

**In the Arbitration Under the Arbitration Rules of the
United Nations Commission on International Trade Law
and the North American Free Trade Agreement
(Case No. UNCT/14/2)**

ELI LILLY AND COMPANY

Claimant

v.

GOVERNMENT OF CANADA

Respondent

SECOND EXPERT REPORT OF JAY ERSTLING

Professor of Law Emeritus, William Mitchell College of Law

I. INTRODUCTION

1. In my initial report, I explained the Patent Cooperation Treaty (PCT) and discussed the “form and contents” requirements under that treaty. Canada’s expert David T. Reed asserts that my initial report suggested that the “form and contents” requirements of the PCT harmonize the substantive criteria for patentability.¹ I made no such suggestion; to the contrary, my report made clear that the PCT does *not* govern substantive patent law.² The fundamental point of my initial report, apparently missed by Mr. Reed, is that Canada’s new requirement to include proof or evidence of soundly predicted utility in the patent application is a matter of “form and contents” governed by the PCT, and is at odds with the structure and purpose of the PCT.

2. In this report, I respond to Mr. Reed’s mischaracterization of the “form and contents” requirements under the PCT and provide my observations on other aspects of the PCT where Mr. Reed’s descriptions are inconsistent with my understanding based on my experience, including my former role as Director of the Office of the PCT and Director-Advisor for PCT Matters at the World Intellectual Property Organization (WIPO). I also respond to Canada’s mischaracterization of the relevance and role of the PCT definition of industrial applicability.

II. THE PROCEDURAL “FORM AND CONTENTS” REQUIREMENTS OF THE PCT ARE A CRITICAL ELEMENT OF INTERNATIONAL PATENT FILING

3. As explained in my initial report, the form and contents requirements of the PCT specify what information must be included in an international patent application. Significantly, the PCT prohibits member countries from imposing any additional form and contents

¹ See Reed Report at ¶¶ 31-33.

² See, e.g., Erstling First Report at ¶ 22 (“Once an application enters the national phase, a Contracting State is free ‘to prescribe such substantive conditions of patentability as it desires.’”).

requirements that differ from those of the treaty or its regulations.³ Form and contents refer not only to physical requirements and identifying data, but also to the form and manner of describing and claiming.⁴ These requirements, by design, enable an applicant to “know[] 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.”⁵

4. The PCT does *not* govern Canada’s substantive utility requirement; on this point, Mr. Reed and I agree. But it *does* govern what must (and need not) be disclosed in an international patent application regarding the utility of an invention. By requiring disclosure of the factual basis for a sound prediction of utility, Canada has improperly required additional “contents” to be included in the application. This rule undermines the basic function of the PCT.

5. Specifically, Canada requires that the contents of a patent application as originally filed must include the underlying facts and “sound line of reasoning” to establish that the utility of the invention was soundly predicted as of the filing date. According to this rule, a patent for which the inventor has sufficient evidence to support a sound prediction of utility may nonetheless be invalidated in Canada for lack of utility if that evidence was not included in the patent application itself.⁶

6. It is this requirement to include proof or evidence of predicted utility in the patent application that is at odds with the structure and purpose of the PCT system. Requiring that the basis for sound prediction be disclosed in the application imposes “form and contents requirements” on PCT applicants entering the national phase in Canada that are both “different

³ Erstling First Report at ¶¶ 24-25.

⁴ Post-Conference Documents: Records of the Washington Diplomatic Conference, at 751, ¶ 57, WIPO (1970) [hereinafter Post-Conference Documents] (C-109).

⁵ *Id.*

⁶ See Claimant’s Memorial at ¶¶ 73-75.

from [and] additional to those which are provided for in [the] Treaty and the Regulations.”⁷ Canada’s rule is thus at odds with Article 27(1) of the PCT, and is particularly troublesome to applicants whose priority application originated outside of Canada.

