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 A. ARMITAGE

I. Personal Background

1. My name is Robert Armitage. I am a citizen of the United States and a resident of Marco Island, Florida. I received a Bachelor of Arts in Physics and Mathematics in 1970 from Albion College, a Master's degree in Physics in 1971 from the University of Michigan and a Juris Doctor in 1973 from the University of Michigan Law School.

2. From January 1, 2003, until my retirement on December 31, 2012, I was Senior Vice President and General Counsel of Eli Lilly and Company ("Lilly"). I joined Lilly as Vice President and General Patent Counsel in October 1999. From 1993 to 1999 I was a patent attorney in private practice in Washington, D.C., with the law firm Vinson & Elkins LLP. Prior to that I was chief patent counsel of another multi-national pharmaceutical company, The Upjohn Company, from 1983 to 1993. I own common stock in Lilly that I received under several bonus, incentive and savings plans that the company had established.

3. As Lilly's General Counsel, I had overall supervisory responsibility for the company's patent litigation, particularly the lawsuits that were material to the company's

business, both in the United States and internationally. I also had ultimate responsibility for the work of Lilly's patent professionals, who file for patents on Lilly's behalf in jurisdictions worldwide.

4. Patents today are the lifeblood of Lilly as well as of the research-based biopharma industry as a whole. A large percentage of the market capitalization of research-based biopharma companies, including Lilly, is attributable to the existence of valid and enforceable patents. In my experience, patent challenges by generic firms are common in our industry, but "lack of utility" challenges brought against patents protecting marketed medicines have historically – and for good reason – been all but unknown. Indeed, for medicines that have been approved by regulatory bodies on the basis that they are safe and effective therapies, "inutility" challenges are essentially unheard of outside of Canada. To the best of my knowledge, *successful* challenges of this type are unknown except in the Canadian courts.

5. As General Counsel, I had oversight of Lilly's responses to the cases brought by generic manufacturers in Canada against the Strattera patent (Canadian Patent No. 2,209,735) and the Zyprexa patent (Canadian Patent No. 2,041,113). These patent challenges were, in my view, of material importance to the company, which dictated that I exercise such oversight. My job required that I remain updated on and able to converse fluently about the status of patent challenges with respect to Lilly's commercially significant patents globally. To this end, I received regular reports from the attorneys in my office on litigation risks across Lilly's global patent portfolio, as well as on significant changes to patent law and policy in each of Lilly's major markets. With respect to Zyprexa and Strattera, both medicines have been major commercial successes for Lilly. I am therefore familiar with the general history of both patents, not just in Canada but internationally. I have reviewed company records and other documents to refresh my recollection of certain facts contained in this statement.

6. In addition to my work at Lilly, I have held leadership positions in the intellectual property field. To name just a few examples, while I was Lilly's General Counsel, I served as chair of the Intellectual Property Law Section of the American Bar Association. Prior to joining Lilly, I served as president of the American Intellectual Property Law Association and as president of the Association of Corporate Patent Counsel. I also have served as a member of the Board of Directors of the Intellectual Property Owners Association. Each of these organizations

engages substantively in patent law, patent practice and patent policy issues globally.

7. Even prior to joining Lilly, my work allowed me to become familiar with issues of patent law and patent practice globally. I have prepared hundreds of patent applications and overseen their prosecution globally over most of my 40-year career as a patent professional. Both through my position at Lilly and through my work with a range of intellectual property organizations, I have maintained a general familiarity with the patent laws of non-U.S. jurisdictions, such as Canada. In all countries, inventions must be useful to qualify for patenting. In my experience, the "utility" requirement as applied to new medicines – although expressed in different terminology in different countries – is nonetheless substantially harmonized across jurisdictions. In a nutshell, the "utility" issue never arises with respect to a marketed biopharmaceutical product because the issue of whether a medicine approved for marketing can be put to a specific, practical and credible use simply does not arise. Indeed, generic manufacturers challenge patents on medicines precisely because they work. If the medicines did not work, there would be no market for generic copies. The utility of a drug approved for medicinal use by regulatory agencies based upon large-scale clinical trials is self-evident. This universal tenet of patent law was true even in Canada until relatively recently.

8. Until the Federal Courts of Canada created the "promise utility" doctrine, I fully expected that the utility requirement could not possibly pose an issue for the Strattera and Zyprexa patents, given that both patents disclosed the approved uses for the treatment of specific diseases. Even before these patent applications were filed, Strattera and Zyprexa had already been shown to have utility in human clinical trials.

