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 JAY ERSTLING

# Professor of Law, William Mitchell College of Law

### I. INTRODUCTION

1. I am currently a Professor of Law at William Mitchell College of Law in St. Paul, Minnesota, and a member of the William Mitchell Intellectual Property Institute. I reside in Minneapolis, Minnesota. My primary teaching and research focus is on international and comparative patent law, with a particular emphasis on the Patent Cooperation Treaty (PCT). In addition, I am the founding Director of the William Mitchell College of Law Intellectual Property Law Clinic, which was selected by the U.S. Patent and Trademark Office (USPTO) to participate in its Law School Clinic Certification Pilot Program.

2. I am also currently Of Counsel at Patterson Thuente Pedersen, P.A., an intellectual property law firm in Minneapolis, Minnesota, where I provide advice and counsel on PCT and international filing matters to the firm's clients. I am a member of the Bars of the State of Minnesota and the Commonwealth of Pennsylvania, and I am admitted to practice before the U.S. Court of Appeals for the Federal Circuit.

3. From 2002 to 2007, I worked for the World Intellectual Property Organization (WIPO) in Geneva, Switzerland, where I served as the Director of the Office of the PCT and Director-Advisor for PCT Matters. I also worked for WIPO from 1976 to 1986, where I served as a Legal Officer and Senior Legal Officer in the Industrial Property Division.

4. I am the primary co-author of *The Practitioner's Guide to the PCT*, published in 2013 by the American Bar Association Section of Intellectual Property Law (ABA-IPL). My co-authors are Samson Helfgott and T. David Reed. I am a co-author of *International Patent Law and Policy*, published in 2013 by West Publishing. My co-authors are Margo Bagley and Ruth Okediji.

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7. I am a member of the ABA-IPL and serve as the Liaison to the WIPO Standing Committee on the Law of Patents (SCP). I am also the outgoing Chair of the PCT Issues Committee of the American Intellectual Property Law Association (AIPLA), of which I am a member. From 2011 through 2014, I served as chair and member of the faculty of the AIPLA PCT Annual Seminar.

8. I am the recipient of two Fulbright Senior Scholar awards and an Indo-American Fellowship. I earned B.S. and J.D. degrees from Cornell University. Attached as Appendix A is a copy of my *curriculum vitae*, which further details my qualifications.

9. Prior to May 2009, neither Patterson Thuente Pedersen nor I had done any work on behalf of Eli Lilly (Lilly). In May 2009, Lilly asked me to review the Canadian Federal Court decisions relating to Lilly's drug Evista (raloxifene) and to discuss my view of those decisions in the context of the PCT requirements for patent applications. As a result of my review, I prepared an affidavit that was filed by Eli Lilly in the Supreme Court of Canada in support of Lilly's application for leave to appeal from the Federal Court of Appeal. In January 2012, Lilly requested that Patterson Thuente Pedersen undertake an independent study of patentable utility requirements, which resulted in the preparation of an article entitled "Usefulness Varies by Country: The Utility Requirement of Patent Law in the United States, Europe and Canada,"<sup>1</sup> authored by myself, Amy Salmela, and Justin Woo (counsel with Patterson Thuente Pedersen). Lilly subsequently requested that I share the results of the article at a comparative intellectual property law symposium entitled "Utility Requirements: Converging and Diverging Approaches," in Ottawa, Canada, on April 4, 2012, and that I repeat my presentation on a panel

<sup>&</sup>lt;sup>1</sup> The article was published in Cybaris, an Intellectual Property Law Review at William Mitchell College of Law (Vol. 3, Issue 1, 2012; available on-line at http://web.wmitchell.edu/cybaris/wp-content/uploads/2012/06/Erstling-Salmela-Woo.pdf) (C-100).

at the 2012 ABA Annual Meeting, Chicago, Illinois, USA, on August 3, 2012. I confirm that I have no other relationship to Eli Lilly and Company or any of its affiliates.

10. For this report, I have been asked to provide testimony about treaties for the filing of patent applications in multiple jurisdictions, the role of the PCT in the international framework for patent protection, and PCT requirements relating to the description of the industrial applicability/utility of an invention within the patent.

### II. TREATIES GOVERNING THE FILING OF PATENT APPLICATIONS

11. Although patent protection is national in scope, international agreements dating as far back as 1883 exist to facilitate the filing of patent applications throughout the world and limit discrimination against foreign applicants.<sup>2</sup> The Paris Convention for the Protection of Industrial Property of 1883 (Paris Convention)<sup>3</sup> was the first successful effort to create an international framework for protecting inventions across national boundaries. Canada has been a contracting party since 1925, Mexico since 1903, and the United States since 1887.<sup>4</sup> The Paris Convention established three bedrock principles of patent law that strive to guarantee equal treatment for inventors and inventions in all contracting states. Those principles are the independence of patents,<sup>5</sup> national treatment,<sup>6</sup> and the right of priority, and they remain the foundation of international patent law today.<sup>7</sup>

<sup>&</sup>lt;sup>2</sup> The Paris Convention for the Protection of Industrial Property of March 20, 1883 (C-101).

