Case No. UNCT/14/2

Under the Arbitration Rules of the United Nations Commission on International Trade Law and the North American Free Trade Agreement

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ELI LILLY AND COMPANY

Claimant

v.

GOVERNMENT OF CANADA

Respondent

WITNESS STATEMENT OF PETER GEORGE STRINGER

I. Personal Background

1. My name is Peter George Stringer. I am a British subject. I reside in Indianapolis, Indiana. I received a Bachelor of Science degree in Chemistry (B.Sc.) from Manchester University in England in 1966. I became a Chartered Patent Attorney (C.P.A.) in 1974 in England and a European Patent Attorney (E.P.A.) in 1978.

2. In 1970, I joined the patent department of The Wellcome Foundation, a pharmaceutical research institution that is now part of GlaxoSmithKline, as a patent trainee. In February 1974, I joined Eli Lilly's research establishment in the United Kingdom, which is located at Erl Wood, in Surrey, England. Shortly after I qualified as a C.P.A., I was made -Patents Manager of the patent group at Erl Wood.

3. I remained in this role until 1979, when I accepted a two-year temporary assignment in Lilly's Patent Department in Indianapolis. At the end of that two-year period, I was hired on a permanent basis by Lilly to serve as Foreign Patent Advisor. I served in that role until the early 1990s, when I was made the Director of International Patents. In 1999, I was promoted to be Executive Director of International Patents.

4. I remained in that role until 2006, when I retired from Lilly. After my retirement, I joined the law firm of Barnes & Thornburg LLP in Indianapolis. Lilly then engaged me through Barnes & Thornburg on a contract basis to advise, on an as-needed basis, regarding international patent issues. I continue to work with Lilly through Barnes & Thornburg to the present day.

II. Lilly's Foreign Patent Committee

5. From the late 1980s to the late 1990s, I was the chair of the Foreign Patent Committee at Eli Lilly. The Foreign Patent Committee was made up of the heads of the various scientific research groups, and senior patent personnel. This Committee met monthly in Indianapolis. The Committee had the sole authority within Lilly to decide whether foreign patent filings were justified for a particular invention and how widespread those foreign filings would be.[1] The Committee played a "gatekeeping" role, ensuring that inventions were appropriately protected by patents in markets in which Lilly sold its products.

6. After an initial patent application was filed for a particular drug (generally but not always in the United States), the Committee was tasked with making the business decision whether the drug should also be patented in foreign jurisdictions. Lilly drafted patent applications with the goal of utilizing a single patent description (sometimes referred to as the disclosure) for use worldwide. Our practice was to draft the standard description so that it met the requirements of every jurisdiction in which we might file. We also made jurisdiction-specific edits to the claims of the standard application, as needed. The reason for this practice was that it was more efficient to draft a single description that satisfied the requirements of every jurisdiction. In later years, our practice was to maintain and follow a standard of drafting applications that complied with the standard established by the Patent Cooperation Treaty ("PCT"), under which we could file a single application that would comply with the form and content requirements

[1] The Foreign Patent Committee was eliminated in the late 1990s as a result of an internal re-organization, and its responsibilities were then handled by the Patent Department through normal reporting channels.

of all PCT member countries. We could then file a single application with the PCT, and designate the specific countries in which we intended to apply for a patent.

7. The list of countries designated for filing depended in part on the drug's clinical and commercial potential, as well as a country's patent laws. If a drug was expected to have strong potential for clinical use, then we would often file in 35 to 50 countries, if not more.

8. Part of my responsibilities as Chair of the Foreign Patent Committee was to monitor changes in patent law in the many national jurisdictions in which Lilly operated. If there were any country-specific concerns about patentability or enforceability of pharmaceutical patents, it would be up to me to make a decision about how to address it. Depending on the circumstances, I would sometimes decide not to file in a particular foreign jurisdiction if the patent protection was not adequate.

9. By the same token, the Foreign Patent Committee would at times begin filing in a country we had previously avoided as a result of a positive change in that country's patent law. For example, in the late 1980s there was a change in the patent law of Czechoslovakia that introduced viable patent protection for pharmaceutical inventions. Accordingly, we began filing for patents in Czechoslovakia.

10. As the Chair of the Committee, it was ultimately my decision how widely to file patent applications. Our decision with respect to a particular drug was embodied in minutes that were kept of the Committee's deliberations. We would often discuss a particular drug at some length before reaching a decision and then embodying that decision in our minutes. However, the minutes of our meetings tended to be short, simply recording the outcome of our deliberations.

11. After the Committee had made its decision, responsibility for filing and prosecuting the various patent applications returned to the responsible patent attorney. The patent attorney was also primarily responsible for coordinating with the product team as the drug moved towards regulatory approval and market launch, including by notifying the product team if there were any unusual or unforeseen developments in the patent situation.