II. Lilly's Patents for Zyprexa and Strattera

9. Lilly obtained patent protection for Zyprexa and Strattera in dozens of countries around the world. As commonly occurs when Lilly has a commercially successful product on the market and has developed a sizeable market for that new product, Lilly's Zyprexa and Strattera patents were challenged by generic drug firms that hoped to manufacture copied versions of these products.

10. The Zyprexa patent was challenged in 24 jurisdictions, including Canada. It was upheld in virtually every case. The Strattera patent was challenged in 3 jurisdictions, including Canada, and was also uniformly upheld. Across all these countries, Canada was the only one

where utility was even raised as a patent invalidity issue.

A. Zyprexa

11. During my tenure at Lilly, the company held Zyprexa patents equivalent to Canadian Patent No. 2,041,113 (the "'113 Patent") in 81 jurisdictions:[1] Argentina, Australia, Austria, Bahrain, Bangladesh, Belarus, Belgium, Belize, Bermuda, Bolivia, Bosnia-Herzegovina, Botswana, Brazil, Brunei, Bulgaria, Burundi, Canada, the Cayman Islands, China, Cyprus, the Czech Republic, the Democratic Republic of the Congo, Denmark, the Dominican Republic, Ethiopia, the European Patent Convention region, Fiji, Finland, France, Gambia, Georgia, Germany, Great Britain, Greece, Guernsey, the Gulf Cooperation Council region, Guyana, Hong Kong, Hungary, Iran, Ireland, Israel, Italy, Jamaica, Japan, Kazakhstan, South Korea, Kosovo, Kuwait, Latvia, Luxembourg, Mexico, Montenegro, the Netherlands, New Zealand, Norway, Oman, Pakistan, Panama, Paraguay, the Philippines, Portugal, Romania, Russia, Rwanda, Saudi Arabia, Serbia, Sierra Leone, Singapore, the Slovak Republic, Slovenia, South Africa, Spain, Sweden, Switzerland, Taiwan, Trinidad & Tobago, Ukraine, the United Arab Emirates, the United States and Uruguay. Each of these 81 Zyprexa patents was similar to the '113 Patent, with some variation in claim drafting.

12. As is customary with our successful products, Lilly expected that its patent for Zyprexa would be challenged by its generic competitors. With regard to the '113 Patent, we had confidence in the validity of the patent. I know of no one in the company, including the many patent attorneys who reported to me, who considered that this patent might be invalidated on the ground of inutility, either in Canada or anywhere else where the patent had been issued. As a patent lawyer, a utility challenge for a marketed medicine, particularly one previously approved for human use by a regulatory agency that has reviewed extensive clinical trials undertaken with the medicine, is simply absurd. Any attempt to prove that an extensively tested and approved medicine lacks utility is gainsaid by the generic copier's own assertion in its application to market a generic version of the drug that the medicine works for its approved uses.

13. The invalidation of the '113 Patent solely on the grounds of inutility represented a stunning departure from international patenting norms. Frankly, I was dumbfounded with the

[1] A list of Zyprexa patents is attached as Attachment A.

articulation of a legal rule that could make no possible sense and serve no legitimate policy objective. The doctrine was especially egregious as applied to the '113 Patent.

14. Prior to its invalidation, the '113 Patent had survived a challenge in the Federal Court of Canada. One of the largest generic manufacturers, Apotex Inc., had sought approval under the Patented Medicines (Notice of Compliance) ("PM(NOC)") regulations to market a generic version of Zyprexa. This action commenced in 2005. Rejecting the PM(NOC) application in April 2007, Federal Court Justice Gauthier found the '113 Patent valid over allegations of anticipation and obviousness. Apotex did not even raise the issue of utility.

15. While we were defending the Apotex case, a second generic competitor also filed suit under the PM(NOC) regulations. In those proceedings, the generic company, Novopharm, did raise an argument related to inutility. However, that argument was not reached by the court, which accepted Novopharm's invalidity contentions based on other grounds ("insufficiency"). While the court permitted Novopharm to begin marketing "at risk" (i.e., without protection against an infringement action), we remained totally confident in the validity of the '113 Patent over any "insufficiency" attack, and we immediately filed suit to enforce the patent.

