

**IN THE MATTER OF AN ARBITRATION UNDER CHAPTER ELEVEN OF THE
NORTH AMERICAN FREE TRADE AGREEMENT
AND THE UNCITRAL ARBITRATION RULES (1976)**

BETWEEN:

ELI LILLY AND COMPANY

Claimant/Investor

AND:

GOVERNMENT OF CANADA

Respondent/Party

(Case No. UNCT/14/2)

EXPERT REPORT OF T. DAVID REED

JANUARY 26, 2015

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1. Background and Qualifications

1. I am a U.S. patent agent with particular expertise in the filing of applications under the *Patent Cooperation Treaty* (“PCT”). I was hired by The Procter and Gamble Company (“P&G”) in Cincinnati, Ohio (where I currently reside) in 1966.¹ I pursued a 40 year career within the company, until my retirement in 2006. In the last 18 years of my career with P&G, I was responsible for the launch of P&G’s international patent filing practice under the PCT, including development and oversight of that practice. From the start of P&G’s PCT practice in 1990 until I retired in 2006, I was the agent of record on or managed the filing of approximately 9500 PCT applications.

2. I am a graduate of Northwestern University, having received a Bachelor of Science degree in Chemical Engineering in 1966. In my early years with P&G I also completed post-graduate studies in chemical engineering at the University of Cincinnati. During the first half of my career at P&G, I worked as a Product Development Engineer, focusing on a variety of projects related to P&G’s products and manufacturing processes. In 1980, I took up responsibility as a Technical Advisor to P&G’s Legal Division and to P&G’s external legal counsel on a number of contentious matters, including two major patent litigations.

3. During my last 18 years with P&G, I was Manager of the company’s International Patent Filing and Prosecution Group (“IPFPG”), and was eventually promoted to Senior Patent Advisor (Section Head) in that position. The IPFPG was responsible for preparing the formalities required for the filing of patent applications in countries outside of the United States,² identifying and working with foreign patent agents and forwarding applications to them, reviewing any notices of objections or rejections issued by national Patent Offices (usually called “official actions”) with regard to patent applications filed by P&G in foreign jurisdictions, and instructing foreign patent agents on how best to respond those official actions.³ In 1988, and in

¹ P&G is one of the world’s largest multi-national corporations, founded in 1837 in the United States. The company develops and markets consumer products across a wide range of fields, including health care and chemical products. Currently, P&G markets its products in over 180 countries worldwide.

² Non-US patent filings in Europe were handled by P&G’s European patent staff. The IPFPG was responsible for filings in Canada, Latin America, Africa, Asia and the Pacific region.

³ When instructing foreign patent agents for national patent filings in the countries under my supervision, we generally focused on explaining and clarifying statements in patent filings, helping respond to technical issues raised by national patent examiners.

connection with my taking over responsibility for the IPFPG, I became registered to practice as a Patent Agent before the United States Patent and Trademark Office.

4. In my capacity as Manager of the IPFPG, I notably managed the transition to and development of P&G's international patent filing practice under the PCT. Specifically, I put in place the procedures and work flow of P&G's PCT practice, and trained P&G's Intellectual Property Division staff on the PCT process, with a view to maximizing P&G's benefits from practice under the Treaty. In December 1990, under my management, P&G fully converted its foreign patent filing practice in PCT Contracting States to a PCT practice.⁴ This meant that instead of simply filing in one jurisdiction and thereafter re-filing parallel applications in multiple national jurisdictions (*i.e.* the practice under the *Paris Convention*, which I will explain in more detail below), P&G needed only to file one international application under the PCT (typically on the basis of a national patent application filed in the previous 12 months), which could then be converted into equivalent national patent applications in all PCT Contracting States where we wished to seek patent protection.⁵

5. P&G's PCT practice quickly grew. In fact, P&G became the world's largest single user of the PCT early in the period during which I oversaw its practice.

6. Due to the size of P&G's PCT practice and the experience I was gaining as the agent of record in all of P&G's PCT filings, I was approached in 1996 by the World Intellectual Property Organization ("WIPO")⁶ and asked if I would be willing to present the PCT from a user's

and advising on how to overcome prior art rejections (*i.e.* interim conclusions by national examiners that an invention was non-patentable in that, in light of prior known inventions, the subject of the patent lacked novelty, or did not represent an inventive step). On matters of foreign formal and substantive requirements and practice, we generally deferred to the expertise of the foreign agent.

⁴ In non-PCT Contracting States, the practice of solely relying on the *Paris Convention* continued. As countries in which P&G regularly filed patents joined the PCT, we would move to practice under the PCT in those countries. Though most countries are now Contracting States to the PCT, countries such as Argentina and Taiwan are not and so in those cases patent filings would still be handled under the *Paris Convention*, at 12 months.

⁵ Note that the PCT is a treaty under the umbrella of the *Paris Convention*. All PCT Contracting States must also be Contracting States to the *Paris Convention*. This is so that a priority claim in a PCT application is valid under the *Paris Convention* in the national phase of the PCT and also in cases where an applicant wishes to use the same priority date, established in the PCT application, as the basis for a *Paris Convention* priority claim in an application not filed under the PCT (for example, in a country which is a Contracting State to the *Paris Convention* but not the PCT).

