

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

ELI LILLY AND COMPANY

Claimant

v.

GOVERNMENT OF CANADA

Respondent

EXPERT REPORT OF PHILIP THOMAS

Former Senior Director-Advisor, World Intellectual Property Organization

I. Background and Introduction

1. I have spent over forty years working on issues of patent law and policy, at both the national and international levels.

2. I began my career at the Australian Patent Office. Starting as a patent examiner specializing in biotechnology patents, I rose to become Assistant Commissioner of Policy, with responsibility for legislation and national and international patent policy. In that role, I also advised the responsible government minister on patent-related issues.

3. In 1990, I joined the World Intellectual Property Organization (“WIPO”) as a Senior Legal Officer. Over the next 20 years, I served in a range of senior positions, including as Director of the PCT Legal Development Division and Director of the Patent Policy Department. I retired in 2010 as Senior Director-Advisor (PCT and Patents). In each of these roles, I worked extensively with government representatives of member states, national patent offices, patent practitioners, inter-governmental organizations and non-governmental organizations in the patent arena. My complete C.V. is attached to this report.

4. While at WIPO, I was heavily involved in the negotiation, drafting and implementation of international agreements. Among other things, I participated in all meetings of the WIPO Standing Committee on the Law of Patents (the “SCP”) from 2001 through 2004 as a member of the secretariat team supporting the meetings. The SCP was the principal body responsible for the negotiation of draft text for inclusion in the proposed Substantive Patent Law Treaty (the “SPLT”). I do not recall Professor Gervais attending any of those meetings.

5. This statement sets out my recollection of the course, nature, and significance of international discussions and agreements addressing substantive patent law. I address the period from the 1980s to the present, and I focus in particular on the industrial applicability (utility) requirement of patentability. My principal recollections,

which differ in important respects from the conclusions reached by Professor Gervais, are the following:

- The central tenet of the industrial applicability (utility) requirement – that an invention have some practical use – has not attracted controversy in international negotiations at WIPO over substantive patent law.
- On the contrary, WIPO negotiations have focused on issues such as “first to file” versus “first to invent” rules, the scope of prior art, and the scope of exclusions from patentable subject matter.
- As suggested by the double-barreled term by which it has come to be known, the industrial applicability (utility) requirement is given effect using somewhat varying language under different national legal systems. It is, however, understood to achieve the same practical results.

II. Overview of Patent Law Harmonization in the Context of WIPO

6. In the decade preceding the conclusion of NAFTA in 1992, and in the two decades since, there have been two principal attempts in WIPO to conclude a multilateral treaty setting out a detailed international agreement on substantive patent law. These attempts, which were ultimately not fruitful, were the negotiations from 1983 that led up to the 1991 Diplomatic Conference that considered a proposed Treaty Supplementing the Paris Convention as far as Patents Are Concerned (the draft text known as the “Basic Proposal”) and the negotiations from 2000 to 2004 over a proposed Substantive Patent Law Treaty (the “SPLT”).

7. As noted, I was involved in the SPLT negotiations. I also tracked discussions prior to and surrounding the 1991 Basic Proposal, first in the 1980s as a member of the Australian Patent Office responsible for policy development, and later at WIPO.

8. None of these efforts yielded a substantive patent law treaty. But, contrary to Professor Gervais’s view, the lack of success had nothing to do with the core industrial applicability (utility) requirement.

9. Attempts to conclude substantive patent law treaties within WIPO have failed as a result of disagreement on a limited number of politically charged issues. These disagreements were, in particular: “first to file” versus “first to invent” rules for establishing the right to a patent; the scope of prior art and the so-called “grace period” that permits certain disclosures to be excluded from the scope of prior art; exclusions from patentable subject matter; and, relatedly, the application of patent law to genetic resources.

10. These issues cannot be entirely divorced from the core patentability criteria. For example, the definition of prior art changes the circumstances under which a patent will be found to be obvious or anticipated (*i.e.*, not novel). But, from my vantage point, WIPO member states shared – and continue to share – a common core understanding of what it means for a patent to be novel, inventive (non-obvious), and industrially applicable (useful).