III. The Foreign Patent Committee's Consideration of Zyprexa (Olanzapine)

12. The Committee considered Zyprexa at a meeting on 13 February 1991. I attach the minutes of that meeting to this statement as **Appendix I** (C-88).

13. The "Critical Date" identified in the Minutes is 25 April 1991. The Critical Date was calculated based on the date of the initial patent application. Under the Paris Convention for the Protection of Industrial Property, we had twelve months from the date of the initial patent application to file counterpart applications in other countries. If we filed outside that time period, then we would lose the benefit of the "priority date" of the initial application. In the case of Zyprexa, unless we filed foreign patent applications by 25 April 1991, we would have lost the priority date of our initial UK patent application and any intervening publication of olanzapine would have invalidated foreign counterparts.

14. The fact that the initial patent application for Zyprexa (LY 170053) was filed in the U.K., rather than the U.S., made the drug somewhat unusual. The minutes reflect the fact that the initial patent application was filed in the U.K. in the third section, which notes "Particulars: U.K. Application No. 9009229.7. Inventor(s): Hotten, Tupper."

15. Zyprexa was also unusual insofar as it was being considered by the Committee after preliminary (Phase II) human clinical trials designed to gauge efficacy had been successfully completed. The comments note that "[t]he compound has shown encouraging results in clinical trials designed to assess its use in the treatment of schizophrenia."

16. During my career, I have examined many patent specifications (likely several thousand) relating to new pharmaceutical agents. It is unusual for such a patent specification to include Phase II human clinical studies demonstrating efficacy. Normally, Lilly (and indeed other pharmaceutical and biotech companies) file patent applications (both initial and foreign) before any clinical trials have taken place based on the results from laboratory experiments or animal studies. There is a major risk in waiting to file a patent application until human clinical trial data has been collected. It is difficult to conduct confidential clinical trials. If knowledge of successful clinical trials

becomes public, that can invalidate later patent filings on the invention on the grounds of novelty or non-obviousness.

17. This risk is reflected in the Foreign Patent Committee minutes for Zyprexa. It is noted on the second page of the Minutes that "It is believed that publication of [Zyprexa] may already have occurred and we are thus committed to completion of this application." In other words, the unusually extensive testing of Zyprexa, which had been performed to show human efficacy, may have resulted in inadvertent publication of the invention in the period between the priority date and the "completion" (foreign filing) date.

18. As can be seen from the Minutes, the Foreign Patent Committee decided to file widely for patent protection for Zyprexa. As mentioned previously, Canada was always an important market for Lilly and it was one of the jurisdictions we filed in most frequently. Canada was one of the 35 jurisdictions in which we initially filed for a Zyprexa patent. The decision to file broadly (including within the European Patent Convention region) reflected the recognition at the time that Zyprexa was likely to be a commercial success, which it turned out to be.

19. As I have also noted, as part of the Foreign Patent Committee decision making process, any potential patentability issues were evaluated. If utility had been a concern in any jurisdiction, we would have addressed that concern prior to filing. In 1991, when we considered Zyprexa, we had no reason to suspect that any foreign filing, including in Canada, could be invalidated for lack of utility. Indeed, the very opposite is true. Because of the unusually extensive testing which had been carried out, this is the last thing one would have expected.

20. The Canadian patent application was filed on 24 April 1991. As expected, utility was not an issue during the prosecution process. The application eventually issued as Canadian Patent No. 2,041,113 in July 1998.

IV. The Foreign Patent Committee's Consideration of Strattera (Atomoxetine)

21. The Foreign Patent Committee considered Strattera at a meeting on 12 July 1995. I attach the minutes of that meeting to this statement as **Appendix II** (C-89).

As with olanzapine, I chaired the meeting where foreign filing of the Strattera (known at the time as "tomoxetine") was authorized.

22. The initial patent application for Strattera was filed in the United States. This is identified in the third line of the minutes: "Particulars: U.S. Serial No. 08/371341." The Critical Date for Strattera was 11 January 1996.

23. The minutes for Strattera reflect the fact that clinical trials were ongoing while the Foreign Patent Committee was making its decision. The minutes state: "Dr. Ward reported that clinical trials are ongoing." To carry out human clinical trials represents a major investment both in time and money (even Phase II clinical trials cost millions of dollars). Very few of the inventions which came before the Foreign Patent Committee were ever deemed sufficiently important to be evaluated in humans. And, as I already stated regarding Zyprexa, there is a major risk in waiting to file patent applications until clinical trial data has been collected because if knowledge of successful clinical trials becomes public prior to filing, that can invalidate later patent filings on the invention.

24. The Committee decided to file widely for foreign patent protection for Strattera. The minutes reflect that the decision was to "[f]ile PCT, designating all countries, including US." As I have mentioned, PCT stands for Patent Cooperation Treaty. This note indicates that Lilly decided to apply widely, reflecting that the company considered Strattera to have great market potential, which it did.