<sup>&</sup>lt;sup>3</sup> *Id.* (C-101).

<sup>&</sup>lt;sup>4</sup> WIPO-Administered Treaties, Contracting Parties > Paris Convention, available at http://www.wipo.int/ treaties/en/ShowResults.jsp?treaty\_id=2 (C-102). There are 176 total Contracting Parties to the Paris Convention. *Id.* 

<sup>&</sup>lt;sup>5</sup> Article 4*bis* of the Paris Convention ensures that a Paris Convention member country cannot be obliged to grant or refuse a patent simply on grounds that the patent was granted or refused in another member country. (C-101).

<sup>&</sup>lt;sup>6</sup> Article 2 of the Paris Convention requires each member country to grant the same protection to nationals of the other member country as it grants to its own nationals. (C-101).

<sup>&</sup>lt;sup>7</sup> Summary of the Paris Convention for the Protection of Industrial Property, available at http://www.wipo.int/treaties/en/ip/paris/summary\_paris.html (C-103).

12. The right of priority is established in Article 4 of the Paris Convention.<sup>8</sup> Under this right, when patent applicants file an application in a member country of their choosing, all subsequent applications for the same invention filed within the following twelve months in other member countries must be treated by those countries as if they had been filed on the same day as the first application.<sup>9</sup> The later applications thereby benefit from the first application's filing date, and enjoy a priority status over any competing application filed during the twelve-month priority period. The later applications also enjoy immunity from acts carried out after the priority filing date that would normally destroy an applicant's right to a patent, such as publication or disclosure of the invention. The right of priority can therefore have a determinative impact on an applicant's entitlement to a patent, and may result in a foreign applicant prevailing over a national applicant if the foreign applicant's priority filing date predates the filing date of the national applicant.

13. The right of priority is essential to the functioning of the international patent system and plays an integral role in the international system created by the PCT, a multilateral treaty that establishes an international patent application filing system.<sup>10</sup> The PCT, which was adopted in 1970 and entered into force in 1978, is administered by the World Intellectual Property Organization (WIPO). There are currently 148 countries that are party to the PCT, including Canada, which became bound in 1990, Mexico, which became bound in 1995, and the United States, which became bound in 1978.<sup>11</sup> The PCT refers to member countries as

<sup>&</sup>lt;sup>8</sup> Paris Convention, Art. 4 (C-101).

<sup>&</sup>lt;sup>9</sup> *Id.* (C-101).

<sup>&</sup>lt;sup>10</sup> PCT – The International Patent System, available at http://www.wipo.int/pct/en/ (C-104).

<sup>&</sup>lt;sup>11</sup> PCT Contracting States, available at http://www.wipo.int/pct/en/pct\_contracting\_states.html (C-105).

Contracting States.<sup>12</sup> In addition to the Treaty, a set of Regulations under the Treaty governs the PCT system.<sup>13</sup>

14. The PCT was created to provide applicants with a user-friendly, cost-effective, and efficient system for filing international patent applications. It enables patent applicants to seek protection for their inventions in a large number of countries by filing a single international application instead of having to file a separate application in every country.<sup>14</sup> An international application may be filed in any language with the patent office of a PCT Contracting State or directly with the International Bureau of WIPO.<sup>15</sup> Since the PCT became operative, more than 2,000,000 international applications have been filed, with 205,300 applications filed in 2013.<sup>16</sup> In accordance with Article 11 of the PCT, an international application "has the effect of a regular national application" in each PCT Contracting State.<sup>17</sup>

15. The vast majority of PCT international applications take advantage of the Paris Convention right of priority by claiming priority to national applications filed within the preceding twelve months.<sup>18</sup> In other words, applicants initially file a national application with their national patent office and then within the following twelve months file an international application that is based on and claims priority to their first-filed national application. In order to

<sup>&</sup>lt;sup>12</sup> *Id.* (C-105).

<sup>&</sup>lt;sup>13</sup> PCT Treaty, Regulations and Administrative Instructions, available at http://www.wipo.int/treaties/en/ registration/pct/ (C-106 and C-188).

<sup>&</sup>lt;sup>14</sup> PCT – The International Patent System, *supra* note 10 (C-104).