⁶ WIPO is a specialized agency of the United Nations located in Geneva, Switzerland. WIPO is responsible for administering numerous international treaties on matters related to intellectual property, including the *Paris Convention for the Protection of Industrial Property*, the *PCT*, the *Madrid Agreement Concerning the International Registration of Marks* and the *Protocol*

perspective, in countries that were either relatively new to the PCT or were considering joining the PCT. P&G agreed to supply my time for WIPO's request. Since 1996, I have presented dozens of talks, seminars and speeches on the PCT from a user's perspective for WIPO and also for other organizations, including the American Intellectual Property Law Association (AIPLA), the Intellectual Property Institute of Canada (IPIC), the International Association for the Protection of Intellectual Property (AIPPI), the Asociación Costarricense de Ingenieros en Producción Industrial (ACIPI), the Intellectual Property Owners Association (IPO), the Licensing Executives Society (LES), and the Association of Legal Administrators (ALA). I have spoken on the PCT from a user's perspective in Argentina, Brazil, Canada, China, Egypt, India, Indonesia, Japan, South Korea, Malaysia, Mexico, Singapore, South Africa, Switzerland, Trinidad & Tobago, United Arab Emirates, United Kingdom, United States ("U.S."), and Uruguay. Since 1998, I have also taught basic and advanced PCT training seminars for the Patent Resource Group, a respected U.S.-based commercial provider of seminars on a wide variety of patent law topics.

7. Following my retirement from P&G in 2006, I became an independent consultant to WIPO on PCT issues. In my capacity as a WIPO Consultant for the U.S. and Canada, I have presented more than 90 seminars on the PCT from a user's perspective. Until 2014, I also operated a virtual PCT Help Desk, to which applicants and others were invited to call in or e-mail to obtain answers to questions related to the PCT. In addition, from 2006 to 2013, I acted as a Consultant for the Patrick Mirandah Company (pmc), an intellectual property law firm with offices in Singapore, Malaysia and other ASEAN countries. In that capacity, I provided advice and technical support on PCT filing practices. I have authored numerous articles on the PCT and foreign patent practice in ASEAN countries, submitted by pmc for publication in a variety of trade journals.

8. In 2011, I was approached by the Claimant's expert witness, Mr. Jay Erstling, and asked to join him and U.S. patent attorney Mr. Samson Helfgott in authoring a book on the practical use of the PCT. The book, *The Practitioners Guide to the PCT*, was published by the American

Relating to the Madrid Agreement (concerning trademarks), and the Hague Agreement Concerning the International Registration of Industrial Designs (concerning industrial designs), among others.

Bar Association (ABA) in 2013. For this practical guide, I authored Chapters 2 (PCT Procedures), 4 (Post-Filing Procedures: Publication, Withdrawals, and Recording Charges) and 5 (Procedural Safeguards: Helpful Options when Things Go Wrong). Mr. Helfgott authored Chapters 6 (Entering the National Phase), 7 (Entry into the U.S. National Phase) and 9 (PCT Strategies and Recommendations), and Mr. Erstling authored the remaining Chapters 1 (An Overview of the PCT System), 3 (International Search and Preliminary Examination), 8 (Entry into the National Phase in Europe, China, and Elsewhere), 10 (WIPO Resources), and 11 (Afterword – The Future of the PCT).

2. Mandate and Undertakings as an Expert Witness

9. Based upon my above noted qualifications and experience, I have been asked by the Respondent, the Government of Canada, to provide my views on the following issues:

- a. the role of the PCT in worldwide patent filings, including its advantages and limitations in the patent filing practices of large multi-national enterprises;
- b. my understanding of the nature of the PCT's "form and contents" requirements;
- c. my expectations as a consistent and intensive multi-jurisdictional PCT user with regard to the substantive harmonization of national patent laws; and
- d. my expectations of the role of national Patent Offices relative to national courts with regard to final determinations on patent validity.

10. The views I provide here on these issues are strictly my own. They do not represent the views of WIPO or any other organization for which I have worked. I have never had, and do not currently have, any relationship or affiliation with the Claimant, Eli Lilly and Company, or with the Respondent, the Government of Canada, other than in relation to the production of this report.

3. Summary

11. The PCT is a useful tool for facilitating patent filings for the same invention in multiple national jurisdictions. Its primary advantage from a user's perspective is that it allows applicants to rely on the filing of a single international application to establish a filing date in all PCT

Contracting States, and on the basis of that application to be eligible for consideration for a patent by national Patent Offices during the PCT's national phase. So long as the international application complies with the basic "form and contents" requirements of the PCT (*i.e.* contains a title, request, claims, description of the invention, and drawings (if required), formatted in accordance with PCT requirements), the application will be accepted into the international phase of the PCT and be eligible for continuation into the national phase. Fulfillment of the PCT's "form and contents" requirements is typically reviewed by clerks.

12. What the PCT does not accomplish is international harmonization of substantive patent laws. To say that an international application complies with the bare minima of the PCT's "form and contents" requirements does not mean that the application complies with any substantive patentability requirements, which the PCT expressly reserves for national law. While an international application accepted under the PCT is thereby eligible for consideration at the national level in PCT Contracting States, applicants must still be conscious of and seek to reflect in that application, any national substantive patentability requirements relevant to the jurisdictions where they may ultimately seek patent protection. Otherwise the international application, although admitted under the PCT, runs a significant risk of rejection at the national level. Users of the PCT system understand that despite the enhanced procedural convenience brought by PCT, the system does not override national substantive patent laws.

13. Having filed thousands of patents around the world on behalf of a large US multi-national corporation, based upon my own experience, there has been no substantive harmonization of patent laws worldwide. National substantive patent rules continue to differ from country to country, often substantially.

14. Finally, as an experienced user of patent systems around the world, I am very conscious that national Patent Office decisions regarding the patentability of a claimed invention typically remain subject to review by national courts, which are charged with ultimate interpretation and application of national patent laws.

4. The PCT Offers Procedural and Technical Advantages

15. In my experience the PCT offers several procedural and technical advantages, notably:

- a. extending the date by which filings need to be made in national jurisdictions from 12 months (under the *Paris Convention* system) to up to 30 months under the PCT;
- b. providing a preliminary review of the patent application, which can generate useful information relevant to judging the novelty and non-obviousness of a claimed invention; and
- c. ensuring that through filing a single international application under the PCT, that application will be eligible for consideration as national patent application by any PCT Contracting State.

I will address each of these in turn.

