

**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)

WITNESS STATEMENT OF DR. MICHAEL GILLEN

JANUARY 26, 2015

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1. Background and Qualifications

1. My name is Dr. Michael Gillen. I reside in Ottawa, Ontario, and I am a former federal public servant, having worked for the Canadian Patent Office¹ from 1988 until my retirement in June, 2014. I have a background in organic chemistry and more than 25 years of experience at the Patent Office, where I held various positions including those of senior patent examiner and Chair of the Patent Appeal Board. At the time of my retirement, I was Chief of the Biotechnology Division in the Patent Branch² of the Canadian Intellectual Property Office (“CIPO”).

2. I completed a Bachelor of Science in Honours Chemistry at St. Francis Xavier University in 1975, and a Doctorate in Organic Chemistry at McGill University in 1980. After leaving McGill, I worked from 1980 to 1983 as a chemist for a private biotechnology company in Ottawa, where I conducted research on gene synthesis, including an automated process that used a “gene machine” to synthesize long chain polynucleotides. From 1984 to 1988, I was a Research Associate at the Institute of Biological Sciences at the National Research Council of Canada in Ottawa, where I worked as a molecular biologist investigating liver cancer.

3. In 1988, I joined the Patent Office as a patent examiner. I underwent 2 years of mandatory training, which included classroom study of the *Patent Act* and *Patent Rules*, Patent Office practice and patent-related jurisprudence, and on-the-job training conducting patent examinations under the guidance of a senior patent examiner. In 1990, I was promoted to the “working level” and began examining patent applications without the assistance of a senior patent examiner. As an examiner (from 1988 to 1992) and senior examiner (from 1992 to 2002), I examined approximately 3000 patent applications for inventions such as genetically engineered micro-organisms, synthetic genes and pharmaceuticals. While I was a senior patent examiner, I also acted as an on-the-job trainer for 10 newly hired examiners who were completing the 2 year mandatory training program.

¹ The Patent Office is currently part of the Canadian Intellectual Property Office (CIPO). Prior to the establishment of CIPO in 1992, the Patent Office was part of Consumer and Corporate Affairs Canada (now Industry Canada).

² The processing and examination of patent applications is carried out by CIPO’s Patent Branch and Patent Appeal Board.

4. In 2002, I was appointed a Member of the Patent Appeal Board (“PAB”). The PAB reviews patent and industrial design applications that have been rejected by examiners and makes recommendations to the Commissioner of Patents as to whether or not these applications should be refused. The PAB also oversees conflict proceedings between applicants in cases where priority of inventorship of an invention between two applicants is at issue. In my capacity as a Member of the PAB, I reviewed rejected patent and industrial design applications, drafted recommendations to the Commissioner of Patents with respect to those applications, and was called upon to provide advice on patent issues to senior management. The patent applications that come before the PAB are for all types of inventions, including pharmaceuticals. During my tenure on the PAB, I was the only Member with a background in biotechnology and chemistry.

5. In 2003, I was appointed Chair of the PAB. In addition to managing the day-to-day activities of the PAB, I also sat as a member of the CIPO Senior Executive, the International Strategic Planning Committee, the Intellectual Property Policy Committee, and the Patent Issues Working Group (“PIWG”). The PIWG was the group responsible for overseeing updates to the Manual of Patent Office Practice (“the MOPOP”).

6. In 2006, I left the PAB to become Chief of the newly-formed Biotechnology Division in the Patent Branch at CIPO.³ As Chief, I had oversight of 75 patent examiners, including section heads and senior examiners, who were responsible for the examination of patent applications filed nationally in Canada and through the Patent Cooperation Treaty (“PCT”) by Canadian and foreign individuals and companies. My duties as Chief also included reviewing difficult and complex patent issues dealt with by examiners, approving all Final Actions,⁴ and ensuring that examiners were following Patent Office practice, including the *Patent Act*, *Patent Rules*, and relevant patent jurisprudence, in conducting their examinations.

7. As Chief of the Biotechnology Division, I was also responsible for overseeing the training program for newly hired patent examiners and on-going training programs for the more experienced examiners. In that capacity, I supervised the Program Manager of Training, who

³ Prior to 2006, biotechnology patent examiners were part of the Patent Branch’s Chemical Division.

⁴ A Final Action is an examiner’s report that notifies an applicant that their patent application has been rejected, and sets forth the reasons for the rejection. Applicants are allowed to respond to a Final Action within a specified time frame. If an applicant’s response does not overcome the reasons given by the examiner for the rejection, the application is forwarded to the PAB for review.

managed a team that sought to ensure that all newly hired patent examiners were provided with the necessary training to allow them to be promoted to the “working level”, and also to ensure that more experienced examiners were provided with continuous professional, scientific, and personal training to facilitate their professional development.

8. Given my extensive experience at the Patent Office, including as a patent examiner during the period in which Eli Lilly’s patents for olanzapine and atomoxetine were filed, examined, and granted in Canada, I believe that I am qualified to provide the testimony set out below.

9. I confirm that I do not currently, and have never, had a relationship or affiliation with the Claimant, Eli Lilly and Company. As explained above, the extent and nature of my previous and current relationships with the Respondent, the Government of Canada, reflect my status as a former federal public servant.

2. Instructions

10. I have been asked to provide testimony on the following matters:

- a. the role of the Patent Office in relation to that of the courts in Canada’s patent system;
- b. the nature of the Manual of Patent Office Practice (“the MOPOP”);
- c. Patent Office examination practice for determining if the utility criterion had been met in the late 1980s and 1990s;
- d. the basis on which the patents for olanzapine and atomoxetine were granted; and
- e. the effect of the Patent Cooperation Treaty (“PCT”) on Patent Office examination practice.

