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

ELI LILLY AND COMPANY

Claimant

v.

GOVERNMENT OF CANADA

Respondent

NOTICE OF ARBITRATION

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Claimant Eli Lilly and Company ("Lilly"), on its own behalf and on behalf of its enterprise Eli Lilly Canada Inc. ("Lilly Canada"), hereby demands that the following dispute against the Government of Canada be submitted to arbitration pursuant to Article 3 of the Arbitration Rules of the United Nations Commission on International Trade Law ("UNCITRAL") and Articles 1116, 1117, and 1120 of the North American Free Trade Agreement ("NAFTA").

I. OVERVIEW

1. The innovative pharmaceutical sector relies upon patent protection as the cornerstone of bringing innovative medicines to market. Patent protection and the accompanying guarantee of market exclusivity provide a critical economic incentive to invest in drug development. Bringing an innovative medicine to market today involves an average investment of $1 billion or more. Not every patented pharmaceutical invention results in a commercially and medically successful product. To the contrary, many inventions never make it past initial testing stages in the laboratory. As a result of this development lifecycle for the typical pharmaceutical, and the additional need for health regulatory approval before a medicine may be marketed to patients, an innovative pharmaceutical typically comes on the market many years after the initial patent application is filed.

2. Lilly is a global pharmaceutical company whose lifeblood is intellectual property protection for innovation. In the 1990s, Canada granted patents protecting Lilly's pharmaceutical products, Strattera and Zyprexa. These medicines treat attention-deficit hyperactivity disorder ("ADHD"), and schizophrenia and related psychotic disorders, respectively. Both medicines have been approved by Health Canada as safe and effective. Strattera and Zyprexa are used by hundreds of thousands of patients in Canada and are commercially successful products.

3. The NAFTA Parties resolved to "ensure a predictable commercial framework for business planning and investment" and to "foster creativity and innovation, and promote trade in goods that are the subject of intellectual property rights." (NAFTA Preamble). The Parties further highlighted the importance of a strong and predictable environment for intellectual property, stating explicitly that one of the objectives of NAFTA is to "provide adequate and effective protection and enforcement of intellectual property rights in each Party's territory[.]" (*Id.* Article 102(1)(d)). Canada has taken away Lilly's patent rights by applying a unique "promise utility doctrine," described more fully below. In so doing, Canada has undermined the agreed upon objectives of NAFTA and breached its investment obligations to Lilly under NAFTA Chapter 11.

4. Canadian courts have invalidated Lilly's Strattera and Zyprexa patents on the ground that they were not "useful." This occurred notwithstanding that Strattera and Zyprexa were approved as safe and effective by Health Canada and were used by hundreds of thousands of patients in Canada, and despite the fact that Lilly's competitors sought to replicate Lilly's commercial success by selling copies of the very same medicines. Canada's "promise utility doctrine," applied by Canadian courts to invalidate the Strattera and Zyprexa patents, is contrary to Canada's treaty obligations to protect patent rights and has resulted in the unlawful expropriation of Lilly's intellectual property. The retroactive, arbitrary, and discriminatory application of the promise utility doctrine to Lilly's patents also contravenes the minimum standard of treatment owed to Lilly as an investor in Canada.

(a) NAFTA's Patent Obligations

5. NAFTA Chapter 17 sets forth obligations related to intellectual property protection that create a common baseline of substantive patent protection in all three NAFTA countries.

Canada has committed to "provide in its territory to the nationals of another Party adequate and effective protection and enforcement of intellectual property rights, while ensuring that measures to enforce intellectual property rights do not themselves become barriers to legitimate trade." (*Id*. NAFTA Article 1701(1)). Canada is required to grant patents for inventions that "are new, result from an inventive step and are capable of industrial application." (*Id*. NAFTA Article 1709(1)). Further, such "patents shall be available and patent rights enjoyable without discrimination as to field of technology" and Canada may only revoke a patent on grounds that would have justified a refusal to grant the patent in the first instance. (*Id.* Article 1709(7) & (8)).

6. Canada has failed to abide by these obligations, and that failure, along with other conduct, has resulted in the unlawful expropriation of Claimant's investments under NAFTA Article 1110 and a violation of the minimum standard of treatment mandated by NAFTA Article 1105.

7. Specifically at issue here is the requirement that inventions be "capable of industrial application." This concept, synonymous with the term "useful" in the Canadian *Patent Act* and often referred to as the "utility" requirement, is normally easily met by pharmaceutical inventions, which are capable of industrial applicability in that they treat illness and disease.

8. Canada's *Manual of Patent Office Practice* ("MOPOP" or "Patent Office Manual") in effect in 1994 when NAFTA entered into force articulated this patent utility requirement in the following way:

> Section 2 of the [Patent] Act requires utility as an essential feature of the invention. If an invention is <u>totally useless</u>, the purposes and objects of the grant would fail and such grant would consequently be void on the

> grounds of false suggestion, failure of consideration and having tendency to hinder progress.

(MOPOP § 12.02.01, Jan. 1990) (Emphasis added). Canada's approach at that time reflected the utility standard adopted by Canada's NAFTA partners, which focused on industrial applicability.

9. Since 2005, there has been a dramatic and unanticipated shift in Canada's utility standard. Specifically, the judiciary in Canada has created a new doctrine to assess whether an invention meets the condition of being "useful" or "capable of industrial application." The doctrine, referred to herein as the "promise doctrine" or "promise utility doctrine," is inconsistent with the utility standard embodied in NAFTA Chapter 17, is significantly out of step with the law of utility in Canada's NAFTA partners, and is a dramatic departure from the standard in Canada when the Zyprexa and Strattera patents were filed and granted.

(b) Canada's Promise Utility Doctrine

10. Canada's promise utility doctrine has three related aspects: (1) an arbitrary and unpredictable approach whereby a judge subjectively construes the "promise of the patent" from the patent specification; (2) a heightened evidentiary standard for proof of utility, which requires that the promised utility either be "demonstrated" or be based on a "sound prediction" of utility as of the date the patent application was filed; and (3) with regard to "sound prediction," a heightened disclosure requirement whereby evidence establishing a "factual basis" and "sound line of reasoning" for the predicted utility must have been disclosed in the original patent application. This promise doctrine was not the test for whether an invention was "capable of industrial application" when Lilly applied

for the Strattera and Zyprexa patents or when the Canadian Intellectual Property Office thoroughly examined and issued these patents.

