

**AN ARBITRATION UNDER CHAPTER 11 OF THE NAFTA AND THE UNCITRAL  
ARBITRATION RULES, 1976**

between

**ELI LILLY AND COMPANY**

Claimant

and

**GOVERNMENT OF CANADA**

Respondent

**(CASE NO. UNCT/14/2)**

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**APPLICATION FOR LEAVE TO FILE AMICUS SUBMISSIONS  
BY  
DR HENNING GROSSE RUSE-KHAN, DR KATHLEEN LIDDELL AND  
DR MICHAEL WAIBEL**

**UNIVERSITY OF CAMBRIDGE**

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**12 February 2016**

Address for Correspondence  
Lauterpacht Centre for International Law  
5 Cranmer Road  
CB3 9BL Cambridge  
United Kingdom  
kml23@cam.ac.uk; hmg35@cam.ac.uk; mww27@cam.ac.uk

## **INTRODUCTION**

1. On 5 November 2015 the Tribunal in *Eli Lilly and Company v. Government of Canada* (ICSID Case No. UNCT/14/2) invited any person or entity that was not a disputing party in the arbitration to apply to the Tribunal for permission to file a written submission as an amicus curiae. On 15 January 2016 the Tribunal subsequently extended the deadline to apply for permission to file a written submission until 12 February 2016.
2. The Tribunal stated that it will be guided by the Statement of the NAFTA Free Trade Commission on non-disputing party participation ('NAFTA FTC Statement'). This application sets out reasons justifying why Dr Kathleen Liddell, Dr Henning Grosse Ruse-Khan and Dr Michael Waibel should be granted leave to file a non-disputing party brief to the Tribunal, based upon the NAFTA FTC Statement. These three legal academics are associated with three research centres at the University of Cambridge with expertise directly relevant to this arbitration.

## **THE AMICUS BRIEF WILL BE OF ASSISTANCE TO THE TRIBUNAL**

3. The arbitration presents novel questions at the intersection of patent and international investment law that are a matter of considerable public interest. The Tribunal's determination of the issue will have important implications for patent law flexibilities. The Tribunal would benefit from having the widest possible range of views, including our view.
4. Our joint expertise spanning patent law, pharmaceuticals, international intellectual property law and international investment law would assist the Tribunal in its determination of legal issues related to this arbitration by bringing an independent perspective, particular knowledge, and insight that is different from the disputing parties and their legal experts, and goes beyond their perspective in important respects.
5. We are academics with considerable experience at the University of Cambridge, one of the leading law schools. We are fellows at three research centre at Cambridge with expertise directly relevant to this arbitration. The three research centres are the Centre for Law, Medicine and Life Sciences ('LML') the Centre for Intellectual Property and Information Law ('CIPIL') and the Lauterpacht Centre for International Law ('LCIL'). Each centre is well-known in its area of expertise.
6. Dr Liddell is the Herchel Smith Senior Lecturer in Intellectual Property Law and Director of LML; Dr Grosse Ruse-Khan is Acting Director of CIPIL and University Lecturer in Intellectual Property Law; Dr Waibel is University Senior Lecturer in International Law and Deputy Director of the Lauterpacht Centre for International Law.
7. Dr Liddell's expertise would assist the Tribunal with its determination of the legal issues related to the arbitration because:

- Her expertise is on the laws that control the development and commercialisation of biotechnology, including patent law and pharmaceuticals, and other legislation and common law affecting medical research and technology.
  - Her experience in these matters includes her position as a Member of the Working Party that composed the Nuffield Council on Bioethics' report on Medical Profiling and Online Medicine.
8. Dr Grosse Ruse-Khan's expertise would assist the Tribunal with its determination of the legal issues related to the arbitration because:
- His expertise concerns international intellectual property protection and development issues; as well as the interfaces of intellectual property protection with international investment- and human rights law.
  - He has advised International organization such as WIPO and governments in developing and developed countries on international intellectual property law, including the intersection with international investment law.
  - He has been working on international intellectual property and its interfaces with other areas of international law for more than fifteen years at universities in Europe, Asia, and the Americas and regularly teaches on these topics at six institutions. He convenes the international IP law course at Cambridge.
9. Dr Michael Waibel's expertise would assist the Tribunal with its determination of the legal issues related to the arbitration because:
- Dr Waibel's expertise is in public international law and international economic law with a particular focus on the settlement of international disputes.
  - He writes regularly on international investment law and convenes the international investment law course at the University of Cambridge.
10. In addition, the three legal academics on this brief have also collaborated specifically on a project on the investment-patent law interface in 2015 and 2016. Dr Grosse Ruse-Khan organised a workshop at King's College in the University of Cambridge in April 2015. At the workshop on "Intellectual Property Rights and Public Interests in International Investment Law", legal academics presented six draft papers.<sup>1</sup> Dr Grosse Ruse-Khan presented a paper on "Litigating International Intellectual Property Norms in Investor-State Dispute Settlement", and Dr Liddell and Dr Waibel co-authored a paper on "Fair and Equitable Treatment and Judicial Patent Decisions". Alongside other papers presented at the workshop, these two papers will be published as part of a special issue in the Journal of International Economic Law in March/April 2016.<sup>2</sup>