3. The Role of the Patent Office in Relation to that of the Courts in Canada’s Patent System

11. Patents are granted in Canada by the Commissioner of Patents. The Commissioner is Head of the Patent Office, which is the administrative body responsible for receiving, processing and examining patent applications to determine whether they meet the requirements under the

Patent Act. The Patent Office acts as a “gatekeeper” to the patent system, ensuring that, through the examination of patent applications by patent examiners, patent rights are granted to qualified applicants whose inventions appear to satisfy the *Patent Act*’s basic requirements for patentability, namely patentable subject matter, novelty, non-obviousness, utility, and sufficient disclosure.

12. In carrying out its responsibilities, the Patent Office faces systemic pressures. This is due to the large volume of patent applications handled by the Patent Office each year, and the comparatively small number of examiners on staff. During my tenure at the Patent Office, the number of applications we received trended upwards annually and there was an increase in the average number of claims in each application, making examination more complex for examiners. Even in years where the number remained the same or decreased slightly, the number of applications overall remained quite high. This is still the case today. In 2012-2013, the year before I retired, the Patent Office received approximately 36,000 new applications.⁵ The numbers of patent examiners employed to handle these applications was, and still is, comparatively small. Until the 1990s, there were fewer than 100 examiners at the Patent Office. Although this number has increased over the past 20 years, to roughly 430 patent examiners the year I retired, there is still a large disparity between the number of patent applications and the number of examiners available to review them.

13. As a result of these systemic pressures, patent examinations are of necessity time-limited in nature. Based upon productivity objectives, an examiner would typically allot roughly 5½ hours, on average, for the full review of a patent application for a pharmaceutical invention. Examiners are also instructed to adopt various assumptions in favour of the applicant during the examination process. For example, an application may say that the applicant has conducted an experiment and achieved a certain positive result. If the result the applicant purports to have achieved is scientifically plausible and not something contrary to the laws of nature, the examiner will take that statement at face value. Examiners have neither the time nor the means to confirm the scientific validity of every statement made in an application. Examinations are conducted on the basis of the information contained in the application itself, on the results of a

⁵ Canadian Intellectual Property Office, CIPO Annual Report 2012-2013, 2 September 2014, online: <http://www.cipo.ic.gc.ca/eic/site/cipointernet-internetopic.nsf/eng/wr03785.html#patents> (R-306).

prior art⁶ search conducted by the examiner, and on any information provided by the applicant in response to an Office Action.⁷ Although examiners have the authority to request specimens from applicants in order to carry out post-filing experiments, this is generally not done. It is not practicable to obtain “specimens” for certain types of inventions, including chemical inventions.⁸

14. The nature of the examination of patent applications by the Patent Office appropriately reflects the Office’s administrative role in the overall patent system in Canada. This role, as well as the presumptively valid but ultimately revocable nature of the patent grant, is well understood by participants in the patent system. In my experience, participants understand that the validity of a patent granted by the Patent Office is, under the *Patent Act*, always subject to confirmation by the court, and that the administrative grant of a patent by the Office does not mean that that patent is immune from challenge by a third party with an adverse interest.⁹

15. Unlike the examination conducted by the Patent Office, court assessment of a patent’s validity is conducted with significantly more time and resources. Patent trials can last for weeks or longer. Courts have the benefit of often substantial competing expert and fact evidence on technical issues relevant to a patent’s validity, generated in an adversarial context. This appropriately reflects the role of the courts in the overall patent system in Canada. It would be inefficient for such extensive resources to be used by the Patent Office during its examination of patent applications. If the Patent Office subjected every single patent application to that sort of extensive review, the entire system would grind to a halt.

16. The difference in resources available to the Patent Office and the courts also reflects the statutory bases upon which they operate, in terms of analysing and applying the *Patent Act*, *Patent Rules*, and case law. In granting patents, the Patent Office seeks to the extent possible to apply the *Patent Act* and *Patent Rules* as the courts have interpreted them. However, only the

⁶ Prior art refers to existing scientific publications and/or existing patents or patent-related documents which are relevant to a given patent application.

⁷ An Office Action is an examiner’s report to an applicant describing in what way or ways a patent application does not comply with the *Patent Act* or *Patent Rules*. If the application was filed via the PCT, the examiner may also have the benefit of the International Search Report and written opinion on patentability from the PCT International Searching or Preliminary Examining Authority (“ISA” or “IPEA”).

⁸ The basis of the examiner’s authority to obtain samples from an applicant for the purposes of experimentation is s. 38 of the *Patent Act*. See Claimant’s Memorial, at para. 72 (discussing the authority of the Patent Office to conduct post-filing experiments with specimens provided by the applicant).

⁹ *Patent Act*, ss. 42, 43(2), and 60(1) (R-001).

courts have the statutory authority to definitively interpret and apply the *Act* and *Rules* in validity disputes between private parties.

4. The Nature of the Manual of Patent Office Practice (“the MOPOP”)

17. I take issue with the statement made by Mr. Murray Wilson that, in his experience, the MOPOP was “tantamount to a rulebook to be followed by patent examiners and patent agents during the prosecution of applications filed with the Patent Office”.¹⁰ While the MOPOP provides a useful high-level overview of the legal, regulatory, and administrative framework of patenting in Canada for examiners and participants in the system, it is simply that - an overview. It has no statutory basis in the *Patent Act* or *Patent Rules*, and it is neither authoritative nor a complete code on the application of patent law.

18. The MOPOP is prepared at the initiative of the Patent Office as a reference tool. Every edition of the MOPOP since its first publication in 1977 has warned readers that it is solely a guide and should not be considered a legally binding authority.¹¹ The MOPOP broadly explains different elements involved in the examination process and notes relevant legislative, regulatory, or judicial authorities applied or considered by examiners at each stage. However, it is not intended to be a comprehensive statement of patent law in Canada.