11. The promise doctrine has led to absurd results, not only for Strattera and Zyprexa, but for other pharmaceuticals as well. Under this doctrine, medicines approved as safe and effective by Health Canada for use in Canada, and that are in fact used by hundreds of thousands of patients in Canada, are determined by the Canadian courts to lack usefulness or utility. Since the advent of the promise doctrine, 18 pharmaceutical patents have been invalidated for lack of utility in Canada. In the prior 25 years, only two pharmaceutical patents were invalidated for lack of utility, and those were invalidated under a traditional utility test (*i.e.*, the claimed invention was devoid of utility in fact). Significantly, every patent invalidated since 2005 for lack of utility has been a pharmaceutical invention.[1]

12. Canada's adoption of the promise doctrine was a watershed event in the development of Canada's intellectual property regime. Not only is Canada applying a utility test that violates the standard required under NAFTA, it is also applying the utility test in a way that discriminates against pharmaceuticals as a field of technology. This itself contravenes Canada's obligation under NAFTA Article 1709(7) to make patents available and patent rights enjoyable without discrimination.

13. Canada's violation of its obligations under NAFTA Chapter 17 support Lilly's NAFTA Chapter 11 claims.[2] Through the promise doctrine, its discriminatory application, and

[1] Since 2005, there has been only one case outside the pharmaceutical sector in which claims in a challenged patent were found to lack utility. In that case, the patent as a whole was upheld as valid based on the utility of one of its claims. *See Eurocopter v. Bell Helicopter Textron Canada Ltd*., 2012 F.C. 113, ¶¶ 367-372.

[2] Consistent with the Free Trade Commission Notes of Interpretation of Certain Chapter 11 Provisions of July 31, 2001, a breach of NAFTA Chapter 17 does not, alone, establish a breach of Article 1105(1).

other measures, Canada has expropriated Claimant's investments, including in particular its patent rights in both Strattera and Zyprexa, and has failed to provide Lilly with fair and equitable treatment as required under NAFTA Article 1105. Canada has paid no compensation for these breaches of its international obligations, and Claimant is entitled to full compensation under NAFTA Chapter 11 and customary international law for the damages caused by Canada's actions.

II. PARTIES TO THE DISPUTE

14. The Claimant is a United States company duly incorporated under the laws of the state of Indiana. The Claimant's principal place of business is:

Eli Lilly and Company
Lilly Corporate Center
Indianapolis, Indiana 46205
U.S.A.

15. Correspondence to Lilly should be served upon counsel at the addresses listed below:

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16. Lilly Canada is an enterprise of Canada and is indirectly owned and controlled by Lilly. The principal place of business of Lilly Canada is:

Eli Lilly Canada Inc.
3650 Danforth Avenue
Toronto, Ontario
Canada M1N 2E8.

17. Canada is a sovereign state and a party to NAFTA. Pursuant to NAFTA Article 1137(2) and Annex 1137.2, delivery of notices and documents to the Government of Canada should be made to the following address:

Office of the Deputy Attorney General of Canada
284 Wellington Street
Ottawa, Ontario
Canada K1A 0H8.

III. ARBITRATION AGREEMENT AND CONSENT TO JURISDICTION

18. Claimant brings this dispute pursuant to NAFTA Articles 1116, 1117, and 1120. Pursuant to NAFTA Article 1122, both Claimant and Respondent have consented in writing to submit this dispute to arbitration. Respondent expressed its consent in NAFTA Article 1122(1). Claimant has expressed its consent in its Notice of Intent to Submit a Claim to Arbitration described below and ratifies its consent in writing by filing this Notice of Arbitration. Executed consents by Lilly and Lilly Canada are attached to this Notice of Arbitration as Annex A.

19. Pursuant to NAFTA Article 1119, Claimant delivered a Notice of Intent to Submit a Claim to Arbitration to Canada with regard to the Strattera patent on November 7, 2012. A second Notice of Intent to Submit a Claim to Arbitration was delivered to Canada with regard to both the Strattera and Zyprexa patents on June 13, 2013. Both Notices of Intent raised identical claims, but the second Notice of Intent added the Zyprexa patent to the complaint. Claimant later withdrew its Strattera-only Notice of Intent in reliance on

Canada's representation that it would not raise any jurisdictional or other preliminary objection specifically relating to the withdrawal.[3] The parties consulted on the matters herein on several occasions and were unable to resolve this dispute.

20. Actions challenging both the Strattera and Zyprexa patents have run their course in the Canadian courts. Canadian company Novopharm challenged the Strattera patent in an action filed on May 22, 2008, before the Federal Court, alleging that the patent was invalid on a number of grounds, including inutility. The Federal Court trial judge invalidated the Strattera patent on the sole ground of inutility on September 14, 2010. With regard to Zyprexa, Claimant filed an infringement action against Novopharm on June 6, 2007. Novopharm alleged that the patent was invalid on a number of grounds. After an initial decision that focused on other issues was appealed and remanded, the Federal Court trial judge invalidated the Zyprexa patent on the sole ground of inutility on November 10, 2011.

21. Both trial court decisions were unsuccessfully appealed to the Federal Court of Appeal, and the Supreme Court of Canada denied leave to hear Claimant's further appeals with regard to the Strattera patent on December 8, 2011, and the Zyprexa patent on May 16, 2013.

22. No more than three years has lapsed since Claimant first acquired knowledge of the alleged breach and knowledge that Claimant had incurred loss or damage, and more than six months has passed since the events giving rise to the claims herein. As such, the claim is within the limitations periods in NAFTA Articles 1116(2) and 1117(2), and the six-month period in NAFTA Article 1120(1) has run.

[3] *See* Letter dated July 9, 2013, to Richard G. Dearden from Sylvie Tabet, General Counsel and Director, Trade Law Bureau, Department of Foreign Affairs and International Trade.

23. Pursuant to Article 1120(1)(c) of NAFTA, Lilly refers this dispute to arbitration under the UNCITRAL Arbitration Rules. Pursuant to NAFTA Article 1121, Lilly and Lilly Canada waive their right to initiate or continue before any administrative tribunal or court under the law of any Party to the NAFTA, or other dispute settlement procedures, any proceedings with respect to the measures alleged to be a breach referred to in Articles 1116 or 1117, except for proceedings for injunctive, declaratory or other extraordinary relief, not involving the payment of damages, before an administrative tribunal or court under the laws of Canada. Lilly and Lilly Canada have executed these waivers, attached as Annex A.

