In the Arbitration 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

EXPERT REPORT OF DANIEL J. GERVAIS

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About the Author

1. I have been working in the field of international and comparative intellectual property law for 25 years.

2. I am a Full Professor at Vanderbilt University Law School (Nashville, Tennessee) and have served as Director of the Vanderbilt Intellectual Property Program since 2008, where I teach U.S., international and comparative intellectual property law.¹ I am a member of the American Law Institute and Associate Reporter of the Restatement of Copyright, First.

3. Prior to joining Vanderbilt University, I was a Full Professor and Acting Dean, as well as University Research Chair in Intellectual Property and Osler Professor of Technology Law at the Faculty of Law of the University of Ottawa (Common Law Section), where I taught Canadian, comparative and international intellectual property law between 2001 and 2008.

4. I have also taught intellectual property law at several other universities in Asia, Canada, Europe, and the United States. Since 2003, I have been a visiting lecturer every summer in a postgraduate program at the University of Amsterdam. In February 2014, I will be the Yong Shook Lin Professor in Intellectual Property at the National University of Singapore. I have also been a Research Affiliate at Victoria University of Wellington in New Zealand for a number of years. I have been serving as Editor-in-Chief of the *Journal of World Intellectual Property,* published by Wiley-Blackwell (a division or affiliate of John Wiley & Sons, New York) since 2006.

5. In 2012, I became the first law professor in North America elected to the Academy of Europe.

6. Prior to my teaching career, I served *inter alia* as Head of the Copyright Projects Section at the World Intellectual Property Organization ("WIPO"); and Legal Officer at the GATT (World Trade Organization or "WTO") during the Uruguay Round. I have worked with government officials from several WTO Members in Africa, Asia, the Caribbean, Latin America (on behalf of the WTO and the InterAmerican Development Bank and sometimes directly hired by national governments) to answer questions about the Agreement on Trade-Related Aspects of

¹ The views in this Report are my own and do not purport to reflect those of Vanderbilt University or any other person or institution.

Intellectual Property Rights ("TRIPS") and offer advice on the implementation of the Agreement.

7. I have authored or coauthored or am in the process of writing books published by Cambridge University Press, Oxford University Press, Sweet & Maxwell (Thomson Reuters) and Kluwer Law International. I have edited or contributed chapters to (or am in the process of contributing to) a total of 51 books related to intellectual property and have written on intellectual property law for journals around the world, including the *Columbia Journal of Law* & the Arts, Fordham Law Review, Cardozo Arts & Entertainment Law Journal, European Intellectual Property Review, American Journal of International Law, Chicago-Kent Law Review, Vanderbilt Journal of Technology and Entertainment Law, the Journal of the Copyright Society of the USA (my article won the Charles B Seton Award for best article in 2002-03)and the Journal of Intellectual Property Law. Two of my articles were republished in Intellectual Property Law Review (2011 and 2013), which are collections of the best intellectual property articles of 2010 of 2012, respectively. I am also coauthor of a textbook on intellectual property law in Canada published by Carswell/Thomson.

8. My book on the history and interpretation of the TRIPS Agreement², now in its fourth edition, was cited *inter alia* in two opinions of the Supreme Court of the United States (*Golan v. Holder*, 2011 and *Wiley v. Kirtsaeng* (2013)), by the Supreme Court of Canada and in various opinions of the Advocate General of the Court of Justice of the European Union. It has also been cited in over 300 law review articles and book chapters in Australia, New Zealand, Canada, South Africa, the United Kingdom and the United States. A French-language edition was published in 2010 and a Chinese-language edition is in preparation.

9. I studied law at McGill University and the University of Montreal, where I obtained LL.B. and LL.M. degrees and received several awards. I am a member of the Bar of Quebec and the Law Society of Upper Canada (Ontario). I also received a Diploma *summa cum laude* from the Institute of Advanced International Studies in Geneva and a doctorate *magna cum laude* from the University of Nantes (France). My full educational background is set forth as part of my curriculum vitae, attached hereto as Exhibit A.

² Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis 4th ed.* (London" Sweet & Maxwell, 2012) (**R-209**).

10. Before accepting the task of preparing this report for the Government of Canada, I was approached by lawyers from the law firm Gowlings to prepare a report for the Claimant. I did not receive any non-public information about this matter from the Claimant's counsel. This retainer did not materialize as I declined the offer.

11. In the interest of full disclosure, my wife is a Foreign Service Officer at the Department of Foreign Affairs, Trade and Development, Canada. This in no way influenced the opinions contained in this report.

Overview

12. The Government of Canada asked me to review the Memorial of the Claimant Eli Lilly & Company (the "Claimant") with respect to its arguments on the international law of patents, in particular, with respect to TRIPS, NAFTA Chapter Seventeen, and the Patent Cooperation Treaty ("PCT"). I have also been asked to review the expert reports of Professors Siebrasse, Merges and Salazar to the extent their opinions impact on my analysis of international intellectual property law.

13. My conclusion, as set out in this report, is that the Claimant substantially misstates international law as it applies to patents. I find the Claimant's arguments with respect to patent obligations in international law, in particular with respect to NAFTA Chapter Seventeen, TRIPS and the PCT, to be self-serving and without legal foundation. Contrary to the views expressed by the Claimant, it is my opinion that there is no binding substantive definition of the utility requirement in Article 27.1 of TRIPS and its counterpart Article 1709(1) of NAFTA. Neither NAFTA nor TRIPS dictate the specific content of the "utility" requirement to be applied by Member States. Applicable treaties leave it to the domestic regimes of States to define the criteria and implement the patent bargain.

14. As this report will demonstrate, since the mid-1980s States have attempted on many occasions to harmonize patentability requirements and reach consensus on a definition of "utility" or "industrial applicability". Such harmonization efforts have proven unsuccessful on every occasion. This failure is due notably to the different ways countries apply the patentability requirements provided for in TRIPS and NAFTA. The international reality is fundamentally at

odds with the Claimant's argument that "utility" in NAFTA has a fixed meaning that has been infringed by the Canadian courts in the two matters at issue.

15. The Claimant's interpretation of the PCT as restricting the substantive definition of utility that can be applied by a PCT Member is incorrect. The PCT only provides for administrative, not substantive, obligations and is not binding in any way on defining how the notion of utility should be applied or interpreted domestically.

16. This report is divided as follows. In Part I, I review the early efforts of the international community to devise substantive rules on patents, including a definition of utility, which all failed. In Part II, I explain that, arising out of the failure to develop substantive definitions, the international community settled on a basic framework in the TRIPS agreement that left ample room for national variations in defining and applying utility domestically. In Part III, I explain how international efforts since NAFTA and TRIPS not only have failed to produce consensus on the notion of utility, but demonstrate a willingness to preserve policy flexibility. Finally, in part IV, I examine how NAFTA Chapter Seventeen is similar to TRIPS and does not provide for a substantive harmonization of the patentability criteria; how the subsequent practice of the Parties reinforces this conclusion; and why the definition of "industrial applicability" contained in the PCT is irrelevant to interpret the scope of "utility" in NAFTA.

I – Harmonization Efforts Pre-TRIPS/NAFTA Have Failed

17. In 1983, discussions were launched between WIPO members (including Canada, the United States and Mexico) "on the legal effects of an international grace period on patent law". This work gradually expanded into a "draft Treaty Supplementing the Paris Convention as far as Patents are concerned", also known as the "Basic Proposal".³

18. The Basic Proposal draft text contained provisions aimed at harmonizing various aspects of both administrative and substantive patent law, including definitions of the terms "novel" and "involve an inventive step".⁴ However, for the criterion of "utility" or "industrial applicability",

³ WIPO, *Patent Law Harmonization*, online: <u>http://www.wipo.int/patent-law/en/patent_law_harmonization.htm</u> (**R-211**).

⁴ For a detailed review of the draft, see Edward G. Fiorito, 'The "Basic Proposal" for Harmonization of U.S. and Worldwide Patent Laws Submitted by WIPO (1993), 73 *J. of Patent & Office Society* 83-109 (**R-212**).

it proposed no definition and expressly left members with the choice to apply either of them. The draft text included the following provision:

In order to be patentable, an invention shall be novel, shall involve an inventive step (shall be non-obvious) and shall be, at the option of the Contracting Party, either useful or industrially applicable.⁵

19. WIPO Members discussed the Basic Proposal at a conference in The Hague in 1991 ("the Conference").⁶ The Conference failed due to a failure to reach consensus, including on definitions of patentability criteria.

20. As a result, WIPO members abandoned the Basic Proposal in favour of more modest goals. Notably, they instead pursued potential harmonization of procedural issues. These discussions ultimately led in 2000 to the adoption of the Patent Law Treaty ("PLT"). The PLT does not harmonize the definitions of substantive patentability criteria, but rather focusses on national patent formalities, such as filing date requirements, electronic filing and standardized forms.⁷

21. This means that in the 1990s, work on harmonization on substantive patentability criteria was dropped from the multilateral agenda. It is significant in the context of this report because those negotiations were contemporaneous with the TRIPS and NAFTA discussions, both of which took place in the late 1980s and early 1990s.

II – TRIPS Did Not Harmonize Patent Law

22. The TRIPS Agreement does not define "utility". In fact it does not even require WTO members to apply "utility". Article 27.1 of the TRIPS Agreement provides as follows:

Subject to the provisions of paragraphs 2 and 3, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.^a

⁵ WIPO, *Text of the Basic Proposal for the Treaty and the Regulations as Submitted to the Diplomatic Conference for the Conclusion of a Treaty Supplementing the Paris Convention as far As Patents Are Concerned*, The Hague, June 3 to 28, 1991, document SCP/4/3, 2 October 2000, online: http://www.wipo.int/edocs/mdocs/scp/en/scp_4/scp_4_3.pdf, p. 20 (**R-213**).

⁶ WIPO, *Records of the Diplomatic Conference for the Conclusion of a Treaty Supplementing the Paris Convention as Far as Patents are Concerned*, Volume I: First part of the Diplomatic Conference, the Hague, 1991 (**R-214**).

⁷ See WIPO, *History*, online: <u>http://www.wipo.int/patent-law/en/plt.htm</u> (R-215).

Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

(a) For the purposes of this Article, the terms "inventive step" and "capable of industrial application" may be deemed by a Member to be synonymous with the terms "non-obvious" and "useful" respectively.⁸

23. In my book on the TRIPS Agreement, I reproduce the formal and informal draft texts that led to the final text of this provision.⁹ The initial composite draft (prepared by the GATT Secretariat on the basis of proposals by a number of GATT parties and the European Communities) in 1990 shows essentially the same language on the identification of the criteria:

Patents shall be [available] [granted] for [any inventions, whether products or processes, in all fields of technology,] [all products and processes] which are new, which are unobvious or involve an inventive step and which are useful or industrially applicable.¹⁰

24. The drafting of TRIPS Article 27.1 was informed by the failed Basic Proposal discussed above. Changes made to the TRIPS draft text between the initial draft of 1990 and the adoption of the WTO package in 1994 included no definition of utility. During informal TRIPS negotiation meetings in October 1990, the expression "industrially applicable" (which is used in the PCT) was changed to "capable of industrial application," which more closely tracks the expression commonly used in European legislation. In November 1990, an attempt was made to use "capable of industrial application" followed by the term "useful" in parentheses. This suggestion was not retained and the footnote on possible deemed synonymy was adopted instead.

