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*

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# REPLY EXPERT REPORT OF MURRAY WILSON

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## I. Introduction

1. The purpose of this Reply Expert Report is to respond to certain statements of Dr. Michael Gillen about my First Report, dated September 26, 2014 (hereinafter "First Report").

## II. Instructions

2. I have been asked to reply to Dr. Gillen's witness statement regarding:

(i) The patent examination process in the Patent Office, which is part of the Canadian Intellectual Property Office ("CIPO")

(ii) The role of and changes to the Manual of Patent Office Practice (also referred to as "MOPOP")

(iii) The Patent Office practice for determining if the utility requirement has been fulfilled in the late 1980s and 1990s compared to the 2000s.

(iv) The validity of Eli Lilly's olanzapine and atomoxetine patents.

## III. Patent Examination Process

3. Dr. Michael Gillen states in paragraphs 12 and 13 of his witness statement ("Gillen Report") that patent examinations at CIPO are time-limited and superficial, in essence rubber stamps.[1] I disagree. Patent examination is a rigorous, substantive review of each application and is performed by trained examiners. The Patent Office employs a corps of examiners who examine every application after the request for examination fee has been paid. The minimum educational requirement for examiners is a degree in engineering or an honours degree in chemistry, physics or biotechnology from a recognized university, with a number of examiners holding advanced degrees, including Ph.Ds.[2]

[1] Gillen Report at ¶¶ 12-13; Resp. CM at ¶¶ 70-72.

[2] *See also* Wilson First Report at ¶ 13.

4. When an examiner is hired, he or she is given 3 months of classroom training in patent law and patent examination practice.[3] This training includes a review of the *Patent Act*, *Patent Rules*, jurisprudence and the Manual of Patent Office Practice ("MOPOP"), how to search the prior art, and how to write examiner's reports (known as "Office Actions").

5. After classroom training, each new examiner is assigned to work under the direct supervision of a senior examiner. This phase of training lasts until the examiner is assessed as being able to work independently. The work of all examiners is reviewed on a random basis to ensure quality and thoroughness.

6. Examiners are assigned applications which relate to their field of expertise. Most examiners examine applications in the same field of technology for long periods of time. Because examiners are very familiar with the material and understand the background technology before examination begins, they are able to examine applications in a very efficient manner.

7. In my over 35 years of experience at CIPO, examiners did not have to spend much time examining the utility of an invention. Because of the examiners' knowledge of the underlying subject matter and the simple requirement for establishing utility, no lengthy review of utility was necessary. Examiners spent most of their time ensuring that the invention was new and non-obvious and was properly disclosed and claimed.

8. Therefore, Dr. Gillen's statement in paragraph 13 that examiners would typically spend 5 ½ hours on average examining a pharmaceutical patent application does not support the proposition that the examination was superficial or that the examiner merely applied a rubber stamp approval of the patent application. Instead, examiners were efficient, especially

[3] *See also* Wilson First Report at ¶ 14.

in assessing utility, because of their significant expertise in the relevant field and the low bar for establishing utility, which according to the MOPOP at the relevant time merely required that an invention was "not totally useless" or had "industrial value".[4]

9. Dr. Gillen also states that patent examiners apply certain "assumptions" in favor of an applicant and suggests that these assumptions are driven by CIPO's limited resources as compared to the courts.[5] I disagree. The patent examiner applies the patent law as established by the *Patent Act* and the courts as of the date of the examination of the patent application. There are certain presumptions that are made in favor of the applicant during this process, but they do not detract from thorough review and are grounded in the law, not due to limited CIPO resources. During my time at CIPO, although examiners often relied on the face of the application to assess utility, they could also request additional information if the stated utility was not credible. As I explained in my First Report, any presumptions applied in favor of the applicant are not a result of CIPO's limited resources but are a product of the substantive utility standard itself. Because the standard only required a "mere scintilla," unless the examiner had reason to doubt that the invention worked, the utility inquiry ended there.[6]

10. The patent examination process at CIPO is not superficial nor a rubber stamp. Examiners are highly trained to ensure that each application meets all of the requirements of patentability, including utility, before a patent application is allowed and a patent granted.

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[4] *See* Canadian Intellectual Property Office -- Patent Office, Manual of Patent Office Practice, §§ 12.02.01 (January 1990) (C-53); Canadian Intellectual Property Office -- Patent Office, Manual of Patent Office Practice, §§ 16.02.01 (March 1998) (C-57).

[5] Resp. CM at ¶ 72; Gillen Report at ¶¶ 13, 42-43.

[6] Wilson First Report at ¶ 30.