IV. SUMMARY OF FACTS GIVING RISE TO THE CLAIM[4]

(a) The Patent Rights at Issue

24. Under Canada's *Patent Act*, a patent confers on the patent owner "the exclusive right, privilege and liberty of making, constructing and using the invention and selling it to others to be used." (*Patent Act*, R.S.C. 1985, c P-4, § 42). According to the Supreme Court of Canada:

> the granting of a patent means the kind of contract between the Crown and the inventor in which the latter receives an exclusive right to exploit his invention for a certain period in exchange for complete disclosure to the public of the invention and the way it operates.[5]

25. There are two patents at issue in this case. The '735 patent relating to the drug Strattera ("Strattera patent") was filed in Canada on January 4, 1996, and would have expired on

[4] This is a general and abbreviated description of the relevant facts in this dispute. Claimant will present a full statement of facts and law, as well as supporting evidence, at the appropriate stages of this proceeding.

[5] *Pioneer Hi-Bred Ltd. v. Canada (Comm'r of Patents)*, [1989] 1 S.C.R. 1623.

January 4, 2016.[6] The patent claims the use of the compound atomoxetine for treating ADHD in adults, adolescents, and children. ADHD is a serious psychiatric disorder characterized by significant difficulties with attention, impulsivity, and excessive activity, existing to such an extent that they impair a patient's ability to function in everyday settings and activities. Not only is it debilitating to those suffering from the disorder, it is also taxing on family members, educators, and friends. Its pathology is complicated, involving multiple neurotransmitters including dopamine, norepinephrine, and serotonin. Even today, the etiology, or cause, of ADHD remains unknown. Prior to the '735 invention, physicians had limited treatment options. The only approved treatments were stimulants, which were first used to treat ADHD in the 1930s. Stimulants, however, are known to cause significant side effects and are ineffective in about 25-30 percent of patients. Atomoxetine was the first non-stimulant approved for the treatment of ADHD in Canada.

26. On December 24, 2004, Strattera was deemed safe and effective and approved for use in Canada by Health Canada. Strattera is commercially successful and used by hundreds of thousands of patients in Canada.

27. The '113 patent relating to the drug Zyprexa ("Zyprexa patent") was filed in Canada on April 24, 1991, and would have expired on April 24, 2011.[7] The Zyprexa patent claims the use of the compound olanzapine for the short- and long-term treatment of schizophrenia and related psychotic disorders, and for the short-term treatment of manic or mixed episodes in bipolar I disorder. It is a second-generation antipsychotic that

[6] Claimant is the owner (patentee) of the '735 patent relating to Strattera.

[7] Claimant's wholly-owned subsidiary, Eli Lilly and Company Limited (U.K.), is the owner (patentee) of the '113 patent relating to Zyprexa.

exhibits a low incidence of side effects (*e.g.*, involuntary twitching and painful body distortions) that were associated with first-generation antipsychotics. On October 28, 1996, Zyprexa was approved as safe and effective for use in Canada by Health Canada. Zyprexa is commercially successful and used by hundreds of thousands of patients in Canada. Zyprexa fundamentally changed the treatment of a devastating disease.

(b) The Law On Utility in the 1990s

(1) Canada

28. Under the Canadian *Patent Act*, patents are granted to all inventions that are new, non-obvious, and useful. The "useful," or utility, requirement is embodied within the definition of "invention" in section 2 of the *Patent Act*, which provides:

> "invention" means any new and useful art, process, machine, manufacture or composition of matter, or any new and useful improvement in any art, process, machine, manufacture or composition of matter.

29. At the time NAFTA entered into force in 1994, the Canadian Patent Office Manual explained: "[U]tility [is] an essential feature of invention. If an invention is totally useless, the purposes and objects of the [patent] grant would fail and such [patent] grant would consequently be void . . . ." (MOPOP § 12.02.01, Jan. 1990). The Manual further explained that "[u]tility, as related to inventions, means industrial value." (*Id.* § 12.03). Read together, as long as an invention had some industrial purpose and was not inoperable, the invention satisfied the utility requirement.

(2) Other NAFTA Parties

a) United States

30. Utility was defined similarly in the United States and was accepted as an uncontroversial requirement, easily met, including in the pharmaceutical sector. In the United States, an

invention must have specific, substantial, and credible utility. (MPEP § 2107 (6th ed., rev. 1 Sept. 1995). In order to show specific utility, a pharmaceutical patent must simply disclose a specific condition against which the invention is useful. With regard to whether the disclosed use is credible, proof of pharmacological activity (even in a petri dish) constitutes a showing of credible utility. There also must be an assertion of a substantial (*i.e.*, practical), non-frivolous use. Only one assertion of specific and substantial utility must be deemed credible in order to meet the utility requirement. In other words, an invention must be operable for "at least one stated objective." (*See* MPEP § 2107.01, 7th ed., July 1998 (noting that "an applicant need only make one credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. 101")).

31. The U.S. Court of Appeals for the Federal Circuit, in the 1995 case *In re Brana*, explained:

> Usefulness in patent law, and in particular in the context of pharmaceutical inventions, necessarily includes the expectation of further research and development. The stage at which an invention in this field becomes useful is well before it is ready to be administered to humans. Were we to require Phase II testing in order to prove utility, the associated costs would prevent many companies from obtaining patent protection on promising new inventions, thereby eliminating an incentive to pursue, through research and development, potential cures in many crucial areas such as the treatment of cancer.[8]

32. The 1998 U.S. Patent Examination Manual stated that "[a] small degree of utility is sufficient," emphasizing that "the defense of non-utility cannot be sustained without proof of total incapacity." (MPEP § 2107.01, 7th ed., July 1998).

[8] *In re Brana*, 51 F.3d 1560, 1568 (Fed. Cir. 1995).

b) Mexico

33. In Mexico, under Mexico's Law of Industrial Property (*Ley de la Propiedad Industrial*), an invention that is novel, results from an inventive activity, and is "susceptible of industrial application" is eligible to receive patent protection. For an invention to qualify as "susceptible of industrial application," there must be a possibility that the invention has a practical utility or can be produced or used in any economic activity for purposes described in the application. Under Article 12 of the Law, "Industrial application" is defined as "the possibility that an invention may have a practical utility or can be produced or used in any branch of economic activity, for the purposes described in the patent application."

