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 ROBERT POSTLETHWAIT

I. Personal Background

1. My name is Robert Postlethwait. I am a citizen of the United States and reside in the city of Zionsville, Indiana. I received a Bachelor of Science degree in chemical engineering from Purdue University in 1970. I received a Master of Business Administration degree from Butler University in 1974. I completed the Advanced Management Program at Harvard University in 1988.

2. I first joined Eli Lilly and Company ("Lilly") in 1970 as a staff engineer. In 1974, I became a project engineer for Lilly's affiliate in Brazil. From 1974-1979, I held several different positions in Brazil, including project manager for design and construction of a new factory in Cosmopolis, Brazil. I returned to Indianapolis in 1979 to serve as the marketing advisor for Elanco Products Company, Lilly's animal health and agricultural products division for Latin America.

3. In 1981, I was named director of agricultural chemical marketing for Lilly in Italy. In 1983, I was promoted to be General Manager of the Lilly affiliate in Buenos Aires, Argentina. In this position, I was responsible for all of Lilly's Argentina-based operations,

including over 450 local employees, and marketing of Lilly pharmaceuticals and Elanco animal health products.

4. In 1985, I was named General Manager and President of Lilly do Brasil, Lilly's affiliate in Brazil. In 1988, I returned to Indianapolis as Executive Director of Corporate Engineering for Eli Lilly and Company. In 1992, I was named Area Vice President of Lilly International (Western Europe). In 1993, I returned to Indianapolis and was named vice president of Central Nervous System (CNS) Planning. This was a corporate planning role that required me to interact across the Lilly CNS drug development and marketing process.

5. In August 1994, I was named President of the Neuroscience Product Group. In this capacity, I was responsible for planning and oversight of the late stage development, launch, marketing, and sale of all of Lilly's neuroscience products. As part of this role, I oversaw the development of global product lifecycle plans for our neuroscience products, a key part of which was ensuring that our products were appropriately protected by patents in the markets where we launched. I served in this role until May, 1999, when I retired from the company. I own stock in Lilly that I received as part of the company's standard compensation and retirement plans.

6. Since my retirement from Lilly, I have remained involved in the life sciences industry. From late 2009 until December 2012, I served as the CEO of AgeneBio, Inc. AgeneBio is a neuroscience pharmaceutical company that focuses on developing treatment for diseases that impact memory, including Alzheimer's disease. Before becoming CEO of AgeneBio, I previously served on the board of directors of DarPharma, another neuroscience pharmaceutical company that focused on developing drugs to treat neurological conditions like Parkinson's.

7. In addition to my service with these companies, I also actively volunteer for several civic organizations, and have served as a member of the President's New Freedom Commission on Mental Health in 2002 and 2003. I am currently a trustee of Butler University, a liberal arts and science college based in Indianapolis, Indiana. I serve as a member of the board of directors of the International Center of Indiana, a business outreach organization that seeks to foster international commerce in Indiana. Finally, I serve as a member of the board of directors of the Eskenazi Health Foundation, a philanthropic organization that supports Eskanazi Health, a leading health care provider in central Indiana.

8. Lilly has asked me to provide this declaration to describe Lilly's development and global launch of the drug Zyprexa, including in Canada. I am not a medical doctor, and although I am trained as a chemical engineer, I was not directly involved in the scientific research for Zyprexa. Rather, my role was as a senior business executive with planning responsibility for the overall development of the drug, including late-stage clinical trials, and manufacturing, marketing, and pricing.

II. Background of Zyprexa

9. Zyprexa was a groundbreaking antipsychotic medicine that addressed a pressing need among patients suffering from schizophrenia. Schizophrenia is a well-recognized mental illness that has a variety of debilitating symptoms, including confusion, delusions, and hallucinations. Individuals suffering from schizophrenia have difficulty performing tasks that require abstract thinking and sustained attention. These symptoms are often severe enough to cause profound social, educational, and occupational dysfunction among those afflicted. In addition, schizophrenia can cause early mortality due to suicide. Approximately one percent of the global population is diagnosed with schizophrenia.