16. When the Novopharm trial court judge issued his first ruling in our infringement case, he rejected Novopharm's allegations of obviousness, misrepresentation, and deemed abandonment, finding the patent invalid on the sole ground that it was "not a valid selection patent." Given that this sole ground of invalidity had (and has) no basis in Canadian law, we again felt quite confident the trial judge would be reversed on appeal. Indeed, that is precisely what happened. After the expected reversal was handed down on appeal, we were quite simply incredulous when, on remand, the trial judge invalidated our patent solely on the ground of inutility. It was understandably shocking to us that the Federal Court of Canada could invalidate a patent like the '113 Patent, where its utility-in-fact had been accepted by the Canadian Patent Office, and where that utility was evidenced through a Health Canada approved, commercially successful medicine. Moreover, as disclosed in the patent itself, we had conducted unusually extensive testing on Zyprexa prior to our patent filing, including clinical studies in both healthy volunteers and patients suffering from schizophrenia.

17. By the time the Canadian courts invalidated the '113 Patent on grounds of inutility in 2011, equivalent Zyprexa patents had already withstood validity challenges in

jurisdictions around the world. Our patents on Zyprexa were ultimately challenged in 24 of the 81 jurisdictions where we held a patent. Aside from Canada, our patents were upheld in every one of those 24 jurisdictions except Slovenia and Saudi Arabia. In Slovenia, a single claim was invalidated on novelty grounds. In Saudi Arabia, where Zyprexa was protected by both a Saudi patent and a Gulf Cooperation Council patent, the Saudi patent was struck down on an issue related to the calculation of priority dates. The Gulf Cooperation Council patent, however, remained valid and enforceable in Saudi Arabia.

18. Notably, the utility requirement was not even raised as a validity issue in any jurisdiction other than Canada. Canada was a complete outlier in this respect.

B. Strattera

19. During my tenure at Lilly, the company held Strattera patents equivalent to Canadian Patent No. 2,209,735 (the "'735 Patent") in 36 jurisdictions:[2] Australia, Austria, Belgium, Canada, the Czech Republic, Denmark, the European Patent Convention region, Finland, France, Germany, Great Britain, Greece, Hungary, Ireland, Italy, Jamaica, Latvia, Liechtenstein, Lithuania, Luxembourg, Mexico, the Netherlands, New Zealand, Norway, Poland, Portugal, Romania, Russia, Singapore, Slovenia, Spain, Sweden, Switzerland, Turkey, Ukraine and the United States. Each of these patents claimed priority to the United States filing date through a single PCT application.

20. Lilly did not market Strattera in many of the jurisdictions in which it had patented Zyprexa in part because ADHD, the condition treated by Strattera, was not as widely recognized as a disease or condition in many countries. Typically, in such countries, it would not be covered by health plans. For these reasons, among others, this made the international market for Strattera smaller than the market for Zyprexa.

21. Of the 35 jurisdictions where Lilly has a patent for Strattera, the patent was challenged in just three. The only successful challenge was in Canada.

22. When Canada invalidated the '735 Patent solely on the grounds of inutility in 2010, we found this development outrageous. As with the later Zyprexa ruling, we were

[2] A list of Strattera patents is attached as Attachment B.

convinced the Canadian legal doctrine simply could not be a proper application of any rational patent law. The Canadian Patent Office had granted our patent in 2002 without raising any formal questions or objections about the utility requirement at any stage in the application process. The generic challenger had taken a "kitchen sink" approach to the litigation, alleging lack of novelty and obviousness as well as making a factually inconsistent inutility allegation. While none of these claims should have been found meritorious (and the court rejected the novelty and obviousness challenges), the inutility allegation stood out at the time because of the advanced state of clinical development for Strattera prior to the filing of the '735 Patent. At that time, Lilly had received positive results from a placebo-controlled, double-blind, crossover study of the compound in 22 adult patients with ADHD. The results of that successful study, conducted by doctors at the Massachusetts General Hospital, were later published in a well-known, peer reviewed journal, the *American Journal of Psychiatry*. It was inconceivable to us that the Canadian courts could fairly adjudicate the inutility issue without considering the most salient facts—namely, evidence of utility from a clinical trial conducted at one of the world's best known research hospitals, as well as the views of Health Canada who had approved the drug as safe and effective precisely because it was determined to be useful in treating ADHD.