19. It is important to distinguish between the role of the MOPOP in providing a high-level overview of Patent Office practice, and the notion that examiners rely exclusively on it in examining patent applications. Examinations are not governed by the MOPOP but by the *Patent Act*, *Patent Rules*, and relevant jurisprudence. Likewise, newly hired patent examiners are trained on the basis of the *Patent Act*, *Patent Rules* and relevant jurisprudence, not on the basis of the MOPOP.

20. An inherent weakness of the MOPOP, and one that is well understood by examiners and other participants in the patent system, is that it cannot be relied upon to be completely up to date. Although the Patent Office seeks to keep the MOPOP as current as possible, it is

¹⁰ Wilson Report, para. 22.

¹¹ “*Manual of Patent Office Practice*”, Consumer and Corporate Affairs Canada, Patent Office (August 1989, January 1990, March 1998, September 2004, February 2005, April 2006, January 2009, December 2009, November 2013, December 2013, and May 2014) (R-025). “*Manual of Patent Office Practice*,” Corporate and Consumer Affairs Canada (September 2014), Forward (“This manual is solely a guide and should not be considered to be a binding legal authority. In the event of any inconsistency between this guide and the applicable legislation, this legislation must be followed”) (R-045).

impractical and unreasonable to expect that it will always exactly reflect Office practice at any given point in time. Updates to the MOPOP require significant resources and lengthy consultations between senior officials at the Patent Office, and occasionally with other government departments. The resources and capacity of the Office to handle MOPOP updates vary over time. Over the past ten years or so, the Patent Office has made an effort to revise the MOPOP on a more frequent basis. However, this has not always been the case. There are no guarantees that these efforts will remain as frequent in the future.

21. In addition to resource issues that make regular updates to the MOPOP challenging for the Patent Office, the law itself is constantly evolving. As it develops in response to new and untested patent issues that come before the courts, the examination practices of the Office need to reflect this as much as possible. As examiners, our training on developments in the patent law was on-going. For example, during my tenure at the Patent Office, examiners had the benefit of training seminars on issues such as patentable subject matter, computer related inventions, divisional applications, and double-patenting. Examiners could also consult patent Practice Notices¹² circulated by the Office. We did not wait for the MOPOP to catch up before applying in practice what we understood to be the state of the law.

22. The result is that there is inevitably a lag between changes to Patent Office practice and corresponding updates to the MOPOP to reflect those changes. Changes to the MOPOP often take place after the fact, but are consistent with the examination practice already being applied by the Office. As an examiner and senior examiner, the extent to which I consulted the MOPOP in examining patent applications was consistent with my understanding of it as primarily a reference tool.

24. I am unaware of any examiner, patent applicant, or patent agent who would consider the MOPOP to be a complete and authoritative guide on Patent Office practice or patent law in Canada at any given point in time. Participants in the system are aware of the extent to which they can rely on the MOPOP, and the point at which they must instead turn to the *Patent Act*, *Patent Rules*, and case law itself to determine what they should include in a patent application or how the law might apply to a certain aspect of their case.

¹² Practice Notices are published notices related to changes to Patent Office practice.

25. It is for these reasons that Mr. Wilson's suggestion that the plain references to utility in 1990s editions of the MOPOP are all that were considered by Patent Office examiners at that time, is misleading.¹³ Those references are simply a very high level explanation of utility, which note that inventions that do not work lack utility. Those references do not purport to address a variety of specific circumstances relevant to utility, including what to do when it is unclear whether utility has been established as of the filing date, an issue which I will address below.

5. Patent Office Examination Practice for Determining if the Utility Criterion had been Met in the Late 1980s and 1990s

26. In his Report, Mr. Wilson says that he "[...] was not surprised to see the 2009 and 2010 MOPOPs required significant changes to the utility doctrine in light of the court decisions on the patent utility doctrine"¹⁴ and that "[t]he changes made in 2009 and 2010 contained extensive requirements for utility that did not exist when Eli Lilly applied for its olanzapine (Zyprexa) and atomoxetine (Strattera) patents".¹⁵ I disagree with his characterization of the changes that were made to the MOPOP chapters on utility and description in 2009 and 2010 respectively. For the reasons explained above and for the additional reasons I will give below, these changes to the MOPOP were not only unsurprising, but they were also consistent with longstanding Patent Office practice.

Promise of the Patent

27. I disagree with Mr. Wilson that, before the 2009 and 2010 changes to the MOPOP, examiners only looked for "any utility"¹⁶ and "did not consider advantages of the invention that were stated in the disclosure to be equivalent to the utility of the invention".¹⁷ Nor do I agree with his suggestion that utility was limited to the sole issue of operability (*i.e.* whether the invention works).¹⁸ I also disagree with his assertions that "[t]here had to be some indication of

¹³ Wilson Report, paras. 32 (citing passages from Chapter 12 of the 1990 Edition of the MOPOP and Chapter 9 of the 1996 Edition of the MOPOP, in place when the Claimant's patent application for olanzapine was examined) and 40 (citing passages from Chapters 16 and 9 of the 1998 Edition of the MOPOP, in place when the Claimant's patent application for atomoxetine was examined).

¹⁴ Wilson Report, para. 47.

¹⁵ Wilson Report, para. 48.

¹⁶ Wilson Report, para. 46.

¹⁷ Wilson Report, para. 29.

¹⁸ Wilson Report, para. 28.

what the invention would be used for, however additional benefits of the type frequently described by an application - such as if the drug had fewer side-effects, was easier to manufacture, or could be taken less often - were not constructed as part of the “utility” of the invention”, and that while “these assertions may contribute to the explanation of why an invention is “inventive”, they were not considered in determining whether the invention was useful”.¹⁹

28. As a general rule, patent applications are examined and patents granted on the basis of the language employed by applicants themselves in an application. This includes, in addition to the description of the invention and how to make it, what an applicant says the alleged invention will do; that is, what the applicant says is the invention’s utility.