16. From a user's perspective, the PCT's primary advantage is that it extends the time by which final decisions need to be made about patent filings in multiple national jurisdictions.

17. Under the *Paris Convention* system, which has been in place since the 19th century, individuals filing a patent application in one *Paris Convention* Contracting Party would have only 12 months to file in the jurisdictions of other Contracting Parties to secure the initial filing date as their priority date.⁷ In effect, this meant that the prior art (*i.e.* existing knowledge in the particular field of invention at the time of filing which is relevant to the patent application) against which the invention would be assessed would be that as of the first rather than as of any subsequent filing date. This difference in timing could be crucial when a national Patent Office sought to determine whether the invention was novel or non-obvious for purposes of granting the patent. If the date the patent application was filed in subsequent jurisdictions was instead taken as the date for assessing novelty and non-obviousness, there was an increased likelihood that by that time the claimed invention would be considered to be anticipated (*i.e.* no longer being judged as novel in relation to the prior art) or to be obvious in light of the prior art.

⁷ *Paris Convention for the Protection of Industrial Property*, World Intellectual Property Organization, (1883) ("*Paris Convention*"), Article 4(A)(1) (R-036).

18. While the *Paris Convention* system was useful in this sense, it still had limitations. In practice, it was difficult to judge within 12 months of an initial filing in one jurisdiction, whether it was commercially worthwhile to pursue patent protection in other jurisdictions. For large multinational companies such as P&G, this often led to the filing of patent applications in multiple jurisdictions that later proved to be of little commercial value, or to the failure to file in jurisdictions that later proved to be commercially important.

19. When the PCT came into force in 1978,⁸ it offered applicants a means of extending the period for making decisions on countries in which to seek patent protection, from 12 months to up to 30 months. This gave applicants a longer period of time before they needed to decide whether to pursue multiple national filings after filing an initial patent application in one jurisdiction. Under the PCT procedures in force as of 1990, an applicant could file an international application, and then (under initial PCT practice) have at least 20 months from the earliest priority date claimed in the international application to decide whether and where to proceed with the application before the national Patent Office of any PCT Contracting State. Moreover, where an applicant took advantage of the PCT's optional preliminary examination procedures under Chapter II of the Treaty, the 20 month time limit was extended to 30 months in total.⁹ This 30 month deadline later became standard PCT practice irrespective of any request for the optional preliminary examination. This additional timing provides an overall significant advantage, in that often times commercial and technical information, more readily available within 30 months as opposed to the 12 months provided for under the *Paris Convention*, provides better insight into whether or not it is worthwhile to pursue patent filings in various national jurisdictions. In this way, the PCT allows companies like P&G to make more targeted and informed decisions about where to seek patent protection worldwide for any given invention.

⁸ The PCT came into force in 1978 when 18 countries had ratified the treaty. The US joined the PCT in 1978, but at that time took a reservation to the PCT Chapter II procedures, which meant that US applicants could not use Chapter II to obtain either a preliminary examination or the additional 10 months of time. The US withdrew its reservation to Chapter II in July 1987, making preliminary examination and the 30 months of time available to US applicants. At that point the PCT became of greater interest to US applicants.

⁹ Under the procedures in effect in 1990, the additional 10 months gained by utilizing the optional international preliminary examination procedure was needed to allow time for the advisory examination process to take place and the final non-binding examination report to be issued. In April 2002, a change in the PCT procedure allowed all PCT applications the advantage of a 30-month deadline to enter the national phase regardless of whether the optional examination procedure was used.

20. The second, and more technical, advantage of the PCT is that applicants are also provided an initial review of patentability criteria, conducted by specified International Searching Authorities (“ISAs”) and, optionally, International Preliminary Examining Authorities (“IPEAs”). This review notably produces a prior art search and a non-binding written opinion advising an applicant as to the novelty, inventive step and industrial applicability of a claimed invention.

21. Once an international application is accepted into the international phase an ISA will, under Chapter I of the PCT, conduct a search of the prior art and prepare an international search report (ISR) identifying any prior art found during that search. Since 2004, the ISA will also prepare a written opinion detailing how the cited prior art effects the novelty and inventive step of the invention claimed in the international application. Prior to 2004, the ISA would not prepare a written opinion, and so to obtain further information on the apparent patentability of a claimed invention, an applicant had the option, under Chapter II of the PCT, of requesting an international preliminary examination from an IPEA. The IPEA would issue its own written opinion, and would allow an applicant to respond to that opinion with arguments and/or amendments if they chose to do so.

22. As noted, the aim of this process of search and preliminary examination is to give applicants an independent look at the novelty, inventive step and industrial applicability of the claimed invention in light of the prior art found during the ISA’s search, the assessment of the IPEA, and also taking into consideration any amendments and/or arguments submitted by the applicant.

23. The final outcome of this process is an International Preliminary Examination Report (“IPER”) which is available to both applicants and all national Patent Offices from which an applicant may subsequently decide to seek patent protection. This is helpful for the applicant, but also for alleviating the work load of national Patent Offices, in particular those with more limited examining capacities and technical knowledge (such as in developing countries). National Patent Offices can rely to the extent they see fit on searches conducted by ISAs under the PCT, but may also conduct their own, further searches.

24. The preliminary, non-binding written opinion on the patentability of the claimed invention generated by the IPEA (and since 2004 the ISA) is conducted on the basis of general definitions for basic patentability criteria, that are set out in Article 33 of the PCT expressly for purposes of the preliminary international examination only.¹⁰ These can be relied upon to a greater or lesser degree by national Patent Offices. The extent of that reliance will typically depend both upon on how well PCT practice accords with substantive rules and procedures in a particular national jurisdiction, and upon the capacity of a particular national Patent Office.