7. The PCT provisions relating to utility are straightforward. PCT Rule 5.1(a)(iv) states 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.” The rule goes on to state that “the term ‘industry’ is to be understood in its broadest sense.”⁸ However, the PCT does not require that the contents of the patent application contain particular proof or evidence to substantiate an invention’s utility, only that the utility be expressly stated if not readily apparent. Indeed, the PCT International Search and Preliminary Examination Guidelines provide that “[i]n most cases, industrial applicability will be self-evident and no more explicit description on this point will be required.”⁹ Since the PCT does not provide that proof or evidence to support utility must be included in the patent application, PCT member countries cannot unilaterally require patent applicants to include that category of information in the international application. It is therefore surprising to me that Canada, as a PCT member, would impose this additional disclosure obligation on applicants.

8. The form and contents requirements of the PCT do not mean that PCT member countries are prevented from obtaining proof or evidence. As I explained in my initial report, the PCT expressly permits member countries to request that proof or evidence be furnished

⁷ PCT Article 27(1) (CL-73).

⁸ PCT Rule 5.1(a)(iv) (C-188).

⁹ PCT International Search and Preliminary Examination Guidelines, § 14.05 (C-114).

separately to the patent office to allow the office to verify that the invention is capable of achieving the utility that the applicant asserts.¹⁰

9. Mr. Reed acknowledges that during the national phase, the applicant is permitted to submit evidence to convince the examiner that the substantive conditions for patentability were met as of the date of filing.¹¹ Such evidence may include data of the type that Canada is now requiring to be included in the patent application itself. However, I disagree with Mr. Reed's statement of the purpose, and therefore also the effect, of providing proof or evidence during prosecution, outside of the patent application. The purpose of such proof or evidence is to support or substantiate an assertion already made and present in the patent application; it is not to introduce new information to remedy a deficient disclosure. When Mr. Reed says there is nothing in PCT Article 27(6) indicating that an applicant may overcome a "disclosure that is deficient under national law" at the time of filing via a post-filing submission,¹² he seems to misunderstand that Canada's new requirement is not directed at the sufficiency of an application's disclosure (which, as discussed below, is a separate requirement), but rather at utility that is based on sound prediction. Canada's new sound prediction rule imposes an additional requirement according to which "promises" of utility derived from the patent will be considered to have been soundly predicted only if there is proof or evidence in the patent to support the prediction.¹³ To my knowledge, Canada is the *only* country to consider a disclosure deficient because it does not include adequate proof or evidence of utility.

¹⁰ Erstling First Report at ¶¶ 30-31.

¹¹ Reed Report at ¶¶ 42, 55.

¹² *Id.* at ¶ 42.

¹³ See Claimant's Memorial at ¶ 57.

10. The penalty for failing to comply with Canada's additional disclosure rule is grave: rejection of the application or invalidation of the granted patent. The Canadian requirement is therefore precisely the kind of additional, different, and stricter requirement that the PCT seeks to prevent.

11. Mr. Reed correctly identifies that a primary advantage of the PCT is that it extends the time by which final decisions need to be made about patent filings in multiple national jurisdictions.¹⁴ His report does not, however, address the centrality of Article 27(1) to this key advantage, or the risks posed by unauthorized form and contents requirements.

12. Most PCT applications claim the benefit of priority of a previously filed national application, which in turn permits the applicant to claim the benefit of the priority date of that national application when entering the national phase in PCT member countries.¹⁵ If the applicant has to amend the patent application during the national phase to add additional content required by a particular member country, the amendment may be considered to add new subject matter to the patent application.¹⁶ That new subject matter has a priority date only as of the date on which it was added, not the earlier priority date of the original application.¹⁷ Without the benefit of the earlier priority date, the applicant may be unable to obtain a patent because prior art published after the international application, but before the national phase application with new subject matter, may render the invention anticipated or obvious.

¹⁴ See Reed Report at ¶¶ 15-19.