25. The negotiating history of TRIPS shows no serious attempt to agree on a definition of utility or industrial applicability. Rather, TRIPS left ample room for national variations in this

⁸ Annex 1C of the Marrakesh Agreement establishing the World Trade Organization, signed in Marrakesh, Morocco on April 15, 1994, 1869 U.N.T.S. 299; 33 I.L.M 1197 (1994), Article V, art. 2.1 ("TRIPS") (**RL-001**).

⁹ Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis 4th ed.* (London" Sweet & Maxwell, 2012), at pp. 421-425 (**R-209**).

¹⁰ Negotiating Group on Trade-Related Aspect of Intellectual Property Rights, including Trade in Counterfeit Goods, *Status of Work in the Negotiating Group*, Chairman's Report to the GNG, 23 July 1990 (document MTN.GNG/NG11/W/76) (**R-216**).

regard. Theses broad flexibilities left in place under TRIPS have been universally recognized, including by WIPO itself.¹¹ In a 2001 Report, WIPO's International Bureau states, specifically with regard to the definition of "utility", that:

It is to be noted that the TRIPS Agreement provides for minimum requirements only, and that the term "industrial applicability (utility)" used in that agreement is not further defined.¹²

26. In a 2002 report, WIPO further notes:

WTO members have the flexibility to design their national intellectual property (*IP*) systems within the minimum standards set by the TRIPS Agreements, in cognizance of a country's economic, developmental and other objectives, including public health.¹³

27. The foregoing demonstrates that in 1991 there was no indication that WTO members, including Canada, the United States and Mexico, had a shared understanding on the precise scope of the patentability criteria. In fact, the opposite is true – TRIPS not only failed to define the utility criterion, but it expressly allowed states to adopt either "utility" or "industrial application" as the applicable standard.

III- Harmonization Efforts Post-TRIPS/NAFTA Have Failed

I now review the (failed) efforts since TRIPS/NAFTA (post 1995) to harmonize substantive patent law. This will confirm both that (a) clearly there was no consensus on definitions of patentability criteria as of 1993-1994 (when TRIPS and NAFTA were signed), and (b) that there is still no consensus today.

¹³ WTO, WIPO and WHO, *Promoting Access to Medical Technologies and Innovation*, Intersections between public health, intellectual property and trade (2013) online: http://wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf, p. 171 (emphasis added) (**R-220**).

¹¹A famous author in international law and former TRIPS negotiator (for Switzerland) expressed the view that the TRIPS "is best characterized by a model of multilayered governance where some, but not all, legal requirements are defined on the global level, while others are left to regional and national law. International law defines the policy spaces allocated to domestic law: Thomas Cottier, "Industrial property, International protection", Max Planck Encyclopedia of Public International Law, Oxford Public International Law, 2010, para. 27 (**R-217**). Two other well-known experts state: "Yet, [TRIPS], which did not attempt to create a uniform or deeply harmonized global patent regime, left ample room for national variations and approaches": Jerome H. Reichman and Rochelle Cooper Dreyfuss, "Harmonization without consensus: critical reflections on drafting a substantive patent law treaty", Duke Law Journal, 2007 vol 57:85, p. 89 (**R-218**).

¹² WIPO, Notes, document SCP/6/4, 3 October 2001, online <u>http://www.wipo.int/edocs/mdocs/scp/en/scp_6/scp_6_4.pdf</u>, para. 12.03 (emphasis added) (**R-219**).

(a) The Failed Substantive Patent Law Treaty

29. Attempts led by WIPO to harmonize substantive patentability requirements resurfaced in 2000, six years after NAFTA entered into force and over a decade after the failure of the Basic Proposal, when WIPO's Standing Committee on Patents ("SCP") launched negotiations for a potential Substantive Patent Law Treaty ("SPLT").¹⁴ The SCP was initially tasked with focusing on a number of "unaddressed" issues in international patent law. These included the definition of novelty, of inventive step, and of industrial applicability/utility.¹⁵

30. This confirms that NAFTA and WTO Members did little to clarify the subsequent WIPO discussions on harmonization of patentability requirements. If they had agreed to definitions of these requirements, this would have no doubt informed the WIPO negotiation, which it did not.

31. A 2000 WIPO report published in the opening of the SPLT negotiations, entitled "suggestions for the further development of international patent law" noted that "utility" and "industrial applicability" do not have the same meaning:

[The terms "utility" and "industrial applicability"] do not have exactly the same meaning:

(a) In those systems which use the term "industrial applicability," it means in general that the invention must be able to be used in any kind of industry, whereby the term "industry" has to be understood in a broad sense, including agriculture.

(b) *The term "utility," on the other hand, is a somewhat more complex notion*, according to which it may be examined, in particular, whether an invention is able to do something, whether it works to solve the problem it is supposed to solve, and whether it has some social benefit.¹⁶

32. Following this report, the Chair of the SCP invited comments on the issue of utility and industrial application. Canada and the United States responded as follows:

84. The Delegations of Canada and the United States of America sought clarification on the meaning of the phrase "which may only be used for private purposes" that appeared

¹⁴ The draft SPLT should not be confused with the *Patent Law Treaty* (PLT), signed in 2000 the purpose of which is to harmonize and streamline procedures in respect of national and regional patent applications and patents. As of this writing of the NAFTA Parties only the United States is party to the PLT.

¹⁵ WIPO, *Suggestions for the Further Development of the International Patent Law*, document SCP/4/2, 25 September 2000, online: <u>http://www.wipo.int/edocs/mdocs/scp/en/scp_4/scp_4_2.pdf</u>, para. 9 (**R-221**).

¹⁶ WIPO, *Suggestions for the Further Development of the International Patent Law*, document SCP/4/2, 25 September 2000, online <u>http://www.wipo.int/edocs/mdocs/scp/en/scp_4/scp_4_2.pdf</u>, para. 24 (**R-221**).

at the end of paragraph 23 of document SCP/4/2, *while noting the different meaning of the terms "industrial applicability" and "utility"*. The International Bureau explained that this phrase related to the term "industrial applicability," and not to the term "utility".

85. *The Delegation of the United States of America emphasized the importance of achieving true harmonization on this item*. As regards the legal instrument, the Delegation said that this item could be included either in a treaty or in guidelines. It further stated that, *whatever standards would be established*, they should not be considered in a way to exclude certain categories of invention from patentable subject matter.¹⁷

33. In other words, as of 2000, the United States explicitly acknowledged the lack of substantive harmonization on the utility requirement.

34. In May 2001, the SCP put forward a first draft of the proposed SPLT. For each provision, two alternatives were proposed. For "novelty" and "inventiveness", the draft proposed two different definitions as "Alternative A" and "Alternative B". For "utility", the proposal contained one definition, suggesting in the alternative to remove the definition altogether.¹⁸ These alternative approaches were debated between the members and "revealed different national practices and divergent views".¹⁹

35. Before the session that followed, the SCP circulated a second draft of the proposed SPLT. While it retained the concepts and definitions of "novelty" and "inventive step", the standard of "utility" was entirely removed and instead subsumed under the provision addressing "patentable subject matter."²⁰ However, the majority of the SCP members supported the retention of industrial application as a distinct requirement.²¹ The "utility" requirement therefore reappeared in the following draft in May 2002.²²

¹⁷ WIPO, *Report*, document SCP/4/6, 7 December 2000, online: <u>http://www.wipo.int/edocs/mdocs/scp/en/scp_4/scp_4_6.pdf</u>, para.84 (emphasis added) (**R-222**).

¹⁸ WIPO, *Draft Substantive Patent Law Treaty*, document SCP/5/5, 4 April 2001, online: <u>http://www.wipo.int/edocs/mdocs/scp/en/scp_5/scp_5_2.pdf</u>, p. 20 (**R-223**).

¹⁹ WIPO, *Report*, document SCP/5/6, 27 November 2001, online: <u>http://www.wipo.int/edocs/mdocs/scp/en/scp_5/scp_5_6.pdf</u>, para. 146 (**R-224**).

²⁰ WIPO, *Draft Substantive Patent Law Treaty*, document SCP/6/2, 24 September 2001, online: <u>http://www.wipo.int/edocs/mdocs/scp/en/scp_6/scp_6_2.pdf</u>, p. 30 (**R-225**).

²¹ WIPO, *Report*, document SCP/6/9, 6 May 2002, online: http://www.wipo.int/edocs/mdocs/scp/en/scp_6/scp_6_9.pdf, para. 192 (**R-226**).

²² WIPO, *Draft Substantive Patent Law Treaty*, document SCP/7/3, 6 March 2002, online: <u>http://www.wipo.int/edocs/mdocs/scp/en/scp_7/scp_7_3.pdf</u>, p. 24 (**R-227**).

36. "Utility" remained in the text with one corresponding definition, until November 2002 when the Standing Committee on Patents inserted three competing definitions of "utility" in a further draft.²³ Members could not agree on which one to adopt.

37. Seeking to resolve this impasse, the United States and EU jointly proposed that WIPO's International Bureau prepare a study on the commonalties and differences between the "industrial applicability" and the "utility" standards.²⁴ All WIPO Members were invited to participate through written submissions explaining how each defined and applied this requirement within their respective systems.²⁵

38. On the basis of these submissions, WIPO produced a report entitled "'Industrial Applicability' and 'Utility' Requirements: Commonalities and Differences".²⁶ This Report is relevant for two reasons.

39. First, it confirmed that the practice of the parties regarding "industrial applicability" and "utility" can "differ substantially".²⁷ In fact, the Report concluded that even members using the same terminology (i.e. either "utility" or "capable of industrial application") applied that same term in several different ways: "[t]he scope of the term 'industrial applicability' differs from one country to another, and so does the term 'utility".²⁸ With respect to the practice of the members that use that "industrial applicability" phraseology, the Report notes:

[...] national and regional laws and practices concerning the industrial applicability requirement vary significantly. At one of the spectrum, the requirement of industrial applicability is met as long as the claimed invention can be made in industry without taking into account the use of the invention...

²³ WIPO, *Draft Substantive Patent Law Treaty*, document SCP/8/2, 16 October 2002 online: <u>http://www.wipo.int/edocs/mdocs/scp/en/scp_8/scp_8_2.pdf</u>, p. 26 (**R-228**).

²⁴ WIPO, *Report*, document SCP/8/9, 12 May 2003, online: <u>http://www.wipo.int/edocs/mdocs/scp/en/scp_8/scp_8_9-main1.pdf</u>, para. 313 (**R-229**).

²⁵ As of 1 January 2002, WIPO had 179 members. As of 1 January 2015, it has 188 Members. WIPO, "*Industrial Applicability*" and "Utility" Requirements: Commonalities and Difference, document SCP/9/5, 17 March 2003, online: <u>http://www.wipo.int/edocs/mdocs/scp/en/scp_9/scp_9_5.pdf</u>, para. 2 (**R-230**).

²⁶ WIPO, "Industrial Applicability" and "Utility" Requirements: Commonalities and Difference, document SCP/9/5, 17 March 2003, online: <u>http://www.wipo.int/edocs/mdocs/scp/en/scp_9/scp_9_5</u>, (**R-230**).

²⁷ *Ibid.*, para. 56 (emphasis added) (**R-230**).

²⁸ *Ibid.*, para. 53 (emphasis added) (**R-230**).