(c) Canada's Unique Promise Doctrine

34. Years after NAFTA was implemented and the examination and issuance of both the Strattera and Zyprexa patents under laws that existed in the 1990s, the Canadian Federal Courts created a new common law doctrine to assess whether an invention meets the utility criterion. The promise doctrine could not possibly have been anticipated when the Strattera and Zyprexa patents were granted by Canada. Yet it has been applied by the Federal Courts to invalidate numerous pharmaceutical patents as not "useful," even for medicines that have been approved by Health Canada as safe and effective and are undeniably useful in fact.

35. Under the promise doctrine, the utility of an invention is assessed subjectively against the "promise" that is derived by the courts from the patent specification. If the patent application is said to contain a promise, the patentee must then prove that it had "demonstrated" or "soundly predicted" this promised utility as of the date of filing its patent application. Where "sound prediction" is relied on to establish utility, the courts

have imposed additional disclosure obligations that require the patentee to have disclosed within the patent application evidence of the "factual basis" and "sound line of reasoning" for the predicted utility.

36. Thus, the promise doctrine presents three hurdles to fulfill the utility requirement to obtain a patent in Canada. In the first instance, a judge subjectively construes the "promise of the patent." Second, a heightened evidentiary standard for proof of utility is applied, which requires that the "promised" utility either be "demonstrated" by the patentee or be based on a "sound prediction" of utility as of the date of filing. Third, with regard to "sound prediction," a heightened disclosure requirement mandates that evidence establishing utility must have been disclosed in the original patent application.

37. With regard to the first element, a court looks to the patent specification to construe the patent's "promise." The patentee's intentions as expressed in the claims of the patent are not necessarily controlling. For example, part of the specification may describe the advantages observed by the inventor of a claimed compound over the prior art in terms of side effects. Contrary to the patentee's intentions, those observed advantages may become part of the "promise" against which utility is measured.

38. Regarding the second element, the court's broad and often unpredictable reading of the patent's "promised" utility serves as the basis for evaluating evidence as to whether utility was "demonstrated" as of the date of filing or, alternatively, whether the patent application made a "sound prediction" of the promised utility. Where "sound prediction" is relied on to show utility, the question before the court is whether the promise of the patent as found by the court is supported by a factual basis, and by a sound line of reasoning from the factual basis to the promise, at the time of filing. Canadian courts

often scrutinize the pre-clinical or clinical trials conducted before the patent application filing date in evaluating whether the patentee demonstrated or soundly predicted utility. In Canada, even completed human clinical trials have been deemed insufficient to demonstrate or even soundly predict utility.

39. As for the third element, where the patentee has not "demonstrated" the promised utility as of the date of filing, there is a heightened evidentiary requirement whereby the patentee must have disclosed within the patent application sufficient factual evidence to support a "sound prediction" of the promised utility. The disclosure must include adequate support for both the factual basis of the predicted utility and the line of reasoning from which the predicted result can be inferred. The effect of this requirement is that evidence that was not originally included in the patent application cannot be relied upon to substantiate the soundness of a prediction, and any clinical trials or other evidence not expressly stated in the patent specification, whether concluded before or after the patent filing date, are excluded from the analysis.

(d) Canada's International Obligations With Regard to Pharmaceutical Patents

(1) North American Free Trade Agreement

40. NAFTA Chapter 17 sets forth substantive intellectual property obligations binding on Canada. NAFTA, which entered into force on January 1, 1994, requires Canada to grant patents for inventions, in all fields of technology, that "are new, result from an inventive step and are capable of industrial application." (NAFTA Article 1709(1)). At issue here is the requirement that inventions be "capable of industrial application." NAFTA states that this concept of "capable of industrial application" is synonymous with the patent term-of-art "useful." It is the term "useful" that appears in the Canadian *Patent Act*. The concept is often referred to generally as a "utility" requirement. When the United States,

Canada, and Mexico agreed to substantive intellectual property obligations under NAFTA, they did so with a shared understanding of the patentability criteria mandated by NAFTA Article 1709(1).

41. NAFTA also requires that "patents shall be available and patent rights enjoyable without discrimination as to field of technology" (NAFTA Article 1709(7)), and that Canada "may revoke a patent only when: (a) grounds exist that would have justified a refusal to grant the patent" (NAFTA Article 1709(8)).

42. The utility test and anti-discrimination mandate embodied in NAFTA are also enshrined in the World Trade Organization Agreement on Trade-Related Aspects of Intellectual Property Rights ("TRIPS Agreement"), concluded in 1994.[9] This is to be expected, since NAFTA Article 1709 was based on a December 1991 draft of the TRIPS Agreement.[10]

43. NAFTA Chapter 17 also includes an overarching obligation to provide "adequate and effective protection and enforcement of intellectual property rights, while ensuring that measures to enforce intellectual property rights do not themselves become barriers to legitimate trade." (NAFTA Article 1701(1)).

(2) Patent Cooperation Treaty

44. The *Patent Cooperation Treaty* ("PCT") permits investors to seek patent protection simultaneously in a large number of countries by filing an international patent application. The PCT harmonizes the requirements for international applications so that such applications will have the same effect as a national application in each member

[9] *See* Annex 1C of the Marrakesh Agreement establishing the World Trade Organization, signed in Marrakesh, Morocco on April 15, 1994, 1869 U.N.T.S. 299; 33 I.L.M. 1197 (1994).

[10] *See* Panel Report, *Canada – Patent Protection of Pharmaceutical Products*, Doc. WT/DS114/R (March 17, 2000), ¶ 4.6 & n.29.

country in which protection is sought. The PCT entered into force in 1970 and Canada became a member of the PCT on January 2, 1990.

45. Canada, as a member of the PCT, is prohibited from imposing "requirements as to the form or contents of the international application different from or additional to" those that are provided for in the PCT, as this would defeat the single application objective. (PCT Article 27(1)). Pursuant to Article 27(4) of the PCT, applicants that file patents using an international application are entitled to insist before the courts of member countries that the form and content requirements provided for by the PCT and its Regulations be applied to their international application.