¹⁵ The national phase typically must be entered within 30 months of the earliest priority date; some member countries permit national phase entry later, at 31 (or more) months.

¹⁶ New subject matter typically is any information not disclosed in or supported by the patent application as of its priority date.

¹⁷ Formal entry of new subject matter after filing of a patent application (i.e., after entering the national phase) is almost universally prohibited.

13. Even if Mr. Reed were correct that international patent applicants must scrutinize the form and contents requirements of each of the 148 PCT jurisdictions in which they may enter national phase to ensure their applications comply with the requirements of each jurisdiction (an outcome that would undermine the very purpose of the PCT), Article 27(1) would remain in place so that additional requirements could not be imposed *after* the international application has been prepared and filed. For this reason, exceptions to the PCT form and contents requirements may not be imposed unilaterally; instead they are negotiated by member states and explicitly adopted, giving proper notice to applicants.¹⁸ No exception has been proposed or granted for Canada's unique "contents" requirement regarding evidence of soundly predicted utility.

III. ADDITIONAL ISSUES REGARDING THE PCT SYSTEM

14. Mr. Reed's report implies that other countries do something similar to Canada by requiring the patent applicant to provide, in the application, examples across the entire range of critical claim parameters when the application claims a range.¹⁹ But this is a question of sufficient disclosure and enabling the invention across the claimed range. The PCT recognizes the need for adequate disclosure by expressly requiring that the claims in an international application "shall be fully supported by the description," but the disclosure requirement is not at issue here.²⁰

¹⁸ Where PCT member countries agree that the inclusion of particular evidence or data is necessary to support patentability, they adopt regulations accordingly. For example, according to PCT Rule 5.2, if an invention in the field of biotechnology discloses "one or more nucleotide and/or amino acid sequences, the description shall contain a sequence listing complying with the standard provided for in the Administrative Instructions." The same is true with respect to the treatment of "best mode" in PCT Rule 5.1(v). The rule takes into account that a small number of countries may require the description to include a statement of "the best mode contemplated by the applicant for carrying out the invention," but that most countries do not. Therefore, the rule expressly includes a requirement to "set forth at least the best mode" in the description, but it goes on to state that "failure to describe the best mode contemplated shall have no effect" in any country that does not require it.

¹⁹ See Reed Report at ¶¶ 43, 47 & 48.

²⁰ PCT Article 6 (CL-73). The Regulations prescribe that the applicant must sufficiently describe the invention by describing "the way in which [the invention] can be made and used." PCT Rule 5.1(a)(vi) (C-188). This is a

15. In particular, the need to provide examples across the entire range of the claims does not relate to utility, and it does not imply that member countries may impose additional form and contents requirements beyond those prescribed by the PCT. Where required, examples are aimed at ensuring that when a range is claimed, the claims are not overbroad with respect to the supporting disclosure.²¹ If the claims are overbroad, and not supported by the disclosure, the applicant may amend the claims to cover the range in line with the disclosure or cancel the claims. By contrast, when a Canadian court finds that the patent itself did not contain sufficient evidence or proof of utility, the remedy for the range issue discussed by Mr. Reed (i.e., amending the claims to correspond with the scope of the range disclosed in the patent application) is not available, and the patent will be invalidated.

16. In a similar vein, Mr. Reed’s statement that the “form and contents” requirements refer only to the “basic categories of information that must be included in an international application,” such as those specified in PCT Article 11, is not supported by the language of the treaty.²² In this respect, Mr. Reed confuses the duties of PCT Receiving Offices with those of patent examiners during the national phase.²³ The responsibility of PCT Receiving Offices is to accept and review international applications for conformity with the clerical formalities

requirement prescribed by the PCT, and applicants accept that the application will need to contain adequate information in order to comply.

