

**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)**

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**SECOND WITNESS STATEMENT OF MICHAEL GILLEN**

**DECEMBER 7, 2015**

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Trade Law Bureau  
Departments of Justice and of Foreign  
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1. I write this second statement to respond to certain assertions made by Mr. Murray Wilson in his Reply Expert Report dated September 9, 2015. In particular, I will comment further on the patent examination process, the manner in which applications were assessed for utility in the relevant period, and the significance of MOPOP updates.

#### **A. Patent Examination Process**

2. I agree with Mr. Wilson that patent examination is “not superficial nor a rubber stamp.”<sup>1</sup> Having been personally involved in training activities at the Patent Office for 16 years, I can attest to the fact that patent examiners are well-trained. They assess each patent application for compliance with the *Patent Act*<sup>2</sup> and only refuse an application if there is a basis in law.<sup>3</sup>
3. However, patent examiners must meet time-based goals in their review. The Patent Office also has service standards for patent application review.<sup>4</sup> Given the large volume of applications and the relatively small number of patent examiners, patent examiners must work efficiently to meet both their goals and the Office’s service standards.<sup>5</sup>
4. For example, patent examiners use assumptions – or presumptions (as Mr. Wilson would prefer to call them) – in favour of the applicant as a means to assess an application.<sup>6</sup> In fact, taking a statement in an application at face value is necessary for some arts. In the pharmaceutical and biotechnology fields, there is no way that an examiner can look at a compound or chemical formula as stated in an application and know what it does. Further, the Patent Office does not have the means to test chemical formulations. While the *Act* provides a basis for requesting samples, as a practical matter, this is not normally feasible for these kinds of arts. Such samples and testing are more pertinent for the mechanical arts. Patent examiners will thus always take scientifically plausible statements in applications at

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<sup>1</sup> Wilson Reply Report, para. 10.

<sup>2</sup> Gillen Statement, para 11.

<sup>3</sup> *Monsanto Company v. Commissioner of Patents*, [1979] 2 SCR 1108, (“*Monsanto 1979*”) (R-023).

<sup>4</sup> CIPO Service Standards, 1999-2011 (R-380).

<sup>5</sup> See Gillen Statement, paras. 12-13.

<sup>6</sup> Gillen Statement, para. 13.

face value.

5. I did not introduce the systemic pressures faced by the Patent Office in my first statement to diminish the significance or thoroughness of patent examiners' review. Rather, I intended to place examiners' review in context and to offer a contrast between the roles of the Patent Office and the courts in assessing patent validity. As set out in my first statement, the courts assess a patent's validity in a different context and on the basis of a different and more comprehensive evidentiary record than does the Patent Office.<sup>7</sup> Given this reality, it is not surprising that the courts may come to a different conclusion with respect to a patent than the Patent Office.

## **B. Patent Examiner Review of Utility and Disclosure Requirements**

### **a. Standard of Utility**

6. Mr. Wilson and I agree that the *Patent Act* provides for the same standard of utility for all types of inventions. However, we seem to disagree on what the standard is. If the patent specifies the invention's utility, beyond a mere scintilla, then that is the utility the invention must have.
7. Mr. Wilson also seems to overlook the fact that the application of this standard to different types of inventions may lead to different inquiries. For example, inventions in the mechanical arts frequently rely on evident utility, whereas inventions in the chemical and biotechnology arts frequently rely on sound predictions to establish utility. When an invention's utility is evident on its face, there is no need to spend any further time examining it. By contrast, when utility is based on a sound prediction, it is logical that more time might be spent assessing the factual basis for the prediction and the sound line of reasoning.
8. In the specific context of evident utility, I would agree with Mr. Wilson's statement that "utility was not questioned unless an examiner had doubts that an invention would work."<sup>8</sup> In

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<sup>7</sup> Gillen Statement, paras. 12-16. For example, the Patent Office reviews only the applicant's information, while the court reviews both the applicant (now patentee)'s information, as well as the information of a party opposed in interest.