46. Patent disclosure obligations are a matter of form and content to which the PCT applies, with the effect that the PCT prohibits member countries from imposing more onerous disclosure requirements than those required by the PCT. The basic disclosure obligation as set out in PCT Article 5 is to "disclose the invention in a manner sufficiently clear and complete for the invention to be carried out by a person skilled in the art." As regards the disclosure of utility, the PCT Regulations provide that the description shall:

> indicate explicitly, when it is not obvious from the description or nature of the invention, the way in which the invention is capable of exploitation in industry and the way in which it can be made and used, or, if it can only be used, the way in which it can be used . . . .

(Rule 5.1(a)(iv)).

47. The PCT form and content requirements relating to utility do not require disclosure in the patent application of data or other evidence to support the utility of the invention. While national patent authorities can request such evidence during their examination, it is not a required part of the international application.

(e) Invalidation of the Strattera and Zyprexa Patents Through the Retroactive Application of the Promise Doctrine

48. The arbitrary and subjective nature of Canada's promise doctrine is perhaps best explained by looking at the Strattera and Zyprexa patents themselves.

(1) Strattera Patent

49. Strattera (atomoxetine) is a non-stimulant medication that functions to enhance the availability of norepinephrine, a neurotransmitter that plays a significant role in attention and focus. Its claimed utility is a method of treating ADHD, comprising administration of an effective amount of the medicine to a patient in need of such treatment. The Strattera patent disclosed the way in which atomoxetine could be used in the treatment of ADHD.

50. In support of the claimed utility for Strattera, Lilly relied on a Massachusetts General Hospital ("MGH") study, a seven-week placebo controlled, double-blind, cross-over pilot study involving 22 adult patients with ADHD. The results of the study, obtained after the filing of the PCT international patent application but prior to the filing of the Canadian patent application, showed a positive and statistically significant response for atomoxetine over a placebo that met the predetermined standard set by evaluators. These results were published in a prestigious peer-reviewed journal and accepted by Health Canada in the dossier leading to the approval of atomoxetine, although they were not disclosed in the Canadian patent application.

51. In a September 14, 2010, decision, the Federal Court held:

> [U]tility is assessed against the inventive promise of the patent. . . . An invention is only useful if it does what the inventor claims it will do. In this case the requirement of utility would be met if, at the Canadian filing date of the '735 Patent, there was sufficient evidence that atomoxetine was

> clinically useful in treating some patients with ADHD or, alternatively, that such efficacy could be soundly predicted.[11]

52. The court then read into the Strattera patent an implied promise (*i.e.*, a promise that was not claimed or stated anywhere within the patent specification), based on the nature of ADHD as a chronic condition: "[T]he inventors claimed a new use for atomoxetine to effectively treat humans with ADHD. What is implicit in this promise is that atomoxetine will work in the longer term."[12] In the view of the court, to meet the utility requirement, Lilly would have had to demonstrate or soundly predict the clinical effectiveness of atomoxetine for long-term treatment of ADHD at the date of the filing of the patent application. This "implied" promise was construed from the patent notwithstanding the fact that Strattera is indicated – and approved by Health Canada – for short-term treatment of ADHD, in addition to extended treatment.

53. The trial judge held that the utility of atomoxetine for the "long-term treatment of ADHD" had not been "demonstrated" by the MGH study, since it was a "clinical trial that was too small in size and too short in duration to provide anything more than interesting but inconclusive data."[13] The court stated that in some cases, evidence such as the MGH study might provide a basis for a sound prediction of utility, but held that Lilly was unable to rely on the doctrine of sound prediction because Lilly did not disclose the MGH study within the patent application itself, and that "[i]n a case involving a claimed sound prediction of utility, it is . . . beyond debate that an additional disclosure obligation arises."[14] That atomoxetine had been approved by Health Canada as safe and effective

[11] *Novopharm Ltd. v. Eli Lilly & Co.*, 2010 FC 915, ¶ 93.

[12] *Id.*, ¶ 112.

[13] *Id.*, ¶ 113.

[14] *Id.*, ¶ 117.

and had been used by hundreds of thousands of patients in Canada was irrelevant to the court's utility analysis.

54. In a decision rendered on July 5, 2011, the Federal Court of Appeal dismissed Lilly's appeal. Lilly applied for leave to the Supreme Court of Canada. That application for leave to appeal was denied on December 8, 2011, thereby exhausting all domestic appeals regarding the Strattera patent. In stark contrast, the Strattera patent was upheld by the U.S. Court of Appeals for the Federal Circuit. In the United States, the question arose in the context of whether the patent application adequately taught "how to use" the invention rather than utility in fact, which was not in dispute.[15] The U.S. patent application contained identical disclosures to the Canadian patent; however, as of the date of filing the U.S. patent, the MGH study had been initiated but not completed. The U.S. Court of Appeals noted that the patent claimed a practical utility for the invention, namely the treatment of ADHD. The asserted utility was not so incredible as to require additional evidence. The U.S. Court held:

> The utility of this product to treat ADHD is not so incredible as to warrant the special procedures that are authorized for use when the examiner doubts the described utility, as in *In re Swartz*, 232 F.3d 862 (Fed. Cir. 2000) (cold fusion); *Newman v. Quigg*, 877 F.2d 1575, *modified* 886 F.2d 329 (Fed. Cir. 1989) (perpetual motion); and for subject matter in once notoriously intractable areas such as cures for baldness or cancer.[16]

55. The U.S. Court of Appeals further emphasized that the mere initiation of a clinical trial justifies presumptive utility, explaining:

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[15] "The defendants do not dispute that the '590 patent describes the utility of [atomoxetine] for treatment of ADHD, and that the utility is correctly described." *Eli Lilly & Co. v. Actavis Elizabeth LLC*, 435 F. App'x 917, 923 (Fed. Cir. 2011)

[16] *Id.* at 924.

> The Manual of Patent Examining Procedures instructs examiners to give presumptive weight to the utility for which human trials have been initiated:
>
> > MPEP § 2107.03 (8th ed. 2008). IV . . . [A]s a general rule, if an applicant has initiated human clinical trials for a therapeutic product or process, Office personnel should presume that the applicant has established that the subject matter of that trial is reasonably predictive of having the asserted therapeutic utility.[17]

56. The only other jurisdiction in which the Strattera patent has been challenged on utility is Denmark, in proceedings brought before the Danish Patent Office. The patent was found valid and the decision was not appealed. Canada is the only jurisdiction in the world that has invalidated the Strattera patent on the basis of inutility.