## IV. Role Of The Manual Of Patent Office Practice

11. Dr. Gillen's report says that the MOPOP is simply a "high-level overview" that is not an authoritative reference on the application of patent law and "cannot be relied upon to be completely up to date."[7]

12. The MOPOP is not binding law, but it is a very important reference tool for examiners and is a reflection of the current state of the law. Dr. Gillen misstates the importance of the MOPOP when he describes the MOPOP as merely a "high-level overview of the legal, regulatory, and administrative framework of patenting in Canada....".[8] In fact, the MOPOP is a day-to-day reference tool to which examiners and patent agents often refer during the prosecution of a patent application. The MOPOP takes the *Patent Act*, the *Patent Rules* and jurisprudence and explains, in practical terms, how examiners should use them to examine patent applications.

13. Contrary to Dr. Gillen's report, I never referred to the MOPOP as the "complete code on the application of patent law."[9] I stated in my First Report that the MOPOP "is to be considered solely as a guide".[10] But the fact that the MOPOP is not "law" does not mean that the MOPOP is not a compilation and reflection of existing law and is relied on extensively by examiners and patent agents. CIPO's website page on "How to become a registered patent agent" cites the MOPOP in its list of reference materials.[11] In my experience, every patent examiner had a copy of the MOPOP on his or her desk (now accessible

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[7] Gillen Report at ¶¶ 17-20.

[8] Gillen Report at ¶ 17.

[9] *Id.*

[10] Wilson First Report at ¶ 22.

[11] Canadian Intellectual Property Office, "How to become a registered patent agent," online: <www.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/h_wr02066.html> (C-409).

electronically), which serves as the examiner's primary reference tool. Further, examiners cite the MOPOP in their Office Actions.

14. In preparing the first MOPOP, the staff of the Patent Office started with the provisions of the *Patent Act* and *Patent Rules* and combined them with relevant court decisions to create a document providing a practical explanation of how examiners are to deal with situations encountered during examination. Without the MOPOP, each examiner would have to individually determine the relevance of every court decision, which would result in a lack of consistency in the examinations. It is important to recognize that examiners are not lawyers, and so are not expected to individually digest cases and properly apply them in their examinations of patent applications absent additional guidance. After thorough review and approval internally by CIPO (and sometimes by stakeholders), the MOPOP synthesizes the law and presents it to examiners in a clear, easy-to-use format.

15. The MOPOP is updated in light of new legal developments. When 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. There are several steps involved, including internal quality review, and generally input from external stakeholders. In his report, Dr. Gillen states that the 2009 and 2010 MOPOP amendments incorporating the promise utility doctrine were not a response to recent court decisions but were merely catching up with Patent Office requirements that examiners had been applying since the 1990s.[12] CIPO's website states under the heading "MOPOP Updates" that "the MOPOP is maintained to ensure that it reflects the latest developments in Canadian patent laws and practices."[13] Although the

[12] Gillen Report at ¶¶ 22, 26.

[13] Canadian Intellectual Property Office, "Manual of Patent Office Practice - MOPOP Updates, online: <www.cipo.ic.gc.ca/eic/site/cipoInternet-Internetopic.nsf/eng/wr00758.html> (C-410).

process of amending the MOPOP is not instantaneous, it would not have taken over 10 years as Dr. Gillen seems to suggest.

## V. Traditional Utility Requirement

16. During my time at CIPO, examiners understood the utility requirement to be a simple and easy-to-satisfy test. As stated in the 1990 MOPOP, if the invention was "not totally useless" it satisfied the utility requirement in section 2 of the *Patent Act*.[14] Similarly, the 1998 MOPOP explained that "utility" meant "industrial value."[15] Utility was not questioned unless an examiner had doubts that an invention would work. This traditional notion of utility was reflected in the 1990s editions of the MOPOP.

17. Dr. Gillen's report states that I was misleading when I said that the plain references to utility in the 1990s editions of the MOPOP are all that were considered by Patent Office examiners at the time.[16] I was not misleading at all. I am not aware of any written or oral instruction that examiners would have followed to hold applicants to a more stringent utility test other than the test articulated in the MOPOP. In my experience there was no long standing practice of examiners reviewing patent applications in search for promises against which to assess the utility of the invention. I also believe that examiners would not have been able to force applicants to comply with a more demanding test that was not supported by any legislation or jurisprudence. When I was acting Chair of the Patent Appeal Board, one of my responsibilities was to assign rejected applications to the most appropriate member of the Board

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[14] *See* Canadian Intellectual Property Office -- Patent Office, Manual of Patent Office Practice, §§ 12.02.01 (January 1990) (C-53).