29. This attention to the language of the application, with particular regard to what an applicant says the alleged invention will do, is especially important in cases where the invention is itself an alleged discovery of a particular utility. Two notable cases where this occurs are (i) where the invention is the alleged discovery of a new use of a known compound - as was the case for atomoxetine, and (ii) where the invention is for a “selection”, that is the alleged discovery that a particular molecule or compound from a known and previously patented chemical genus provides a substantially better effect than other members of the same genus - as was the case for olanzapine.²⁰

30. During the 1990s, when the patents for olanzapine and atomoxetine were filed at the Patent Office, examiners would have very much paid attention to assertions of utility contained in an application, when presented with applications for new use or selection patents. In those cases, the asserted use was in essence the invention itself. The mere scintilla standard of utility, which Mr. Wilson suggests was exclusively applied, would have been inappropriate in such circumstances. In cases of new use or selection patent applications, it was and remains necessary for the applicant to establish that the invention in question has a utility beyond the utility claimed in the original use or genus patent. Otherwise, there is no consideration for the patent monopoly awarded to the applicant for the alleged invention. If only the same utility for the invention as for

¹⁹ Wilson Report, para. 29.

²⁰ A genus is a class, kind, or group of compounds or molecules marked by one or more common characteristics.

the original use or genus patent is claimed, then the application would fail for obviousness. The asserted utility in relation to the prior art was therefore naturally, in the late 1980s and 1990s, the standard against which both the utility and the disclosure of the alleged invention was judged.

31. Consideration of asserted utility in relation to the prior art arose as a result of the number and types of patents being filed at the Patent Office in the late 1980s and 1990s. During this period, there was an increase in overall filings, but notably more so with regards to new use and selection patents. This increase was due to a number of factors. First, the Supreme Court introduced the sound prediction doctrine in its 1979 decision in *Monsanto Co. v. Commissioner of Patents*, which allowed applicants to file applications on the basis of a predicted, rather than a demonstrated utility.²¹ This prompted applicants to file relatively early in their research process, before the utility of an invention had definitively been demonstrated. Second, the Supreme Court confirmed the acceptability of new use patents in its 1982 decision in *Shell Oil Company v. Commissioner of Patents*,²² which meant that applicants could seek to obtain patents for alleged new uses of known chemical compounds, rather than relying on process claims for the discovery of the new use, as had been the case in earlier applications of the *Patent Act*. Third, the switch in Canada from a first-to-invent to a first-to-file system of patenting in 1989, combined with the allowance of sound prediction of utility, further prompted applicants to file patent applications at the earliest possible stage in the process. Finally, the acceptance of applications for pharmaceutical products *per se* in 1987 (where previously, claims to food and medicine had to be defined in terms of the process by which they were made), and the elimination of compulsory licensing for pharmaceuticals in 1993,²³ meant that applicants were more inclined to seek patent protection for alleged new pharmaceutical uses of known chemical compounds, or selection patents claiming one or several compounds out of a previously-patented genus.

32. When the MOPOP chapter on utility was updated in 2009²⁴ to reflect recent jurisprudence, that update was consistent with longstanding Patent Office practice. In the 1990s,

²¹ *Monsanto Company v. Commissioner of Patents*, [1979] 2 SCR 1108 (“*Monsanto 1979*”) (R-023).

²² *Shell Oil Company v. Commissioner of Patents*, [1982] 2 SCR 536 (R-046).

²³ Through the granting of a compulsory licence, the Commissioner of Patents would allow someone else to produce a patented product or carry out a patented process without the patent holder’s permission. In 1993, Parliament repealed the compulsory licence provisions of the *Patent Act* by in Bill C-91 (S.C. 1993, c. 2), see Dimock Report, para. 40.

²⁴ “*Manual of Patent Office Practice*,” Consumer and Corporate Affairs Canada, Patent Office (December 2009), Chapter 12 – Subject Matter and Utility (R-038).

examiners notably were considering the asserted utility of inventions in cases of new use and selection patents on the basis of what the application itself said, and using that as the standard against which to measure whether the utility criterion appeared to have been fulfilled by the alleged invention. 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.

Timing of the Invention

33. I also disagree with Mr. Wilson that “the 2009 and 2010 MOPOP amendments [...] now require that applicants relying on sound prediction disclose all evidence of utility in the description”, and his suggestion that “[t]his limitation on how and when evidence of utility could be presented to the examiner did not exist” at the time that the olanzapine and atomoxetine patents were examined.²⁵

34. The Patent Office has always required that utility be established as at the date an application is filed. This requirement has its foundations in Canada’s first-to-invent system of patent filing. It continues to apply today in Canada’s first-to-file system, in all cases, including in cases where an applicant relies on demonstration or sound prediction to establish utility.

35. It is a basic assumption that when an applicant files for a patent, he or she is asserting that their claimed invention fulfils the basic conditions of patentability, namely patentable subject matter, novelty, non-obviousness, utility, and sufficient disclosure. This assumption was especially ingrained as a result of the first-to-invent system of patenting in Canada, in place until 1989. Under that system, it was assumed by the Patent Office that an applicant filing for a patent would be able to confirm, if challenged, that they were indeed the first to invent the invention for which their application was filed.

36. Patent applications filed before 1989 were closed to the public until the patent was granted. As a result, it occasionally happened that two separate applicants would have pending applications before the Patent Office for the same alleged invention. This resulted in what was

²⁵ Wilson Report, para. 49.

known as a conflict proceeding.²⁶ In the course of a conflict proceeding, the two applicants would have to provide evidence (such as lab notebooks, office memos, or other objective contemporary evidence) which confirmed that they were indeed the first to have invented the invention. It was not an option for an applicant to file first and invent later. During a conflict proceeding, if an applicant was unable to prove that she had indeed been the first to invent a fully realized invention, her application would be rejected in favour of the other applicant.