(2) Zyprexa Patent

57. As previously noted, Zyprexa is indicated for the short- and long-term treatment of schizophrenia and related psychotic disorders, and for the short-term treatment of manic or mixed episodes in bipolar I disorder. It is a second-generation antipsychotic that exhibits a low incidence of the extra-pyramidal side effects (*e.g.*, involuntary twitching and painful body distortions) that were associated with first-generation antipsychotics.

58. At the time the '113 patent for Zyprexa was filed in Canada, Lilly had conducted extensive pre-clinical work, including one completed human clinical trial and four ongoing trials, all of which were disclosed within the patent application and showed positive results regarding the medicine's antipsychotic effects. In addition, though not disclosed in the patent, additional trials had been completed that evaluated the side effects of the compound.

[17] *Id.*

59. The Zyprexa patent was originally challenged by Novopharm for lack of novelty, double-patenting, wrong inventorship, obviousness, misrepresentation, and deemed abandonment. Novopharm also alleged that the Zyprexa patent was not a "valid selection patent."[18]

60. In a decision rendered on October 5, 2009, the Federal Court found the Zyprexa patent invalid on the ground that it was not a "valid selection patent." Among the factual findings made by the court were that:

> Olanzapine is regarded as a relatively safe, and often effective, medicine for treating schizophrenia. Olanzapine is widely prescribed and is a commercial success.[19]

61. In a decision rendered on July 21, 2010, the Federal Court of Appeal overturned the trial court's decision on the basis that there is no foundation in law for an independent challenge on a patent on grounds that it is not a valid selection patent. A selection patent is the same as any other patent and may be challenged only on the grounds set out in the *Patent Act*. In other words, the invention, like any other, is patentable if it is new, non-obvious, and useful. After finding Zyprexa to be both novel and non-obvious, the Court remanded on the issues of utility and sufficiency of disclosure.[20]

62. In a second decision rendered on November 10, 2011, the Federal Court trial judge invalidated the Zyprexa patent on the sole ground of inutility. Following the direction set out by the Federal Court of Appeal, the Court rejected what it referred to as the "usual

[18] A patent for a selection of compounds from a larger class of compounds described in a prior genus patent is known in patent jargon as a "selection" patent. This characterization of an invention as a "selection" has no significance as to whether the claimed invention is useful. The compound olanzapine claimed by the Zyprexa patent was discovered from a broad class of compounds with potential use in the treatment of central nervous system disorders that were claimed by the '687 patent, which expired in 1995.

[19] *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2009 F.C. 1018, ¶ 1.

[20] *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2010 F.C.A. 197, ¶¶ 109, 123.

requirement" for utility.[21] The Court proceeded to invalidate the patent because it failed to meet a construed promise of marked superiority over other known antipsychotic agents, which the court held implicitly included doing so over the "long term." The Court then held that Lilly failed to demonstrate this promise, explaining:

> If the utility of the invention in the '113 patent relates merely to a compound with potential antipsychotic properties that might have relatively low EPS liability [side effects], that utility had been demonstrated by the tests conducted prior to the filing date. However, I cannot accept that the '113's promise was so small. As stated above, based on the wording of the '113 patent and the evidence, I find that the promise of the patent is that olanzapine treats schizophrenia patients in the clinic in a markedly superior fashion with a better side-effects profile than other known antipsychotics.
>
> As recently held by the Federal Court of Appeal, where a patented compound is claimed to be safe and effective in the treatment of a chronic condition, utility will be demonstrated if the patent discloses studies showing that the patented compound, when administered over a long term, meets that promise: *Pfizer Canada Inc. v Canada (Minister of Health)*, 2011 FCA 236, para. 30 [*Pfizer 2011*]. Clearly, schizophrenia is a chronic condition. In my view, the evidence available to Lilly in April 1991 did not demonstrate that olanzapine could meet the promise of the '113 patent that it would provide markedly superior clinical treatment of schizophrenia with a better side effects profile than other known antipsychotics.[22]

63. Lilly had conducted extensive pre-clinical and clinical tests prior to filing its patent application, but these data did not meet the elevated evidentiary burden placed on the patentee to demonstrate or soundly predict the promise of the patent, as interpreted by the court. Nor was it relevant that olanzapine had been approved by Health Canada as safe and effective and used by hundreds of thousands of patients in Canada.

64. In a decision rendered on September 10, 2012, the Federal Court of Appeal dismissed Lilly's appeal of the November 10, 2011, decision invalidating the Zyprexa patent on

[21] *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2011 F.C. 1288, ¶ 84.

[22] *Id.* ¶¶ 209 & 210 (emphases added).

grounds of inutility.[23] Lilly applied for leave to appeal to the Supreme Court of Canada. Lilly's application for leave was denied on May 16, 2013, thereby exhausting all domestic appeals regarding the Zyprexa patent.[24]

65. The patent for Zyprexa has been challenged and upheld throughout the world, including in the United States, United Kingdom, Australia, Germany, Netherlands, Austria, Czech Republic, Russia, Portugal, Hungary, Romania, Slovakia, China, Finland, Norway, Spain, Bulgaria, and Korea, where all validity challenges were rejected. Canada is the only jurisdiction in the world that has invalidated the Zyprexa patent on the basis of inutility.

(f) Canada's Promise Doctrine Discriminates Against the Pharmaceutical Sector

66. The promise doctrine also has a disproportionate effect on the pharmaceutical sector. Numerous Canadian patents for highly effective, commercially successful medicines have been invalidated on grounds of inutility. In contrast, other industries have been virtually untouched by the promise doctrine. Since 2005 and the advent of the promise doctrine, 18 pharmaceutical patents have been invalidated for lack of utility.[25] In the prior 25 years, only two pharmaceutical patents were invalidated for lack of utility, and those were invalidated under the traditional utility test (*i.e.*, the claimed invention was devoid of utility in fact). Every patent invalidated from 2005 to the present for lack of utility has been a pharmaceutical invention. This includes the Strattera and Zyprexa patents.

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[23] *Eli Lilly Canada Inc. v. Novopharm Ltd.*, 2012 F.C.A. 232.