[15] Canadian Intellectual Property Office -- Patent Office, Manual of Patent Office Practice, §§ 16.02.01 (March 1998) (C-57). The 1998 MOPOP also describes the patentability requirements as merely requiring that an invention relate to the "useful arts," be "operable," have "a practical application in industry, trade, or commerce," and be "more than a mere scientific principle or abstract theorem." *Id.* §16.03.

[16] Gillen Report at ¶ 25.

for review. As a result, I was aware of all of the different issues which caused patent applications to be rejected by examiners. The Board did not prepare a recommendation to the Commissioner of Patents on any applications which had been rejected by an examiner based on the more stringent utility test during my tenure on the Board.

18. Therefore, the fact that the test set out in the 1990s editions of the MOPOP was simple does demonstrate that the actual legal test for utility was simple, namely, the invention must not be "totally useless" and must have some "industrial value".

19. The 1990, 1996 and 1998 editions of the MOPOP are the relevant MOPOPs in existence when Eli Lilly's olanzapine (Zyprexa) and atomoxetine (Strattera) patent applications were filed and examined. These versions of the MOPOP concisely set forth what an examiner looked for when examining for utility. The bar was low. As soon as an examiner found that the invention had a single utility, that was enough to meet the utility requirement. There was no requirement for a patent applicant to meet multiple levels of utility.

20. The applicant could make claims about the invention's advantages but that was of no interest to an examiner when assessing utility. Additional 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. Contrary to Dr. Gillen's statements,[17] during my time at CIPO, examiners did not comb through each application searching for promises and did not consider advantages of the invention as "utility." Failing to prove all of the statements of the advantages in the application's disclosure certainly would not have been grounds for an examiner to reject the entire application for lacking utility.

[17] Gillen Report at ¶ 27.

21. With respect to applications which claim a new use for a known compound and for compounds selected from a group of compounds, the utility criterion was the same as for all other applications. I disagree with Dr. Gillen that examiners would have applied a different standard of utility to new use and selection patents in the 1990s.[18] The MOPOP sets out one test for utility and, until the 2009 and 2010 amendments to the MOPOP, it was a simple test, namely that the invention must not be "totally useless" and must have some "industrial value."[19] Even if the patentee may have been required to show a new use or an advantage for the purpose of novelty or obviousness, there was no heightened *utility* requirement. In fact, the utility of such inventions was often obvious in light of the prior invention.

22. Because the bar to establish utility was low and the utility requirement easily satisfied, clinical data were not required.[20] Examiners would therefore not have expected human and clinical data to be included in the patent application to prove utility. However, as there is no restriction on how much information an applicant could submit in an application, some applicants did submit this type of information, even if it was not necessary to establish utility.

23. I disagree with Dr. Gillen that applicants would provide as many working examples as possible for the purpose of establishing utility.[21] Applicants would provide as many examples as they believed were necessary to help establish not only that the claimed invention has utility, but also that it satisfies the other criteria of patentability (*e.g.* novelty, non-obviousness). Applicants might also provide additional working examples to satisfy the

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[18] Gillen Report at ¶ 30.

[19] Canadian Intellectual Property Office -- Patent Office, Manual of Patent Office Practice, §§ 12.02.01, 12.03 (January 1990) (C-53).

[20] *See also* Wilson First Report at ¶ 30.

[21] Gillen Report at ¶ 46.

disclosure requirement, which is a separate requirement from utility. It was unnecessary to provide large amounts of data to establish utility when the utility bar was so low. Also, from a practical point of view, including large amounts of data in a patent application can delay the filing of an application. In my experience at CIPO, once a utility has been established, additional data on utility would not have been necessary.

## VI. Traditional Utility-Related Disclosure Requirements

24. Prior to the mid-2000s, there was no requirement in the MOPOP that an applicant disclose all evidence related to sound prediction in the application as filed. This is not surprising, since before the 2002 Supreme Court of Canada decision in *Apotex Inc. v. Wellcome Foundation Ltd.*, 2002 SCC 7 (*AZT*) 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.

25. I disagree with Dr. Gillen that examiners would not accept evidence of utility after the initial filing.[22] In my experience, applicants were permitted to submit additional evidence during the prosecution of the application before the Patent Office. This evidence could be filed in a reply to an Office Action.

26. An example of this practice can be seen in Commissioner's Decision 388 (June 20, 1977).[23] When the application which was subject to Commissioner's Decision 388 was being examined, the examiner refused the application because the specification did not meet the requirements of the *Patent Act* with respect to the description of utility. The applicant attempted to amend the application to amplify the description of utility and to include data in

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[22] Gillen Report at ¶ 41.