10. Schizophrenia is treated with antipsychotic medicine, alone or in combination with other kinds of therapies. The first generation of antipsychotics were discovered in the 1950s. One significant problem with this first generation of drugs was that they were only partially effective in treating the symptoms of schizophrenia. Feelings of apathy and social withdrawal were not addressed by these first-generation medicines. First generation antipsychotics also did not address the impaired focus and abstract thinking skills that are associated with schizophrenia.

11. In addition to their limited efficacy, the first generation of antipsychotics also posed considerable risks for severe side effects. These side effects included so-called "extrapyramidal symptoms" or "EPS," which refers to the inability to initiate or control movement. These problems with the first generation of antipsychotics, at times irreversible with drug withdrawal, created a profound need for new medicines that treated the debilitating symptoms of schizophrenia with fewer and less serious side effects.

III. The Discovery of Zyprexa as a Medicine for Schizophrenia

12. By the time I became the President of the Neuroscience Product Group in 1994, the development of Zyprexa was already underway. As part of my responsibilities as the business lead for the group that included Zyprexa, I became well-versed in the history of the drug's development.

13. Zyprexa is a "second-generation" antipsychotic that has efficacy in treating symptoms of schizophrenia and exhibits a lower incidence of side effects, including the EPS side effects that were associated with first-generation antipsychotics. Because of its efficacy and low incidence of side effects, Zyprexa represented a significant therapeutic and patient safety benefit when compared to first-generation antipsychotics.

14. I understand that Zyprexa (the chemical name of which was olanzapine) was first synthesized by Lilly scientists in 1982 at its Erl Wood research campus in the United Kingdom. By 1983, animal test results had been obtained that suggested that olanzapine would be effective in treating schizophrenia and mania and have low incidence of EPS. Based on these results, the company decided to advance olanzapine as a candidate for development.

15. Between 1983 and 1990, Lilly engaged in seven years of intensive research on olanzapine. This research began with animal studies, and in 1986 progressed to human clinical trials. In 1986 and 1987, Phase I human clinical trials were carried out with healthy volunteers, and in 1989 further trials were conducted in patients with schizophrenia.

16. The results of these trials were positive. Olanzapine appeared to be a safe and effective new antipsychotic product with less tendency to induce EPS and other side effects. Based on these results, the company decided to seek patent protection for olanzapine, to conduct additional human clinical trials, and to pursue regulatory approval to bring the product to market.

IV. Bringing Zyprexa to Market

A. Applications for Patent Protection and Regulatory Approval

17. As part of my overall responsibilities for the development of the product, I learned about the status of our pending applications for patent protection for Zyprexa and our efforts to secure regulatory approval in the various jurisdictions where we intended to market Zyprexa.

18. The initial patent application for Zyprexa was filed in the United Kingdom on April 25, 1990. We then filed applications in the United States and Canada in April 1991. Concurrently, we began the process of obtaining health regulatory approvals from authorities around the world.

19. The olanzapine patent we applied for is what is known as a "selection" patent. This means that the compound olanzapine was part of a larger class (or "genus") of compounds with potential use in the treatment of central nervous system disorders that we had claimed in earlier patents.

B. Patent Considerations in Planning for Zyprexa's Global Launch

20. As I have mentioned, I was responsible for planning and overseeing the business preparations for the worldwide launch of Zyprexa. As part of this responsibility, I received regular updates about the prosecution of the Zyprexa patents in the various jurisdictions where we were seeking protection.

21. Strong patent protection was a key factor in deciding where and when to launch any new medicine, including Zyprexa. This was particularly true for major markets like Canada and the United States, which required Lilly to devote substantial resources to launch a product. Based on my prior experiences with Lilly, I was highly attuned to the consequences of doing business in countries with weak or uncertain patent protection. When I was the General Manager of Lilly's affiliates in Argentina and Brazil, for example, I spent a substantial portion of my time dealing with issues raised by those countries' patent systems. In fact, weaknesses in Argentina's patent regulatory framework were an important consideration in the company's decision to close our affiliate in that country in 1985.