25. The preliminary search and examinations conducted under the PCT therefore provide applicants, particularly large multinational enterprises such as P&G, important early signaling about whether a claimed invention will be judged to be novel or inventive in light of the prior art. As useful as these early assessments are, however, they always need to be taken with caution. The prior art searches and written opinion on patentability criteria are non-binding, and the definitions and interpretations of the basic patentability criteria applied by the ISAs and IPEAs may differ than those applied by Patent Offices at the national level. Indeed, the PCT itself expressly says in Article 35(2), that “[t]he international preliminary examination report shall not contain any statement on the question whether the claimed invention is or seems to be patentable or unpatentable according to any national law”.¹¹ I was always aware, and expected, that regardless of the outcome of the prior art search and preliminary examination under the PCT, decisions on patentability would be left solely to each country based upon the application of domestic patent law.

26. Finally, the PCT offers the third advantage of an efficient process for multi-jurisdictional patent filings. Under the *Paris Convention* system, an applicant would first file in the jurisdiction of one Contracting Party, but would then be required to re-file separate applications in the jurisdictions of any other Contracting Parties where patent protection was sought. Under the PCT, an applicant intending to seek patent protection in the jurisdictions of more than one PCT Contracting State needs only to make a single filing (*i.e.* the international application), generally in the applicant’s national Patent Office and language. That singular filing establishes a filing

¹⁰ PCT Articles 33(1) and 33(5). (R-037).

¹¹ PCT Article 35(2) (R-037).

date in all PCT Contracting States (148 as of this writing, about 45 in 1990 when P&G first launched its PCT practice). This means that if the application is continued on to the national phase of the PCT process, that date is effectively equivalent to a national filing date in each of the jurisdictions in which the applicant decided to seek patent protection.

27. For an international application to be accepted under the PCT and therefore to be eligible for continuation into the national phase, it needs simply to comply with the basic “form and contents” requirements set out in PCT, notably that it has to include a request, claims, a description, and comply with PCT formatting standards.¹² Such standardization of formalities avoids the need for applicants to redraft an application merely to comply with national requirements concerning the general presentation of information. Under the PCT, an applicant instead submits a single international application that will serve in all jurisdictions. It is reassuring to know that as long as such things as bibliographic information, form and order of presenting information in the application, general list of subjects to be disclosed, style of claim dependencies, and other formal requirements set out in the PCT and PCT Regulations are complied with, an application will both be accepted as an international application under the PCT and thereafter is eligible for be accepted for review by the national Patent Office of any PCT Contracting State.

28. As I will further elaborate below, this procedural efficiency is not, however, an invitation to ignore the differences in substantive requirements of patentability that exist between countries, in drafting an international application under the PCT. Nor is it an excuse to fail to comply with all of the substantive criteria for patentability required by each national jurisdiction, notably the requirement that the patent claims be fully supported by the patent disclosure.

29. Given the advantages I have identified here, P&G's patent filing practice under the PCT proved very beneficial to the company. The additional time to make final decisions on where to seek patent protection resulted in substantial efficiency gains, notably by allowing us to avoid commercially unnecessary applications.

¹² *PCT*, Article 3(2) (R-037).

5. Harmonization of “Form and Contents” Does not Extend to Harmonization of Substantive Patent Requirements

30. In his report, Mr. Erstling argues that “[h]armonization of form and contents requirements among all of the member countries is a fundamental advantage and attraction to patent applicants who chose to file under the PCT”,¹³ as applicants can be assured that in successfully filing a single international application under the PCT, that application will be found to meet the “form and contents” requirements of any PCT Contracting State in which the applicant may subsequently decide to seek patent protection.¹⁴ Mr. Erstling also explains that under the PCT, although Contracting States are allowed to impose their own national substantive criteria for patentability, they are not allowed to impose criteria that are additional to the “form and contents” requirements provided for in the Treaty.¹⁵

31. I take issue with Mr. Erstling’s characterization of the PCT’s “form and contents” requirements. By omission, they overstate the advantages of the PCT as a mechanism to facilitate multi-jurisdictional patent filings. Mr. Erstling’s report gives the impression that the benefit of harmonization of “form and contents” under the PCT somehow includes harmonization of substantive criteria for patentability which are related to “form and contents” (*i.e.* disclosure requirements).¹⁶ This is misleading. Mr. Erstling fails to clarify that an international application’s compliance with the PCT’s “form and contents” requirements only means that that application will be admissible for review both during the international phase under the PCT and subsequently by national Patent Offices. Compliance does not mean that, upon admission to a national Patent Office for review, an application is also guaranteed to be found to meet the substantive criteria for patentability of that jurisdiction, based on its contents.

¹³ Erstling Report, para. 26.

¹⁴ Erstling Report, para. 22.

¹⁵ Erstling Report, para. 29.

¹⁶ Mr. Robert Armitage also put forwards this mischaracterization in his witness statement, where he says that the PCT “[...] standardizes the form and content requirements for patent applications (including the information that must be disclosed in the patent for it to be valid) and prohibits member countries from imposing any additional requirements as to the content of patent filings” (Armitage Statement, para. 24).

32. Understanding “form and contents” in the manner suggested by Mr. Erstling would lead to the conclusion that the PCT somehow harmonizes substantive criteria for patentability, which it expressly does not do. Notably, PCT Article 27(5) clearly states that:

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, any 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 content of the applications.¹⁷
(emphasis added)

33. Mr. Erstling seeks to challenge this well-recognized conclusion in his report, by substantially overstating the role that the PCT’s “form and contents” requirements play in the overall patenting process. As I will discuss below, the PCT’s “form and contents” requirements simply refer to the basic categories of information that must be included in an international application filed under the PCT. The issue of whether the actual content of the information included in an international application complies with substantive patentability requirements, and therefore whether the claimed invention is deserving of a patent, is a separate issue which is decided upon by national Patent Offices according to national law. Indeed, this is a tension at the heart of the PCT system: while the Treaty allows applicants to rely on a single application to gain admission for review by national Patent Offices, the actual contents of that application must still comply with the often differing substantive patentability requirements of each PCT Contracting State in which an application seeks patent protection.