At the other end of the spectrum, the "usefulness" of the claimed invention is fully taken into consideration for the determination of industrial applicability.²⁹

40. Similarly, regarding those countries that include the "utility" requirement in their domestic law, the Report concludes:

As in the case of the industrial applicability requirement, *practices in the countries which require utility (or usefulness) vary.*³⁰

41. Second, the Report included in the competing definitions of utility the Canadian "promise" approach as one of the possible approaches. In my opinion, a country whose laws reflect the state of the law on promises as described in the WIPO summary in this context means that it is in line with international norms and practices:

A finding that the alleged invention is not useful may be expressed in a way that the invention will not work, either in the sense that it will not operate at all or, more broadly, that *it will not do what the specification promised it would do ("false promise")*. It is sufficient if the specification correctly and fully describes the invention and its operation or use as contemplated by the inventor, so that a person skilled in the art may be able to use the invention as successfully as the inventor himself. Further, if a genus claimed is not proved by a person attacking the patent in suit to include inoperable species, *if the claim includes so many species that not all could have been tested and found by the inventor to have the promised utility, the claim is invalid, absent a possible showing by the patentee that the entire claim could be soundly predicted to have the requisite utility ("sound prediction")*.

[...]

The *essential principle* is that the invention should allow the addressee to achieve the *effects or results promised by the patentee*.³¹

42. Beyond the naming of the criteria, there is thus very little "uniformity" among WIPO member States in this area. For example, in discussing how utility and the notion that an invention must be industrially applicable (*gewerblich anwendbar* in German) are applied differently, a European commentator noted recently that:

²⁹ *Ibid.*, paras. 25 & 26 (emphasis added) (**R-230**).

³⁰ *Ibid.*, para. 49 (emphasis added) (**R-230**).

³¹ *Ibid*, at paras. 41 and 46 (emphasis added) (**R-230**).

[A]nother major difference between the situation in Europe and that in the United States would appear to be that the new provisions on industrial applicability in European patent law are applicable to sequences or partial sequences of genes only, whereas the new US Utility Guidelines are applicable to all areas of technology. Although Recital 22 of the Biotechnology Directive states that patentability for biotechnological inventions should be subject to the same criteria as in all other areas of technology, Art.5(3) of the Directive, and the identical r.23e(3) EPC, specifically require that the industrial application of a sequence or a partial sequence of a gene be disclosed in the patent application. A comparable requirement does not appear to exist for inventions in other technical fields.³²

43. In comparing Australia to Europe, another commentator explained that:

Utility (industrial applicability in European law) requires that the invention has some commercial value. In Australia, this requirement is in part dealt with through the 'manner of manufacture' test in the Patents Act 1990 (Cth) s 18(1)(a), as interpreted in NRDC. There is also a usefulness ground, but this is not examined prior to grant, and it requires only that the invention does what it was intended to do and that the end in itself is useful. Commercial practicality or viability is not a necessary requirement, except that if a particular result is claimed, that result must be achievable.³³

44. After several rounds of negotiations on the basis of those WIPO documents, the United States, the European Union and Japan presented in 2004 a proposal (the "Joint Proposal") to try to move the debate forward. The Joint Proposal, even though it suggested limiting the scope of discussions, fell through. The cause was in part opposition by developing countries but also a recognition that harmonization might "boomerang against its developed-country advocates" in various ways, such as reduced scientific advancement, and unknown impact on, and reduced flexibility to adopt policy changes for, emerging industries.³⁴ As WIPO itself explained,

While delegations recognized the importance of the work of the SCP and emphasized that the work on patent law harmonization should progress taking into account the interests of

³² Rob J. Aerts, 'The industrial applicability and utility requirements for the patenting of genomic inventions: a comparison between European and US law', *European Intellectual Property Review* 2004, 26(8), 349-360, at 357 (emphasis added) (**R-231**).

³³ Dianne Nicol, 'On the Legality of Gene Patents' (2005), 29 Melbourne Univ. Law Review 809, at 823 (R-232).

³⁴ Jerome H. Reichman and Rochelle C. Dreyfuss, Harmonization Without Consensus: Critical Reflections On Drafting A Substantive Patent Law Treaty, 57 *Duke L. J.* 85, at 93 (2008) (**R-233**).

all parties, they did not reach agreement as to the modalities and scope of the future work of the Committee. As a result, the SPLT negotiations were put on hold in 2006.³⁵

45. For the purposes of this Report, it is important to note key excerpts from the abovementioned Joint Proposal:

[S]everal provisions included in the draft treaty have been extremely controversial and of a high political sensitivity. [...] We propose a revised approach that focuses on an initial package of priority items. In doing this, it is suggested that a logical place to begin discussions is with prior art-related issues, more specifically, the following topics:

- Definition of Prior Art
- Grace Period*
- Novelty
- Non-obviousness/Inventive Step".³⁶

46. There are thus several noteworthy aspects to this Joint Proposal. First, it is an acknowledgement by three of the most important players in international trade and intellectual property matters, including the United States, that the issue of possible patent law harmonization is extremely complex. *Second, utility and industrial applicability are <u>not</u> <i>included in the list of issues suggested to be ripe for possible international harmonization or even discussion in the SPLT context*, rather, that requirements was seen as best left to the discretion and interpretation of Member States themselves.

47. In other words, WIPO Member States who issued this proposal believed that fruitful discussions were possible on novelty (and non-obviousness / inventive step) but utility did not make the cut. If utility, industrial applicability or both had been an easy target for negotiators and an easy "win" for WIPO and the negotiators, it would have been on the list or at the very least been mentioned as such.

³⁵ WIPO, *Draft Substantive Patent Law Treaty*, available at <u>http://www.wipo.int/patent-law/en/draft_splt.htm</u> (last visited January 2014) (**R-234**).

³⁶ WIPO, *Proposal from the United States of America, Japan and the European Patent Office Regarding the Substantive Patent Law Treaty (SPLT)*, document SCP/10/9, 22 April 2004, available at http://www.wipo.int/edocs/mdocs/scp/en/scp_10/scp_10_9.pdf, pp. 1, 2 (**R-235**).

(b) WIPO's Work After the Failed SPLT

48. Since the failure of the SPLT negotiations, WIPO has prepared and keeps updating a "Report on the International Patent System".³⁷ This report discusses patentability criteria but it leaves utility aside. If the criteria of utility (and industrial applicability) were the object of an emerging consensus of some sort, it is logical to assume that WIPO would at least report on it or mention it. ³⁸ Rarely does one see such a convincing acknowledgment of the lack of uniformity of views, both among countries and within them.

49. There is more. There are three international intergovernmental organizations that manage intellectual property instruments and/or have a normative role in the area, namely (a) WIPO, which administers the Paris Convention, the PLT, the PCT and many other patent-related instruments; (b) the WTO, which administers the TRIPS Agreement, the patent provisions of which closely resemble those contained in NAFTA; and (c) the World Health Organization (WHO), which has worked on patents and public health, including the development of and access to pharmaceuticals for several years.

50. WTO, WIPO and the WHO produced in 2013 (to my knowledge, this was a first) a joint report on access to medical technologies and innovation, including as significant discussion of patents and pharmaceuticals. The report notes the following:

Even though the same essential patentability criteria are found in the vast majority of countries, there is no agreed international understanding about the definition and interpretation of these criteria. This creates some *policy space* regarding their establishment under the applicable national law. Accordingly, *patent offices and courts interpret and apply national patentability requirements on a case-by-case basis within the applicable legal framework.*³⁹

51. This desire for policy space and the resulting lack of uniformity on substantive issues is not new. It has been the situation for a very long time. As Carl Moy explained:

³⁹ WTO, WIPO and WHO, *Promoting Access to Medical Technologies and Innovation*, Intersections between public health, intellectual property and trade (2013) online:

http://wto.org/english/res_e/booksp_e/pamtiwhowipowtoweb13_e.pdf,, at 57 (emphasis added) (R-220).

³⁷ WIPO, Report on the International Patent System, document SCP/12/3 Rev. 2, 3 February 2009 (R-237).

³⁸ For example, the agenda for the November 2014 meeting of the SCP. *See* WIPO, *Draft Agenda*, document SCP/21/1, 9 October 2014, online: <u>http://www.wipo.int/edocs/mdocs/scp/en/scp_21/scp_21_1_prov_2.pdf</u> (**R-236**).

The [Patent Harmonization] treaty [...] is only the latest in a long series of international agreements that have addressed foreign patenting. [...] The basic structure of international patenting transactions remains unchanged from at least the 1800's: an inventor seeking foreign patent rights must enter the legal system of that foreign country and submit to its requirements for patenting. Patent systems remain instruments of national policy. For these reasons, the basic problems of international patenting, and the general concerns that affect their resolution, should be largely unchanged.⁴⁰

52. Efforts by major patent offices to discuss differences in patent practice and law as part of the Trilateral Policy Dialogue Meeting among the Intellectual Property Offices of China (SIPO); Japan (JPO); and Korea Office (KIPO), launched in September 2001 have also failed to produce consensus on this topic.⁴¹

53. In July 2011, representatives from the patent offices of Denmark, France, Germany, Japan, the United Kingdom, the United States, and the European Patent Office at a meeting convened in Tegernsee, Germany (as a result, this is known as the "Tegernsee Group") decided, as its May 2014 report notes, to launch "a new dialogue on the state of affairs concerning international harmonization of substantive patent law. The participants identified the issues of: first-inventor-to-file, grace period, prior user rights, scope of prior art, definition of novelty and non-obviousness/ inventive step".⁴² The Report does not discuss the harmonization of utility or industrial applicability. The United States Patent and Trademark Office (USPTO), in a public notice of a Roundtable on substantive patent harmonization issued after the May 2014 report of the Tegernsee Group asked for "stakeholder comments on the following key patent examination-related issues: The definition and scope of prior art; the grace period; and standards for assessing novelty and obviousness/ inventive step".⁴³ Again, utility and industrial applicability are left out. It bears repeating that this notice was issued in September 2014.

⁴⁰ R. Carl Moy, "The History of the Patent Harmonization Treaty: Economic Self-Interest as an Influence", 26 *John Marshall L Rev* 457 (1993) at 471-472 (footnotes omitted) (**R-238**).

⁴¹ See Trilateral Cooperation Secretariat, *Intellectual Property Rights*, available at <u>http://www.tcs-asia.org/dnb/board/list.php?board_name=3_2_4_ipr</u> (**R-239**).

⁴² Consolidated Report on the Tegernsee User Consultation on Substantive Patent Law Harmonization (May 2014), at 5. Available at <u>http://www.uspto.gov/ip/global/patents/tegernsee_survey/teg-final_consol_report_june_2014.pdf</u> (**R-240**).

⁴³ United States Patent and Trademark Office, Notice on Roundtable on International Harmonization of Substantive Patent Law, 18 September 2014, Fed.Reg. Vol. 79, No. 181 at 57061 (**R-241**).

54. The reality on the ground is clear. The interpretation and application of patentability criteria has been and continues to evolve in courts and legislatures. Utility, the other two basic patentability criteria and other aspects of patent law (such as the definition of patentable subject matter) are frequently adapted to reflect changes in technology in an effort to uphold the patent bargain. This has been so for decades. Past and ongoing efforts show that there is no consensus on a stable, uniform or narrowly defined notion of utility or of industrial applicability, even if one assumes that both notions may be "deemed" to be synonymous.