[24] *Eli Lilly Canada Inc., et al. v. Novopharm Ltd.*, 2013 CanLII 26762 (SCC).

[25] This figure includes infringement proceedings in which the patents were declared invalid, as well as proceedings under Canada's Patented Medicines (Notice of Compliance) Regulations in which allegations of invalidity were accepted and the generic product could therefore be marketed.

67. The application of the promise doctrine imposes an unacceptable hurdle to patentability, particularly for pharmaceuticals. Assessing utility against a promise that is derived from the patent specification has a "Catch-22" effect that makes it quite difficult for a patent holder to defend its patent. If, for example, the promise is construed to be effectiveness to treat a chronic disease over the long term, utility will not have been demonstrated at the date of filing, since the patent must be filed prior to conducting long-term clinical studies in humans. Yet, a patent applicant who seeks to comply with the promise doctrine's heightened utility standard by conducting longer-term clinical studies prior to the filing of the patent application faces an elevated risk of patent invalidity on the basis of obviousness or lack of novelty, since such studies are published and in the public domain once concluded.

(g) The Promise Doctrine Is Inconsistent with NAFTA Chapter 17 and the PCT

68. The promise doctrine imposes a significantly higher burden on the patentee than the standard of utility mandated by NAFTA. Canada cannot re-interpret a core patentability requirement enshrined in NAFTA in a way that contradicts the standard accepted by the NAFTA parties at the time the treaty was negotiated. The adoption of the "promise doctrine" in Canadian law is inconsistent with Canada's obligation to make patents available to inventions that are "capable of industrial application."

69. Further, NAFTA obligates Canada to grant patents without discrimination as to field of technology, and the adverse consequences of Canada's new utility standard have fallen almost exclusively on the pharmaceutical sector, including the Strattera and Zyprexa patents. The promise doctrine also contravenes NAFTA because Canada may only revoke a patent on grounds that would have justified a refusal to grant the patent in the first instance. The promise doctrine did not exist when the Strattera and Zyprexa patents

were examined by the Canadian Intellectual Property Office ("CIPO"). As such, CIPO could not have rejected these patents for lack of utility based on the application of the promise doctrine. Both patents met the utility standard set out in MOPOP and in effect when NAFTA entered into force. In short, Canada has failed to provide adequate and effective protection for Lilly's patent rights consistent with NAFTA Chapter 17.

70. The additional disclosures required under the promise doctrine when sound prediction is relied upon to establish utility are also inconsistent with Canada's obligations under the PCT. The Canadian *Patent Act* incorporates by reference the PCT disclosure requirements,[26] and Section 27(3) of the Canadian *Patent Act* mirrors these requirements. The result of the imposition of the non-statutory disclosure obligations under the promise doctrine is that patents are invalidated on the basis that the evidence supporting utility was not disclosed in the patent application. This is so even where the patent specification otherwise met the PCT requirements.

71. In these and other ways, the promise doctrine, pursuant to which the Strattera and Zyprexa patents were invalidated, contravenes Canada's NAFTA and PCT obligations, including by:

(i) providing inadequate and ineffective protection and enforcement of patent rights;

(ii) imposing onerous and additional patentability requirements that have the effect of denying patent protections to inventions that are new, non-obvious, and capable of industrial application and therefore meet all of the required conditions precedent to patentability under NAFTA;

[26] *See Patent Rules*, SOR/96-423, § 51 and *Regulatory Impact Analysis Statement*, C. Gaz. II (1996), at 2754, 2800, as amended; SOR/99-291, C. Gaz. II (1999), at 1846, 1850.

(iii) discriminating against pharmaceutical patents, contrary to the requirement that patents be made available in all fields of technology under NAFTA;

(iv) revoking patent rights on grounds that would not have justified a refusal to grant the patent in the first instance;

(v) imposing form and content requirements relating to international patent applications that are different from or additional to those provided in the PCT and Regulations; and

(vi) denying to the patent holder the right to insist before national courts that the requirements provided for by the PCT and Regulations be applied to the applicant's international patent application.

V. CLAIMS

72. Canada's application of the promise doctrine to the Strattera and Zyprexa patents, and Canada's failure to bring its utility standard into compliance with Canada's NAFTA and PCT obligations, breach Canada's obligations under NAFTA Chapter 11.

73. As a result of Canada's breach of its obligations under NAFTA Chapter 11, Lilly and its enterprise Lilly Canada have incurred damages in relation to its investments. Those investments include the exclusive rights conferred by the Strattera and Zyprexa patents and Lilly's ability to enforce those rights – which constitute intangible property acquired in the expectation, or used for the purpose, of economic benefit or other business purposes under NAFTA Article 1139. Lilly also claims for damages to its enterprise Lilly Canada.

(a) Canada's Breach of Obligations Under NAFTA Article 1110 – Expropriation

74. NAFTA Article 1110 ("Expropriation and Compensation") provides that:

> 1. No Party may directly or indirectly nationalize or expropriate an investment of an investor of another Party in its territory or take a measure tantamount to nationalization or expropriation of such an investment ("expropriation"), except:
>
> (a) for a public purpose;
>
> (b) on a non-discriminatory basis;
>
> (c) in accordance with due process of law and Article 1105(1); and
>
> (d) on payment of compensation in accordance with [certain specified requirements].

75. Through the measures in issue, Canada has directly expropriated Lilly's exclusive patent rights conferred by the Strattera and Zyprexa patents. The effect of the promise doctrine and other measures was to revoke the patents *ab initio*, thereby depriving Lilly of its exclusive rights to prevent third parties from making, constructing, using, or selling its patented products during the patent term and to enforce those rights during the patent term or thereafter. In the alternative, Canada has indirectly expropriated Lilly's exclusive patent rights conferred by the Strattera and Zyprexa patents through the measures in issue. The measures in issue have had the effect of destroying the value associated with Lilly's investments. Canada's violations of NAFTA Chapter 17 and the PCT support Lilly's claims under NAFTA Article 1110.

76. Lilly could not reasonably have expected that Canada's patent regime, upon which its investments in the Strattera and Zyprexa patents were predicated, would be transformed in a manner that departs markedly from Canada's NAFTA and PCT obligations, nor could it expect that such transformation would deprive Lilly of its investments in the

Strattera and Zyprexa patents. When the Strattera and Zyprexa patents were applied for and granted by the CIPO, Canada had been consistently applying the utility standard required under NAFTA.

