law. PACEOMICS (Personalized, Accessible, Cost-Effective Applications of 'Omics Technologies), a project sponsored by Genome Prairie, Genome Alberta, Genome Quebec and the Canadian Institutes for Health Research, specifically funds direct engagement in litigation.
5. The CIPP's mandate to assist other countries in ensuring balance with their own patent systems, using Canadian law as an exemplar, is supported by a grant from Grand Challenges Canada, which itself is funded by the Government of Canada and is dedicated to supporting novel approaches to attaining global health.
6. National and international organizations rely on the CIPP for research and policy advice. These include the World Health Organization, the World Intellectual Property Organization, the Ontario Ministry of Health and Long Term Care, and the Canadian Biotechnology Advisory Committee. Heavily involved in the Russian Civil Reform Project (2001-2007), the CIPP's work has been credited with having both strengthened legislation and helped accelerate the Russian reform process.
7. Through its Members, the CIPP submitted amicus curiae briefs on the patentability of human genes in the *AMP v Myriad Genetics* 569 US 12-398 (2013) case before the Supreme Court of the United States and the United States Court of Appeals for the Federal Circuit.
8. The pursuit of fair and balanced intellectual property systems has historically informed, and continues to inform, the research and policy agenda of the CIPP. For example, the CIPP's Abuse of Rights of Intellectual Property Law research project has been ongoing since 2007 and addresses the dangers involved in both the distortion of intellectual property rights from their original spirit and their application in a manner contrary to their intended function.

INDEPENDENCE OF THE APPLICANTS

9. As with all public universities in Canada, the University of Ottawa and McGill University receive funding from the federal government. However, neither CIPPIC nor CIPP receive core funding or operational funding from the Government of Canada. CIPPIC is entirely self-funded; CIPP receives some federal government financing through arms-length agencies. CIPPIC and CIPP have no affiliation with Eli Lilly and Company. Neither CIPPIC nor CIPP are being funded in any way by any third party in respect of their potential involvement in this arbitration.

ISSUES OF FACT AND LAW RAISED BY THE APPLICANTS

10. If permitted to intervene, CIPPIC and CIPP will submit:
 - a. Throughout the history of Anglo-American patent law, Canadian courts have played a supervisory role to ensure that the Crown does not abuse the public by granting overly broad patents. This is why it is the courts, and not the Patent Office, that have the last word on the patentability of inventions.
 - b. NAFTA was never intended to prescribe substantive patentability requirements that are frozen in time. Rather, Chapter Seventeen of NAFTA establishes the minimum requirements that each Party must address in its domestic patent laws; how to implement the laws are up to nations.
 - c. Trade law requires comparison of the overall effect of NAFTA Parties' patent laws, not their individual patent rules. The relevant question for the Tribunal is, therefore, whether Canadian patent law overall has a different effect from that of its trading partners.
 - d. A functional comparison of Canadian, American, and Mexican patent law reveals that utility in Canadian law is functionally equivalent to (a) the United States requirements of utility and enablement, and (b) the Mexican requirements that an invention be capable of industrial application and sufficiently described.

WHY THE TRIBUNAL SHOULD ACCEPT THESE SUBMISSIONS

11. **CIPPIC and CIPP offer a different and unique perspective:** As independent bodies with highly relevant expertise, CIPPIC and CIPP are in a unique position to assist the Tribunal in appreciating the domestic and international contexts and implications of the issues that arise in this arbitration. CIPP

has conducted research precisely on the issues raised in this arbitration and this research has been submitted to peer review and published by both academic and professional journals.

12. Free from the private interests of both the brand name and generic pharmaceutical industries (and free from funding from either), CIPPIC and CIPP will advance submissions that are different from the other parties. As small academic institutions, CIPPIC and CIPP are well-positioned to present a unique perspective, different from that of the Government of Canada. CIPPIC and CIPP bring a critical understanding of the comparative legal study of patent laws of Canada, Mexico and the United States. The submissions will be solely motivated by CIPPIC and CIPP's missions to promote functional and effective patent regimes and helping other countries learn from Canada's experience. CIPPIC and CIPP have no economic stake in the outcome of the arbitration, but because of their commitment to the public interest, are deeply concerned with the implications of the issues involved.
13. There is no similar independent institution with a mission similar to that of CIPPIC and CIPP likely to address the foundational principles underlying the disposition of this arbitration. Only CIPPIC and CIPP are likely to seek to assure that Canadian, Mexican and American patent laws are compared on the basis of their overall effect, consistent with fundamental principles of trade law.
14. Should CIPPIC and CIPP's arguments not be heard, the Tribunal will forgo the opportunity to fully hear and appreciate the public interest at stake, as there is no other independent organization with sufficient expertise to raise such issues in a comprehensive manner. Protecting the public interest is at the very core of the Centres' missions; CIPPIC and CIPP will therefore unavoidably suffer prejudice if leave to intervene were not granted.
15. **Matters within the arbitration:** All of CIPPIC and CIPP's submissions are directly relevant to the issues raised by Parties in the course of their pleadings. We adduce no external evidence, and rely upon the pleadings of the arbitrating parties to establish the legal parameters of these proceedings. While CIPPIC and CIPP bring their own perspective and expertise to these issues, nothing in the attached submissions lies outside of these parameters.
16. **CIPPIC and CIPP have a direct and compelling interest in the issues before the tribunal:** Led by their shared missions to advocate for the public interest, and expertise in comparative patent law, CIPPIC and CIPP have a direct and compelling interest in the issues before the Tribunal. CIPPIC and

CIPP's core mandate is to intervene on public policy matters of fundamental importance. This arbitration is just such a case. The present arbitration raises issues concerning each NAFTA Party's ability to create and fine-tune their own patent laws, proper comparative law methods in the context of trade law, and the functional equivalence between Canada's patentability requirements and those of its trading partners.

17. In CIPPIC and CIPP's view, NAFTA did not create harmonized substantive patent law requirements between Canada, the United States, and Mexico. Applying a narrow interpretation of Chapter Seventeen would risk each Party's autonomy to implement patent laws responsive to their own unique legal and social systems. Further, CIPPIC and CIPP seek to demonstrate how a functional comparison of the overall outcomes of the Parties' patent laws reveals that each Parties' patentability requirements interact synergistically to enforce promises made in patent applications.
18. **The public interest in this arbitration:** This arbitration raises important issues regarding the ability of NAFTA Parties to craft domestic patent laws that meet the unique social, economic, and legal needs of nations. More specifically, issues of whether and to what extent NAFTA permits the evolution of the Parties' domestic laws and jurisprudence are raised. The public interest of each NAFTA Party's autonomy to implement patent laws within their unique legal and social systems, and to permit patent law evolution to respond to new technologies is at stake. This arbitration also raises questions about what NAFTA and other trade agreements have to say about the substantive content of patent law, and more broadly, the substantive content of copyright and trademark law. Addressing these issues of fundamental public concern is crucial to maintaining a robust and dynamic marketplace for patented inventions.

Respectfully submitted this 12th day of February, 2016, by counsel for the Applicants,



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