23. We were also wholly perplexed by the court's reasoning in disregarding the results of the Massachusetts General Hospital study demonstrating Strattera's real world usefulness. The court held that the publication could not be relied on by Lilly to show that the invention had utility as of the date the patent was filed solely because there was no express reference to it in the patent. This again makes no sense – the patent filing contained a complete disclosure of the medicine's usefulness. In addition, peer reviewed clinical work had confirmed that usefulness. The fact of the medicine's usefulness should have been beyond contention. Nonetheless, Canadian courts imposed a non-statutory requirement for confirmatory proof of utility in the patent application itself.

24. The Strattera patent had been filed in Canada using the Patent Cooperation Treaty (PCT) process, which standardizes the form and content requirements for patent applications (including the information that must be disclosed in the patent for it to be valid) and prohibits member countries from imposing any additional requirements as to the content of patent filings. That our patents would be held invalid on the basis that proof of utility was not disclosed in the patent itself was wholly unexpected. Given that Canada is a member country of

the PCT and its Patent Office had adopted the PCT's form and content requirements, we could not have expected that Canadian courts would impose this new and additional requirement.

25. The new requirement (that the underlying proof or evidence supporting utility must be included in the patent itself) operates, moreover, as a retroactive requirement. The requirement was not in place when the patent applications at issue were drafted and granted. Lilly expected that, as a member country of the PCT, Canada would consistently apply the PCT form and content requirements to patent applications filed within Canada, and would not, in any event, retroactively impose a requirement that never previously existed in Canadian law.

26. As with Zyprexa, Strattera's utility was not raised as an issue in any jurisdiction other than Canada.

III. Conclusion

27. Lilly's entire business rests on the ability to secure reliable intellectual property protection for our new medicines. If these new Canadian utility requirements for securing valid patents existed globally, it is difficult for me to imagine any research-based biopharma company sustaining its existence for very long. Simply put, Lilly's new medicines would not exist without reliable patent protection, secured through stable and rational requirements for patentability that the judiciary of Canada – at least in the case of the utility requirement – has abandoned.

28. The Canadian "promise utility" standard has invalidated patents on medicines that are unquestionably useful – medicines that have been approved as safe and effective by Health Canada and have been prescribed millions of times.

Signed at Framingham, MA (U.S.A.) on September 27, 2014.

[Signed]
Robert A. Armitage

Attachment A

Zyprexa Patents

as of August 1, 2014

	Country	Patent or Application No.	Validity Challenge?	Utility Challenge?	Invalidation?
1	Argentina	319518	-	-	-
2	Australia	75186/91	Yes	No	No
3	Austria	913036779.4	Yes	No	No
4	Bahrain	962/95	-	-	-
5	Bangladesh	115/95	-	-	-
6	Belarus	2191-01	-	-	-
7	Belgium	91303679.4	-	-	-
8	Belize	88/295/2002	-	-	-
9	Bermuda	170	-	-	-
10	Bolivia	236	-	-	-
11	Bosnia-Herzegovina	BAP 98313A	-	-	-
12	Botswana	98/00081	-	-	-
13	Brazil	PI1100012-0	-	-	-
14	Brunei	18/98	-	-	-
15	Bulgaria	98434	Yes	No	No
16	Burundi	196/BUR	-	-	-
17	Canada	2041113-9	Yes	Yes	Yes
18	Cayman Islands	0454436	-	-	-
19	China P.R.	91103346.7	Yes	No	No
20	Cyprus	1900	-	-	-
21	Czech Republic	PV1168-91	Yes	No	No
22	Democratic Republic of Congo	NP/21/EXT/98	-	-	-
23	Denmark	91303679.4	-	-	-
24	Dominican Republic	376	-	-	-
25	Ethiopia	ET/PT/03/00028	-	-	-
26	European Patent Convention	91303679.4	-	-	-
27	Fiji	837	-	-	-
28	Finland	911986	Yes	No	No
29	France	91303679.4	-	-	-
30	Gambia	9/1998	-	-	-
31	Georgia	3621/01	-	-	-
32	Germany	91303679.4	Yes	No	No
33	Great Britain	91303679.4	Yes	No	No
34	Greece	91303679.4	Yes	No	No
35	Guernsey	EP0454436B1	-	-	-
36	Gulf	GCC/P/2000/795	-	-	-