22. If our patent team had any concerns about our ability to protect Zyprexa in any of the countries where we had submitted an application — particularly a major market — those concerns would have been raised to me. We had frequent and periodic coordinating meetings — both formal and informal — to review all aspects of the launch decision, including legal issues such as patent protection. In addition, based on my past experiences in Argentina and Brazil, I would specifically ask my team if there were any patent issues about which we should be concerned.

C. Preparing for the Launch of Zyprexa in Canada

23. At the time we were preparing for global launch of Zyprexa, it was expected that we would launch in Canada. This expectation was based on two facts. First, Canada was a major market for Lilly. Second, the Canadian regulatory framework (both patent and health approval) was well-understood and did not pose any unique challenges.

24. The issue we had in Canada for Zyprexa was pricing. More specifically, in negotiating with the Canadian government regarding the pricing of our products, one issue we faced was convincing the Canadian government that part of the value of innovative pharmaceutical products like Zyprexa is that they lower the costs of the health system overall. However, this issue was a general one that we faced as a company, and was not specific to Zyprexa.

25. By contrast, I do not recall any concerns that we would be unable to protect Zyprexa with a patent in Canada. Specifically, I do not recall any discussions about Zyprexa's "utility" — which I understand to be the ground upon which the Canadian courts later invalidated the patent. Nor do I recall any discussions about the "promise" of the Zyprexa patent, which I understand to be a concept related to utility. I was very surprised to learn when I was asked to provide testimony in this proceeding that utility had become an issue in Canada with respect to our Zyprexa patent.

26. In fact, my recollection is that at the time, Canada was actively seeking investment in the pharmaceutical space from the United States, and that it was holding out its reliable framework for patent protection as a reason why U.S. companies should feel confident investing in Canada. I took two trips to visit our Canadian affiliate during the pre-launch planning for Zyprexa, and I remember that Canada's efforts to attract investment — including its strong framework for patent protection — came up during these visits.

D. The Launch of Zyprexa in Canada and Subsequent Approval of the Canadian Patent Application

27. We received regulatory approval for Zyprexa in the United States and in Canada around the same time, in the fall of 1996. We launched in both countries immediately after receiving approval.

28. The reason we were so eager to launch Zyprexa was because we believed in the drug and knew it could help patients in a very high-risk population. There is a high suicide rate among those with schizophrenia, and we wanted to make Zyprexa available as soon as possible to people we thought it could help. The phrase "the patient is waiting" was a driving principle.

29. When we launched Zyprexa in Canada, our patent application had not yet been granted. At the same time, we did not see any realistic prospect that the patent application would be rejected, particularly when Health Canada had approved Zyprexa as safe and effective. As I have explained, we were very focused on patent protection, and our patent attorneys had not flagged any issues with our Canadian patent application. The fact that no issues were raised gave us confidence that we would receive a patent, which in turn was a key consideration in our decision to proceed with the Canadian launch.

30. As we had predicted, our Canadian patent application was granted in the summer of 1998. Although we had already launched Zyprexa, the granting of the patent application was still an important step. The market exclusivity provided by the patent was critical to succeeding in the market.

E. The Success of the Zyprexa Launch

31. Zyprexa's launch was a major success. Zyprexa quickly became the world's top-selling antipsychotic for the treatment of schizophrenia. Later research also revealed Zyprexa's effectiveness in treating bipolar disorder, a notoriously difficult-to-treat condition.

32. A basic challenge faced by innovative pharmaceutical companies is that we have to study many different compounds to identify a very few with the properties that make them potential medicines. And even for those compounds that are identified as potential medicines, only a handful make it to market. Still fewer have a transformational impact on the treatment of a serious disease. Zyprexa was one of these rare drugs. I feel very fortunate to have done my part in its development.

Signed at Zionsville, Indiana on 9/25/2014

[Signed]
Robert Postlethwait