[23] Application No. 139,256 (Patent No. 1,029,723), Decision of the Commissioner of Patents number 388 (June 20, 1977) (C-411).

support of the utility. The examiner refused to allow the amendment on the grounds that it included new subject matter. But the Patent Appeal Board recommended to the Commissioner that the amendment be entered into the application and the Commissioner agreed. The Board noted that the amplified utility, as stated in the proposed amendment, was clearly known to the applicant prior to the filing date of the application (this knowledge was proven by way of an affidavit). The Board concluded that the Applicant should be permitted to amend the disclosure to introduce the additional data. Commissioner's Decision 388 therefore demonstrates the Patent Office considered post-filing evidence of utility.

## VII. The 2009 and 2010 Amendments to MOPOP

27. Dr. Gillen states that the 2009 and 2010 "changes to the MOPOP were not only unsurprising, but they were also consistent with long standing Patent Office practice".[24] Dr. Gillen also states "when the MOPOP chapter on utility [chapter 12] was updated in 2009 to reflect recent jurisprudence, that update was consistent with long standing Patent Office practice".[25] I am unaware of this long-standing Patent Office practice.

28. Compared to the traditional utility test discussed above, the utility test set out in the 2009 and 2010 editions of the MOPOP demonstrate a fundamental and significant departure from past practice. The 2009 and 2010 amendments to the MOPOP included new criteria from the 2002 Supreme Court of Canada decision in *AZT* and subsequent decisions of the Federal Court. Because the MOPOP is updated to reflect major changes in Canadian patent law, the 2009 and 2010 MOPOP amendments on utility demonstrate a change in the law on utility.

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[24] Gillen Report at ¶ 26.

[25] Gillen Report at ¶ 32.

29. Contrary to paragraphs 26 and 32 of Dr. Gillen's report, the 2009 and 2010 amendments to MOPOP were not consistent with long standing Patent Office practice.[26] These MOPOP amendments were not minor clarifications of existing practice and reflect a significant and fundamental change in the law of utility.

30. Paragraph 32 of Dr. Gillen's reports says: "when patents granted in the 1990s eventually did start to come before the courts in the 2000s, in their consideration of what a patent promised that an invention would do, judges were essentially applying the same analysis that we had been applying as examiners since the 1990s". I disagree. The utility analysis the courts applied in the 2000s was not the same as the utility analysis that the Patent Office was conducting during examinations in the 1990s. There was no examination of the utility requirement based on promises in the patent prior to the mid-2000s. The Patent Office implements and follows court decisions. The Patent Office only began to apply the promise utility doctrine to patent applications after the court decisions rendered in the mid-2000s. Dr. Gillen has not produced any documentation or instructions that could have provided examiners with guidance on how to apply and implement the promise utility doctrine prior to the mid-2000s.

31. The MOPOP was updated three times in the 1990s (in 1990, 1996 and 1998). None of these amendments included the heightened utility requirements that are part of the promise utility doctrine. If the promise utility doctrine existed in the 1990s, it would have been incorporated in one of the 1990s' versions of the MOPOP. The 2009 and 2010 amendments to the MOPOP do not reflect a longstanding Patent Office practice. Instead, they

[26] Gillen Report at ¶¶ 26, 32.

reflect a new Office practice that only started to be implemented by examiners after the mid-2000s.

32. The absence of earlier Patent Appeal Board and Commissioner's Decisions rejecting applications on the basis of lack of utility also demonstrates a change in the law. The absence of Patent Appeal Board or Commissioner's Decisions dealing with applications that had been rejected by examiners for failure to meet a promised utility prior to 2010 further supports the fact that there was no "longstanding" practice as stated by Dr. Gillen.[27] Prior to the mid-2000s, examiners had not rejected applications for failing to satisfy the criteria set out in the *AZT* and subsequent court decisions. Only after 2005 did examiners start to reject applications on that basis, which eventually resulted in reviews by the Patent Appeal Board and in Commissioner's Decisions. The first Commissioner's Decision which dealt with the issue of a sound line of reasoning for sound prediction was not handed down and signed until 2010.