<sup>&</sup>lt;sup>15</sup> PCT FAQs, Question 12, available at http://www.wipo.int/pct/en/faqs/faqs html (C-107).

<sup>&</sup>lt;sup>16</sup> Of the total number of PCT applications filed in 2013, 2,851 originated from Canada, 233 from Mexico, and 57,239 from the United States. WIPO, *Patent Cooperation Treaty Yearly Review, 2014*, p. 33 (C-108). 2013 is the latest year for which statistics are available.

<sup>&</sup>lt;sup>17</sup> PCT, Art. 11: "Any international application fulfilling the requirements listed in items (i) to (iii) of paragraph (1) shall be equivalent to a regular national filing within the meaning of the Paris Convention for the Protection of Industrial Property." (C-106).

<sup>&</sup>lt;sup>18</sup> Claiming priority is governed by Article 8 of the PCT and Rule 4.10 of the Regulations. Because almost all international applications are subsequent filings that benefit from the priority filing date, dates and deadlines throughout the PCT procedure are generally calculated from the priority filing date, and PCT timelines begin with the filing of a priority application.

prevent loss of the priority filing date, international applications generally closely resemble or are identical to the national applications to which they claim priority.

16. The PCT lays down the form and contents requirements for international applications. These requirements are binding on all Contracting States, which are not permitted under the Treaty to add to or vary from them.<sup>19</sup> As stated in the Post-Conference Documents included in the Records of the Washington Diplomatic Conference on the PCT (Post-Conference Documents), a major advantage of the PCT is therefore that "[t]he applicant knows that an international application which is good as far as form and contents are concerned in his home country is also good in any of the Contracting States."<sup>20</sup>

# III. OVERVIEW OF THE PCT PROCEDURE

17. The PCT procedure created by the Treaty and Regulations consists of two phases: an international phase, and a national phase.<sup>21</sup> Both phases include important harmonizing requirements for Contracting States without which the PCT system could not operate. A fundamental requirement that links both phases is the preservation of the Paris Convention right of priority.<sup>22</sup> A single international application filed in any Contracting State within twelve months of the filing date of the priority application will not only have the same legal effect as if a national application had been filed in every Contracting State, but will also maintain the filing

<sup>&</sup>lt;sup>19</sup> PCT Art. 27(1): "No national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this Treaty and the Regulations." (C-106).

<sup>&</sup>lt;sup>20</sup> Post-Conference Documents: Records of the Washington Diplomatic Conference, at 751 ¶ 57, WIPO (1970) [hereinafter Post-Conference Documents], *available at* http://www.wipo.int/export/sites/www/pct/en/texts/pdf/ washington\_p739\_to\_764.pdf (C-109).

<sup>&</sup>lt;sup>21</sup> PCT FAQs, *supra* note 15, at "Overview of the PCT System" (C-107).

 $<sup>^{22}</sup>$  *Id.* (C-107) at Question 2: "PCT route: you can file an application under the PCT, directly or within the 12-month period provided for by the Paris Convention from the filing date of a first application, which is valid in all Contracting States of the PCT and, therefore, simpler, easier and more cost-effective than both, direct or Paris route filings."

date of the priority application.<sup>23</sup> Although international applications subsequently undergo national examination during the national phase, and are subject to the same national laws and requirements as national applications filed in each Contracting State, the priority filing date will remain unchanged.<sup>24</sup>

18. The objectives of the international phase are generally: to ensure that applicants have properly filed their international applications and that the applications meet the form and contents requirements of the PCT<sup>25</sup>; to subject international applications to a standardized level of scrutiny to help determine if the claimed inventions to which they relate appear patentable; and to publish international applications and their accompanying documents so that they form part of the world's body of prior art. It is in the international phase that international applications are examined for conformity with the form and contents requirements of the PCT and, once those requirements are considered to have been met, Contracting States may not require different or additional requirements in the national phase.<sup>26</sup>

19. PCT applicants begin the PCT process by filing an international application most often with the patent office of their own Contracting State.<sup>27</sup> That office, which is referred to as a "receiving Office" when it exercises its authority to accept and review international applications, examines international applications for conformity with the requirements prescribed in Article 11 of the PCT.<sup>28</sup> To meet the requirements of Article 11, the applicant (or one of the applicants if there are several) must be a national or resident of a PCT Contracting State, and the

<sup>&</sup>lt;sup>23</sup> *Id.* (C-107).

<sup>&</sup>lt;sup>24</sup> The preservation of the priority filing date assumes that the applicant has successfully claimed priority in the international application. If the applicant has, for example, added new matter to the international application that did not appear in the priority application, the applicant may lose the right to claim priority at least for the new matter.