37. In 1989, amendments to the *Patent Act* replaced the first-to-invent system with a first-to-file system, which brought increased transparency to the process. Patent applications filed after 1989 are laid open to the public 18 months after filing, making it easier for competing inventors to keep track of what other patent applications are pending. However, in my view these changes were not intended to suddenly give license to applicants to file for patents without first knowing what they had invented. Nor was it in the applicant's interest to do so. It was understood by applicants, and assumed by examiners, that an applicant would only file first because that applicant had actually realized their invention at the time of filing.

38. As I have mentioned, the requirement that an applicant must have realized (or made) their invention at the time of filing applies in cases of demonstrated utility but also, since the introduction of the doctrine of sound prediction in *Monsanto* in 1979, in cases where an applicant relies on sound prediction to establish utility.²⁷

39. In effect, *Monsanto* broadened the ability of pharmaceutical (and other) applicants to file not only for inventions for which utility had been demonstrated at the time of filing, but also for inventions for which utility could be soundly predicted at the time of filing. Throughout the late 1980s and 1990s, *Monsanto* was relied upon by pharmaceutical applicants to claim beyond the scope of a few fully realized working examples of chemical compounds disclosed in an application, to a larger class of molecules or compounds, where the applicant could soundly predict the utility of the larger class on the basis of the working examples disclosed by the applicant.

40. In my experience, an examiner working in the 1990s would have accepted an alleged

²⁶ Conflict proceedings were held under s. 43 of the "old" *Patent Act*, as it read immediately before October 1, 1989.

²⁷ *Monsanto 1979 (R-023)*.

invention's utility based upon sound prediction (in accordance with *Monsanto*) rather than demonstration, so long as the applicant could show that at the time of filing they had a sound basis to predict that utility. An examiner would have assessed this on the basis of the information included in the patent application itself at the time of filing.

41. The Patent Office has never accepted post-filing evidence to support "predicted" utility. In the 1990s, as is the case now, evidence as to sound prediction of utility submitted after the date of filing was not accepted by the Patent Office. Such evidence would be considered "new matter",²⁸ and would be rejected by the examiner. The only situation in which an examiner would accept evidence of utility after filing was one in which the examiner had doubts as to the credibility of an allegedly demonstrated (not predicted) utility. However, even then the evidence would be required to have pre-dated the filing of the application in question.²⁹ This is consistent with the longstanding Patent Office requirement that an applicant must have realized its invention as of the filing date.

Evidence of Demonstration or Sound Prediction of Utility

42. It is important to recall that in the 1990s, as it remains the case today, given the constraints I have identified above, examiners relied on the language of the patent application itself in looking for evidence of the demonstration or sound prediction of utility. If such evidence was found in the application, the examiner would necessarily apply assumptions in the applicant's favour, accepting that evidence as credible.

43. For example, where a patent application stated in unequivocal terms that a molecule or compound had been confirmed to achieve a particular pharmacological effect³⁰ - giving the impression that the compound had been tested and proven to work - and that pharmacological effect was not completely implausible, an examiner would apply an assumption in favour of the applicant and accept that the invention's utility had been "demonstrated" as at the time of filing. Examiners would do this with the understanding that if challenged in court, the applicant would

²⁸ New matter refers to anything which is not disclosed in an application at the time of filing or which cannot be reasonably inferred from what has been disclosed at the time of filing.

²⁹ This evidence would have been provided as an argument to the examiner in response to an Office Action, but would not have been included as an amendment to the application as filed.

³⁰ A pharmacological effect means the effect of a drug on a living system.

be required to produce evidence predating the application's filing, to prove that the applicant had indeed been able to demonstrate the alleged utility as of the filing date.

44. Alternatively, where the language of the specification suggested that the utility of the invention was "predicted" rather than "demonstrated", the examiner would determine whether or not the prediction appeared to be sound based on the type of research disclosed in the application, the results obtained, and the explanation provided in the specification as to how those results could predict the utility of a subject compound.

45. For patent applications in the chemical arts based upon sound prediction of utility, including those directed to pharmaceuticals, an examiner would expect the application to disclose some reference to positive results of tests performed in cultured human or animal cells, in microorganisms, or in animal models, with an explanation of why a molecule or compound that showed utility in those systems would be expected to be effective in humans. Alternatively, an application might instead include a structural or stereo-chemical comparison of the subject compound with a known compound, the latter of which had a known utility. In the latter case, an examiner might accept that because the subject compound was chemically and structurally similar to the known compound, it could be soundly predicted that the subject compound would have the same utility as the known compound. However, the examiner would expect the application to disclose a structural comparison of the various compounds, as well as a rationale of why the new compound was expected to be useful in the same way as the known compound.

46. It was my experience that applicants understood patent examiners' practice in this regard, and would not claim a utility without providing some explanation or basis for the demonstration or prediction of that utility in their application. To the contrary, in relying upon sound prediction, applicants would typically provide as many working examples as possible, to ensure that the full scope of the claims was supported.

47. When the MOPOP chapter on description was updated in 2010³¹ to reflect recent jurisprudence on disclosure of the basis for sound prediction, that update was consistent with longstanding Patent Office practice. As examiners, we would always look for some explanation

³¹ "Manual of Patent Office Practice," Consumer and Corporate Affairs Canada, Patent Office (December 2010), Chapter 9 – The Description (R-047).

or basis in the patent application itself to show that the applicant had either demonstrated or soundly predicted the utility of an alleged invention as at the time of filing. When the Supreme Court issued its 2002 decision in *Apotex Inc. v. Wellcome Foundation Ltd.* (“AZT”),³² it effectively confirmed the practice that had been employed by the Patent Office since the 1990s in allowing patents based upon a sound prediction of utility, assuming some basis for that prediction was set out in the patent.