25. As with Zyprexa, if utility had been a concern in any jurisdiction for Strattera, we would have addressed that concern prior to filing. In 1995, when we considered Strattera, we had no reason to suspect that any foreign filing, including in Canada, could be invalidated for lack of utility.

26. We filed our Canadian patent application on 4 January 1996, and the patent application issued as Canadian Patent No. 2,209,735 on 1 December 2002. No objections concerning utility were made during its prosecution.

V. Conclusion

27. A routine part of my job at Lilly (and part of my role on the Foreign Patent Committee) was to advise research and development groups, and senior management, as to the prospects of obtaining valid international (*i.e.*, all countries except the U.S.) patent protection. I was familiar with patent laws around the world, including Canada. In the 1990s and early 2000s, I do not remember any concerns vis-à-vis Canada's patent utility requirements. Simply put, utility was not an issue at the time Lilly drafted and prosecuted its patent applications for Zyprexa and Strattera in Canada.

Signed at Indianapolis, Indiana on September 25, 2014

[Signed]

Peter George Stringer

Appendix I to the Witness Statement of
Peter George Stringer

Foreign Patent Committee Minutes for Zyprexa
Dated 13 February 1991
(Also submitted as C-88)

FOREIGN PATENT COMMITTEE
Meeting of February 13, 1991

G.1265
WCM

ACTION : Foreign Filing

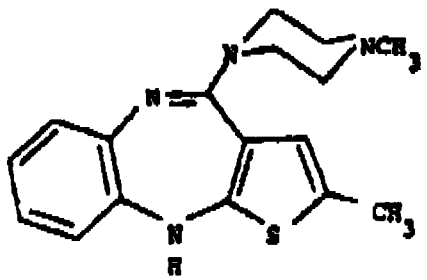
CRITICAL DATE : 25 April, 1991

PARTICULARS : U.K. Application No. 9009229.7
Inventor(s): Hotten, Tupper

SUBJECT : PHARMACEUTICAL COMPOUNDS (LY170053)

CLAIMS : Compound, composition, method, process

COMMENTS : Docket G.1265 provides a compound of the formula

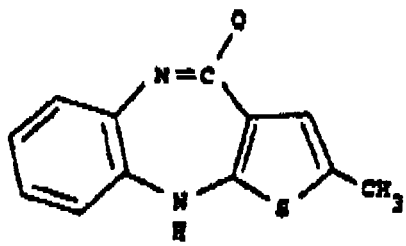


(I)

or an acid addition salt thereof, for use as a pharmaceutical for the treatment of disorders of the central nervous system.

G.1265 also provides a process for producing a compound which comprises

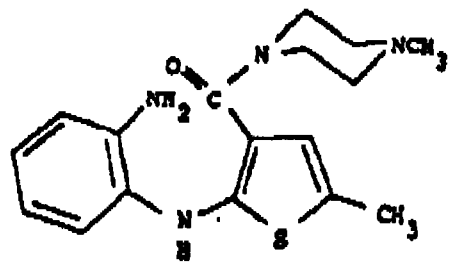
(a) reacting N-methylpiperazine with a compound of the formula



(II)

in which Q is a radical capable of being split off, or

(b) ring-closing a compound of the formula



(III)

COMMENTS : Mr. Hudson advises us that this patent application covers the project team compound LY170053, 2-methyl-4-(4-methyl-1-piperazinyl)-10H-thieno[2,3-b][1,5]benzodiazepine, which is a potent antagonist of dopamine action at the postsynaptic D_1 and D_2 receptors. The compound has shown encouraging results in clinical trials designed to assess its use in the treatment of schizophrenia.

The patent application is based on a selection of LY170053 from the broad disclosure of thienobenzodiazepines in our earlier case G.1111.

NOTE : "It is believed that publication of LY170053 may already have occurred and we are thus committed to completion of this application. Completion in the full pharmaceutical list is recommended", by Erl Wood.

ADVISOR : Dr. Zimmerman

CONSIDERATION: It was discussed that we should follow Erl Wood's recommendation on this case.

DECISION: File in the following COs, List No 1

Comm. Pharm. 35 DOPM

incl. Czechoslovakia

Appendix II to the Witness Statement of
Peter George Stringer

Foreign Patent Committee Minutes for Strattera
Dated 12 July 1995
(Also submitted as C-89)

ACTION : Foreign Filing

CRITICAL DATE : 11JAN96

PARTICULARS : U.S. Serial No. 08/371341

INVENTORS : JH Heiligenstein, GD Tollefson

SUBJECT : TREATMENT OF ATTENTION-DEFICIT/HYPERACTIVITY DISORDER

CLAIMS : Method

COMMENTS : Docket X-9726 provides a method of treating attention-deficit/hyperactivity disorder with tomoxetine, a norepinephrine uptake inhibitor.

CONSIDERATION : Dr. Ward reported that clinical trials are ongoing.

DECISION : File PCT, designating all countries, including US. File independent EPO application.