<sup>&</sup>lt;sup>25</sup> See PCT Art. 27(1), supra note 19 (C-106).

<sup>&</sup>lt;sup>26</sup> *Id*. (C-106).

<sup>&</sup>lt;sup>27</sup> PCT FAQs, *supra* note 15, at Question 6 (C-107).

<sup>&</sup>lt;sup>28</sup> PCT Receiving Office Guidelines, Chapter IV: Article 11(1) "Check: Requirements for International Filing Date", available at http://www.wipo.int/pct/en/texts/ro/ro43\_44 html. (C-110).

application must contain several essential elements, including a description of the invention, at least one claim, and an indication that the application is intended to be filed under the PCT.<sup>29</sup> Applications that meet the requirements are accorded an international filing date by the receiving Office and must be treated by every Contracting State as "equivalent to a regular national filing within the meaning of the Paris Convention."<sup>30</sup>

20. The applications also benefit from an international search, the objective of which is to discover relevant prior art<sup>31</sup> and to determine whether a claimed invention appears to be novel, involve an inventive step, and possess utility (referred to in the Regulations as being "industrially applicable").<sup>32</sup>

21. At the end of the international phase, which is generally either 30 or 31 months from the priority filing date, applicants enter the national phase by converting their single international application into national applications in the patent offices of the PCT Contracting States in which they desire patent protection. The national phase entry process is relatively simple; it usually consists of employing a local patent attorney, paying national fees, and in some cases filing a translation of the international application in the national language or submitting powers of attorney.

22. Once an application enters the national phase, a Contracting State is free "to prescribe such substantive conditions of patentability as it desires," provided those conditions do not constitute "requirements as to the form and contents of applications."<sup>33</sup> According to the

<sup>&</sup>lt;sup>29</sup> PCT Art. 11(1)(iii) (C-106).

 $<sup>^{30}</sup>$  *Id.* at Art. 11(4) (C-106).

<sup>&</sup>lt;sup>31</sup> *Id.* at Art. 15(2) (C-106).

 $<sup>^{32}</sup>$  PCT Rule 43*bis*.1(a)(i) (C-188). This element of international search was added on January 1, 2004. Prior to that date, the examination of whether a claimed invention appeared to meet the conditions of patentability was carried out in a procedure known as international preliminary examination, which still remains an option for applicants who wish to amend their international applications or respond to the results of the international search or written opinion. <sup>33</sup> PCT Art. 27(5) (C-106).

PCT, a duly-filed international application will satisfy the national form and contents requirements of all Contracting States.<sup>34</sup>

23. Prior to the PCT, applicants had to file a separate application in every country in which they wanted protection, and they had only twelve months from the priority filing date in which to do so. The PCT has vastly improved the international patent filing system. It permits a single application to take the place of separate filings, and it gives patent applicants more time and useful information to make effective patenting decisions. For the system to function, however, every Contracting State has to recognize that the form and contents requirements of the Treaty must be deemed to satisfy the form and contents requirements of national law, and that no additional or different requirements may be imposed during the national phase. Failure to do so undermines the essential purpose and benefit of the PCT.

# IV. PCT GOVERNS "FORM AND CONTENTS" VERSUS "SUBSTANTIVE CRITERIA" FOR PATENTABILITY

24. Form and contents are distinguished from substance in the PCT and its Regulations. Article 27(1) of the PCT addresses the national requirements that member countries may impose on international applications: "No national law shall require compliance with requirements relating to the form or contents of the international application different from or additional to those which are provided for in this Treaty and the Regulations."<sup>35</sup> In accordance with Article 27(1), member countries therefore should not implement form or contents requirements that exceed or differ from those of the PCT, as such requirements work against the international filing concept and violate the terms of the PCT.

<sup>&</sup>lt;sup>34</sup> PCT Art. 11, *supra* note 17 (C-106); *see also* Post-Conference Documents, *supra* note 20, at 751, ¶ 57 (C-109).

<sup>&</sup>lt;sup>35</sup> See supra note 19 (C-106).