6. The Basis on Which the Patents for Olanzapine and Atomoxetine were Granted

48. I have reviewed the olanzapine and atomoxetine patents.³³

49. Applying the analysis I have explained above, as an examiner at the Patent Office examining patent applications in the chemical and pharmaceutical arts in the 1990s, I would have concluded on the basis of the assertions in the olanzapine and atomoxetine patents that each of those compounds had already been tested on humans and that the applicant had already “demonstrated” the utility asserted in the patent applications, as at the date of filing.

50. In the olanzapine patent, the disclosure states that “the compound of the invention has shown a high level of activity in the clinical evaluation of psychiatric patients suffering from schizophrenia, and it exhibits this high activity at surprisingly low dosage levels”.³⁴ The patent discloses a “completed open [...] study of the compound of the invention in schizophrenic patients”³⁵ where percentage patient improvement and daily dosages are given, and also discloses that “in clinical situations, the compound of the invention shows marked superiority, and a better side effects profile than prior known antipsychotic agents, and has a highly advantageous activity level”.³⁶ All of these statements would have indicated to me as an examiner that olanzapine had already been tested on human subjects and was proven to be not only effective, but also more effective than other compounds in the genus and having fewer side effects. There is no suggestion in the specification that the patentee was only predicting that olanzapine would provide relatively superior effects as an antipsychotic. Rather, the language of

³² *Apotex Inc. v. Wellcome Foundation Ltd.*, [2002] 4 SCR 153, (“AZT”) (R-004).

³³ Patent Specification CA 2,041,113, (“113 Patent”), (R-030) and Patent Specification CA 2,209,735 (“735 Patent”), (R-026).

³⁴ 113 Patent, page 4 (R-030).

³⁵ 113 Patent, page 5 (R-030).

³⁶ 113 Patent, page 6 (R-030).

the disclosure suggests that the compound's utility had already been demonstrated, that is, it suggests that the applicant would have definitively known that olanzapine was an effective treatment with a reduced side-effects profile and markedly superior effect than other compounds. This relative superiority was perceived because olanzapine was otherwise already covered by a genus patent, which had claimed the use of the class of compounds to which olanzapine belonged for treatment of central nervous system disorders.

51. In the atomoxetine patent, the subject compound is described as “a notably safe drug, and its use in ADHD, in both adults and children, is a superior treatment for that disorder because of its improved safety”,³⁷ and the disclosure states that “[t]he method of the present invention is effective in the treatment of patients who are children, adolescents or adults [...]”.³⁸ The patent does not say that atomoxetine might be a superior treatment or is predicted to be effective. Rather, the patent states that atomoxetine “is” a superior treatment and “is” effective, which would suggest to me, as an examiner, that tests on human subjects have already been conducted, and that the utility of atomoxetine, that is as a superior treatment for ADHD, had already been demonstrated.

52. In the circumstances, in both cases Patent Office practice would have been to take the applicant's assertions at face value and assume that the utility of the invention had been demonstrated based upon the studies conducted by the applicant, before it had filed the olanzapine and atomoxetine applications, knowing that the applicant would have to provide full proof of such studies in any subsequent court challenge. In this context, comments made by Mr. Wilson to the effect that utility was not an issue during the examination of the Canadian patent applications for olanzapine and atomoxetine are misleading.³⁹ They ignore the nature of the examiner's review and the assumptions the examiner would have made based upon the actual language of the olanzapine and atomoxetine applications.

53. The assumptions that the Patent Office would have applied in favour of the applicant during the examinations of the olanzapine and atomoxetine applications would not have been similarly applied by the Federal Courts in their subsequent review of those or any other patents,

³⁷ 735 Patent, page 2 (R-026).

³⁸ 735 Patent, page 7 (R-026).

³⁹ Wilson Report, paras. 36 and 44.

as part of infringement or impeachment proceedings. At that stage of the review, if the court finds that the patentee relied upon demonstrated utility, the patentee is typically required to produce the actual studies on which it relied to demonstrate the utility of the alleged invention at the time of filing. However, if the court finds that the utility was not demonstrated, and therefore that the patentee must rely upon a sound prediction of utility, the court looks to the results of the actual studies disclosed in the patent application, and with the assistance of expert evidence assesses whether the patentee could have indeed soundly predicted the utility of the invention on that basis at the time of filing. In other words, the court seeks to verify that as at the date of filing, the patentee was not simply speculating as to their invention's utility, but really did have sufficient grounds on which to obtain a patent on the claimed invention.

54. My understanding is that when the courts reviewed the olanzapine patent they found that the studies relied upon by the Claimant at the time of filing were not sufficient to demonstrate that olanzapine would treat schizophrenia patients in a markedly superior fashion and with a better side effects profile than other known antipsychotics. The courts further found that although the studies disclosed in the patent provided a factual basis for a sound prediction of utility, the promise of the patent could not be reasonably inferred (*i.e.* there was no sound line of reasoning) from the information disclosed. Similarly, the courts found that for atomoxetine, the Claimant's filing relied on a study that provided only suggestive preliminary results that were insufficient to demonstrate that the compound was a superior treatment for ADHD. The courts also ruled that a person of skill in the art would not have been able to soundly predict the claimed utility based on what was disclosed in the patent.

7. Effect of the Patent Cooperation Treaty (“PCT”) on Patent Office Examination Practice

55. The Patent Cooperation Treaty (“PCT”) came into force in Canada on January 2, 1990.⁴⁰ From a Patent Office perspective, the PCT did not change the examination practices of the Office. This is because the PCT does not impose substantive patentability requirements on PCT Contracting States.⁴¹

56. Under the PCT, Contracting States are only required to comply with the “form and contents” requirements in the Treaty. “Form and contents” requirements are generic categories of information that must minimally be included in an international application in order for that application to be accepted into the PCT’s international phase.⁴² For example, international applications are required to include a request, a description, one or more claims, one or more drawings (if applicable), and an abstract.⁴³ However, beyond requiring that such categories of information are included, the PCT provides only general guidance as to the substance of these categories of information.