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<sup>1</sup> In addition, the following individuals participated in the workshop: Dr Simon Klopschinski, Professor Carlos Correa, Professor Jorge Vinuales, Dr Eva Nanopoulous, Dr Rumiana Yotova, Professor Susy Frankel, Thomas Sebastian, Christophe Bondy and Professor Lionel Bently.

<sup>2</sup> Pre-publications versions of the two papers are available on the Social Science Research Network, <http://ssrn.com/abstract=2463711> (Grosse Ruse-Khan), <http://ssrn.com/abstract=2722452> (Liddell & Waibel).

## MATTERS WITHIN THE SCOPE OF THE DISPUTE

11. Our amicus brief addresses matters within the scope of the dispute between Eli Lilly and Canada by bringing our particular knowledge and insight of on matters contended by the disputing parties to be in dispute. These matters include the following merits issues: (i) the scope of Canada's obligations under NAFTA Articles 1105 and their relationship with both domestic and international intellectual property laws;<sup>2</sup> the intersection of NAFTA's standards of protection and Canada's domestic patent law;<sup>3</sup> the relationship between the NAFTA Chapter 17, TRIPs Agreement and the Patent Cooperation Treaty<sup>4</sup>; the appropriate standard of review for judicial conduct; the importance of patent law flexibilities and the commonality of patent invalidations.

## SIGNIFICANT PUBLIC INTEREST IN THIS ARBITRATION

12. There is significant public interest in this arbitration because of the award's potential implications for intellectual property law.<sup>5</sup> As legal academics who have recently worked on the IP-investment interface, we have engaged in relevant prior research.<sup>6</sup>

13. This arbitration raises important questions regarding the relationship between various international law regimes and domestic law. The outcome of this arbitration will affect the development of international law and domestic patent law; and the interrelationship between the two. The outcome of this arbitration will raise both legal and ethical challenges for States in the field of access to medicines, public health and life sciences. This arbitration raises important questions concerning the applicability, scope and relevance of international standards of protection for intellectual property rights under the international agreements such as NAFTA Chapter 17, TRIPS and the PCT.

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<sup>2</sup> *Eli Lilly and Company v Government of Canada (Claimant's Memorial)* (North American Free Trade Agreement Chapter 11 Panel, Case No UNCT/14/2, 29 September 2014) 73-140; *Eli Lilly and Company v Government of Canada (Statement of Defence)* (North American Free Trade Agreement Chapter 11 Panel, Case No UNCT/14/2, 30 June 2014) 36-44.

<sup>3</sup> *Eli Lilly and Company v Government of Canada (Claimant's Memorial)* (North American Free Trade Agreement Chapter 11 Panel, Case No UNCT/14/2, 29 September 2014) 17-70; *Eli Lilly and Company v Government of Canada (Statement of Defence)* (North American Free Trade Agreement Chapter 11 Panel, Case No UNCT/14/2, 30 June 2014) 5-31.

<sup>4</sup> *Eli Lilly and Company v Government of Canada (Claimant's Memorial)* (North American Free Trade Agreement Chapter 11 Panel, Case No UNCT/14/2, 29 September 2014) 83, 95-97, 101-102; *Eli Lilly and Company v Government of Canada (Statement of Defence)* (North American Free Trade Agreement Chapter 11 Panel, Case No UNCT/14/2, 30 June 2014) 32-36.

<sup>5</sup> Cf. *Methanex Corporation v United States of America (Application for Leave to Make Amicus Submission by Bluewater Network, Communities for a Better Environment and the Center for International Environmental Law)* (NAFTA Chapter 11 Panel, 9 March 2004) 3-4; *Methanex Corporation v United States of America (Petition to the Arbitral Tribunal submitted by the International Institute for Sustainable Development)* (NAFTA Chapter 11 Panel, 25 August 2000) [32]-[35].