34. Eligibility for admission to review by national Patent Offices in PCT Contracting States based upon compliance with the PCT’s “form and contents” requirements is established by Article 27(1) of the PCT, which states that “[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”.¹⁸ (emphasis

¹⁷ PCT, Article 27(5) (R-037).

¹⁸ PCT, Article 27(1) (R-037).

added) Notably, Article 27(1) refers to “form and contents” but does not define what that means, other than referencing that those requirements “are provided for” in the Treaty and Regulations.

35. While the reference to “different from or additional to those which are provided for” might at first glance seem restrictive, the PCT itself, in confirming the meaning of “form and contents”, simply lists broad categories of information that must be included in the international application, and provides directions as to their order and format of presentation. Therefore, in practice, PCT references to “form and contents” do not include substantive criteria or interpretations that PCT Contracting States may impose at the national level on those categories of required information.

36. Specifically, PCT Article 3 (The International Application) identifies 5 categories of information, or elements, that an international application must contain, namely a request, a description, one or more claims, one or more drawings (where required), and an abstract.¹⁹ PCT Article 3 also notes that an international application must comply with prescribed language and physical requirements.²⁰ PCT Articles 4 to 7 elaborate on the categorical requirements listed in Article 3(2), but only by means of broad statements as to the nature of the information that is to be included in each category. For example, Article 5 (The Description) simply states that “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”.²¹ Article 6 (The Claims) provides that “The claim or claims shall define the matter for which protection is sought. Claims shall be clear and concise. They shall be fully supported by the description.”²²

37. The text of Articles 5 and 6 provides limited guidance as to the substantive meaning of each category of information. For example, there is no guidance about what it means to disclose “the invention”, what is “sufficiently clear and complete” as a description, or what it means for claims to be “fully supported by the description”. Thus, while the PCT requires that an international application must include a description and claims, the text of the PCT itself

¹⁹ PCT, Article 3(2) (R-037).

²⁰ PCT, Article 3(4) (R-037).

²¹ PCT, Article 5 (R-037).

²² PCT, Article 6 (R-037).

suggests that any description or claims which simply fulfill the broad criteria of those Articles will comply with the “form and contents” requirements relating to the description and claims for purposes of the PCT. This is reflected in PCT Article 11, which only requires a Receiving Office to check whether an international application at least contains “a part which on the face of it appears to be a description” and “a part which on the face of it appears to be a claim or claims”.²³ It also reflects my own experience, in that the review of an international application’s compliance with the PCT’s “form and contents” requirements is typically done by clerks, and not patent examiners.

38. Mr. Erstling further draws attention to PCT Rule 5.1(a)(vi), in suggesting that disclosure requirements related to industrial applicability are part of the PCT’s “form and contents” requirements.²⁴ I strongly disagree with Mr. Erstling on this point. Much like Article 5, Rule 5.1(a)(vi) contains only broad statements as to the information in the description that should be included in an international application. PCT Rule 5.1 stipulates the “manner of the description”, specifically the ordering and the nature of the information that must be contained in the description and on the question of industrial applicability, only provides that:

The description shall [...] 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; the term “industry” is to be understood in its broadest sense as in the Paris Convention for the Protection of Industrial Property.²⁵

Again, PCT Rule 5.1(a)(vi) provides no real guidance to help an applicant determine what must be the nature of the invention, what must be disclosed, or what constitutes an explicit indication of industrial applicability such that the claimed invention will be considered as having adequately shown that it is industrially applicable (or has utility).

39. Indeed, Mr. Erstling’s characterization of “form and contents” as somehow extending to related substantive criteria for patentability, is also directly contradicted by the PCT text itself,

²³ PCT, Articles 11(a)(iii)(d) and 11(a)(iii)(e) (R-037).

²⁴ Erstling Report, paras. 33-34.

²⁵ *Regulations under the Patent Cooperation Treaty*, World Intellectual Property Organization, 1 July 2014, Rule 5.1(a)(vi) (R-040).

which, as I have explained above, expressly states in Article 27(5) that issues concerning fulfillment of substantive requirements (which includes industrial applicability and disclosure), are reserved for national law.²⁶ Accordingly, irrespective of compliance with the PCT's bare "form and contents" requirements pertaining to the description under Article 5 and Rule 5.1(a)(vi), adequacy or inadequacy of the disclosure in the specification for the purpose of determining whether an invention is industrially applicable (or useful) will be determined under each national law. As disclosure requirements related to industrial applicability (or utility) are a substantive condition of patentability, the PCT rightfully places the decision whether a given application has met those requirements on the national Patent Offices during the national phase.

40. In his report Mr. Erstling also asserts that 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 PCT Contracting States obligations under PCT Article 27(1) and 27(5).²⁷ He further argues, on the basis of PCT Articles 27(2)(ii) and 27(6), that Contracting States may only require additional evidence or proof to verify that a patent meets national requirements substantive criteria of patentability separately from the patent application (*i.e.* after the application has been filed).²⁸

41. I also strongly disagree with Mr. Erstling on this point. Mr. Erstling fails to recognize that substantive patent validity is judged around the world based upon what the application has actually stated in the patent itself (*i.e.* in the disclosure of the patent specification), rather than upon any materials filed thereafter. It is therefore imperative, to ensure a patent's validity, that an international application, as filed under PCT, already includes sufficient disclosure to support national substantive patentability requirements in whichever jurisdiction patent protection may be sought. In every jurisdiction of which I am aware, when filing a patent application (national, regional or through the PCT) the claimed invention must fulfill the requirements necessary to obtain a patent in that jurisdiction as of the date the application is filed. The invention must be

²⁶ PCT, Article 27(5) (R-037).

²⁷ Erstling Report, para. 29.