57. A Receiving Office makes a determination whether an international application has met the PCT’s “form and contents” requirements when the international application is filed.⁴⁴ In Canada, the “form and contents” review of an international application filed under the PCT is conducted by non-technical clerical staff at the Patent Office. As the PCT’s own guidelines confirm, this review is “formal in nature” and “do[es] not go into the substance of the

⁴⁰ WIPO Patent Cooperation Treaty, “The PCT now has 148 Contracting States”, online: http://www.wipo.int/pct/en/pct_contracting_states.html (R-044).

⁴¹ Patent Cooperation Treaty (“PCT”), Article 27(5) (R-037).

⁴² An international PCT application is an application for a patent that has been filed under the PCT and which has been accorded an international filing date by a Receiving Office or by the International Bureau of the World Intellectual Property Organization (“WIPO”). The international phase of a PCT application begins once the application has been given a filing date and continues until the application enters the national phase where it is processed and examined by the national Patent Office of a Contracting State which has been designated in the international application. For example, consistent with PCT Article 11(1), clerical staff would review the international application to verify that it contained a section which “on its face” appeared to be a description, and a section which “on its face” appeared to be a claim or claims.

⁴³ PCT, Article 3 (R-037). The abstract provides a short technical description of the invention and is not meant for interpreting the scope of the protection sought.

⁴⁴ A Receiving Office is the national Patent Office or intergovernmental organization with which the international application has been filed (PCT, Article 2 (R-037)).

invention”.⁴⁵ If a Patent Office clerk finds that the PCT’s “form and contents” requirements have been met (*i.e.* that the application at least includes each of the required categories of information), the application will be admitted to the PCT’s international phase and thereafter eligible for continuation during the national phase in any PCT Contracting State.

58. The determination by a clerk that an application meets the PCT’s “form and contents” requirements is entirely separate from a determination by a patent examiner whether that application meets the substantive requirements for patentability under Canadian law. Admission of an application to the PCT’s international phase, after having been found to meet the PCT’s “form and contents” requirements, is by no means a guarantee that that application will result in a patent grant during the PCT’s national phase.⁴⁶ During the national phase, applicants are still required to comply with substantive patentability requirements relevant to each country where they wish to seek patent protection, in order to obtain a patent. National offices have the sole decision-making authority whether to grant a patent to an applicant who has chosen to use the PCT process.

59. In this context, I disagree with Mr. Jay Erstling’s characterization that the PCT “form and contents” requirements extend to the “manner of describing and claiming” the invention.⁴⁷ Every international application filed under the PCT must include a description of the invention in order to meet the “form and contents” requirements of the Treaty and therefore be eligible for review by national Patent Offices during the national phase. However any description, no matter how bare, will comply with the “form and contents” requirements for the purposes of the PCT. The substantive evaluation of what the description actually consists of is outside of the scope of the PCT, and is governed exclusively by the domestic patent law of any given jurisdiction. Unlike the review of an application’s “form and contents” by non-technical clerical staff during the international phase, the substantive evaluation of the description of an invention in an application is conducted by trained Patent Office examiners, during the PCT’s national phase.

⁴⁵ PCT Applicant’s Guide (International Phase), World Intellectual Property Organization (WIPO) International Bureau (July 24, 2014), Chapter 6 – Processing of the International Application by the Receiving Office, s. 6.001 (**R-042**).

⁴⁶ In the national phase, an international PCT application is processed and examined in the national Patent Office of a Contracting State which has been designated in the international application. During this phase, the international PCT application has the effect of a nationally filed application and the decision to grant a patent lies with the national Office (PCT Applicant’s Guide (National Phase), World Intellectual Property Organization (WIPO) International Bureau (July 24, 2014), Chapter 2 – Entry into the National Phase, s. 2.001) (**R-048**).

⁴⁷ Erstling Report, para. 25.

60. During the PCT's international phase, an International Searching Authority ("ISA")⁴⁸ will conduct an international search to identify any relevant prior art, and will also issue a preliminary written opinion on novelty, non-obviousness and industrial applicability⁴⁹ of the international PCT application. However, these results are strictly advisory in nature. National patent offices are not required to defer to them. In my experience, ISA results would be considered by Patent Office examiners primarily to assist in an examiner's evaluation of an invention's novelty and non-obviousness. This is because the international examination phase seeks to collect worldwide evidence of prior art, which can be extremely useful at the national phase in determining whether the invention was anticipated - that is, whether it is or is not "novel" - or whether the invention would have been obvious to a person of ordinary skill in the art.

61. Likewise, in the event that a patent granted by the Patent Office is the subject of an infringement or impeachment proceeding before the courts, the fact that the patentee filed the patent application using the PCT process will not impact the court's determination whether the patent ultimately meets the substantive requirements for patentability of that jurisdiction.

8. Conclusion

62. Patent Office examination practice regarding utility has not changed significantly since the late 1980s, including after Canada joined the PCT in 1990. At the times that the patents for olanzapine and atomoxetine were filed and examined, Patent Office examiners were regularly considering asserted utility in cases of applications for new use and selection patents. Also at those times, in allowing applicants to establish utility by way of sound prediction, examiners would require some disclosure in the application of the basis upon which the sound prediction was being made. Changes made to the MOPOP in the 2000s to reflect the decisions of the courts with regard to "promise of the patent" and disclosure of the factual basis for sound prediction were consistent with practices already being applied by the Patent Office at the time they were

⁴⁸ An International Search Authority is a designated national Patent Office or intergovernmental organization tasked with establishing a search report on prior art with respect to an invention described in an international PCT application (PCT, Article 16 (R-037)).