25. The Post-Conference Documents, which include a chronological account of the main decisions and consultations leading to the adoption of the PCT and its Regulations,<sup>36</sup> state that "[f]orm and contents mean not only the physical requirements and the identification data but also the form and manner of describing and claiming."<sup>37</sup> "[E]ach Contracting State will maintain its present patent law, or may change it as it pleases in the future, subject only to the restriction that it is not allowed to prescribe different, stricter, formal requirements for the international application than the Treaty prescribes."<sup>38</sup>

26. Harmonization of form and contents requirements among all of the member countries is a fundamental advantage and attraction to patent applicants who choose to file under the PCT, as the Post-Conference Documents explain:

Under the Treaty, the applicant, within the priority year, makes only one application (the international application), which may be identical both as to language and form with his own national application, or which involves one – and only one – translation and redrafting. . . . Moreover, the – even greater – cost of redrafting (recasting as to form and expression) for each and every country does not arise, even later, or arises only to a limited extent (when the claims or the description are amended).<sup>39</sup>

27. Both the PCT and Contracting States provide ways in which applicants can amend

the description or claims, though care must be taken in any amendment to avoid the introduction of new matter into the application. New matter is any information not supported by the original disclosure, drawings, and/or claims, and Article 41 provides that, upon national phase entry, "amendments shall not go beyond the disclosure in the international application as filed, unless

<sup>&</sup>lt;sup>36</sup> Post-Conference Documents, *supra* note 20, at 741, ¶ 1 (C-109).

<sup>&</sup>lt;sup>37</sup> *Id.* at 751, ¶ 57 (C-109).

 $<sup>^{38}</sup>$  *Id.* at 748, ¶ 18 (C-109). It is interesting to note that the Patent Law Treaty (PLT), a treaty that was concluded in 2000 in order to harmonize formal national and regional patent application procedures, also contains a provision relating to an application's form and contents. Article 6(1) of the PLT extends the form and contents requirements of the PCT to all patent applications, not just international ones, by prohibiting member countries from demanding compliance with any requirement relating to form and contents other than those provided for in the PCT. Patent Law Treaty Art. 6(1), June 1, 2000, U.N.T.S. Reg. No. I-41939 (C-111). Canada signed the treaty in 2001 but has not yet ratified it. The United States became party to the treaty in 2013.

<sup>&</sup>lt;sup>39</sup> Post-Conference Documents, *supra* note 20, at 754-55, ¶ 92 (C-109).

the national law of the elected State permits them to go beyond the said disclosure."<sup>40</sup> Most Contracting States do not permit amendments that go beyond the disclosure, such that once applicants enter the national phase of prosecution, the applicants generally will not be entitled to add new subject matter to the patent application. Even if such an addition of subject matter were permitted, the priority date for claims relying on such subject matter will be lost. Loss of priority date can be detrimental or even fatal to a patent application, if prior art arose between the priority date, now lost, and the later date of introduction of new matter.

28. As a result, if national laws impose additional form and contents requirements to the PCT application, patent applicants who have availed themselves of the PCT process may be denied a patent. Failure of a Contracting State to harmonize national form and contents requirements therefore defeats a fundamental purpose of the PCT and puts applicants at risk of losing not just the priority date but also patent rights. It is for this reason that Article 27(1) of the PCT forbids Contracting States from imposing different or additional form and contents requirements.<sup>41</sup>

29. PCT Article 27(5) allows Contracting States to establish their own substantive criteria for patentability, but not as regards the form and contents of the application, which as noted includes the manner of describing.<sup>42</sup> Specifically, Article 27(5) of the PCT provides that neither the PCT nor its Regulations limit the freedom of Contracting States to prescribe substantive conditions of patentability, but it goes on to state that Contracting States are free to apply their national laws in respect of conditions of patentability not constituting requirements as

 $<sup>^{40}</sup>$  PCT Art. 41(2); *see also* Art. 28(2), which is a parallel provision that governs applications that have not undergone the optional procedure of international preliminary examination (C-106).

<sup>&</sup>lt;sup>41</sup> See supra note 19 (C-106).

<sup>&</sup>lt;sup>42</sup> See supra note 33 (C-106).

to the form and contents of the application.<sup>43</sup> Thus, while proof or evidence of a substantive condition of patentability may be required by a Contracting State, demanding that such proof or evidence (e.g., clinical data or journals) be provided within the patent application constitutes a requirement as to the form and contents of the application that conflicts with both Article 27(1)and Article 27(5) of the PCT.

30. Article 27(2) reconciles these two provisions by making it clear that the PCT does not preclude any Contracting State "from requiring, once the processing of the international application has started in the designated Office, the furnishing . . . of documents not part of the international application but which constitute proof of allegations or statements made in that application."<sup>44</sup> Article 27(6) adds that Contracting States may require applicants to furnish evidence in support of any substantive condition of patentability.<sup>45</sup> The notes on Article 27(2)(ii) in the Records of the Washington Diplomatic Conference on the Patent Cooperation Treaty state specifically that "allegations or statements to be proved may relate...to the fact that the invention is usable or operational for certain purposes...the documents supporting such allegations may be affidavits...laboratory notes, etc."46

31. Therefore, member countries can require additional evidence or proof to verify that the patent meets national requirements relating to the substantive criteria for patentability (including utility), but that additional evidence or proof must be furnished separately from the patent application. This distinction comports with the fundamental harmonization purpose of the PCT and its prohibition of different or additional form and content requirements, and respects

<sup>&</sup>lt;sup>43</sup> *Id.* (C-106). <sup>44</sup> PCT Art. 27(2) (C-106).