11. In particular, the core of the industrial applicability (utility) requirement is that an invention must have, or be capable of, some practical use. “Industry” is to be understood in a very broad sense. Different countries use different terminology to implement the requirement in their legislation. But the industrial applicability (utility) standard is, as further discussed below, applied in a manner that is remarkably similar around the world: it is a low bar that is rarely the basis for a rejection or invalidation.

12. Given the substantial consistency of practice with regard to the core industrial applicability (utility) requirement among WIPO member states, the issue was not considered to be a priority for harmonization. In particular, I can recall no debate over issues such as: whether the utility required of a patent could be varied by the drafting of the description; whether a patent could ever be required to fulfill multiple utilities; or whether a patent on an invention used daily in a qualifying field of technology could be invalidated for lack of industrial applicability (utility).

13. Industrial applicability (utility) and the other main substantive patentability requirements can be likened to the planks of a hardwood floor. Consistency in international practice creates a floor of secure rights that people and

companies rely on every day to make decisions. Debates in WIPO focused on gaps between these planks. In other words, the substantive talks focused on issues where there were disparate approaches across jurisdictions, and where resolution of those differences would significantly advance the goal of harmonization and further strengthen the floor. In contrast, commonalities in practice, while most definitely relevant, were generally not a focal point of discussion.

14. This focus on the gaps resulted in significant debate and often heated disagreement in the course of substantive patent law negotiations at WIPO. But such political disagreements, on discrete issues, did not undermine the existence of a core foundation of common practice on many other issues. To understand this, it is vital to understand the dynamics underlying the disagreements – in particular, debates among developed countries and debates between developed and developing countries (which, for convenience, I refer to as North-South debates).

15. In the 1991 Basic Proposal, the most prominent debate among developed countries was whether patent ownership should automatically attach to the “first to file” for a patent (as in Europe), or whether states could continue to prefer a more fact-intensive inquiry of identifying the person who was “first to invent” (as in the United States). In later negotiations, this debate was joined by another that was related to the patentability of business methods (such patents were generally available in the United States but not in Europe).

16. North-South debates were less prominent in the failure of the 1991 Basic Proposal, but took on greater significance in negotiations over the draft SPLT. Whereas SPLT negotiations began in 2001 as an attempt by technical patent experts in member states to consolidate and build on the procedural issues that had in the meantime been agreed in the 2000 Patent Law Treaty, they quickly became intertwined with broader political issues. From my perspective in the WIPO secretariat, it often appeared that the negotiating positions adopted by member states were influenced by the Doha Development Round of negotiations at the World Trade Organization and development issues that had emerged during the course of the negotiation and subsequent entry into

force of the 1994 TRIPS agreement. The key Doha Round issues that appeared to have been carried over into SPLT negotiations related to genetic resources and, among other things, whether special disclosure obligations should attach to patents involving genetic resources. The contentiousness of such debates made it difficult to reach agreement on other issues – even some that might in themselves be considered uncontroversial.

17. The debates on controversial issues sometimes spilled over into discussions on matters more centrally related to patent law and practice, including the industrial applicability (utility) requirement. Questions related to the patentability of genetic resources, for example, were raised by some delegations in connection with the industrial applicability (utility) requirement and exclusions from patentability (among other things). Similarly, the debate over business method patents was linked by some delegations to a controversy over whether an invention should be required to have a “technical” character in order to qualify as patentable under the industrially applicable (utility) requirement. But in my experience, the debates on these topics, however heated they became, did not undermine or call into question the substantial commonalities in patent practice among WIPO member states. Put otherwise, the planks of the hardwood floor were not weakened by debates over the gaps.

18. In the remainder of my report I address in greater detail the treatment of the industrial applicability (utility) requirement in negotiations over the Basic Proposal and the SPLT. I will focus on responding to the manner in which Professor Gervais discusses the treatment of industrial applicability (utility) in these negotiations.

III. Treatment of industrial applicability (utility) in negotiations over the Basic Proposal and the SPLT

A. The 1991 Basic Proposal

19. Professor Gervais asserts that there was substantial national variance in the industrial applicability (utility) standard, and that the Basic Proposal was

abandoned, in part, because of disagreements over this standard.¹ His argument is based exclusively on the fact that the Basic Proposal allowed parties to choose their preferred terminology as between industrial applicability and utility.²

20. I find Professor Gervais's argument surprising and without foundation. The terms "utility" and "industrial applicability" are treated as equally acceptable terms that lead to the same practical outcomes. As such, the linguistic choice between these two terms was not a negotiation priority.