²⁸ Erstling Report, paras. 30-31.

novel, have an inventive step, and be industrially applicable (or have utility). Additionally, the disclosure must enable one of ordinary skill in the relevant art to make and use the invention. The claims must be clear and fully supported by the disclosure. If any of these substantive conditions of patentability are not met on the day of filing, the application will be rejected and will remain rejected until the applicant either amends the application to overcome the reasons for rejection or submits arguments that convince the examiner that the application does meet local substantive conditions for patentability.

42. The PCT's confirmation in Article 27(2)(ii) that materials may be provided after an application has been filed,²⁹ certainly does not override the domestic substantive disclosure requirements, regarding what must be included in the patent specification for the patent to be valid, that are in place in each PCT Contracting State. Indeed, PCT Article 27(6) expressly provides that “[t]he national law may require that the applicant furnish evidence in respect of any substantive condition of patentability prescribed by such law”.³⁰ (emphasis added) Again, this is simply a broad statement as to what a national Patent Office is allowed to request. There is nothing in Article 27(6) that indicates that an applicant may overcome a disclosure deficient under national law at the time of filing, via a post-filing submission. Nor is there is a requirement in Article 27(6) for national Patent Offices to make such a request. That Article merely gives national Patent Offices the broad authority to make such a request, should the national law or the examiner deem such a request as material to the decision on patentability.

43. Japan is one example of a PCT Contracting State which does not allow a post-filing submission to fulfill the substantive conditions for patentability. In Japan, one must exemplify the efficacy/working/utility of the invention across the entire range of critical claim parameters and the necessary examples must be in the application at the time of filing. If examples submitted in the application at the time of filing do not cover the complete claimed range, the Japanese Patent Office will not accept a claim until the scope is narrowed to match the range of examples included at the time of filing. This can result in the loss of significant patent rights, particularly if the applicant only included examples covering a narrow range of critical

²⁹ PCT, Article 27(2)(ii) (R-037).

³⁰ PCT, Article 27(6) (R-037).

parameters. Japanese law will not allow post-filing submissions of additional data to broaden the acceptable claim scope.

44. For the reasons I have explained here, it was thus never my practice, in all of my years of filing patent applications on behalf of P&G, to assume that compliance with the PCT's "form and contents" requirements necessarily meant that I had complied with all of the requirements to support substantive patent validity in the jurisdictions where P&G sought patent protection. My understanding of the PCT's "form and contents" requirements has always been that they merely indicate that certain categories of information must be included, in a specific format, in an international application for it to be admitted under the PCT and eligible for consideration by national Patent Offices during the national phase. I was always conscious of the need to also comply with differing national substantive patentability requirements. Through this, I sought to help ensure that an application filed by P&G would not only be admitted for review in a given country via the PCT, but would actually lead to the grant of a patent. At P&G we knew that whenever our applications did not meet national requirements in any particular country, notwithstanding having been filed via the PCT and perhaps being issued as patents in other countries, we risked overall rejection of the application by national examiners, or at the very least a reduction of the scope of the accepted claims to those fully complying with the requirements of national law. In managing P&G's PCT practice on the basis of this understanding, never once was an international application I filed on behalf of P&G under the PCT rejected for failure to comply with the Treaty's "form and contents" requirements.

45. I was never instructed in PCT workings by WIPO itself on the basis of the interpretation of "form and contents" requirements put forward by Mr. Erstling. Nor is that what I teach in WIPO-sanctioned courses offered around the world to facilitate and encourage national use of the PCT. Reflective of my understanding of the relative significance of the "form and contents" requirements to the overall functioning of the PCT, typically when I am providing instruction about the PCT from the user's perspective, "form and contents" requirements are at best the subject of a one line comment out of up to 2½ days of instruction. I always stress the need for the contents of an international application to meet the substantive requirements for patentability in the jurisdictions with the strictest rules.

46. Mr. Peter George Stringer confirms the need to comply with varying national substantive requirements in drafting patent applications for filing in multiple jurisdictions. In his witness statement, Mr. Stringer recalls that that Claimant’s general practice “was to draft the standard [patent] description so that it met the requirements of every jurisdiction in which [Eli Lilly] might file”, and that the Claimant would make “jurisdiction-specific edits to the claims of the standard application, as needed.”³¹ However, in elaborating on the Claimant’s practice under the PCT, Mr. Stringer puts forward the same mischaracterization as Mr. Erstling, in recalling that Eli Lilly would “maintain and follow a standard of drafting applications that complied with the standard established by the [PCT], under which [Eli Lilly] could file a single application that would comply with the form and contents requirements”³² of all PCT Contracting States, without further clarifying that the PCT’s “form and contents requirements” merely require certain categories of information to be included in an international application, and that applicants must still always that they draft their applications to meet the substantive requirements of jurisdictions in which they may seek patent protection.

47. In the book *The Practitioner’s Guide to the PCT*, on which Mr. Erstling was the lead and coordinating author and which I co-authored with him and Mr. Samson Helfgott, there is a discussion of these exact points in reference to redrafting a US priority application for foreign filing:

In order to be sure that your PCT application will be a viable application in foreign countries, care must be given to the various laws in foreign countries that may be different from those on the United States. In many cases the patent laws of many countries have been harmonized, but there are still differences, and these must be considered.³³ (emphasis added)

In other words, an international application must be written to be in compliance with the most stringent requirements across countries of interest. Similarly, in discussing data needed to prove efficacy (utility) by examples included at the time of filing, the book continues:

³¹ Stringer Statement, para. 6

³² Stringer Statement, para. 6.

³³ Jay Erstling, Samson Helfgott and T. David Reed, *The Practitioner’s Guide to the PCT*, Chicago, Illinois: American Bar Association, Section of Intellectual Property Law, (2013) at page 200 (“*The Practitioner’s Guide to the PCT*”) (R-043).