<sup>&</sup>lt;sup>45</sup> *Id.* at 27(6) (C-106).

<sup>&</sup>lt;sup>46</sup> Records of the Washington Diplomatic Conference on the Patent Cooperation Treaty (1970), at 36, available at http://www.wipo.int/export/sites/www/pct/en/texts/pdf/washington p1 to 162.pdf (C-112).

claims to priority that are based on priority applications filed in member countries that do not require evidence or proof that substantive criteria have been met.

# V. PCT REQUIREMENTS RELATED TO DESCRIPTION OF UTILITY

32. What must be described in the patent is the subject of Article 5 of the PCT: "The description shall disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art."<sup>47</sup> This is the basic obligation of PCT applicants for disclosure, with Rule 5 of the Regulations further articulating the manner of describing the invention.

33. Rule 5.1 of the PCT, which is directed to the manner of the description, contemplates variations in the manner in which an invention will be described based upon the nature of the invention, and therefore abstains from dictating any particular manner of description.<sup>48</sup> Rule 5.1(a)(iv) provides that the description in an international application should "indicate explicitly, when it is not obvious from the description or nature of the invention, the way in which the invention is capable of exploitation in industry and the way in which it can be made and used, or, if it can only be used, the way in which it can be used."<sup>49</sup> An international application therefore must disclose, either explicitly or implicitly, the way in which the invention is capable of being exploited and used, i.e., the invention's utility. The PCT Guidelines provide that "[i]n most cases, industrial applicability will be self-evident and no more explicit description on this point will be required."<sup>50</sup>

<sup>&</sup>lt;sup>47</sup> PCT Art. 5 (C-106)

<sup>&</sup>lt;sup>48</sup> The sole exception is expressly set forth in Rule 5.2 for nucleotide and/or amino acid sequence disclosures, for which the PCT requires a sequence listing.

<sup>&</sup>lt;sup>49</sup> Regulations under the Patent Cooperation Treaty, Rule 5.1(a)(vi) (C-188).

<sup>&</sup>lt;sup>50</sup> PCT International Search and Preliminary Examination Guidelines, § 14.05, available at http://www.wipo.int/export/sites/www/pct/en/texts/pdf/ispe.pdf (C-194).

34. As noted, if a PCT member country requires evidence in a particular form in respect of utility, it may only oblige the applicant to furnish such evidence separately from the patent application, during prosecution of the application in the national phase.<sup>51</sup> Any additional obligation to disclose evidence or proof to support utility of the invention within the form and contents of the application itself, however, would offend the PCT and defeat its harmonizing objectives.

Signed at Minespoler on September 27, 2014

[Signed] JAY ERSTLING

<sup>&</sup>lt;sup>51</sup> PCT Arts. 27(2), supra note 44, and 27(6), supra note 45. (C-106).

# Attachment A

# Jay Erstling

1902 Drew Avenue South Minneapolis, Minnesota 55416 (612) 926-8244 jay.erstling@wmitchell.edu erstling@ptslaw.com

# Employment [Variable]

Professor of Law, William Mitchell College of Law, St. Paul, Minnesota - since August 2007

- Teach in the areas of comparative and international patent law, licensing law and property law
- Research and publish in the area of international intellectual property treaty law and policy, trade and development
- Member of the William Mitchell Intellectual Property Institute
- Created the William Mitchell Intellectual Property Law Clinic, one of the first clinics nationwide selected to participate in the USPTO clinical certification pilot program

Of Counsel, Patterson Thuente Pedersen, P.A., Minneapolis, Minnesota – since September 2007

- Advise clients on international patent strategies, PCT issues, intellectual property portfolio management, and developments in intellectual property law and practice
- Represent clients as an expert witness or consultant on matters relating to PCT, TRIPS, NAFTA, or other international treaties

Past Experience:

Director, Office of the Patent Cooperation Treaty (PCT), and Director-Advisor on PCT Matters, World Intellectual Property Organization (WIPO), Geneva, Switzerland – 2002-2007

- Responsible for the functioning and wellbeing of the PCT (international patent) system, including:
  - Administration of the worldwide PCT legal framework
  - Development and implementation of PCT rules and policy
  - Oversight of procedures for search, examination, and processing of PCT applications
  - Maintenance of effective working relations with PCT member countries
  - Provision of information, training, and support to PCT legal and corporate users