<sup>8</sup> Wilson Reply Report, para. 16.

this regard, I note that Mr. Wilson's background as an examiner at the Patent Office is in the mechanical arts.<sup>9</sup>

9. In contrast, my experience is specifically in the biotechnology and chemistry sectors. Examiners working in these areas (including pharmaceuticals) typically spend more time assessing utility for new use and selection patents than for new compound and genus patents. This is because the specified new use, or newly identified advantages of the selection over the genus, forms the basis for the invention.
10. To that end, I disagree with Mr. Wilson when he states that "[a]dditional advantages mentioned in an application might be considered when assessing novelty and inventive ingenuity as part of the inventive step over the prior art but they were not part of the utility assessment."<sup>10</sup> In the case of new use and selection patents – like those granted to Eli Lilly for atomoxetine and olanzapine – the lines between utility and obviousness are blurred.
11. In Mr. Wilson's view, the utility of new use and selection patents "was often obvious in light of the prior invention".<sup>11</sup> I note that this view essentially disposes of the utility requirement for these types of patents altogether. For example, as Mr. Wilson says, an applicant seeking a selection patent needs to establish that the selection accomplishes more than the genus to show the Patent Office that the selection is not obvious. However, on Mr. Wilson's view, it would be enough for utility purposes that the applicant show that the selection accomplishes the same thing as the genus. In my experience, this was not the manner in which patent examiners conducted their review of these types of applications.<sup>12</sup> It would have been incongruous for examiners to define the invention in different ways for different patentability requirements.

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<sup>9</sup> See Wilson Report, para. 5, Attachment A.

<sup>10</sup> Wilson Reply Report, para. 20.

<sup>11</sup> Wilson Reply Report, para. 21.

<sup>12</sup> See Gillen Statement, paras. 28-30.

12. Instead, patent examiners understood that the utility of the selection must be enhanced relative to the genus by virtue of the nature of the invention. Similarly, when a new use is claimed for an existing compound, patent examiners understood that utility beyond the utility claimed in the original patent is required. Otherwise, the applicant gives nothing in return for the patent monopoly sought for the alleged invention.
13. Mr. Wilson quotes from the 1990s versions of the MOPOP to support his view that the utility requirement would have been met at those times if the invention was not “totally useless” and had some “industrial value.”<sup>13</sup> However, the same chapters relied on by Mr. Wilson also state that an invention must “impart industrial value to what is sought to be patented,”<sup>14</sup> and that it must have utility “for its described purpose.”<sup>15</sup> In my view, this is consistent with my previous testimony that patent examiners assessed inventions on the basis of the language employed by applicants, including the description and what an applicant says the alleged invention will do.<sup>16</sup> I note that the MOPOP has long recognized a close link between utility and disclosure.<sup>17</sup>

#### **b. Disclosure Requirements**

14. Mr. Wilson states that, before 2002, there “was no basis in the *Patent Act*, *Patent Rules* or jurisprudence that would permit an examiner to reject an application for failing to disclose evidence of utility in the application at the time of filing.”<sup>18</sup> I disagree. In my experience,

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<sup>13</sup> Wilson Reply Report, para. 21.

<sup>14</sup> Canadian Intellectual Property Office -- Patent Office, Manual of Patent Office Practice, Chapter 12 (January 1990) (Excerpts) (C-54).

<sup>15</sup> Canadian Intellectual Property Office -- Patent Office, Manual of Patent Office Practice, Chapter 16 (March 1998) (Excerpts) (C-57).

<sup>16</sup> See Gillen Statement, paras. 27-32.

<sup>17</sup> See, e.g., cross-references between the chapters in the 1990 version Canadian Intellectual Property Office -- Patent Office, Manual of Patent Office Practice, Chapter 12 (January 1990) (Excerpts) ((C-54) (utility) and Canadian Intellectual Property Office -- Patent Office, Manual of Patent Office Practice, Chapter 6 (January 1990) (Excerpts) (C-53) (disclosure)), 1996 version Canadian Intellectual Property Office -- Patent Office, Manual of Patent Office Practice, Chapter 9 (October 1996) (Excerpts) (C-55), 1998 version Canadian Intellectual Property Office -- Patent Office, Manual of Patent Office Practice, Chapter 16 (March 1998) (Excerpts) (C-57) (utility) and Canadian Intellectual Property Office -- Patent Office, Manual of Patent Office Practice, Chapter 9 (March 1998) (Excerpts) (C-56) (disclosure).