IV- NAFTA Chapter Seventeen

55. In all of the above context, I cannot accept the Claimant's suggestion that NAFTA Chapter Seventeen imposed a fixed substantive definition of "utility" or indeed of other substantive criteria of patentability on the Parties. NAFTA Chapter Seventeen was modelled on TRIPS and was negotiated in parallel with that agreement. I have found no evidence that would suggest that Chapter Seventeen went further than TRIPS and imposed substantive harmonization of the patentability criteria. The reports of Dimock, Holbrook and Lindner confirm this conclusion: the NAFTA Parties apply the patentability requirements, including "utility", in a different way and in different combinations to achieve their respective national policy objectives. In addition, these reports indicate that the domestic patent law of every NAFTA Party has continued to evolve post NAFTA. Finally, I do not agree with Claimant's reliance on the PCT to argue that a precise definition of "utility" was agreed by the Parties in TRIPS and NAFTA: the PCT is a procedural treaty, the negotiation of which well predated later failed attempts at harmonization, and on its express terms has nothing to do with substantive patenting rules.

(a) Chapter Seventeen of NAFTA Is Similar to TRIPS

56. There is no basis for asserting that NAFTA Chapter Seventeen imposes a substantive harmonization of terms such as "utility", any more than does TRIPS. Both treaties were negotiated at the same time period, in a similar trade context, and use virtually identical language in referring to basic criteria for patentability (Article 27.1 TRIPS and Article 1709 NAFTA). The text of NAFTA Chapter Seventeen was based on a 1991 draft text of TRIPS known as the "Dunkel draft" (because it was under the responsibility of then Director General

Arthur Dunkel),⁴⁴ which included a version of Article 27.1 TRIPS essentially identical to the one adopted in April 1994.

57. Both Article 27.1 TRIPS and Article 1709(1) of NAFTA expressly give States the choice to adopt either "utility" or "industrial applicability" as a basic criteria of patentability. This alone signals the absence of harmonization: as we have seen, these two terms are internationally recognized as being different. If there had been even a tendency to consider industrial applicability as the norm, industrial applicability alone would be mentioned in Article 27.1 TRIPS (or NAFTA Article 1709(1)) and there would be no reference to the fact that States may "deem" industrial applicability and utility as equivalent for the purposes of the treaty. The NAFTA negotiators and WTO members insisted on keeping both, as they did for inventive step and non-obviousness, pointing to their desire to maintain flexibility.

58. Like the TRIPS text upon which it is based, NAFTA Chapter 17 also incorporates no specific definition for terms such as "industrial applicability" or "utility". When the Parties were negotiating NAFTA Chapter Seventeen, there were well aware of the recent failed attempts to agree on definitions for utility in the Basic Proposal, and of the fact that in TRIPS WTO members had consequently made no attempt to define the criteria. The fact that NAFTA (like TRIPS) contains no definitions suggests that the intention of the NAFTA Parties was to keep the same flexibility for domestic implementation as they have under the TRIPS Agreement. If there had been any ambition to add further substance to the concept of utility, it would in my opinion be reflected in the NAFTA text.

59. I have seen no credible evidence that the NAFTA Parties intended to give an agreed special meaning of the term utility that confirms what the Claimant argues. In particular, I have seen no evidence suggesting that there was an intention to impose the United States domestic law model as the NAFTA standard. That is not true with respect to the TRIPS, and in my opinion, it must also be the case with respect to NAFTA Chapter Seventeen.

60. To the contrary, it has long been recognized that each country is free to implement its patent bargain and that one country's interpretation "does not rule the world". As the United States Supreme Court explained in *Microsoft Corp. v. AT&T Corp.* in 2007:

⁴⁴ The text is known in the literature as the "Dunkel text". See Daniel Gervais, *The TRIPS Agreement: Drafting History and Analysis 4th ed.* (London" Sweet & Maxwell, 2012) (**R-209**).

The presumption that United States law governs domestically but does not rule the world applies with particular force in patent law. The traditional understanding that our patent law "operate[s] only domestically and d[oes] not extend to foreign activities," Fisch & Allen ['The Application of Domestic Patent Law to Exported Software: 35 U. S. C. §271(f)', 25 U. Pa. J. Int'l Econ. L. 557 (2004)] 559, is embedded in the Patent Act itself, which provides that a patent confers exclusive rights in an invention within the United States. 35 U. S. C. § 154(a)(1) (patentee's rights over invention apply to manufacture, use, or sale "throughout the United States" and to importation "into the United States"). [...] Thus, <u>the United States accurately conveyed in this case</u> [in an amicus curiae brief filed by the US government]: "Foreign conduct is [generally] the domain of foreign law," and in the area here involved, in particular, <u>foreign law "may embody different policy judgments about the relative rights of inventors, competitors, and the public</u> in patented inventions".⁴⁵

61. The principle that the patent bargain may be applied differently by countries is notably recognized by the most widely adhered to instrument in the field of industrial property (including patents): the *Paris Convention for the Protection of Industrial Property*. Its original text dates back to 1883. As of January 2015, it had 176 member States, including all NAFTA Parties. The Convention enshrines the *principle of independence of patents*, as follows:

(1) Patents applied for in the various countries of the Union by nationals of countries of the Union shall be independent of patents obtained for the same invention in other countries, whether members of the Union or not.

(2) The foregoing provision is to be understood in an unrestricted sense, in particular, in the sense that patents applied for during the period of priority are independent, *both as regards the grounds for nullity and forfeiture*, and as regards their normal duration.

(3) The provision shall apply to all patents existing at the time when it comes into effect. 46

62. This article of the Convention was unreservedly incorporated into NAFTA and the TRIPS Agreement.⁴⁷

⁴⁵ Microsoft Corp. v. AT&T Corp., 550 U.S. 437 at 454-455 (2007) (emphasis added) (R-242).

⁴⁶ Paris Convention for the Protection of Industrial Property, World Intellectual Property Organization, (1883), art. 4bis (**R-036**).

⁴⁷ North American Free Trade Agreement, ("NAFTA") art 1701(2) (**R-243**); TRIPS (**RL-001**).

(b) Subsequent Practice of the Parties

63. The subsequent practice of the NAFTA Parties reinforces the above conclusions.

64. The expert reports of Dimock, Holbrook and Linder demonstrate that Canada, the United States and Mexico apply the patentability requirements in different ways and in different combinations to achieve their respective domestic policy objectives.

65. This can include using factors and criteria beyond those specifically listed in Chapter Seventeen, for example, disclosure requirements. The disclosure required by each Party will be assessed in each country at different points in the overall analysis. For example, as Professor Holbrook explains, the United States *Patent Act* contains requirement of a "full, clear, concise, and exact" written description of the invention, and also enablement of the invention.⁴⁸ This amounts to a dual requirement, both that the inventor demonstrates "possession of the invention" at the time of filing of the application, and that it provide a person "skilled in the art" of the patent the information necessary to practice the invention and as the Claimant should know failure to comply is a cause for invalidation.⁴⁹ In Canada, as Mr. Dimock sets out, where an applicant asserts a particular utility for his invention on the basis of his or sound prediction, the applicant is required to set out the factual basis for that sound prediction and a line of reasoning in the patent specification. In Mexico, as Ms. Lindner points out, such issues may arise in connection with the sufficiency of examples given that demonstrate the specific industrial applicability of the invention.

66. This highlights the weakness of Claimant's attempt to consider and fix the functioning of one criteria, that of "utility", in isolation to any other requirements and tools used by the NAFTA Parties to implement the patent bargain. In each patent system, individual concepts will be combined in different overall analytical schemes, and in the result their function cannot adequately be appreciated except taken as a whole.

⁴⁸ See In re Wright, 999 F.2d 1557 at 1561 (Fed Cir 1993) ("In re Wright") (**R-080**).

⁴⁹ See Ariad Pharmaceuticals, Inc. v. Eli Lilly & Co. 598 F.3d 1336 (Fed. Cir. 2010) (en banc) ("<u>Ariad</u>") (**R-099**). For a comment see Michael A. Greene "Gilding the Lilly: The § 112 Written Description Requirement Separate From Enablement" 52 Boston College. L. Rev. E-Supplement 213 (2011) (**R-244**).

67. For this reason, Professor Merges's statement that United States courts rarely use *utility* as a cause for invalidation,⁵⁰ without explaining the major differences in the respective roles played by the current notions of utility and enablement in United States law (as compared to Canadian law for example), is potentially misleading. NAFTA Parties and WTO Members assess patentability on the basis of a range of criteria including patentable subject-matter, novelty, inventiveness or non-obviousness, utility or industrial applicability, adequacy of disclosure and enablement. The use each makes of these various criteria will reflect that country's particular overall balance: utility may in one country be more stringently applied, while obviousness may be applied more loosely. In another country, it may be the reverse. Given that each country generates its own "mix", comparisons of single points in different systems will be misleading. The international patent law system accommodates such flexibilities, reflecting the lack of consensus on the "optimal mix", and the desire to maintain policy space going-forward.

68. The expert reports of Dimock, Holbrook and Linder also demonstrate that state practice before, during and after TRIPS and NAFTA has been subject to ongoing evolution, including in the interpretation and application of patentability criteria by national courts. This state of affairs (which can be seen as well in other major jurisdictions) confirms that there is no currently accepted binding international standard of utility and/or industrial applicability.

69. Evolution in the interpretation and application of patentability criteria, particular as novel issues arise, are part and parcel of any system. When those decisions clarify how patent criteria should apply in particular circumstances, this can have an impact on the validity of previously-issued patents. Indeed, the court can go further, reversing prior interpretations of patent law previously upheld by the courts. This is inherent in the system and is nothing new.

70. I see no indication in NAFTA that the Parties wished to depart from this principle.

71. As the foregoing highlights, the application and interpretation of patentability criteria are far from uniform. Countries apply different techniques to enforce the patent bargain. Whether the utility requirement is the best policy vehicle to implement or "enforce" promises contained in

a patent application is a matter on which reasonable people can disagree. Indeed, I read most of the Merges and Siebrasse expert reports as arguing that the promise of the patent form of utility is suboptimal policy for Canada and that United States law is somehow "better". Like most policy matters, this is a proper matter for debate. Indeed, all patentability criteria are regularly up for discussion. In my opinion, there is, however, nothing in NAFTA or TRIPS that directs NAFTA Parties to apply utility in a specific way.

(c) The PCT does not support the Claimant's assertion

72. The Claimant argues that "there was a common understanding of 'capable of industrial application' that was reflected in the PCT" at the time that the NAFTA was negotiated.⁵¹ Specifically, Claimant points to the definition of industrial applicability in PCT Article 33(4) as relevant for interpreting the meaning and scope of industrial applicability and utility as contained in NAFTA.

73. PCT Article 33(4) states that "a claimed invention shall be considered industrially applicable if, according to its nature, it can be made or used (in the technological sense), in any kind of industry. 'Industry' shall be understood in its broadest sense, as in the Paris Convention for the Protection of Industrial Property".⁵²

74. I take strong exception to these arguments. They are unfounded and contradicted by the text of the PCT itself. The definition of "industrial applicability" which the Claimant points to in PCT Article 33(4) is expressly intended only for the purpose of the PCT's international examination procedure. This procedure is intended to provide the applicant with a preliminary and non-binding advisory opinion as to the patentability of claimed invention.⁵³ There is no valid basis to claim that a PCT Contracting State is bound, for the purpose of national patent examinations, by the definition of industrial application that is applied during that procedure. In fact, the text of the PCT says exactly the opposite. Article 33(5) explicitly states: "The criteria described above [Articles 33(2-4)] *merely serve the purposes of the international preliminary*

⁵¹ Claimant's Memorial at para. 206.

⁵² Claimant's Memorial at para 203, citing PCT Article 33(4).