²¹ For example, a claim may recite “a compound comprising 1 milligram (mg) to 3 mg of sodium.” In most member countries, the disclosure of the application containing this claim must disclose amounts of sodium ranging from 1 mg to 3 mg for the claim to be supported. If prior art disclosing the same compound but with 2.5 mg or more of sodium is cited during prosecution, the applicant may consider amending their claim to recite, for example, “a compound comprising 1 milligram to 2.4 milligrams of sodium.” In some member countries (e.g., the U.S.), this narrowed range would likely be considered to be supported by disclosure of the broader original range, even though less than that entire range is now claimed. In other jurisdictions (e.g., the EPO), the narrowed range would be considered to be disclosed only if the patent application also specifically listed the narrowed range in the disclosure. If the disclosure included only 1 mg to 3 mg of sodium, the EPO would not permit the applicant to amend their claim to 1 mg to 2.4 mg. of sodium. The EPO would do this because the narrowed range is not considered to be sufficiently disclosed in the application to support the claim, not because the narrowed range somehow lacks utility.

²² Reed Report at ¶ 33.

²³ See Reed Report at ¶ 37.

prescribed in PCT Article 11 for the issuance of an international filing date.²⁴ If the Receiving Office determines that an international application complies with Article 11, it accords the application an international filing date and processes the application so that it may be subjected to international search, published, and ultimately enter the national phase.

17. Contrary to what Mr. Reed suggests, the role of the PCT's form and contents requirements is not limited to the screening function of Receiving Offices. Rather, those requirements become particularly relevant within the national phase: crucially, they limit what PCT member countries may require as regards the contents of the patent application. This gives the applicant confidence that the international application will not draw content-based objections in PCT member countries, and thus promotes the coordinating objectives of the treaty.²⁵ Mr. Reed argues that 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."²⁶ The PCT does abstain from informing the applicant whether the nature of the invention will be considered patentable subject matter or whether the industrial applicability requirement will be met during national phase, because those questions are matters of substantive patent law. PCT Rule 5.1(a)(vi), however, is explicit about "what must be disclosed" regarding industrial applicability: under the PCT, the utility of an invention

²⁴ To meet the requirements of Article 11 listed by Mr. Reed, an applicant must be a national or resident of a PCT member country, and the international application must include several elements, including a description of the invention, at least one claim, and the designation of at least one PCT member country for the purpose of entering the national phase. *See* PCT, Article 11(1) (CL-73). Additional information related to making these determinations can be found in Rule 20 of the Regulations under the PCT.

²⁵ For example, the WIPO website assures applicants: "[I]f you comply with certain formal requirements set out in the Treaty and Regulations, which are binding on all of the PCT Contracting States, subsequent adaptation to varying national (or regional) formal requirements (and the cost associated therewith) will not be necessary." *See* "Protecting your Inventions Abroad: Frequently Asked Questions About the Patent Cooperation Treaty (PCT) (status on April 2015)," <http://www.wipo.int/pct/en/faqs/faqs.html> (C-416).

²⁶ Reed Report at ¶ 38.

must be readily apparent or expressly stated. In terms of disclosure of utility in an international application, nothing more is required.

IV. THE PCT AND ITS GUIDELINES ARTICULATE AN ACCEPTED DEFINITION OF “INDUSTRIAL APPLICABILITY”

18. Canada asserts that the PCT definition of industrial applicability is of no relevance outside the PCT,²⁷ but this claim seriously understates the role of the PCT in the international patenting system and the degree to which member countries share a common understanding of the term. While the PCT does not harmonize substantive patent law, the definition of industrial applicability in the PCT and Examination Guidelines is instructive as to the commonly held international understanding of the requirement.

19. The PCT plays an important role in setting requirements for the form and contents of international patent applications, but this is not the only function of the system. During the international phase, after the PCT applicant has filed and obtained an international filing date, there are two key steps before the application enters the national phase. First, the International Searching Authority chosen by the applicant conducts an international search to find prior art documents relevant to the application. The results of this search are provided in an International Search Report (ISR), which is published by the International Bureau of the PCT. Second, the International Searching Authority conducts a preliminary examination, which results in the issuance of a Written Opinion on questions of novelty, inventive step, and industrial applicability or utility. The Written Opinion is in turn published by the International Bureau as an International Preliminary Report on Patentability (IPRP).