<sup>18</sup> Wilson Reply Report, para. 24.

since the Supreme Court decided the *Monsanto* case in 1979,<sup>19</sup> patent examiners have applied the same principles of disclosure in sound prediction cases as they have more recently. While the terms “factual basis” and “sound line of reasoning” were not introduced until the Supreme Court of Canada’s 2002 decision in *AZT*,<sup>20</sup> applicants and examiners alike had been including and looking for the same type of information in the application.<sup>21</sup>

15. For example, the disclosure relating to a sound prediction was at issue in Commissioner’s Decision No. 1206. This Decision was rendered in December 1995 with respect to a patent application entitled “New Retrovirus Capable of Causing AIDS, Means and Methods for Detecting it In Vitro.”<sup>22</sup> The Commissioner upheld the Examiner’s rejection of two of the patent’s claims because no basis for a sound prediction had been disclosed.<sup>23</sup> The Patent Appeal Board (whose analysis the Commissioner accepted) found that the Applicant had not “show[n] by examples or broad statements the steps that were successfully used to produce” the matter claimed.<sup>24</sup> Had any of the matter been prepared, the Board stated:

it would have been arguable that [other examples of the matter], which were claimed but unprepared or prepared but untested, could be allowable in view of the ‘sound prediction’ principle. In this case there is no consideration given by the disclosure to any [of the claimed matter] so that there is nothing upon which to base a sound prediction.<sup>25</sup>

16. While the Commissioner refused to grant a patent containing those claims on the basis of now-subsection 27(3) of the *Patent Act* (which covers disclosure rather than utility), it is clear that the examiner, the Patent Appeal Board, and the Commissioner all found the patent invalid because of the failure to disclose in the patent a factual basis for the sound prediction

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<sup>19</sup> *Monsanto* 1979 (R-023).

<sup>20</sup> *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 SCR 153 (R-004).

<sup>21</sup> Gillen Statement, paras. 38-47.

<sup>22</sup> Commissioner’s Decision 1206, relating to Application No. 529,362, December 11, 1995 (R-381).

<sup>23</sup> Commissioner’s Decision 1206, relating to Application No. 529,362, December 11, 1995 (R-381).

<sup>24</sup> Commissioner’s Decision 1206, relating to Application No. 529,362, December 11, 1995, p. 9 (R-381).

<sup>25</sup> Commissioner’s Decision 1206, relating to Application No. 529,362, December 11, 1995, pp. 9-10 (R-381).

as well as a sound line of reasoning.

17. I also disagree with Mr. Wilson with respect to his position on post-filing evidence for sound prediction cases.<sup>26</sup> As I discussed in my first statement, an invention must be complete at the time it is filed.<sup>27</sup> Subsection 38.2(2) of the *Patent Act*, which prohibits amendments to the description to add matter “not reasonably to be inferred” from the specification as originally filed, exists for this reason.<sup>28</sup> If you need to alter the description of your invention, chances are that you have not finished inventing.<sup>29</sup> The *Patent Act* is not for protecting research ideas or plans. It is designed to protect actual inventions.
18. It is also for this reason that, if an application was found to be inconsistent as between the claims and the description, the Patent Office historically preferred to issue an Office Action on the basis of Rule 84, which requires that the claims shall be “fully supported by the description”. Unlike changes to the description, changes to claims typically did not add matter. This principle would also apply in a case of sound prediction, where the prediction would be in the claims. The claims would need to be supported by the description, meaning both the basis for, and the soundness of; the prediction would need to be disclosed.
19. In response to Office Actions, applicants often filed evidence to support their arguments. However, the manner in which this could or would be used to support the application varied. For example, if a patent examiner had some doubt as to an applicant’s assertion that claimed demonstrated utility, the examiner could ask to look at some studies that pre-dated the application. These studies would not go into the application, but would reassure the examiner of the demonstrated nature of the claimed utility.

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<sup>26</sup> Wilson Reply Report, para. 25.

<sup>27</sup> Gillen Statement, paras. 35-37.

<sup>28</sup> *Patent Act*, RSC 1985, c P-4, s. 38.2 (**R-001**).

<sup>29</sup> I note that the *Patent Act* allows an applicant to narrow its application. See *Patent Act*, RSC 1985, c P-4, s. 38.2 (**R-001**), *Patent Rules*, SOR/96-423, ss. 31-34 (**R-206**).