⁵³ Patent Cooperation Treaty, World Intellectual Property Organization (1970), Article 33(1) (**R-037**).

examination. Any Contracting State may apply additional or different criteria for the purpose of deciding whether, in that State, the claimed invention is patentable or not".⁵⁴

75. Article 27(5) of the PCT further clarifies that Article 33(4) of the Treaty should not be read as binding national Patent Offices to the definition of industrial applicability found in the Treaty. Article 27(5) provides as follows:

Nothing in this Treaty and the Regulations is intended to be construed as prescribing anything that would limit the freedom of each Contracting State to prescribe such substantive conditions of patentability as it desires. In particular, any provision in this Treaty and the Regulations concerning the definition of prior art is exclusively for the purposes of the international procedure and, consequently, <u>any</u> Contracting State is free to apply, when determining the patentability of an invention claimed in an international application, the criteria of its national law in respect of prior art and other conditions of patentability not constituting requirements as to the form and contents of applications. (emphasis added).⁵⁵

76. There is no basis to claim an expectation on the part of an applicant that any or all PCT Contracting States will apply the same notion of industrial applicability (or utility), and that that notion will not evolve in each jurisdictions. The determinations made in the national phase of the PCT are made by each PCT Contracting State independently of the outcome preliminary and non-binding examination. Leading commentator, frequent lecturer and tutor on the PCT, Dr. Cees Mulder, emphasized this point in recent commentary on the Treaty:

It is important to note, however, that while the PCT increased uniformity in procedural and formal matters, nothing in the PCT limits the freedom of Contracting States to apply their own substantive conditions of patentability. In particular, when determining the patentability of an invention claimed in an international application, any PCT Contracting State is free to apply the criteria of its national law in regard to prior art and other conditions of patentability (subject, of course, to other applicable international rules, such as those contained in the TRIPS Agreement.

[...]

⁵⁴ PCT Article 33(5) (emphasis added) (**R-037**).

⁵⁵ PCT Article 27(5) (emphasis added) (**R-037**).

The designated/elected offices use the international preliminary report on patentability established during the international phase as a mere starting point for their own work. 56

77. In addition, while the text of the PCT refers only to industrial applicability, TRIPS and NAFTA expressly give the option to the Parties to adopt either that or the utility criterion. As Christopher Wadlow explains:

[I]t may seem surprising that no mention was made of 'utility' as an alternative to 'industrial application' [in the PCT], but there are at least two ready explanations. First, <u>the international preliminary examination was entirely non-binding, so</u> <u>countries with a utility requirement, or other non-standard criteria of patentability,</u> <u>were perfectly free to apply those during the national phase</u>. Secondly, United States practice in 1970 and before was noticeably divergent from the rest of the world.⁵⁷

78. The Claimant's arguments that the PCT influenced TRIPS, which in turn influenced NAFTA, is misleading. While many negotiators were no doubt aware of the existence of various instruments, the most they could agree on was on the naming of patentability criteria - and in two cases, only by providing alternative language. The PCT itself is a procedural treaty, presented as such by WIPO⁵⁸, adopted 30 years prior to the failed attempts at substantive patent law harmonization, which I have detailed above. All attempts to go beyond this in the content of the PCT, the initial versions of the PLT, the SPLT and discussions since have failed. Work and reports by expert commentators, including WIPO, have shown why: there are a variety of definitions and ways of implementing the criteria in each jurisdiction, and these criteria have continued to evolve since NAFTA and TRIPS. This fully comports with my personal experience having been present at almost every negotiating session concerning the TRIPS text.

⁵⁶ Cees A.M. Mulder, "The Patent Cooperation Treaty" in Daniel Gervais (ed), International Intellectual Property (Cheltenham: Edward Elgar, 2015) 317-318 and 336-337 (**R-248**)

⁵⁷ Christopher Wadlow, 'Utility and industrial applicability', in Toshiko Takenaka (ed), Patent Law and Theory (E. Elgar, 2008), 355, at 372 (emphasis added) (**R-196**).

⁵⁸ WIPO lists treaties it administers in three different categories: (a) "Substantive IP Protection" (including the Paris Convention), (b) "Global Protection", which are meant to "simplify and reduce the cost of making individual applications or filings"; and finally (c) "Classification", which are meant to "create classification systems that organize information." WIPO, 'WIPO-Administered Treaties', online: <u>http://www.wipo.int/treaties/en/</u> (**R-255**). The PCT is in the *second* category, not the first.

Conclusion

79. As Claimant itself acknowledges, NAFTA and TRIPS were molded from the same clay. It is clear in both NAFTA and TRIPS – as it has been in WIPO negotiations before and after those instruments were signed – that utility and industrial applicability have different meanings and change over time. Utility is defined neither in NAFTA nor in TRIPS. This lack of definition is visible in the absence of a credible effort in the past two decades to even *try* to define a notion of utility.

80. Reflecting the lack of harmonization of substantive patent law at the international level, NAFTA Parties and WTO Members can opt between applying either the 'utility' or 'industrial applicability' criteria, both of which are undefined. The interpretation of whichever of the two criteria they chose can and must be carried out domestically, through their respective national laws, a role typically left to patent offices and to the courts. Courts will interpret these criteria in light of changing technological environments and policy contexts. This frequently gives rise to questions about how longstanding principles should be reflected in current decisions. The policy space to define and interpret patentability criteria in an evolving manner is regularly employed by WTO Members, including the members of NAFTA. This suggests that they consider this space to be both available, and necessary.

81. NAFTA Parties and other WTO Members use various policy levers to enforce the patent bargain. To isolate one from the equation is misleading.

82. As for Canada's "promise" approach to utility being off-side any international norms, it bears repeating that WIPO itself said in respect of utility that

[F]inding that the alleged invention is not useful may be expressed in a way that the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promised it would do ('false promise') [...] [C]ertain characteristics commonly applicable to the utility requirement can be identified. Firstly, inoperative inventions or, more broadly, *inventions which do not work in a way they promised to do, do not comply with the utility requirement*. In other words, claimed inventions which are clearly not operative, *or which could not be*

soundly predicted to have the requisite utility, do not meet the utility requirement.⁵⁹

83. With the foremost intergovernmental IP policy organization citing "promise" as our possible approach to utility, it is highly not credible to support that same approach is "off side" international norms.

84. Claimant's assertion that Canada is bound to apply a static notion of utility whether it be the current United States notion (whatever it may be) or the Mexican notion of industrial applicability, is not supported by the negotiating history of TRIPS (on which NAFTA is based), state practice at the time or detailed discussions since. Simply put, there is no credible evidence of an agreed meaning. The evidence reviewed in this Report points in the opposite direction, and specifically both an inability to define the criteria and a desire to maintain policy flexibility.

85. Claimant, in particular in the Siebrasse and Merges reports, tries to make the case that the promise of the patent is a poor policy choice for Canada. Perhaps; perhaps not. What is clear is that it in no way constitutes a violation of NAFTA Chapter 17.

Signed at: Nashville on: January 23, 2015

[signed] Daniel J. Gerv**i**is ⁵⁹ See WIPO, WIPO, "Industrial Applicability" and "Utility" Requirements: Commonalities and Difference, document SCP/9/5, online: <u>http://www.wipo.int/edocs/mdocs/scp/en/scp_9/scp_9_5</u>, pp. 12-13 (emphasis added) (**R-230**).

APPENDIX A

CURRICULUM VITAE

Daniel J. Gervais

PART I – EMPLOYMENT & HONORS

a) CURRENT POSITION

Professor of Law, Vanderbilt University Law School Director, Vanderbilt Intellectual Property Program Faculty Director, LL.M. Program Faculty Advisor, *Vanderbilt Journal of Technology and Entertainment Law*

b) OTHER CURRENT POSITIONS AND AFFILIATIONS

- 1. Editor-in-Chief, *Journal of World Intellectual Property*, peer-reviewed, published by Wiley-Blackwell (2006-)
- 2. Associate Reporter, Restatement of Copyright, First (American Law Institute) (2014-)
- 3. Member, American Law Institute
- 4. Research Affiliate, New Zealand Centre of International Economic Law
- 5. Editor of <u>www.tripsagreement.net</u>
- 6. Member, Editorial Board, WIPO-WTO Colloquiums for Intellectual Property Teachers
- 7. Member, Executive Committee, International Association for the Advancement of Teaching and Research in Intellectual Property (ATRIP) (2011-)
- 8. Panelist, UDRP, WIPO Arbitration and Mediation Center
- 9. Member of the Law Society of Upper Canada (Ontario Bar) and of the Bar of Quebec
- 10. Twitter: @danielgervaisIP
- 11. Languages: English, French, Spanish. German (functional). One year of Mandarin

c) EDUCATION

- Doctorate, University of Nantes (France), 1998
 - magna cum laude ("très honorable")
- Diploma of Advanced International Studies, Geneva (Switzerland), 1989
 - summa cum laude ("très bien")
- LL.M., University of Montreal, 1987
- Computer science studies University of Montreal, 1984-1985
- LL.B. (McGill University/University of Montreal), 1984

D.E.C. (Science, Jean-de-Brébeuf College, Montréal), 1981

d) PREVIOUS EMPLOYMENT & POSITIONS

- Chair, American Bar Association (ABA) Committee on International Copyright Laws & Treaties (2012-2014)
- Acting Dean, Common Law Section, University of Ottawa (Feb-Jul 2006 and Sep-2007-July 2008)
- University Research Chair, Common Law Section, University of Ottawa (2006-2008)
- Vice-Dean, Research, Common Law Section, University of Ottawa (2003-2006)
- Full Professor, Common Law Section, University of Ottawa (2005-2008)
- International editor, Journal of Intellectual Property Law & Practice (Oxford Univ. Press) (2005-2008)
- Associate Professor, Common Law Section, University of Ottawa (2001-2005)
- Vice-President, International, Copyright Clearance Centre, Inc., Massachusetts, USA, 1997-2000
- Consultant, Organization for Economic Cooperation and Development (OECD), Paris, 1997
- Assistant Secretary General, International Confederation of Societies of Authors and Composers (CISAC), Paris, 1995-1996
- Head of Section, World Intellectual Property Organization (WIPO), Geneva, 1992-1995
- Consultant & Legal Officer, General Agreement on Tariffs and Trade (GATT/WTO), Geneva, 1990-1991
- Lawyer, Clark, Woods, (Montreal), 1985-1990

e) VISITING PROFESSORSHIPS

- Yong Shook Lin Professor of Intellectual Property, National University of Singapore, February 2015
- Visiting Professor, *Université de Strasbourg* (Centre for International Intellectual Property Studies (CEIPI), France), Nov.-Dec. 2009, March 2012 and May 2014
- Gide Loyrette Nouel Visiting Chair, *Institut d'études politiques de Paris* (Sciences Po Law), Feb.-Apr. 2012
- Visiting Lecturer, Washington College of Law, American University, June 2011
- Visiting Professor, *Université de Liège* (Belgium), March 2010 and 2011
- Visiting Professor, *Université de Montpellier*, France (Feb. 2007 and Apr. 2008)
- Visiting Professor, University of Haifa (2005)
- 2004 Trilateral Distinguished Scholar-in-Residence, Michigan State University, Detroit College of Law (April-May 2004)
- Visiting Scholar, Stanford Law School, Feb-Apr. 2004
- Visiting Professor, DEA (graduate) program, Faculty of Law, University of Nantes, France (May 2003)
- Visiting Professor, Faculty of Law, Graduate program in intellectual property (DESS), Centre universitaire d'enseignement et de recherché en propriété intellectuelle (CUERPI), Université Pierre Mendès-France (Grenoble II), France
- Visiting Professor, Faculty of Law, University of Puerto Rico (June-July 2002--instruction in Spanish and English)
- Lecturer, Institute for Information Law, Faculty of Law, University of Amsterdam, Postdoctoral Summer Program in International Copyright Law (every year since 2000; last in July 2013)