Officer, Fredrikson & Byron P.A., Minneapolis, Minnesota – 2000-2002

• Member of the Intellectual Property and International Law Practice Groups, with a practice focus on international patent prosecution and litigation, international licensing, and copyright and trademark litigation support

Professor and Chair, Department of Legal Studies in Business, University of St. Thomas, St. Paul, Minnesota – 1986-2000

- Taught courses in International Business Law, Intellectual Property Law, Legal Environment of Business, and Science and the Law
- Director, London semester study-abroad program

Legal Officer/Senior Legal Officer, Industrial Property Division, WIPO, Geneva, Switzerland – 1976-1986

- Assisted developing countries in the creation and modernization of industrial property legislation
- Drafted industrial property policy studies and legislative texts for consideration by intergovernmental bodies

Legal Officer, International Labor Organization (ILO), Geneva, Switzerland – 1975-1976

Drafted study and legislative survey on the right of workers to organize

Associate, Thorp, Reed and Armstrong, Pittsburgh, Pennsylvania – 1974-1975

- Associate in the firm's labor law department
- Drafted Respondent's US Supreme Court brief in a successfully argued veterans' reemployment rights case

International Consulting Activity:

Consultant on intellectual property reform, TRIPS compliance, legal education, and international business practices:

- US Agency for International Development (USAID): Nepal (NEAT project), Jordan (AMIR Project) Lebanon, Sri Lanka, and Asia Private Enterprise Branch
- US State Department: Nigeria and Sri Lanka; State Department speaker in Barbados, Egypt, India, Israel, Jamaica, Nepal, Saudi Arabia, Turkey, and the West Bank
- The Asia Foundation: Bangladesh, Nepal, and Sri Lanka

# **Distinctions**

Fulbright Scholar

- Fulbright Senior Scholar, Sri Lanka (1988-1989) and Cyprus (1997)
- Recipient, Fulbright Alumni Initiatives Award (1999)

Indo-American Fellow in New Delhi and Bangalore (1992)

Visiting/Adjunct Professor:

 University of Minnesota Law School, University of Hawaii (Manoa), Northwest University (Xian, China), National Law School of India (Bangalore), University of Colombo Faculty of Law (Sri Lanka), Intercollege (Nicosia, Cyprus), Vitautus Magnus University Faculty of Law (Lithuania)

# Languages

Fluent in French Basic reading knowledge of Spanish

## Education

JD, Cornell University Law School, 1974 BS, Cornell University, 1971

# **Affiliations**

Member of the Bars of Minnesota and Pennsylvania

American Bar Association - Section of Intellectual Property Law

- Liaison to the WIPO Standing Committee on the Law of Patents
- Member of the ABA-IPL Books Editorial Board

American Intellectual Property Law Association (AIPLA)

- Chair, PCT Issues Committee (term ends October 25, 2014)
- Vice-Chair, Special Committee on Pro Bono Practice

International Association for the Protection of Intellectual Property (AIPPI) and AIPPI-US

Minnesota Intellectual Property Law Association (MIPLA)

#### Professional Involvement

America Invents Act Pro Bono Advisory Council

Member, Steering Committee

#### LegalCORPS

- Founding Member, LegalCORPS Inventors Assistance Program
- Member, Inventors Assistance Committee

#### Selected Recent Publications

Books:

*International Patent Law and Policy*, West (American Casebook Series), 2013 (with Margo Bagley and Ruth Okediji).

The Practitioner's Guide to the PCT, ABA-IPL, 2013 (with Samson Helfgott and David Reed).

*Union Security in Public Employment: Of Free Riding and Free Association*, Ithaca, Institute of Public Employment, New York State School of Industrial and Labor Relations, 1978 (with K. Hanslowe and D. Dunn).

The Right to Organise: A Survey of Laws and Regulations Relating to the Right of Workers to Establish Unions of Their Own Choosing, Geneva, International Labour Office, 1977.

#### Articles:

"A Different State of Grace: The New Grace Period under the AIA," 5 *Landslide* 48 (publication of the ABA Section of Intellectual Property Law, July/August 2013) (with Heath Hoglund and Frederik Struve).

"Usefulness Varies by Country: The Utility Requirement of Patent Law in the United States, Europe, and Canada," 3 *Cybaris: William Mitchell College of Law Intellectual Property Law Review* 1 (2012) (with Amy Salmela and Justin Woo).

"Patent Law and the Duty of Candor: Rethinking the Limits of Disclosure," 44 *Creighton Law Review* 329 (February 2011).