The use of examples is extremely important both for U.S. and foreign filing. [...] When a particular range is recited, the examples should be adequately dispersed to cover the scope of the broadest claimed range. An example should be given at the low end, the high end, and the mid-range. Furthermore, where values are critical, you must give examples out of the range to show lack of inventive benefits for those values. These will serve as a control to prove the inventiveness of your critical range.³⁴ (emphasis added)

48. PCT Article 5 and Rule 5.1(a)(vi), concerning the “form and contents” of the description as required for admission to the international phase of the PCT, are silent on whether or not examples are required. At best, Article 6 provides that the claims “shall be fully supported by the description”, so in effect the better reading of the PCT’s “form and contents” requirements regarding disclosure is that the disclosure needs to fully support the claims, notably through the provision of working examples confirming that the applicant is indeed in possession of the invention. During the national phase, it has been my experience that examples will often be critical to the determination of patentability and/or the scope of allowed claims under national law.

6. There is no Substantive Harmonization of National Patent Laws

49. I have also been asked to comment on my expectations, as a longstanding and intensive user of the PCT and national patent systems around the world, regarding the level of substantive harmonization in patent laws between different jurisdictions.

50. I think it is clear from my comments above that PCT itself certainly did not bring about substantive patent law harmonization. Nor in my experience has such substantive harmonization been achieved by other means. To the contrary, while I am aware of many past and some ongoing attempts at achieving that goal, the most striking thing is that all past and ongoing attempts have to date failed. Certainly, as a longstanding user of the PCT and of national patent systems on behalf of one of the world’s largest and most intensive users of patent protection worldwide, it was neither my experience, nor my expectation, that national patent systems were, or are, substantively harmonized.

³⁴ *The Practitioner’s Guide to the PCT*, at page 222 (R-043).

51. I am in particular aware of ongoing attempts for over 30 years under the auspices of WIPO and other organizations to bring the countries of the world together and find an agreement on both formal and substantive issues related to patentability. There were several attempts at devising a Substantive Patent Law Treaty (“SPLT”), which failed due to underlying and persistent differences between countries. Despite many efforts, to date the SPLT remains just a hoped-for, but unrealized goal.³⁵

52. The only progress that has been made has related to the harmonization of procedural or formal requirements. But as I have outlined above, such procedural harmonization does not mask the underlying substantive differences, which remain and must be taken into account. For example, a more recent agreement on harmonization of formalities is the Patent Law Treaty (“PLT”). The PLT standardizes such issues as what is needed to establish a filing date, the reinstatement of rights, the form of universal request, procedures related to translations, and priority documents. The U.S. has signed, ratified and brought the PLT into force as of 13 December 2013. Canada has signed the PLT, but has not yet ratified the Treaty.³⁶

53. Beyond this, there has been piecemeal harmonization of underlying rules, such as when the U.S. abandoned its first-to-invent system of patenting and instead followed the rest of the world in agreeing to move to a first-to-file system.³⁷

54. In the absence of any treaty formally harmonizing substantive patent laws, national Patent Offices have instead sought to further enhance the efficiency of multi-jurisdictional filings by encouraging work-sharing between Offices. This is particularly useful with regard to identifying applicable prior art against which such issues as novelty and non-obviousness of the invention may be judged. This is in effect similar to reliance on search reports of prior art under the PCT. Indeed, it is generally helpful as an application to advise a national Patent Office that the patent sought has already been granted in another jurisdiction. Even prior to practicing under the PCT, when instructing foreign agents on behalf of P&G regarding a response to an official

³⁵ My colleague, Professor Daniel Gervais opines on international efforts to conclude a Substantive Patent Law Treaty in his Expert Report.

³⁶ World Intellectual Property Organization, *The PCT Now has 148 Contracting States*, WIPO website: http://www.wipo.int/pct/en/pct_contracting_states.html (R-044).

³⁷ Note that in the United States it is known as a first inventor to file system.

action in a case where allowance or acceptance of an application had been previously gained in another country, I always informed the foreign agent of the earlier acceptance and suggested that the agent inform the examiner of the allowance or acceptance as well. If the allowed claim scope in the prior accepted application met the commercial needs of P&G, I would generally restrict the claims undergoing examination to those previously allowed. This often helped the examiner reach the conclusion that the amended claim set was patentable in his/her country. However, acceptance was never a given, as the granting of the patent remained (and remains) subject to national requirements.

55. For example, notwithstanding that a patent had already been issued for the same invention elsewhere, if an examiner raised substantive issues of patentability (such as lack of novelty, inventive step or industrial applicability) these would have to be fully addressed in P&G's response to an official action. Reporting an earlier acceptance by another Patent Office was never taken as an opportunity to avoid fully addressing any substantive issues raised by the patent examiner. If the claims were allowed by an examining country, responsive arguments coupled with the conformance of the allowed claims were often persuasive to an examiner. The application, however, was still examined against national law and practice and was only accepted if and when it met the criteria of patentability as set out in the law of that jurisdiction.

56. The patent world has extended the work sharing concept through pilot agreements known as Patent Prosecution Highways ("PPH"). If an applicant receives a favorable report on patentability in one participating country (including in some PPH programs the International Search Report and written opinion generated under the PCT), and the claims in a parallel application filed in another country are conformed to those already granted elsewhere, the application in the secondary jurisdiction will be examined on an expedited basis. The theory is that work done by the examiner in the first examining country will be helpful to the examiner in the second country. Each country participating in a PPH program must nonetheless make its own determination whether the application complies with national law. The PPH program simply allows the examiner to review the application on an expedited basis, in light of the earlier positive results.

7. National Courts have the Final Word on Patent Validity

57. I have also been asked to comment on my expectations, as a heavy user of the PCT system, regarding the finality of a patent grant by national Patent Offices and whether I would necessarily expect that grant to survive court review.