<u>f) HONORS</u>

- Member, Academy of Europe (2012-)
- Selected (by student vote) as Commencement speaker, Vanderbilt Law School, May 2014
- FedEx Research Professorship, Vanderbilt University Law School (2011-2012)
- Ontario Research Excellence Award (ex PREA), 2005¹
- Charles B. Seton Award, 2003 (see under "Articles in English" below)
- Quebec Bar 1985. Finished first *ex aequo* out of 600+ candidates—received all available awards, including:
 - Quebec Bar Award
 - Quebec Young Bar Award
 - Paris Bar Prize
- Two Excellence Awards, Faculty of Law, University of Montreal, 1984

g) ACADEMIC EVENTS

- Moderator, Beyond Regulation: The US Government as Funder, Creator, and User of Intellectual Property, Annual Symposium of the Vanderbilt Journal of Technology and Entertainment Law, January 23, 2015
- Lecturer, "Patentability criteria as TRIPS Flexibilities," University of London in Paris/Queen Mary, December 4, 2014
- Lecturer, "Collective management", University of Nottingham, December 1, 2014
- Moderator, Is Copyright Working for Music Creators event, Vanderbilt Law School, October 24, 2014.
- Panelist, Kernochan Center for Law, Media, and the Arts 2014 Symposium, Columbia Law School, New York, October 10, 2014
- Moderator, panel on the future of moral rights, ALAI Annual Congress, Brussels, September 19-20, 2014
- Chair, Breakfast Panel, Annual ATRIP Conference, Montpellier (France), July 8, 2014
- Panelist, "Rights in the mix" session, Information Influx International Conference, University of Amsterdam, July 2-3, 2014
- Speaker, Intellectual Property and the Performing Arts, event organized by Indiana University, Maurer School of Law (Bloomington), Indiana University Jacobs School of Music, and the Indiana Arts Commission, Indianapolis, , "Performers rights in comparative perspective" May 16, 2014
- Speaker, Rethinking International Intellectual Property, CEIPI, Strasbourg (France), "The Role of WIPO" May 12, 2014
- Speaker, "Trademarks and Tobacco Packaging", Florida International University, Miami, FL, March 18, 2014
- Lecturer, Concordia University, John Molson School of Business, Montreal, November 4, 2013;
- Speaker, The Future of Corporate Governance and Intellectual Property Protection, FGV Direito, Rio de Janeiro, Brazil, May 24, 2013,
- Moderator, From Berne to Beijing, Symposium of the Vanderbilt Journal of Entertainment and Technology Law, January 25, 2013
- Speaker, "Patents on Science or Technology?", Colloquium of the Department of Physics, Vanderbilt University, January 8, 2013
- Co-Host, Evolution and Equilibrium in Copyright Conference, Wellington, New Zealand, November

¹ Of the 64 awards in that round, only one to a Law Professor.

20-21, 2012

- Speaker, ALAI Congress, Kyoto, Japan, October 15-16, 2012
- Speaker, Amsterdam workshop on copyright formalities, University of Amsterdam, July 7, 2012;
- Speaker, Workshop on When Technology Disrupts Law: How Do IP, Internet and Bio Law Adapt?, AALS Mid-Year Meeting, Berkeley, CA, June 11, 2012;
- Speaker, Law & Business Conference, organized by Vanderbilt Law School; with the Indian School of Business (ISB) and NALSAR, ISB, Hyderabad, India, May 30-31, 2012;
- Speaker, The International Copyright System and Access to Education: Challenges, New Access Models and Prospects for New Principles, Max-Planck Institute, Munich, Germany May 14-15, 2012;
- Speaker, Chicago IP Colloquium, Loyola Law School, Chicago, April 17, 2012
- Participant, Workshop "Intellectual Property at the Edge," Columbia Law School, April 13, 2012
- Panelist, Fordham International Intellectual Property Law & Policy Conference, New York, April 12, 2012
- Speaker, Faculty of Law, University of Nantes, Nantes (France), March 23, 2012
- Speaker, European and International IP Center (CEIPI), Strasbourg (France), March 19, 2012
- Speaker, IP Colloquium, Washington University, St. Louis, Feb. 27, 2012
- Speaker, Canada-Israel Israeli Canadian Workshop on Copyright Law Reforms & Developments, The Hebrew University Of Jerusalem, Feb. 20 -21, 2012
- Moderator, Vanderbilt Intellectual Property Association/Hyatt Fund event, Lockdown on Password Sharing, Feb. 1, 2012
- Moderator, 2011-2012 Symposium of the Vanderbilt Journal of Entertainment and Technology Law (JETLaw), Copyright & Creativity: Perspectives on Fixation, Authorship, & Expression, Jan. 27, 2012
- Moderator & organizer, <u>Melbourne-Vanderbilt Global Debate</u>, Vanderbilt Law School, Nashville, November 15, 2011
- Speaker, IP Colloquium, Indiana University Maurer School of Law, Bloomington, IN, November 3, 2011
- Speaker, Copyright in a borderless online environment Symposium, Thoresta Herrgård, Bro, Sweden, October 27-28, 2011
- Speaker, International Law Weekend, Intellectual Property Law in National Politics and International Relations, New York, NY, Oct. 21-22, 2011
- Panelist, American Intellectual Property Law Association (AIPLA), Annual Meeting, Washington DC, October 20, 2011
- Speaker, Golan v. Holder Roundtable, Harvard Law School, September 23, 2011
- Moderator, Max-Planck Institute Workshop on Economic Partnership Agreements of the EU: A Step Ahead an International IP Law?" Frauenchiemsee, Germany, June 26-28, 2011
- Keynote speaker, 39e Colloque annuel International de l'AFEC, Stretching borders: How far can Canada Go?, Montpellier, France, June 15-17, 2011
- Moderator, Vanderbilt University Law School Program, Beijing, China, May 21, 2011
- Moderator and panelist, 19th Annual Conference on Intellectual Property Law & Policy, Fordham University Law School, New York, April 28-29, 2011
- Chair, Invitation-only Intellectual Property Workshop, Canadian International Council, Ottawa, March 31-April 1, 2011
- Moderator, Patent Unrest, Vanderbilt Law School. February 24, 2011
- Keynote speaker, Annual Symposium of the Kernochan Center for Law, Media & the Arts, Columbia Law School, New York, January 28, 2011
- Speaker, Intellectual Property Institute of Australia (IPRIA), University of Melbourne, Australia, December 13, 2010
- Speaker, Trade, Intellectual Property and the Knowledge Assets of Indigenous Peoples: The Developmental Frontier, Victoria University, Wellington, New Zealand, December 8-10, 2010
- Speaker, Computer Programs and TRIPS, TRIPS@10 Conference, Columbia University, November

16-18, 2010

- Speaker, International Law Weekend, American Branch of the International Law Association, Fordham Law School, New York, October 22-23, 2010
- Speaker, Bits Without Borders conference, Michigan State University, East Lansing, MI, September 25-26, 2010
- Speaker, World Trade Forum, Bern, Switzerland, September 3-4, 2010
- Speaker, Copyright @ 300, UC Berkeley School of Law, Berkeley, CA, April 9-10, 2010
- Speaker, The Statute of Anne 300 Birthday, Cardozo Law School, New York, March 24-25, 2010
- Panelist, Access to Knowledge (A2K) conference, Yale Law School, February 12-13, 2010
- Speaker, IUS COMMUNE, Reinventing the Lisbon Agreement, Maastricht University, The Netherlands, November 26, 2009
- Speaker, The Lisbon Agreement, CEIPI (Université de Strasbourg, France), November 17, 2009
- Keynote speaker, Signifiers in Cyberspace: Domain Names and Online Trademarks Conference, Case Western Reserve University, Cleveland, Ohio, November 12, 2009
- Speaker, Beyond TRIPS: The Current Push for Greater International Enforcement of Intellectual Property, American University (Washington College of Law), November 5, 2009
- Speaker, Intellectual Property Developments in China: Global Challenge, Local Voices conference, Drake University, Des Moines, Iowa, October 15-16, 2009
- Speaker, University of Hong Kong, June 12-13, 2009
- Speaker, Conference on 100th Anniversary of the 1909 Copyright Act, Santa Clara University, April 27, 2009
- Panelist, Fordham International Intellectual Property law & Policy Conference, Cambridge, England, April 15-16, 2009
- Participant, University of Cambridge-University of Queensland Copyright History Roundtable, Cambridge, England, April 15, 2009
- Commentator, Vanderbilt Roundtable on User-Generated Content, Social Networking & Virtual Worlds, Nashville, November 14, 2008
- Distinguished Finnegan Lecturer, Washington College of Law, Washington, D.C., October 18, 2008
- Panelist, International Law Weekend, New York, October 16, 2008
- Speaker, IP Speaker Series, Cardozo Law School, September 22, 2008
- Lecturer, Intellectual Property Research Institute of Australia (IPRIA), Melbourne, June 3, 2008
- Speaker, International Conference on Patent Law, University of New Zealand, Wellington, May 29-30, 2008
- Speaker, Law School of National Taiwan University, March 21, 2008
- Commentator, EDGE Project Conference on Intellectual Property and Development, Hong Kong, March 17-18, 2008
- Speaker, Cardozo Law School Conference on Harmonizing Exceptions and Limitations to Copyright Law, New York, March 30-31, 2008
- Panelist, Fordham Conference on International Intellectual Property Law & Policy, New York, March 27-28, 2008
- *Rapporteur*, International Literary and Artistic Association Biennial Congress (ALAI), Punta del Este, Uruguay, Oct. 31 Nov. 3 2007
- Speaker, Vanderbilt University, Nashville, Tennessee, Oct. 16-17, 2007. "Collective Management of Copyright in North America", (conference organized in cooperation with WIPO)
- Speaker, University of South Carolina, Columbia, SC, October 12, 2007 "The Future of Copyright Law"
- Panelist, Fordham University Conference on International Intellectual Property Law & Policy, New York, April 12-13, 2007
- Speaker, Dean's lectures on intellectual property, George Washington University School of Law, Washington D.C., March 13, 2007
- Speaker, UCLA Conference on the WIPO Development Agenda, Los Angeles, March 9-11, 2007