"Korea's Patent Policy and Its Impact on Economic Development: A Model for Emerging Countries?", 11 *San Diego International Law Journal* 441 (Spring 2010) (with Ryan Strom).

"Using Patents to Protect Traditional Knowledge," 15 *Texas Wesleyan Law Journal* 295 (Spring 2009).

"Transatlantic Patenting," 2 *Landslide* 30 (November/December 2009) (with Gwilym Roberts and Christian Girtz).

El Tratado de Cooperación de Patentes: en el centro del sistema internacional de patentes," *El Derecho, Diario de Doctrina y Jurisprudencia* (Universidad Católica Argentina), No. 12.053, July 2008 (with Martin Etcheverry).

"Harmonisons enfin les brevets" (invited op-ed article), Tribune de Genève, September 26, 2007.

"The Patent Cooperation Treaty: At the Center of the International Patent System," 32 *William Mitchell Law Review* 1583 (2006, with Isabelle Boutillon).

Of Counsel on amicus briefs filed on behalf of the William Mitchell Intellectual Property Institute in *Tafas v. Doll, Tafas v. Dudas, In re Bilski, Cardiac Pacemakers v. St. Jude Medical,* and *Shire v. Sandoz.* 

Complete publications list on request.

#### Selected Recent Presentations

"Collaborative Approaches to Global Patenting," 2014 Design of Medical Devices Conference, University of Minnesota, April 2014

"Patent Law Pro Bono: How and Why," ABA-IPL and ABA Center for Professional Responsibility webinar, August 2013

Faculty and Chair, "AIPLA PCT Annual Seminar," Washington, D.C., July 2013, 2012, and 2011

"The Quest for a Global Patent: How Close Are We Getting?", 2013 Design of Medical Devices Conference, University of Minnesota, April 2013

"US Perceptions of Pharmaceutical Patenting in India," ITAG Global Intellectual Property Conference, Bangalore, India, January 2013

"America Invents Act Pro Bono Program for Inventors and Small Businesses," PLI webinar, January 2013

"America Invents Act and Patent Law Updates," Korean Intellectual Property Office, Daejeon, Korea, October 2012

"New Developments in International Intellectual Property," 2012 Midwest Intellectual Property Institute, Minneapolis, September 2012

"Promises and Predictions: A Paradigm Shift for Patentable Utility?", ABA Annual Meeting, Chicago, August 2012

"International Patent Law and PCT Developments," 2012 Minnesota State Bar Association International Business Law Institute, Minneapolis, May 2012

"Treaty Obligations Pertaining to Patentable Utility," IPIC Comparative Intellectual Property Law Symposium, Ottawa, Canada, April 2012

"The Madrid Protocol: Success, Failure, or Somewhere in Between," Midwest Intellectual Property Institute, Minneapolis, September 2011

"Comparative and International Software Patent Update," AIPLA Computer and Electronic Patent Law Summit, St. Paul, MN, July 2011

"Thinking Globally," Minnesota Inventors Congress, Red Wing, MN, June 2010

"Defending Trademark Rights: An International Perspective," China Trademark Association Annual Meeting, Xining, China, August-September 2010

"Welcome Keynote," China Trademark Association Annual Meeting Development Summit, Qingdao, China, November 2009.

"Developments in US Patent Law," China Science Patent and Trademark Law Agency, Beijing, China, November 2009.

"Updates and Strategies for PCT Searching and Searching Authorities," AIPLA Live Online Seminar, August 2009.

"The Future of International Patenting," LexisNexis IP Summit, Minneapolis, May 2009.

"The Changing Landscape of Patent Law: Recent Developments in India," AIPLA Spring Meeting, Houston, TX, May 2008.

"International Patent Law Update," Minnesota State Bar Association Business Law Section, Minneapolis, January 2008.

"Update on International Trademark Strategy: Keys to Protecting Brands Overseas," China Trademark Association Annual Meeting, Changsha, China, November 2007.

Additional presentations on aspects of international intellectual property law at conferences organized by:

- UCLA Law School, William Mitchell College of Law, Hebrew University Faculty of Law, University of Haifa Faculty of Law, Jerusalem College of Technology (Center for Business Ethics and Social Responsibility), India Institute of Technology (Kharagpur), National Law School of India (Bangalore), Jiaotang University (Xian), Fudan University (Shanghai), Chinese Academy of Engineering
- National Association of Patent Professionals, Intellectual Property Institute of Canada, Féderation internationale des conseils en propriété intéllectuelle, Japan Patent Attorneys Association, International Intellectual Property Society, State Intellectual Property Office of China, Korean Intellectual Property Office, Korean Invention Promotion Agency
- 3M, Cargill, DuPont, Ford, ITW