21. Instead, as noted, the Basic Proposal failed largely because a dispute over whether to make mandatory the "first-to-file" principle for establishing the right to a patent, requiring countries (in particular, the United States) to forgo the "first-to-invent" system.³ Other matters, for example, matters related to prior art and the grace period, were linked to that issue (notably, in connection with the anticipatory effect of prior art published during the period between the date ascribed to the invention and the date of filing of a patent application). The matter was deadlocked, with neither side wishing to see the treaty proceed with the provisions sought by the other side. Ultimately, therefore, the Basic Proposal was pared back to what was adopted in 2000 as the Patent Law Treaty (the "PLT"), which did not address issues of substantive patent law but rather dealt with certain formal and procedural requirements under national patent laws.

B. The 2004 Draft SPLT

22. The draft SPLT revived substantive patent law harmonization efforts and sought to build upon the progress represented by the 2000 PLT. The conclusion of the PLT and passage of almost a decade from the Basic Proposal were hoped to have made a second attempt at substantive harmonization politically feasible.

¹ See Gervais Report at ¶¶ 18-20.

² See *id.* at ¶ 18.

³ See PLT/DC/6 (March 1, 1991) (Proposal of the United States with respect to Draft Articles 9, 11 and 13) (C-406).

23. The SPLT was negotiated in the forum of WIPO's Standing Committee on the Law of Patents ("SCP"). As noted, I was present at the vast majority of SCP meetings in that period as a senior member of the WIPO secretariat staff. I do not recall Professor Gervais attending any SCP meetings, and in any event Professor Gervais was no longer employed at WIPO during these negotiations.

24. The SPLT was an ambitious endeavor. It faced the same "first to file" versus "first to invent" issue that had stalled the 1991 Basic Proposal, as well as new issues introduced in the context of North-South debates. Nevertheless, the documentary record reflects the common understanding among WIPO member states of how the industrial applicability (utility) requirement operated in practice. This is apparent from the very documents that Professor Gervais relies upon: the SPLT drafts circulated in April and October of 2001 and in May and October of 2002; a study on industrial applicability (utility) prepared by the WIPO secretariat in 2004; and the Joint Proposal circulated by the United States, Japan, and the European Patent Office, also in 2004.

1. Proposed Definitions of Industrial Applicability (Utility) in SPLT Drafts

25. The first proposed draft of the SPLT, dated 4 April 2001, included two alternatives for "industrial applicability (utility)."⁴ The first alternative defined industrial applicability (utility) as requiring that an invention "can [be made or used in any kind of industry] [have a specific, substantial and credible utility]." This alternative simply recited both the European and the United States formulations of the requirement, putting brackets around each.

26. A further alternative would have deleted industrial applicability (utility) as an independent treaty requirement altogether. The proposal to delete the industrial applicability (utility) requirement was repeated in the second draft, dated 3 October

⁴ WIPO Document SCP/5/2, at 20 (4 April 2001) (R-223).

2001.⁵ In explaining the proposed deletion, the secretariat expressly noted that “in practice, only very few applications are refused on those grounds [of industrial applicability (utility)].”⁶ In my view, the suggestion that industrial applicability (utility) be removed from the text was consistent with the secretariat’s approach of assisting the parties in moving negotiations forward by separating significant issues meriting negotiation from other issues that did not require focused attention. Industrial applicability (utility) did not require focused attention.

27. The third and fourth proposed draft texts re-inserted the industrial applicability (utility) requirement.⁷ I believe this change was due to a sense that the draft should reflect all three of the basic requirements of patentability under domestic patent laws – regardless of the fact that one of them (industrial applicability) was seldom invoked in practice as an issue in deciding whether a patent should be granted or refused for any particular invention.

28. It is therefore unsurprising that the specific definitions in the third and fourth proposed drafts were again simply intended to “reflect the standard contained in many national/regional legislation [sic].”⁸ This statement also supports the point that the alternatives in the fourth proposal were attempts to reflect and bridge differences in national *nomenclature*, but were not focused on any identified differences in national *practice*. It would have been quite feasible to bridge the gap in nomenclature, as reflected in a proposal in the fourth draft for a “single definition accommodating both industrial applicability and utility.”⁹

⁵ WIPO Document SCP/6/2, at 30 (3 October 2001) (R-225).