77. Canada has a positive obligation to ensure Canadian law complies with NAFTA and the PCT, consistent with the reasonable investment-backed expectations of the investor. Patent law in Canada is statutory. Lilly could not reasonably have anticipated or expected the adoption of the common law "promise doctrine," including its non-statutory disclosure requirements, would operate to invalidate its Strattera and Zyprexa patents years after grant by the CIPO.

78. Canada's expropriation of the Strattera and Zyprexa patents is not in accordance with NAFTA Articles 1110(1)(a) to (d). The expropriations are contrary to the public purpose that is inherent in the grant of a patent, which creates a bargain between the patentee and the government (representing the public interest) pursuant to which the patentee receives an exclusive right to use the invention for a specified period of time in exchange for disclosure to the public of the invention. Canada's failure to fulfill its side of this bargain is unfair and contrary to recognized principles for the protection of intellectual property.

79. The measures used to expropriate Lilly's patent rights were not applied on a "non-discriminatory" basis. The measures discriminate against pharmaceutical patents, including the Strattera and Zyprexa patents, in a manner contrary to NAFTA's obligations to make patents available and patent rights enjoyable without discrimination as to field of technology. The measures also do not accord with NAFTA Article 1105(1), and Lilly has not been compensated for the expropriation of its patent rights.

(b) Canada's Breach of Obligations Under NAFTA Article 1105 – Minimum Standard of Treatment

80. NAFTA Article 1105 ("Minimum Standard of Treatment") provides that:

> 1. Each Party shall accord to investments of investors of another Party treatment in accordance with international law, including fair and equitable treatment and full protection and security.

81. The common law promise doctrine as applied to the Strattera and Zyprexa patents and Canada's failure to rectify the promise doctrine are measures that violate the principle of fair and equitable treatment, including Lilly's legitimate expectations about the treatment of its investments and Canada's obligation to refrain from conduct that is arbitrary, unfair, unjust, and discriminatory. The judicial decisions invalidating the Strattera and Zyprexa patents are improper and discreditable.

82. Lilly was entitled to reasonably rely on the stability, predictability, and consistency of Canada's legal and business framework existing at each stage of the establishment, expansion, and development of Lilly's investment. The Strattera and Zyprexa patents are recognized to be a form of contract between the Government of Canada and Lilly that provided Lilly with exclusive rights to exploit its inventions for a specified period of time in exchange for public disclosure of its inventions. Lilly could not have anticipated that the requirement for utility at the time of its investment would be so drastically altered by the creation of the promise doctrine, which has been applied discriminatorily and arbitrarily to invalidate pharmaceutical patents, including the Strattera and Zyprexa patents.

83. At the time of its Strattera investments, Lilly also reasonably relied on the disclosure obligations in the PCT, which were reflected in Canada's statutory law, and could not

have anticipated that new and additional disclosure obligations adopted years later by the courts would be retroactively applied to invalidate the Strattera patent.

84. Canada's violations of NAFTA Chapter 17 and the PCT support Lilly's claims under NAFTA Article 1105. When making its investments, Lilly took into account and relied upon all of the circumstances surrounding the investments, none of which could reasonably have led Lilly to expect that its patent rights would be revoked by operation of the promise doctrine and its non-statutory disclosure obligations. To the contrary, Lilly had a legitimate expectation that its patent rights would not be revoked in such a manner given the NAFTA and PCT obligations that Canada had undertaken and the domestic legal regime in place at the time the Strattera and Zyprexa patents issued.

VI. REQUEST FOR RELIEF

85. Lilly claims on its behalf and on behalf of Lilly Canada:

(i) damages for the full measure of direct losses and consequential damages sustained as a consequence of Canada's breach of its obligations under NAFTA Chapter 11, estimated in an amount not less than CDN $500 million plus any payments Lilly or its enterprise is required to make arising from the improvident loss of its Zyprexa and Strattera patents or its inability to enforce its Zyprexa and Strattera patents;

(ii) the full costs associated with these proceedings, including all professional fees and disbursements, as well as the fees of the arbitral tribunal;

(iii) pre-award and post-award interest;

(iv) payment of a sum of compensation equal to any tax consequences of the award, in order to maintain the award's integrity; and

(v) such further relief as the arbitral tribunal may deem just and appropriate.

VII. NUMBER AND APPOINTMENT OF ARBITRATORS

86. Pursuant to Article 1123 of NAFTA, Lilly proposes that the Tribunal shall comprise three arbitrators, one arbitrator appointed by each of the disputing parties and the third (presiding arbitrator) appointed by agreement of the disputing parties. Lilly will appoint its arbitrator as provided by the UNCITRAL Rules.

VIII. PROPOSAL AS TO LANGUAGE AND PLACE OF ARBITRATION

87. Claimant proposes that the proceedings be conducted in the English language and that the seat of the arbitration be New York, New York.

September 12, 2013

Respectfully submitted,

[Signed]

GOWLING LAFLEUR HENDERSON LLP
Richard G. Dearden
Wendy J. Wagner

[Signed]

COVINGTON & BURLING LLP
Marney Cheek
John K. Veroneau

ANNEX A

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U.S.A.

Phone 317 276 2000

September 2013

Government of Canada
Office of the Deputy Attorney General of Canada
284 Wellington Street
Ottawa, ON K1A 0H3

Re: CONSENT AND WAIVER

1. Pursuant to Article 1121 of the *North American Free Trade Agreement* ("*NAFTA*") Eli Lilly and Company and Eli Lilly Canada Inc. consent to arbitration in accordance with the procedures set out in the *NAFTA*.

2. Pursuant to Article 1121 of *NAFTA*, Eli Lilly and Company and Eli Lilly Canada Inc. waive their right to initiate or continue before any administrative tribunal or court under the law of any Party to the *NAFTA*, or other dispute settlement procedures, any proceedings with respect to the measures alleged to be a breach referred to in Articles 1116 or 1117, except for proceedings for injunctive, declaratory or other extraordinary relief, not involving the payment of damages, before an administrative tribunal or court under the laws of Canada.

Date: September 10, 2013

ELI LILLY AND COMPANY

ELI LILLY CANADA INC.