58. I have always understood the grant of a patent by any national Patent Office, whether filed using the PCT system or not, to be only the first word regarding the patentability of an invention. In all patent systems, a patent is presumed to be valid once granted by the Patent Office. However, regardless of the competency and the effort expended by the Patent Office, in my experience it is always the national courts that have the final word on patent validity and interpretation of the law. Most laws passed by the legislature have portions that are left open to interpretation. This is also true of the patent law.

59. It is also my experience that the courts frequently exercise their authority to invalidate patents granted by the national Patent Office. It was never my expectation that patent applications I filed using the PCT system in different jurisdictions around the world would, if issued into a patent, necessarily withstand court scrutiny upon challenge by a third party. The actions and decisions by the Patent Office can always be reviewed by the courts.

60. Just as courts have final say with regard to the interpretation and application of the patent law in any given case, they typically have the final say with regard to how the evidence of patentability should be interpreted. Through the adversarial process, courts typically have far more information at their disposal upon which to judge such issues as obviousness, inventiveness, or indeed utility.

61. Overall, the grant of a patent is never absolute. It can always be challenged through the court system or through other procedures available in some jurisdictions. Indeed, this possibility is alluded to as an aim of the PCT: “[...] by “strong” patents is meant patents granted for

inventions which by meeting all the conditions of patentability are likely to withstand challenge in the courts.³⁷ (emphasis added)

Signed at: Cincinnati, OH, US on: 26 JANUARY 2015

[signed]

T. David Reed

³⁷ *Summary and Advantages of the Patent Cooperation Treaty* in Records of the Washington Diplomatic Conference on the Patent Cooperation Treaty (1970), page 747, para. 6 (R-039).

Appendix A

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WORK EXPERIENCE

- 2006 – 2014** **Independent Consultant on international patent filing issues, specializing in the use of the PCT**
World Intellectual Property Organization (WIPO)
- Instruction of WIPO PCT seminars (over 90 to date).
 - Staffing of a WIPO PCT Help Desk, answering questions posed by US and Canadian practitioners on various issues related to the use of the PCT.
- 2006 – 2013** **Consultant**
Patrick Mirandah Company (pmc)
- Advice and technical support on PCT filing practices.
 - Authored numerous articles on the PCT and foreign patent practice in ASEAN countries, submitted by pmc for publication in a variety of trade journals.
- 1998 – Present** **Lecturer/Instructor**
Patent Resources Group
- Instruction of PCT seminars (Basic and Advanced).
- 1990 – Present** **Speaker**
- Have spoken on The Proctor & Gamble Company's PCT practice for: the World Intellectual Property Organization (WIPO); the American Intellectual Property Law Association (AIPLA); the Intellectual Property Institute of Canada (IPIC); the International Association for the Protection of Intellectual Property (AIPPI); the Asociación Costarricense de Ingenieros en Producción Industrial (ACIPI) Intellectual Property Owners Association (IPO); the Licensing Executives Society (LES), and the Association of Legal Administrators (ALA).
 - Have spoken in Argentina, Brazil, Canada, China, Egypt, India, Indonesia, Japan, South Korea, Malaysia, Mexico, Singapore, South Africa, Switzerland, Trinidad & Tobago, United Arab Emirates, United Kingdom, United States, and Uruguay.

1989 – 2006 **Manager (International Patent Filing and Prosecution Section of the Patent Division)**
The Procter & Gamble Company

- Responsibility for filing and prosecution of P&G patents outside the US and Europe.
- Agent of record or managed the filing of approximately 9500 PCT applications.
- Responsibility for the investigation into the PCT, managing the transition from direct filing practice to PCT practice for P&G, with continued management of the function until retirement in 2006.
- Promoted to Senior Patent Advisor (Section Head).

1980 – 1989 **Special Assignment as Technical Adviser (Corporate Legal Division and Patent Division)**
The Procter & Gamble Company

- Advising external trial counsel on numerous product liability and patent infringement lawsuits.

1966 – 1980 **Engineer in Product Research and Development (Toilet Goods Division & Paper Products Division)**
The Procter & Gamble Company

- Worked on a variety of projects related to products and manufacturing processes.
- Promoted to Group Leader.

PROFESSIONAL LICENSES

1988 – Present **Registered US Patent Agent**

EDUCATION

1967-1969 **Post-graduate instruction in Chemical Engineering**
University of Cincinnati, Cincinnati, OH, US

1961-1966 **Bachelor of Science in Chemical Engineering**
Northwestern University, Evanston, IL, US

PUBLICATIONS

Co-author, *The Practitioner's Guide to the PCT*, by J. Erstling, S. Helfgott, & T.D. Reed, The American Bar Association, 2013.

Numerous articles and slide presentations on the PCT from a user's perspective for the World Intellectual Property Organization (WIPO), published on the WIPO PCT website at http://www.wipo.int/pct/en/pct_strategies/index.html.

Contributions to the "Practical Advice" column of the World Intellectual Property Organization (WIPO) *PCT Newsletter*.

Articles on international patenting topics published by the Patrick Mirandah Company in Singapore, Malaysia and other ASEAN countries (typically with one or more non-contributing members of the Patrick Mirandah Company listed as co-author):

"Patenting in Singapore: One Person's View on 'Doing It Right'," *BNA International World Intellectual Report*, Vol. 21, No. 1, January 2008.

"Understanding the National Phase," *Managing Intellectual Property: IP Focus Asia-Pacific 2008*, 6th Ed., 2008, Pg.34-38.

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"New PCT Rules and Their Effect on ASEAN PCT Practice," Authored 2007/2008.

"Alternative Dispute Resolution (ADR) in S,E, Asia,": Authored 2009.

"Getting It Right the First Time: The Importance of Formalities and Procedures," Authored 2009.

“Multi-country R&D vs. National Security Requirements,” Authored 2012.

“Late National Phase Entry; Can It Be Done?” Authored 2013.

“When Sooner is Better than Later: Early National Phase Entry” Authored 2014.