⁶ WIPO Document SCP/6/4, at ¶ 12.02 (3 October 2001) (R-219).

⁷ WIPO Document SCP/7/3, at 24 (6 March 2002) (R-227) and WIPO Document SCP/8/2, at 26 (16 October 2002) (R-228).

⁸ WIPO Document SCP/7/5, at 21 (18 March 2002) (C-407).

⁹ WIPO Document SCP/8/2, 16 October 2002, at 26 (the proposed definition read: “A claimed invention shall be . . . considered industrially applicable (useful) if it can be made or used for exploitation in any field of [commercial] activity”) (R-228).

29. It bears emphasis that, while draft language on industrial applicability (utility) was proposed, limited time was given to discussion of this language in SCP meetings and no significant effort was made to elaborate a definition of industrial applicability (utility). This reflects the lack of controversy associated with the core standard in general. It is notable that when industrial applicability (utility) was discussed by negotiators, the discussion focused on the perceived impact that the definition might have on subject matter exclusions. There was no motivation to agree on a codified definition of industrial applicability (utility), at least while there were other outstanding issues to resolve that were considered higher priority.

2. The IB Study on Industrial Applicability (Utility)

30. Professor Gervais relies extensively on passages in a 2003 WIPO International Bureau (“IB”) study based on a survey of commonalities and differences in national laws and practices on the industrial applicability (utility) requirement.¹⁰ This study, undertaken by the IB in light of the differences in domestic nomenclature, acknowledged differences in terminology but also concluded that “[c]onsiderable overlaps . . . exist between these two requirements [industrial applicability and utility]” and that “decisions based on the lack of industrial application are, in general, very rare.”¹¹ Professor Gervais’s analysis of this study quotes exclusively from passages that note the acknowledged differences in nomenclature across countries.

31. It is notable that this study did not attract the attention of the negotiating parties. No delegation discussed or referenced the study in any subsequent SCP meeting (there is no record of such a reference in SCP meeting reports, and I can recall no such discussion at an informal level). I believe that the lack of discussion accorded to the IB study reflects the lack of controversy surrounding core practices under the industrial applicability (utility) requirement.

¹⁰ Gervais Report at ¶¶ 37-41.

¹¹ See WIPO Document SCP/9/5, at 5-6, 14 (17 March 2003) (R-230).

32. Professor Gervais also argues that the IB study reflected a recognition and acceptance of Canada's promise utility doctrine.¹² I disagree.

33. As just mentioned, the IB study was not discussed in SCP meetings. As such, not a single delegation commented on any of the national nomenclature referenced in the study during the SCP talks.

34. Moreover, I have read the Canadian Zyprexa and Strattera cases and find their approach to utility surprisingly out of line with what I understand to be the practice in other WIPO countries. Nothing similar to the utility test articulated in those cases was ever, to my recollection, discussed in WIPO meetings that I attended.

3. The Joint Proposal and the End of the SPLT Talks

35. Ultimately, the SPLT talks were discontinued as a result of disagreements on many of the same topics (such as "first to file" and genetic resources) that were controversial when negotiations commenced.

36. Before the end of the talks, there was a late attempt (submitted to the SCP in 2004, and known as "the Joint Proposal") by the United States, Japan, and the European Patent Office to promote agreement on a subset of issues. Industrial applicability (utility) was not included in this subset. Professor Gervais asserts that this means industrial applicability (utility) was recognized as an area of particular dispute or disagreement.¹³ That assertion is incorrect.

37. The proposed topics included in the Joint Proposal were selected both because they were viewed as areas where progress was feasible and because they were viewed as important. These two criteria are expressly recognized on the face of the proposal, which makes clear that it is driven by the desire for a "near-term agreement"

¹² See Gervais Report at ¶ 41.