⁴⁹ The PCT refers to "industrial applicability" rather than "utility", however states that the terms may be used synonymously by an ISA or IPEA for the purposes of the non-binding preliminary examination (Patent Cooperation Treaty, *PCT International Search and Examination Guidelines*, World Intellectual Property Organization, 1 July 2014, Appendix to Chapter 14, s. A14.01) (R-041).

made, including during the period in which the patents for olanzapine and atomoxetine were filed and examined.

Signed at: Ottawa, ON on: January 26, 2015

[signed]

Dr. Michael Gillen

Appendix A

MICHAEL F. GILLEN

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EMPLOYMENT HISTORY

**2006-2014 Chief, Biotechnology Division, Patent Branch
Canadian Intellectual Property Office (CIPO), Gatineau, QC**

Duties

- plan, organize and direct the activities of the Biotechnology Division (70 examiners including section heads and senior examiners) involved in a) the search, examination and disposition of applications for patents from Canadian and foreign individuals and companies, and b) the search and examination of applications for patents filed under the Patent Cooperation Treaty
- participate on committees and working groups to provide input to Patent Branch strategic planning and business renewal initiatives, and the development of overall policy, procedures, standards, practices, tools and systems
- liaise with patent applicants and agents/lawyers, and representatives of the Intellectual Property Institute of Canada to consult on proposed revisions to the Patent Act and Regulations and to identify areas of concern
- develop operational plans and procedures in support of CIPO's strategic objectives
- participate in legislative and regulatory initiatives
- develop quality standards and regimes for patent examination services
- direct the implementation of IT/IM projects within the Patent Branch
- forecast trends in the filing of patent applications, predict resource levels needed to meet trends and allocate resources accordingly
- review and approve all Final Actions before these are sent to applicants, and review and approve all briefs to the Patent Appeal Board
- manage the human and financial resources of the Biotechnology Division including the direction of work units through subordinate section heads
- manage the Patent Branch training team ('Program Manager, Training" and support personnel) to ensure that newly hired patent examiners have the tools and training they need to graduate to the "working level" and that there is a continuous learning environment within the Branch such that staff have on-going opportunities for professional, scientific and personal development

**2003-2006 Chairman, Patent Appeal Board (PAB)
Canadian Intellectual Property Office (CIPO), Gatineau, QC**

Duties

- manage the day to day activities of the PAB
- chair PAB hearings and make recommendations to the Commissioner of Patents with respect to rejected patent and industrial design applications
- ensure that requests for patent re-examination and compulsory licence applications are processed according to the provisions of the Patent Act
- ensure that the boards which set the qualifying examinations for patent and trade-mark agents receive administrative support
- provide advice to the Commissioner of Patents
- provide instructions to Department of Justice legal councils on litigation involving the Commissioner of Patents
- member of CIPO Senior Executive, the International Strategic Planning Committee and the Intellectual Property Policy Committee
- co-champion the learning components of CIPO's human resources strategy

**2002-2003 Member, Patent Appeal Board (PAB)
Canadian Intellectual Property Office, Gatineau, QC**

Duties

- participate in PAB hearings and make recommendations to the Commissioner of Patents with respect to rejected patent and industrial design applications
- prepare PAB recommendations for the Commissioner of Patents with respect to which applicant is the first inventor and entitled to claim an invention where two or more applicants are seeking rights over the same invention (conflict procedure)
- provide advice on patent issues to senior management

**1992-2002 Senior Patent Examiner, Patent Branch
Canadian Intellectual Property Office, Gatineau, QC**

Duties

- examine and prosecute patent applications related to biotechnology
- perform novelty and state-of-the-art searches
- initiate conflict proceedings and prosecute conflict applications
- train new examiners
- act in the absence of the Section Head
- participate in special projects as required
- Patent Branch media spokesperson on biotechnology issues
- provide advice on patent issues to senior management

**1988-1992 Patent Examiner, Patent Branch
Canadian Intellectual Property Office, Gatineau, QC**

Duties

- examine and prosecute patent applications related to biotechnology
- perform novelty and state-of-the-art searches
- participate in special projects as required

**1984-1988 Research Associate, Institute of Biological Sciences
National Research Council of Canada, Ottawa, ON**

Duties

- study the tumor-associated protein oncomodulin
- clone and sequence oncomodulin cDNA
- prepare radiolabeled DNA and RNA probes to detect oncomodulin gene expression
- measure oncomodulin gene expression in tumors and fetal tissues
- culture normal and transformed cell lines
- supervise technical personnel

**1980-1983 Organic Chemist / Production Manager
ens Bio Logicals, Inc., Ottawa, ON**

Duties

- automate the synthesis of oligonucleotides ("Gene Machine" design)
- develop procedures for the purification of DNA oligomers
- manage a production unit of 15 technical personnel
- provide technical assistance to customers

EDUCATION

Ph.D. (organic chemistry), 1980, McGill University, Montreal, QC

B.Sc. (honors chemistry), 1975, St. Francis Xavier University, Antigonish, NS

AWARDS

| | |
|-----------|--|
| 2012 | Queen Elizabeth II Diamond Jubilee Medal recipient |
| 1984-1986 | Natural Sciences and Engineering Research Council Post-Doctoral Fellowship |
| 1980-1981 | National Research Council Industrial Post-Doctoral Fellowship |
| 1979-1980 | Quebec Government Post-Graduate Scholarship |
| 1975-1979 | National Research Council Post-Graduate Scholarship |
| 1971-1975 | Imperial Oil Limited Higher Education Award |
| 1971-1975 | St. Francis Xavier University Scholarship |

PUBLICATIONS

Authored 20 publications in the scientific literature (list available upon request).

Appendix B

Publications

MF Gillen and RE Williams, *The Use of the n-Propylammonium and n-Butylammonium Salts of d-10-Camphorsulfonic Acid for the Calibration of Spectropolarimeters: Circular Dichrometer Calibration*, Can. J. Chem. 53, 2351 (1975)

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