²⁷ See Respondent’s Counter-Memorial at ¶¶ 208, 380.

20. During prosecution of the PCT application in the national phase, national and regional patent offices can use the ISR and Written Opinion. The results of a prior art search or preliminary examination are not binding on any member state because, as noted, the PCT does not dictate substantive patent law requirements. Countries, however, rely to varying degrees on the ISR and Written Opinion in deciding whether to grant patents, and a favorable Written Opinion can trigger an expedited national phase examination in the more than 30 national and regional patent offices participating in the fast-growing Patent Prosecution Highway (PPH) program.²⁸

21. When conducting the preliminary examination, the International Authority relies on the definitions of novelty, inventive step, and industrial applicability in the PCT and in the PCT International Search and Preliminary Examination Guidelines (“Guidelines”). The PCT, of course, is the product of negotiations among member countries. Likewise, the Guidelines are not simply drafted by WIPO; they are formulated through extensive discussions among the International Searching and Preliminary Examining Authorities. Accordingly, while the PCT definitions of novelty, inventive step, and industrial applicability are not binding on member countries, those definitions are informed by and reflect the common understanding of PCT member countries.

22. In my experience, the PCT definition of industrial applicability — that an invention is industrially applicable “if, according to its nature, [the invention] can be made or used (in the technological sense) in any kind of industry”²⁹ — is non-controversial. According

²⁸ The PPH program is a series of bilateral agreements signed between national patent Offices to enable patent applicants to request accelerated processing in the national phase. Patent examiners make use of work product from other offices, including the ISR and IPRP. See “PCT-Patent Prosecution Highway Pilot (PCT-PPH),” http://www.wipo.int/pct/en/filing/pct_pph.html (C-417).

²⁹ PCT Art. 33(4) (CL-73).

to Section 14.04 of the Guidelines, to assess industrial applicability “the following steps are applied: (i) determine what the applicant has claimed; and (ii) determine whether a person skilled in the art would recognize the claimed invention to have industrial applicability.”³⁰ As noted, the Guidelines also state that “[i]n most cases, industrial applicability will be self-evident and no more explicit description on this point will be required,”³¹ and that a claim lacks industrial applicability when a “product or process is alleged to operate in a manner clearly contrary to well-established physical laws and thus the invention cannot be carried out by a person skilled in the art.”³²

V. CONCLUSION

23. Mr. Reed states that it was never his practice, when filing patent applications for P&G, to assume that compliance with the PCT’s “form and contents” requirements necessarily meant satisfaction of all substantive requirements in the jurisdictions where P&G sought patent protection.³³ That is prudent — I agree that the PCT does not govern substantive patent law, and that additional evidence may be required during the national phase to show such requirements are met. However, while the PCT is not, as Mr. Reed correctly states, “an invitation to ignore the differences in substantive requirements of patentability that exist between countries,”³⁴ it *is* a promise that member states will not impose form and contents requirements other than those authorized by the PCT. The solution provided by the PCT is straightforward: PCT member countries are free to require evidence of substantive patentability conditions such as utility, but

³⁰ PCT International Search and Preliminary Examination Guidelines, Chapter 14 at 14.04 (C-114).

³¹ *Id.* at 14.05 (C-114).

³² *Id.* at 14.06 (C-114).

³³ Reed Report at ¶ 44.

³⁴ Reed Report at ¶ 28.

they must permit that evidence to be submitted separately from the application — and must not penalize applicants for failing to disclose such evidence in the PCT application. Moreover, Canada’s assertion that the PCT definition of industrial applicability is of no relevance outside the PCT is inaccurate given the role of the PCT in the international patenting system.

Signed at Minneapolis, MN on September 10, 2015.

[signed]

JAY ERSTLING