- Speaker, International Conference on Impact of TRIPS: Indo-US Experience. NALSAR University of Law, Hyderabad (India), Dec. 15-16, 2006
- Speaker, International intellectual property conference, University of Chicago-Kent, October 12-13, 2006
- Speaker, Study days of the International Literary and Artistic Association, Barcelona, June 18-21, 2006
- Moderator, Fourteenth Annual Conference on International Intellectual Property Law & Policy, New York, April 20-21 2006
- Speaker, University of Michigan, Ann Arbor. Intellectual Property & Development, April 14 2006
- Speaker, Michigan State University College of Law (MSU), East Lansing, The International Intellectual Property Regime Complex, April 7-8 2006
- Roundtable participant, Vanderbilt University Law School, Nashville, Tennessee. Private International Law and Intellectual Property Law: Theory and Practice, March 24-25, 2006
- Panelist, Federalist Society, Annual Lawyers Convention. Washington, D.C., November 2005
- Panel Chair, Annual meeting of the International Association for the Advancement of Teaching and Research in Intellectual Property (ATRIP), Montréal, July 11-13, 2005
- Lecturer, Institute of European Studies, Macau (IEEM), Advanced IP course (25 June-1 July 2005)
- Lecturer, Advanced IP conference, Macau, June 27-30, 2005
- Speaker, Conference on the Relationship between international and domestic law McGill University, June 15-16, 2005
- Speaker, Conference on the Collective Management of Copyright, Oslo, May 19-21, 2005
- Keynote speaker, Conference of the Department of Justice on intellectual property and Internet Law, Ottawa, April 21, 2005
- Keynote speaker, LSUC Annual Communications Law Conference, Toronto, April 8-9, 2005
- Speaker, Law & the Information Society Conference, Fordham University, New York, April 6-7, 2005
- Panelist, Fordham International Intellectual Property Law & Policy Conference, New York, March 31-Apirl 1, 2005
- Speaker, Shanghai 2004: Intellectual Property Rights and WTO Compliance. University of East China, Shanghai, China, Nov. 24, 2004
- Speaker, "The Internet: A Global Conversation" Conference, University of Ottawa, Oct. 1-2, 2004
- Lecturer, Office for Harmonization in the Internal Market (Trade Marks and Designs). Alicante (Spain), July 2004
- Organizer and Speaker, Rethinking Copyright Conference, University of Ottawa, May 20-21, 2004
- Panelist, American Intellectual Property Lawyers Association (AIPLA), Dallas TX, May 13-14, 2004
- Speaker, 2004 Computers Freedom & Privacy Conference, Berkeley, California Apr. 20-23, 2004
- Speaker, Intellectual Property, Sustainable Development & Endangered Species Conference. Detroit College of Law, Michigan State University, March 26-27, 2004
- Speaker, Securing Privacy in the Internet Age Symposium, Stanford Law School, March 13-14, 2004
- Keynote speaker, "US Copyright Office Comes to California" Conference, Hastings College of Law, San Francisco, CA, March 3, 2004
- Speaker, Global Arbitration Forum, Geneva, Switzerland, Dec. 4-5, 2003
- Panel Chair and Speaker, "Copyright and the Music Industry: Digital Dilemmas", Institute for Information Law, Amsterdam, July 4-5, 2003. Topic: "Collective Rights Management & the Future of Copyright"
- Conference Fellow, "International Public Goods and Transfer of Technology under a Globalized Intellectual Property Regime" Conference, Duke Law School, Raleigh, NC, USA, Apr. 4-6, 2003
- Speaker, Roundtable on questions arising out of the intersections of technology and questions of social justice, University of Ottawa, March 28, 2003. Topic: "Democracy, Technology and Social Justice" (available at commonlaw.uottawa.ca)
- Speaker, Conference of Copyright Law Association of Japan (CLAJ), Tokyo, Dec. 7, 2002. Topic : "Transactional Copyright: Licensing Tailored Uses"

- Speaker, Facultés universitaires de Saint-Louis, Belgique, May 25-26 2002. Topic : «De l'œuvre à l'auteur »
- Speaker. Institutions administratives du droit d'auteur, colloquium organized by the Université de Montréal, Montreal, Oct. 2001. Topic : « La gestion collective au Canada : fragmentation des droits ou gestion fragmentaire »
- Speaker, Annual Meeting of the International Literary and Artistic Association (ALAI International), Columbia University, New York, 2001. Topic: "Rights Management Systems"
- Lecturer, Swedish School of Economics and the Finnish IPR Institute, Helsinki, Finland, 2000. Topic: "Copyright and Electronic Commerce", lecture presented to graduate students
- Speaker, Fordham University Conference on International Intellectual Property, New York, April 2001. Topic "Electronic Commerce and Copyright"
- Speaker, Fordham University Conference on International Intellectual Property, New York, April 2000. Topic: "The TRIPS Agreement After Seattle"
- Speaker, Ohio State University, Columbus, Ohio, 2000. Topic: "Digital Licensing of Copyright"
- Speaker, Fordham University Conference on International Intellectual Property, New York, April 1999. Topic: "Digital Distance Education: Exemption or Licensing?"
- Speaker, Fordham University Conference on International Intellectual Property, New York, April 1999. Topic: "An Overview of TRIPS: Historical and Current Issues"

h) <u>PUBLIC LECTURES & EVENTS</u>

- Keynote speaker, International Congress of Music Authors (CIAM), Nashville, October 22, 2014
- Speaker, Intellectual Property Institute of Canada (IPIC), 88th Annual Meeting, Halifax, Nova Scotia, October 16-17, 2014
- Panelist, Copyright Office's Roundtable on Music Licensing, Nashville, TN, June 4-5, 2014
- Panelist, Workshop organized by the International Law Research Program at the Centre for International Governance Innovation (CIGI), Waterloo, ON, June 3-4, 2014
- Panelist, USPTO and NTIA Roundtable, Green Paper Green Paper on Copyright Policy, Creativity and Innovation in the Digital Economy, Vanderbilt Law School, May 21, 2014
- <u>Testimony, Subcommittee on Courts, Intellectual Property and the Internet Committee on the</u> <u>Judiciary</u>, United States House of Representatives, 113th Congress, 1st Session, May 16, 2013
- Lecturer, NORCODE/WIPO Course on Collective Management of Copyright, Oslo, Norway, June 12-13, 2013
- Speaker, Intellectual Property Institute of Canada, Annual Congress, Vancouver, B.-C., October 11, 2012
- Speaker, The Copyright Office Comes to Music City, Nashville, TN, April 26, 2012
- Panelist, ABA IP Section, Annual Meeting, Crystal City VA, March 29, 2012
- Speaker, Practising Law Institute, New York, March 28, 2012
- Speaker, Gide Loyrette Nouel, Paris (France), March 14, 2012 ("Non Traditional Trademarks")
- Speaker, Leadership Music, Nashville, TN, March 9, 2012
- Moderator, Canadian International Council conference on Innovation ("Right and Rents"), Ottawa, October 5-7, 2011
- Chair and Speaker, Canadian International Council Workshop on Innovation, Ottawa, March 31 and April 1st, 2011
- Speaker and session leader, High-level (Ministerial) Forum on Intellectual Property for the Least-Developed Countries, WIPO, Geneva, July 24-25, 2009
- Moderator, Copyright Counseling, Management, and Litigation Law Seminar, Seattle, WA,

April 26-27, 2009

- Speaker, Annual Meeting. Commission on Intellectual Property, International Chamber of Commerce, Cambridge, England, April 17, 2009
- Keynote speaker, Asian Copyright Seminar, Tokyo, Japan, February 25-27, 2009
- Speaker, International Copyright Institute, Washington DC, Nov. 28, 2006
- Speaker, International Trademark Association, Trademarks Administrators Conference, Crystal City, Virginia, September 19-20, 2006
- Speaker, General Assembly of the National Association of Publishers (ANEL), Montréal, September 14, 2006
- Speaker, Federalist Society Annual Lawyers Convention, Washington D.C. November 2005.
- Keynote speaker. InSIGHT, Old Mill Inn, Toronto, September 2005. Topic: "Copyright Reform in Canada"
- Speaker. Canadian Institute, , Montréal, 5-6 June, 2005
- Speaker, Canadian Bar Association, Montreal, Nov. 9, 2004. Topic: "Recent developments in Canadian copyright law"
- Speaker, Peer-to-Peer Luncheon speech, The 45th Circuit, Ottawa Centre for Research and Innovation (OCRI), Oct. 5, 2004. Topic: "Peer-to-Peer File-Sharing"
- Speaker, Luncheon conference, ALAI Canada, Toronto, Sept. 13, 2004. Topic: "The Supreme Court decision in SOCAN v. Can. Ass'n of Internet Providers"
- Lecturer, International Copyright Institute, Washington, D.C., May 5, 2004. Topic: "Collective management of copyright"
- Speaker, Biannual Canadian Bar Association/Law Society of Upper Canada Communications Law Conference, Ottawa, April 23-24, 2004. Topic: "The Supreme Court decision in *CCH v. Law Society of Upper Canada*"
- Speaker, Association pour l'avancement des sciences et des techniques de la documentation (ASTED), Annual Meeting, Gatineau, Québec, Nov. 7, 2003. Topic : "Copyright Exceptions and Librarians"
- Keynote speaker, International Conference on National Copyright Administrative Institutions, Ottawa, Oct. 8-10, 2003. Topic: "Status Report on Internet Tariffs"
- Panelist, Intellectual Property Institute of Canada (IPIC), Annual Meeting, Halifax, Sept. 19, 2003. Topic: "Technical Protection Measures and Copyright"
- Speaker, North American Workshop on Intellectual Property and Traditional Knowledge, Ottawa, Sept. 7-9, 2003. Topic: Traditional Knowledge and Intellectual Property: The Issues"
- Speaker, Association des juristes d'expression française de l'Ontario (AJEFO), Ottawa, June 21, 2003. Topic: Law & Technology
- Speaker, Editors Association of Canada, Ottawa, June 15, 2003. Topic : "A Walk Through the Copyright Labyrinth"
- Keynote speaker, Computer Assisted Language Instruction Consortium (CALICO), Ottawa, May 22, 2003. Topic : "Copyright, Copyleft, Copywrong?"
- Speaker, Expert Roundtable on Transactions in Intellectual Property, Amsterdam, May 17-18, 2003. Topic: "Fragmentation of Copyright and Rights Management"
- Speaker, "The 45th Circuit" (OCRI), Ottawa, Apr. 1, 2003. Topic : "Emerging Issues in Digital Rights Management"
- Speaker, Information Highways Conference, Toronto, March 24, 2003. Topic : Digital Rights Management : Balancing Creators Rights and User Interests"

- Speaker, Literary and Artistic Association (ALAI Canada), Montréal, QC, Oct. 22, 2002. Topic: « La gestion collective es-elle en crise? »
- Instructor, World Trade Organization (WTO), Nairobi, Sept. 2002. Topic: The TRIPS Agreement after Doha"
- Instructor, World Trade Organization (WTO), Casablanca, Sept. 2002. Topic: "The TRIPS Agreement After Doha"
- Speaker, Literary and Artistic Association (ALAI Canada), Montreal, May 7, 2002. Topic: « La décision de la Cour suprême dans l'affaire *Galeries d'art du Petit Champlain Inc. c. Théberge* »
- Instructor. International Copyright Institute (Washington, D.C.), Nov. 2000 and Nov. 2001. Topic: "Collective Management of Copyright in the Digital Age"
- Speaker. Annual Meeting of the International Trademark Association (INTA), Denver, CO, USA, May 2000. Topic: "The TRIPS Agreement: Implementation and Dispute Settlement Issues"
- Speaker, New York Bar (NYCLA), 2000. Topic : "Current Rights Clearance Issues"
- Speaker, Society of Scholarly and Professional Publishers (SSP), Boston, Mass., 1999. Topic: "Copyright Licensing Issues"
- Speaker, Canadian Writers Union Conference, Toronto, 2000. Topic: "Copyright Management in the Digital Age"
- Speaker, Heritage Canada Roundtable on Copyright Management, Ottawa, 1999. Topic: "Copyright Management: US Practices"
- Speaker, International Publishers Association (IPA) Congress, Tokyo, Japan, 1998. Topic: "Copyright, Publishing in the Face of Technological Change"
- Speaker, Marché international du multimédia (MILIA), Cannes, France, 1995. Topic : "Droit d'auteur et multimédia"
- Speaker, Chilean Book Fair, Santiago, Chile, 1999. Topic: "El papel de las sociedades de derechos reprográficos y de la IFRRO"
- Speaker, Sydney Bar, NSW, Australia, 1996. Topic: "Intellectual Property and Technology"
- Speaker, Congress of the International Publishers Association, Barcelona, Spain, 1996. Topic: "Online Copyright Licensing"
- Speaker, Pan African Film Festival (FESPACO), Ouagadougou, Burkina Faso, 1994. Topic: "Protection of Intellectual Property in Film"
- Speaker, Chambre française du commerce et de l'exportation (CFCE), Paris, 1990. Topic : "TRIPS: Le point à dix semaines de Bruxelles"
 - h) <u>Publications</u>²

i) Summary

Books authored	
Books edited	

² Where possible, titles are hyperlinked. *See also <u>http://bit.ly/tsGP0y</u>*. The number following the "+" sign indicates the number of forthcoming titles in each category accepted for publication.