33. Although Dr. Gillen states that in the 1990s patent examiners applied the same utility analysis that the judges used when those patents came before the courts in the 2000s,[28] he fails to set out what utility criteria he believes were being applied by the Patent Office in the 1990s. If examiners had in fact been applying the promise utility doctrine in the 1990s, it is inconceivable that all applications filed at that time all met that high standard. It would have been expected that at least one application would have been rejected by an examiner for failing to meet the heightened utility standard as described in the court decisions from the 2000s and have been referred to the Patent Appeal Board for review, recommendation and decision of the Commissioner of Patents. During my time with the Patent Appeal Board — including as the person responsible for assigning all rejected applications — I do not recall

[27] *Id.*

[28] Gillen Report at ¶ 32.

seeing a Commissioner's Decision which dealt with lack of utility related to the question of failure to demonstrate or soundly predict a particular "promised utility". This absence of any application having been rejected by an examiner and referred to the Patent Appeal Board in the 1990s and early 2000s for lack of utility confirms that the examiners were not applying the promise utility doctrine at that time because the doctrine did not exist.

34. The first Decision which relates to lack of a sound prediction of a promised utility was signed by the Commissioner only in 2010.[29] This application was filed on March 2, 1989 and the first Office Action was issued in December 1992. There were two more Office Actions before a pre-final action was issued on September 26, 2005 (almost 13 years later). It was not until the pre-final action that the examiner raised the issue of sound prediction. The Commissioner's Decision was signed on June 4, 2010.

35. Similarly, the application which was the subject of Commissioner's Decision 1310 was filed on November 9, 1987 and the first office Action was issued on December 17, 1990, but the examiner did not raise the issue of utility and sound prediction until the fifth Office Action on December 30, 2004.[30] The Commissioner's Decision was signed on January 20, 2011.

36. Examiners are expected to raise all objections in every Office Action to avoid piecemeal prosecution.[31] But in at least these two cases there was no mention of problems with the invention's utility until many years after prosecution had started. The issue was raised for the first time only after the Supreme Court handed down the *AZT* decision in 2002. This

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[29] Application No. 592,567 (Patent No. 1,341,621), Decision of the Commissioner of Patents number 1303 (June 4, 2010) (C-412).

[30] Application No. 551,406 (Patent No. 1,341,624), Decision of the Commissioner of Patents number 1310 (January 20, 2011) (C-413).

[31] *See* Wilson First Report at ¶ 44.

timing demonstrates that the examiners were not applying the same standard of utility in the 1990s. Otherwise, the examiners would have raised concerns with respect to utility in the earlier Office Actions.

37. Further, the Final Action in application 2,248,228 issued on February 1, 2011 to Bayer demonstrates both that examiners rely on the MOPOP in rejecting patent applications and that changes in the MOPOP affect Patent Office practice.[32] On page 3 of the Final Action under the heading "Legal and Administrative Considerations" the examiner states:

> The claims are now identified as non-complaint with section 2 of the Patent Act.
>
> The claims were previously considered defective from non-compliance with section 84 of the Patent Rules, on the basis that the lack of proper disclosure of a sound prediction implied a lack of proper support for the claims.
>
> Following current Office practice, this objection is now presented as non-compliance with section 2 of the Patent Act (lack of utility). Reference in this regard is made to section 17.03.04 of the Manual of Patent Office Practice, which came into force in January 2009.

This Final Action was upheld by the Patent Appeal Board in Commissioner's Decision 1340 signed on March 28, 2013.[33]

## VIII. Validity of Claimant's Patents

38. Dr. Gillen's report states that the two Lilly patent applications are misleading because they suggest that olanzapine and atomoxetine had already been tested on human subjects.[34] However, Dr. Gillen's report rests on the assumption that the standard for establishing utility at the time those patents were examined was the same standard set out in the Supreme Court of Canada's *AZT* decision of 2002 and subsequent court decisions. Dr. Gillen

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[32] Canadian Intellectual Property Office, Final Action for application 2,248,228 (February 1, 2011) (C-414).

[33] Application No. 2,248,228, Decision of the Commissioner of Patents number 1340 (March 28, 2013) (C-415).

[34] Gillen Report at ¶¶ 50-52.

has maintained that the Patent Office had been using that standard for many years before the Supreme Court of Canada adopted it.[35] Neither the MOPOP nor the decisions of the Commissioner of Patents supports this position. Because Dr. Gillen's conclusions are based on criteria that did not exist when Lilly's patent applications were examined, I do not believe his conclusions are valid.

## IX. Conclusion

39. I have reviewed the witness statement of Dr. Gillen with respect to utility and nothing changes my view that the utility requirement of section 2 of the *Patent Act* was fulfilled by Lilly's atomoxetine (Strattera) and olanzapine (Zyprexa) patent applications when those applications were allowed. If there had been an issue with establishing the utility of either of these inventions, the examiners would have raised the issue in an Office Action, which did not occur.

Signed in Ottawa, Canada on September 9, 2015.

[signed]
**MURRAY WILSON**

[35] *Id.*