¹³ See Gervais Report at ¶ 46 ("Second, utility and industrial applicability are not included in the list of issues suggested to be ripe for possible international harmonization or even discussion in the SPLT context...") (emphasis omitted).

that “would result in consistent examination standards throughout the world, improve patent quality, and reduce the duplication of work performed by patent offices.”¹⁴

38. In light of these criteria, the Joint Proposal focused on prior-art related issues.¹⁵ Such a focus made sense given that one key goal of the parties to the Joint Proposal was to achieve “consistent examination standards throughout the world.”¹⁶ Patent applicants have a great interest in obtaining consistent and predictable outcomes for patent applications for the same invention filed in multiple countries. The cost of obtaining patents internationally is considerable. Being confronted with acceptance by one patent office and rejection by another, of a similarly drafted application, in the light of the same body of prior art, is understandably seen by applicants as an unnecessary and costly complication, and ultimately as a disincentive to investment in innovation and an unjustifiable barrier to international trade and commerce. Moreover, unnecessary differences in patent office practice are an obstacle to work sharing among offices and lead to duplication of work and inefficient utilization of resources. The definition of industrial applicability (utility) did not present a hurdle to consistent patent examination across jurisdictions and therefore was not viewed by those putting forward the Joint Proposal as a priority.

IV. Conclusion

39. I know from many years of experience that there are important areas of divergence, and even politically controversial disputes, among WIPO member states with respect to substantive patent law. But my experience has also taught me that there are equally important areas where the practices of member states are consistent. I disagree with Professor Gervais’s attempt to place industrial applicability (utility) in the first category (of divergence) rather than the second category (of consistency). His

¹⁴ WIPO Document SCP/10/9, at 2 (22 April 2004) (proposal from the United States of America, Japan and the European Patent Office regarding the substantive patent law treaty) (R-235).

¹⁵ *Id.*

¹⁶ *Id.*

position is not supported by the documents he relies upon when they are viewed in their context. Moreover, the account he delivers simply cannot be squared with the negotiations I observed or participated in during my two decades at WIPO.

Done in the Canton of Geneva, Switzerland on 7 September 2015.

[signed]
Philipp Thomas, LL.B.

Philip Thomas

Philip Thomas is a seasoned IP professional who enjoyed a 38-year career in patent law, policy and administration, first in the Australian Patent Office and then in the World Intellectual Property Organization (WIPO). He retired from full-time employment in early 2010, since when he has continued to undertake work as a consultant in the field of patents.

Mr. Thomas commenced work in the Australian Patent Office as a patent examiner in the field of biotechnology, and later became responsible for legislation and policy activities.

Mr. Thomas's experience at WIPO covered policy, law and administration relating to national legislation and international treaties, relations with member States and national and regional patent offices, seminars and training activities, and legislative and procedural matters.

EMPLOYMENT SUMMARY

AUSTRALIAN PATENT OFFICE, CANBERRA

- 1973-1979 Examiner of Patents (biotechnology)
- 1979-1990 Executive Officer, then Assistant Commissioner (legislation; national and international policy)

WORLD INTELLECTUAL PROPERTY ORGANIZATION (WIPO), GENEVA

- 1990-2000 Patent Cooperation Treaty (PCT) Legal Division - Senior Legal Officer, Senior Counselor, then Director
(legal analysis; representation of WIPO at meetings and conferences; development of proposals for improving the PCT system; advice, information and training for WIPO member States and patent offices)
- 2000-2002 PCT Legal Development Division, Director
(development and pursuit of proposals for reform of the PCT system)
- 2002-2004 Patent Policy Department, Director
(development of proposals for improving the international patent system)
- 2004-2010 Senior Director-Advisor (PCT and Patents)
(advice on improving the operation of the international patent system; relations with national and regional patent offices and with interest and user groups)
- 2006-2009 Alternate Chair, WIPO Joint Grievance Panel

SINCE RETIREMENT (in 2010)

Expert consultant for WIPO and the private sector, including: consulting on an internal WIPO evaluation of its patent law program; revision of the WIPO Intellectual Property Handbook and the PCT International Search and Preliminary Examination Guidelines; seminars and training activities.

EDUCATION SUMMARY

- 1966-1969 B.Sc. (Hons.), Flinders University, Adelaide (biological sciences; honors in biophysics)
- 1974-1978 LL.B., Australian National University, Canberra (law)

PERSONAL DETAILS

Nationality: Australia

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