20. In contrast, if an examiner was not convinced that a prediction was sound, an applicant might file studies as part of a response to an Office Action. However, the patent examiner would not consider these studies as support for the predicted utility (*i.e.* for the sound prediction). The date of the studies would not matter because while such studies (if they predated the patent application) might show a prediction was in fact sound, it was understood that evidence of a sound prediction was required in the application as filed.
21. Commissioner's Decision 1206 (from 1995), which I referred to above, is an example of this principle at work. The Board held in that case that the applicant could not rely on post-filing evidence to remedy its insufficient disclosure problems stating:

The Board agrees with the U.S. decision in Re Glass, 181 USPQ 31 (C.C.P.A. 1974) that sufficiency of support is measured as of the date the application is filed, and that post-filing publications cannot be used to fill in what is missing from the teaching of how to make and use the claimed invention.<sup>30</sup>

### **C. The Role of MOPOP and its Updates**

22. In his second statement, Mr. Wilson has continued to place too great an emphasis on the MOPOP. While the Patent Office endeavours to keep the MOPOP up-to-date, it would be impractical to update it with every new case decided by the courts.<sup>31</sup> It is a significant undertaking, involving broad consultation of various interested parties. Mr. Wilson states that, "[w]hen a court hands down a decision which requires changes to patent examination practices, examiners are informed of the change and the process of amending the MOPOP starts."<sup>32</sup> In my experience, there are two factors that drove updates to the MOPOP: (1) administrative changes (for example, amendments to the *Patent Rules*, including instructions on how to file a patent application); and (2) a number of Federal Court cases that impacted Office practice.

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<sup>30</sup> Commissioner's Decision 1206, relating to Application No. 529,362, December 11, 1995, p. 8 (**R-381**).

<sup>31</sup> See Gillen Statement, paras. 20-24.

<sup>32</sup> Wilson Reply Report, para. 15.



23. Updates to MOPOP could also be delayed by logistical and systemic constraints at the Patent Office. In the period between the early 2000s and 2012, the Patent Office hired approximately 200 examiners. During this time, most examiners were training or being trained. Patent Office output slowed down somewhat during this period, as evidenced by the CIPO service standards for a first substantive action during this period increasing from 23 months in 2000<sup>33</sup> to 30 months in 2005.<sup>34</sup> Certain institutional goals – such as updating the MOPOP – also fell somewhat behind during this period. However, between MOPOP updates, the Patent Office was constantly putting together training materials, and holding briefing meetings to discuss new developments in the law.
24. Importantly, the fact that MOPOP was not updated more regularly did not mean that the Office was ignoring developments in the law. To the contrary. As I mentioned above, the *AZT* decision is a good example. The case gave the words “factual basis” and “sound line” to previous inquiries that had been made, and the Patent Office responded by adopting that terminology in its assessment of applications.<sup>35</sup>
25. Mr. Wilson states that it was not until after 2005 that examiners started rejecting applications on the basis of the promise utility doctrine, “which eventually resulted in reviews by the Patent Appeal Board and in Commissioner’s Decisions.”<sup>36</sup> He points to a 2010 Commissioner’s Decision as the first to deal “with the issue of a sound line of reasoning for sound prediction” to support his assertion.<sup>37</sup> I do not share his view that this was the first time that the Commissioner dealt with this issue. As I have already pointed to above, a Commissioner’s Decision from 1995 turned on the disclosure of the basis for a sound

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<sup>33</sup> CIPO Service Standards, 1999-2011, p. 2 (R-380).

<sup>34</sup> CIPO Service Standards, 1999-2011, p. 7 (R-380).

<sup>35</sup> See Office Action dated October 23, 2003, Application No. CA2304657 (R-382); Office Action dated October 7, 2004, Application No. CA2248873 (R-383).

<sup>36</sup> Wilson Reply Report, para. 32.