Zyprexa Patents
as of August 1, 2014

	Cooperation Council				
37	Guyana	1364	-	-	-
38	Hong Kong	95001947	-	-	-
39	Hungary	P/P00335	Yes	No	No
40	Iran	28850	-	-	-
41	Ireland	1348/91	-	-	-
42	Israel	112575	-	-	-
43	Italy	91303679.4	-	-	-
44	Jamaica	18/1/3654	-	-	-
45	Japan	03-228215	-	-	-
46	Kazakhstan	0277/N-96	-	-	-
47	Korea (South)	91-6544	Yes	No	No
48	Kosovo	644	-	-	-
49	Kuwait	GCC/P/2000/795	-	-	-
50	Latvia	P-93-517	-	-	-
51	Luxembourg	91303679.4	-	-	-
52	Mexico	25502	-	-	-
53	Montenegro	P-739/91	-	-	-
54	Netherlands	91303679.4	Yes	No	No
55	New Zealand	237932	-	-	-
56	Norway	P911624	Yes	No	No
57	Oman	GCC/P/2000/795	-	-	-
58	Pakistan	132683	Yes	No	No
59	Panama	079775	-	-	-
60	Paraguay	01467	-	-	-
61	Philippines	42340	-	-	-
62	Portugal	97446	Yes	No	No
63	Republic of Serbia	P-739/91	-	-	-
64	Romania	98-20258	Yes	No	No
65	Russian Federation	5052762.04	Yes	No	No
66	Rwanda	64/ARK	-	-	-
67	Saudi Arabia	95160196	Yes	No	Yes[1]
68	Sierra Leone	232	-	-	-
69	Singapore	9690001-4	-	-	-
70	Slovak Republic	1168/91	Yes	No	No

[1] The Saudi patent was struck down on an issue related to the calculation of priority dates under local legislation implementing the mailbox rule under the TRIPS agreement. The Gulf Cooperation Council patent (line 36) remained valid and enforceable in Saudi Arabia.

Zyprexa Patents
as of August 1, 2014

71	Slovenia	P9110739	Yes	No	Yes[2]
72	South Africa	91/3085	-	-	-
73	Spain	91303679.4	Yes	No	No
74	Sweden	91303679.4	-	-	-
75	Switzerland	91303679.4	-	-	-
76	Taiwan	80105565	-	-	-
77	Trinidad & Tobago	960002	-	-	-
78	Ukraine	93002818	Yes	No	No
79	United Arab Emirates	GCC/P/2000/795	-	-	-
80	United States	07/890348	Yes	No	No
81	Uruguay	24247	-	-	-

[2] Invalidated on novelty grounds.

Attachment B

Strattera Patents

as of August 1, 2014

	Country	Patent or Application No.	Validity Challenge?	Utility Challenge?	Invalidation
1	**Australia**	688665	-	-	-
2	**Austria**	E222757	-	-	-
3	**Belgium**	0721777	-	-	-
4	**Canada**	2209735	Yes	Yes	Yes
5	**Czech Republic**	292226	-	-	-
6	**Denmark**	0721777	Yes	No	No
7	**European Patent Convention**	0721777	-	-	-
8	**Finland**	119354	-	-	-
9	**France**	0721777	-	-	-
10	**Germany**	69623141.7	-	-	-
11	**Great Britain**	0721777	-	-	-
12	**Greece**	0721777	-	-	-
13	**Hungary**	227306	-	-	-
14	**Ireland**	0721777	-	-	-
15	**Italy**	0721777	-	-	-
16	**Jamaica**	3616	-	-	-
17	**Latvia**	0721777	-	-	-
18	**Liechtenstein**	0721777	-	-	-
19	**Lithuania**	0721777	-	-	-
20	**Luxembourg**	0721777	-	-	-
21	**Mexico**	202275	-	-	-
22	**Netherlands**	0721777	-	-	-
23	**New Zealand**	301500	-	-	-
24	**Norway**	317027	-	-	-
25	**Poland**	187573	-	-	-
26	**Portugal**	0721777	-	-	-
27	**Romania**	118374	-	-	-
28	**Russian Federation**	2163802	-	-	-
29	**Singapore**	49532	-	-	-
30	**Slovenia**	0721777	-	-	-
31	**Spain**	0721777	-	-	-
32	**Sweden**	0721777	-	-	-
33	**Switzerland**	0721777	-	-	-
34	**Turkey**	TR199700627B	-	-	-
35	**Ukraine**	43385	-	-	-
36	**United States**	5658590	Yes	No	No