Book chapters	
Articles	
Conference proceedings (refereed)	1
Book reviews	2
Other publications	
Technical Reports, Law Reform, and Commissioned Research Work	6

ii) Detailed description

Books (authored)

- 1. INTELLECTUAL PROPERTY: THE LAW IN CANADA, 3rd ed. (Thomson/Carswell, *forthcoming*) -- with Prof. Elizabeth Judge
- 2. INTERNATIONAL INTELLECTUAL PROPERTY: AN ADVANCED INTRODUCTION (E Elgar, *forthcoming*) with Prof. Susy Frankel
- 3. THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS, 4th edn (Sweet & Maxwell, 2012)
- 4. THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS, Asian edition (Sweet & Maxwell Asia, 2012)
- 5. INTELLECTUAL PROPERTY: THE LAW IN CANADA, 2^d ed. (Carswell, 2011) --with Prof. Elizabeth Judge, 1223 p.
 - a. Cited by the Supreme Court of Canada
- 6. L'ACCORD SUR LES ADPIC: PROPRIÉTÉ INTELLECTUELLE À L'OMC (Larcier, 2010), 733 p.
- 7. THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS, 3rd edn. (Sweet & Maxwell, December 2008), 785 p.
 - a. Cited by the Supreme Court of the United States in Golan v. Holder (2011) and Wiley v. Kirtsaeng (2013)
 - b. This and previous editions cited in several Advocate Generals' Opinions, Court of Justice of the European Union
- 8. LE DROIT DE LA PROPRIETE INTELLECTUELLE, (Yvon Blais, 2006). 702 pages--with Professors Elizabeth Judge and Mistrale Goudreau
- 9. INTELLECTUAL PROPERTY: THE LAW IN CANADA (Carswell, 2005), with Prof. Elizabeth Judge
- THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS, 2ND ed. (Sweet & Maxwell, June 2003). 590 p.
- 11. THE TRIPS AGREEMENT: DRAFTING HISTORY AND ANALYSIS. (Sweet & Maxwell, 1998). 444 p.
- 12. LA NOTION D'ŒUVRE DANS LA CONVENTION DE BERNE ET EN DROIT COMPARÉ. (Librairie Droz, 1998). 276 p.

Books (edited)

- 1. COLLECTIVE MANAGEMENT OF COPYRIGHT AND RELATED RIGHTS, 3rd edn (Kluwer Law International, *forthcoming*) 495 p.
- 2. INTERNATIONAL INTELLECTUAL PROPERTY: A HANDBOOK OF CONTEMPORARY RESEARCH (E Elgar, 2015). 482 pages
- 3. INTELLECTUAL PROPERTY, TRADE AND DEVELOPMENT 2nd edn (Oxford Univ. Press, 2014). 364 pages.
- 4. THE EVOLUTION AND EQUILIBRIUM OF COPYRIGHT IN THE DIGITAL AGE (Cambridge Univ. Press, 2014)—with Prof. Susy Frankel. 325 pages.
- 5. COLLECTIVE MANAGEMENT OF COPYRIGHT AND RELATED RIGHTS, 2nd edn (Kluwer Law International, 2010) 495 p.
- 6. INTELLECTUAL PROPERTY, TRADE AND DEVELOPMENT (Oxford Univ. Press, 2007). 564 p.
- 7. COLLECTIVE MANAGEMENT OF COPYRIGHT AND RELATED RIGHTS (Kluwer Law International, 2006), 464 p.

Book chapters

- 1. *Collective Management in China*, in COLLECTIVE MANAGEMENT OF COPYRIGHT AND RELATED RIGHTS, 3rd edn (D. Gervais, ed., Kluwer Law International, *forthcoming*)—with Fuxiao Jiang
- 2. Collective Management of Copyright and Related Rights in the Digital Age, in id.
- 3. The TRIPS Agreement, in ENCYCLOPEDIA OF LAW & ECONOMICS (A Marciano, ed.), (Springer, *forthcoming*)
- The Limits of Patents, in INTERNATIONAL INTELLECTUAL PROPERTY: A HANDBOOK OF CONTEMPORARY RESEARCH (D. Gervais, ed) (E. Elgar, 2015) (with Elizabeth Judge), pp. 246-271
- 5. The Three-Step Test, in idem. (with Christophe Geiger and Martin Senftleben), pp. 167-189
- TRIPS Articles 10; 63-71, in CONCISE INTERNATIONAL AND EUROPEAN IP LAW, 3D ED. (THOMAS COTTIER AND PIERRE VÉRON, EDS). Kluwer Law International, 2015, pp. 41-44 and 179-198
- <u>IP Calibration</u>, in INTELLECTUAL PROPERTY, TRADE AND DEVELOPMENT, 2d ed. (D. Gervais, ed) (Oxford Univ. Press, 2014) 86-114
- 8. *Originalités*, in MÉLANGES EN L'HONNEUR DU PROFESSEUR ANDRÉ LUCAS, 389-400 (LexisNexis, 2014)
- Patentability Criteria as TRIPS Flexibilities: The Examples of China and India, in GLOBAL PERSPECTIVES ON PATENT LAW (MARGO BAGLEY AND RUTH OKEDIJI, EDS) 541-570 (Oxford Univ. Press, 2014)
- <u>A Cognac after Spanish Champagne? Geographical Indications as Certification Marks</u>, in INTELLECTUAL PROPERTY AT THE EDGE (JANE C. GINSBURG AND ROCHELLE DREYFUSS, EDS) (Cambridge Univ. Press, 2014) 130-155
- 11. Current Issues in International Intellectual Property Norm-Making, in (J Drexl, H Grosse Ruse-Khan and S Nadde-Phlix, eds). MPI Study series (Springer, 2013) 3-16

- 12. <u>The Internet Taxi: Collective Management of Copyright and the Making Available Right, After</u> <u>the Pentalogy</u>, in The Copyright Pentalogy: How the Supreme Court of Canada Shook THE FOUNDATIONS OF CANADIAN COPYRIGHT LAW (M. GEIST, ED.) 373-401 (2013)
- 13. <u>*The TRIPS Agreement and Climate Change,*</u> in RESEARCH HANDBOOK ON INTELLECTUAL PROPERTY AND CLIMATE CHANGE (JOSHUA SARNOFF, ED.) (E Elgar, *forthcoming*)
- 14. *Physionomie et problématiques modernes du monopole octroyé par le droit des brevets*, JURISCLASSEUR QUÉBEC: PROPRIÉTÉ INTELLECTUELLE (S. Rousseau, ed., 2012), pp. 21-1 – 21.18 (with Elizabeth Judge).
- 15. *Copyright, Culture and the Cloud*, in TRANSNATIONAL CULTURE IN THE INTERNET AGE (SEAN PAGER & ADAM CANDEUB, eds.) (E. Elgar, 2012) 31-54;
- 16. *Physionomie et problématiques modernes du monopole octroyé par le droit des brevets, in* JURISCLASSEUR QUÉBEC : PROPRIÉTÉ INTELLECTUELLE (2012), pp. 21-1 -21.18 (with Prof. Elizabeth Judge)
- 17. *Criminal Enforcement in the US and Canada, in* CRIMINAL ENFORCEMENT OF INTELLECTUAL PROPERTY (C. GEIGER, ED) (E. Elgar, 0212), 269-285;
- 18. <u>Traditional Innovation and the Ongoing Debate on the Protection of Geographical Indications</u>, INTELLECTUAL PROPERTY AND INDIGENOUS INNOVATION (PETER DRAHOS AND SUSY FRANKEL, EDS) (Australia National University Press, 2012)
- 19. *Individual and Collective Management of Rights Online, in* COPYRIGHT IN A BORDERLESS ONLINE ENVIRONMENT (J. AXHAMN, ED.). Norstedts Juridik, 2012. 89-100;
- <u>Country Clubs, Empiricism, Blogs and Innovation: The Future of International Intellectual</u> <u>Property Norm-Making in the Wake of ACTA</u>, TRADE GOVERNANCE IN THE DIGITAL AGE (MIRA BURRI AND THOMAS COTTIER, EDS). Cambridge University Press, 2012, pp. 323-343
- 21. *The TRIPS Agreement*, in MAX PLANCK ENCYCLOPEDIA OF PUBLIC INTERNATIONAL LAW (R. Wolfrum, ed.) (Oxford University Press, 2008-), online edition, [www.mpepil.com]
- TRIPS Articles 10; 63-71, in CONCISE INTERNATIONAL AND EUROPEAN IP LAW, 2D ED. (THOMAS COTTIER AND PIERRE VÉRON, EDS). Kluwer Law International, 2011, pp. 38-42 and 168-186
- 23. The International Legal Framework of Border Measures in the Fight against Counterfeiting and *Piracy*, in ENFORCEMENT OF INTELLECTUAL PROPERTY RIGHTS THROUGH BORDER MEASURES, 2d ed. OLIVIER VRINS AND MARIUS SCHNEIDER EDS.). Oxford Univ. Press, 2012, 51-76;
- 24. <u>User-Generated Content and Music File-Sharing: A Look at Some of the More Interesting</u> <u>Aspects of Bill C-32</u>, in FROM "RADICAL EXTREMISM" TO "BALANCED COPYRIGHT": CANADIAN COPYRIGHT AND THE DIGITAL AGENDA (MICHAEL GEIST, ED., Irwin Law, 2010)
- <u>Collective management of Copyright: Theory and Practice in the Digital Age</u>, in COLLECTIVE MANAGEMENT OF COPYRIGHT AND RELATED RIGHTS, 2nd edn (D. Gervais, ed., Kluwer Law International, 2010) 1-28;
- 26. Of Silos and Constellations: Comparing Notions of Originality in Copyright Law, in INTELLECTUAL PROPERTY PROTECTION OF FACT-BASED WORKS (ROBERT F. BRAUNEIS, ED, Edward Elgar, 2010) 74-106—coauthored with Professor Elizabeth Judge;
 - Also published as an article (see below)

- 27. Policy Calibration and Innovation Displacement, in DEVELOPING COUNTRIES IN THE WTO LEGAL SYSTEM (JOEL TRACHTMAN, AND CHANTAL THOMAS, EDS.) (Oxford Univ. Pr., 2009) 363-394;
- 28. *TRIPS 3.0, in* The Development Agenda: Global Intellectual Property and Developing Countries (Neil W. Netanel, ed) 51-75. (Oxford Univ. Pr., 2009)
- 29. <u>A Uniquely Canadian Institution: The Copyright Board of Canada</u>, in A NEW INTELLECTUAL PROPERTY PARADIGM: THE CANADIAN EXPERIENCE (YSOLDE GENDREAU ED). (Edward Elgar, 2009)
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