<sup>37</sup> Wilson Reply Report, para. 32.

prediction.<sup>38</sup>

26. Moreover, Commissioner's Decisions do not tell the whole story of patent office practice. In my experience, only 15 to 20 of the approximately 60,000 Office Actions issued each year are appealed to the Patent Appeal Board. Two further examples of patent examiners' concern with proper disclosure for sound prediction – the issue cited by Mr. Wilson in the 2010 Commissioner's Decision – can be found in Office Actions relating to patent applications filed by the Claimant itself prior to 2005. In an Office Action dated October 23, 2003 pertaining to the Claimant's 2,304,657 patent application for the use of atomoxetine in treatment of conduct disorder, the patent examiner identified the following defect in the application:

Claims 1 to 20 do not comply with Section 84 of the Patent Rules. The description fails to provide a sound line of reasoning for the utility claimed. The factual support described does not lead to the conclusion that the subject matter of these claims would have the predicted utility. (*Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77).<sup>39</sup>

27. Similarly, in an Office Action dated October 7, 2004 pertaining to the Claimant's 2,248,873 patent application for a method for treating pain using olanzapine, a different patent examiner identified the following defect in the application:

Claim 6 does not comply with section 2 of the *Patent Act*. The description fails to provide a sound line of reasoning for the utility of olanzapine for treating inflammation. The factual support described does not lead to the conclusion that the subject matter of these claims would have the predicted utility. (*Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 77).<sup>40</sup>

28. Mr. Wilson also states that “the 2009 and 2010 MOPOP amendments on utility demonstrate a change in the law on utility,” including “new criteria” from *AZT* and subsequent decisions of the Federal Court.<sup>41</sup> In addition to my previous testimony that these amendments codified

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<sup>38</sup> Commissioner's Decision 1206, relating to Application No. 529,362, December 11, 1995, p. 8 (**R-381**).

<sup>39</sup> CIPO Office Action dated October 23, 2003, Application No. CA2304657 (**R-382**).

<sup>40</sup> CIPO Office Action dated October 7, 2004, Application No. CA2248873 (**R-383**).

<sup>41</sup> Wilson Reply Report, para. 28.

existing Patent Office practice, I note that Chapter 12 (Subject Matter and Utility) of the 2009 MOPOP, which Mr. Wilson fails to reference, states the following:

The Supreme Court affirmed in *Consolboard Inc. v. MacMillan Bloedel (Saskatchewan) Ltd.* that, for the purposes of Canadian law, a lack of utility exists if “the invention will not work, either in the sense that it will not operate at all or, more broadly, that it will not do what the specification promises that it will do”<sup>45</sup> and that “[i]f and when used in accordance with the directions contained in the specification, the promised results are obtained, the invention is useful in the sense in which that term is used in the patent law”.<sup>46</sup> **This was merely the reiteration of a long-accepted<sup>47</sup> and extant<sup>48</sup> standard.**<sup>42</sup>

29. The sources cited by the MOPOP to support this last sentence include *Northern Electric Co. v. Brown's Theaters Ltd.*, a 1940 case that was cited in the 1990s versions of the MOPOP's utility chapter for the following proposition:

Utility, as related to inventions, means industrial value. To be acceptable in the patentable sense, it must be something that will impart industrial value to what is sought to be patented (*Northern Electric v. Browns Theatres supra*).

30. In addition, I note that the MOPOP chapter on utility was updated in 2005 to reflect the framework for analysis offered by the Supreme Court for sound prediction cases in *AZT*.<sup>43</sup>
31. Finally, I note that there are a number of items in the 2009 and 2010 updates to the MOPOP's utility and disclosure chapters that were not in previous versions, but there is no possibility to link these significant changes to any “fundamental and significant departure from past practice.”<sup>44</sup> For example, there is a section added to Chapter 9 (Description) in 2010 that discusses in detail the person of ordinary skill in the art (POSITA). There are also sections that provide examples of the application of more general description principles to specific circumstances, such as selections or combinations.<sup>45</sup> There were no changes to the

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<sup>42</sup> Canadian Intellectual Property Office -- Patent Office, Manual of Patent Office Practice, Chapter 12 (December 2009) (emphasis added) (C-59).

<sup>43</sup> Canadian Intellectual Property Office -- Patent Office, Manual of Patent Office Practice, Chapter 12 (February 2005) (C-58).

<sup>44</sup> Wilson Reply Report, para. 28.

<sup>45</sup> See Canadian Intellectual Property Office -- Patent Office, Manual of Patent Office Practice, Chapter 9 (December 2010) (C-60).

POSITA analysis in the 1990s or 2000s. Patent examiners have been assessing applications through the eyes of the person of ordinary skill in the art since patents have been examined. As is evident from Eli Lilly's olanzapine selection patent, patent examiners assessed this kind of application long before 2010.

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Signed at: Ottawa ON on: Dec. 7, 2015

[signed]

Michael Gillen