<sup>6</sup> *Methanex Corporation v United States of America (Application for Leave to Make Amicus Submission by Bluewater Network, Communities for a Better Environment and the Center for International Environmental Law)* (NAFTA Chapter 11 Panel, 9 March 2004) 3-4.

14. We have a significant interest in the development of international law by virtue of conducting, facilitating and publishing on international law. A significant proportion of our work concerns the settlement of investment disputes and their implications for the development of international law raised in this arbitration; research and teaching on legal and ethical challenges at the forefront of medicine and the life sciences.

#### **PUBLIC INTEREST IN THE SUBJECT-MATTER OF THE ARBITRATION**

15. There is a significant public interest in the subject-matter of this arbitration before the Tribunal. First, a public interest in the subject matter of the arbitration may be demonstrated in cases where the ‘substantive issues extend far beyond those raised by the usual transnational arbitration between commercial parties.’<sup>7</sup> Second, a public interest includes questions regarding ‘the legality under international law, not domestic private law, of various actions and measures taken by Governments’ that are likely to ‘raise a variety of complex public and international law questions, including human rights considerations.’<sup>8</sup> Third, a public interest in an arbitration may also arise where the Tribunal’s award has the potential to impact upon some wider interests.<sup>9</sup> On all three criteria, this arbitration raises a significant public interest.

16. This arbitration gives rise to a significant public interest in its subject matter because the substantive issues raised in this arbitration extend far beyond those raised by the usual transnational arbitration between commercial parties and are likely to have a significant impact upon the legal regimes governing access to medicine and public health in both Canada and internationally – with particular important implications for developing countries relying on generic medicines from Canadian suppliers. Findings made in this arbitration are likely to affect, directly or indirectly, the ability and willingness of countries around the world to use the acknowledged flexibilities of the international intellectual property system, in particular under the TRIPS Agreement, for the purpose of public health and access to medicines. It will also affect the likelihood of similar challenges brought by investors holding IP rights in a host state against the latter’s patent law, inter alia by invoking international intellectual property norms which otherwise can only be invoked in state-to-state disputes.

17. Furthermore, the questions raised in this arbitration concern the legality of domestic judicial approaches under international law and these questions give rise to complex and systemic public and international law considerations on the interplay between domestic and

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<sup>7</sup> *Methanex Corporation v United States of America (Decision of the Tribunal on Petitions from Third Persons to Intervene as ‘Amici Curiae’)* (NAFTA Chapter 11 Panel, 15 January 2001) [49].

<sup>8</sup> *Suez, Sociedad General de Aguas de Barcelona SA and Vivendi Universal SA v Argentine Republic (Order in Response to a Petition for Transparency and Participation as Amicus Curiae)* (ICSID Arbitral Tribunal, Case No ARB/03/19, 19 May 2005) [19]-[21].

<sup>9</sup> *Biwater Gauff (Tanzania) Ltd v United Republic of Tanzania (Procedural Order No 5)* (ICSID Arbitral Tribunal, Case No ARB/05/22, 2 February 2007) [53].

international law, the scope of judicial review and the discretion afforded to judges when applying national patent law.

#### **AFFILIATION WITH ANY DISPUTING PARTY**

18. None of the three legal academics on this brief has any affiliation, direct or indirect, with either Eli Lilly or the Government of Canada.

#### **FINANCIAL OR OTHER ASSISTANCE IN THE PREPARATION OF THIS AMICUS BRIEF**

19. We received a grant of £14,509 under the ESRC Impact Acceleration Account (IIA)<sup>10</sup> Programme 2015-2016 based at the University of Cambridge to assist, among others, with the preparation of this amicus brief. The name of impact project as approved is 'Protecting National Patent Law Flexibilities through an Amicus Brief in the Case of Eli Lilly v. Canada: Policy Developments at the intersection of International Investment Law and Pharmaceutical Patent Law.' The purpose of the grant is to allow us to raise the profile and impact of our joint work on the intersection of IP and international law, including through the submission of this amicus brief. Neither the ERSC nor the IIA has provided any input on the substance of the submission.

20. Part of the IIA grant has been spent on research assistance. We benefitted from research and editorial assistance by three current LLM students at the University of Cambridge, Christopher Beaucage, Stephen Olynyk and Matthew Psycharis. They carried out this research assistance in accordance with our instructions.

Respectfully submitted.

Cambridge, 12 February 2016

[signed]  
Dr Henning Grosse Ruse-Khan

[signed]  
Dr Kathleen Liddell

[signed]  
Dr Michael Waibel

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<sup>10</sup> The Economic and Social Research Council is a UK government-funded research and training agency addressing economic and social concerns.