UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

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| ELI LILLY AND COMPANY,<br><br>Plaintiff<br><br>v.<br><br>APOTEX, INC. and APOTEX CORP.,<br><br>Defendants | Civil Action No. 1:18-cv-1037 |

**COMPLAINT**

Plaintiff Eli Lilly and Company ("Lilly") files this Complaint for patent infringement against Apotex, Inc. and Apotex Corp. (collectively, "Apotex") under 35 U.S.C. § 271. This patent action concerns the pharmaceutical drug product Forteo®.

**THE PARTIES**

1. Lilly is an Indiana corporation that has its corporate offices and principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285. Lilly is engaged in the business of research, development, manufacture, and sale of pharmaceutical products throughout the world.

2. Apotex Corp. is a Delaware corporation with a place of business at 2400 North Commerce Parkway, Suite 400, Weston, Florida 33326.

3. On information and belief, Apotex Corp. is a generic drug company that develops, manufactures, markets, sells, and distributes generic pharmaceutical products in the State of Indiana and throughout the United States.

4. Apotex Inc. is a Canadian corporation with a place of business at 150 Signet Drive, Toronto, Ontario, M9L 1T9, Canada.

5. On information and belief, Apotex Inc. is a generic pharmaceutical company that develops, manufactures, markets, and distributes generic pharmaceutical products for sale in the State of Indiana and throughout the United States in concert with its subsidiary Apotex Corp.

6. On information and belief, the acts of Apotex Inc. complained of herein were done with the cooperation, participation, and assistance of Apotex Corp. On information and belief, Apotex Corp. is a wholly owned subsidiary of Apotex Inc., and is controlled and/or dominated by Apotex Inc.

## NATURE OF THE ACTION

7. This is an action for infringement of U.S. Patent No. 7,517,334 ("the '334 patent"). This action relates to Abbreviated New Drug Application ("ANDA") No. 211097 submitted in the name of Apotex Inc. to the U.S. Food and Drug Administration ("FDA") for approval to market a generic version of Lilly's Forteo® (teriparatide [rDNA origin] injection) product, which constitutes an action of infringement under the patent laws of the United States, Title 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(e)(2).

## SUBJECT MATTER JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

9. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338(a).

10. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b).

## PERSONAL JURISDICTION

11. This Court has personal jurisdiction over Defendants because they have purposefully directed activities at residents of the State of Indiana and this action arises out of or relates to those activities. On information and belief, Defendants develop, manufacture, market, and sell pharmaceutical products throughout the United States, including the State of Indiana. Defendants derive substantial revenue from Indiana drug sales and have availed themselves of the privilege of doing business within the State of Indiana. Following any FDA approval of Apotex's ANDA No. 211097, Apotex seeks to sell a product that infringes the '334 patent throughout the United States, including in Indiana and the Southern District of Indiana. Apotex directed its Notice Letter to Lilly, an Indiana corporation, at its corporate headquarters in Indiana, and alleged in the Notice Letter the invalidity, unenforceability, and/or non-infringement of Lilly's '334 patent, thereby deliberately challenging intellectual property held by Lilly, an Indiana company, in Indiana. Exercising personal jurisdiction over Defendants is reasonable and fair.

12. On information and belief, Apotex Corp. is the United States marketing and sales affiliate for Apotex Inc. Defendants issued a press release on May 10, 2011, stating that: "Apotex Corp. is the US Company that markets the products of Apotex, Inc. Through its sales and marketing headquarters in Weston, Florida and its operations center in Indianapolis, Apotex Corp. is committed to providing safe and affordable generic medicines." https://www.apotex.com/ca/en/about/press/20110510.asp

13. Apotex Corp. is a registered corporation in the State of Indiana. Apotex Corp. has been registered in Indiana as a for-profit foreign corporation since at least 2009. Apotex Corp. maintains a registered agent in the State of Indiana at 1657 Commerce Drive, Suite 9B, South Bend, IN, 46628.

14. On information and belief, Apotex Corp. has at least one Indiana distribution facility at 2516 Airwest Blvd., Plainfield, IN 46168, through which it distributes Apotex Inc. products for sale throughout the United States.

15. On information and belief, Apotex Corp., either directly or through distributors, currently sells significant quantities of generic drug products in the United States and in the State of Indiana. These products include, for example, generic versions of Lipitor®, Zithromax®, Plavix®, Cymbalta®, Zyprexa®, and Celebrex®. A list of generic products sold by Apotex can be found at http://www1.apotex.com/products/us/default.asp?qt=All.

16. On information and belief, Apotex, either directly or through distributors or related entities, intentionally markets and provides its generic pharmaceutical drug products to residents of Indiana, sells products to retail drug chains in Indiana, maintains a broad distributorship network within Indiana, and derives substantial revenue from sales of its generic pharmaceutical drug products in Indiana. On information and belief, Apotex has employees based in Indiana.

17. Apotex filed its ANDA for approval to market its Teriparatide Injection USP, 600 mcg / 2.4 mL (250 mcg/mL) ("Apotex's ANDA Product") and sent and/or caused to be sent to Lilly in Indiana a letter dated February 22, 2018 ("Notice Letter"), notifying Lilly that Apotex's ANDA No. 211097 includes a paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of Apotex's ANDA Product before the expiration of the '334 patent, and providing information pursuant to 21 U.S.C. § 355(j)(2)(B).

18. On information and belief, Apotex's Notice Letter purported to provide notice to Lilly relating to Apotex's ANDA No. 211097 and was signed by Kiran Krishnan. On information and belief, Mr. Krishnan signed Apotex's Notice Letter using the title of "Senior

Vice-President, Global Regulatory Affairs, Apotex Corp." Apotex's Notice Letter stated that Mr. Krishnan is the "agent in the United States authorized to accept service of process for Apotex, limited to commencement of a patent infringement suit based on this notification of certification."

19. On information and belief, Apotex Corp. is acting as the agent and official submitter to the FDA of Apotex's ANDA No. 211097 at issue in this case. Apotex Inc. participated in the preparation and submission of ANDA No. 211097 and will benefit directly and indirectly from the approval of ANDA No. 211097.

20. Apotex would not be unfairly burdened by participating in patent litigation in this judicial district. Apotex should have reasonably anticipated being sued in Indiana. Apotex has litigated other ANDA cases in Indiana, and on information and belief, its business model is dependent on such litigation. When Apotex sent its Notice Letter to Lilly in Indiana, it knew or should have known that Lilly was an Indiana corporation, that Lilly has brought suit in Indiana against ANDA filers, including Apotex, in the past, and that if Lilly were to bring suit against Apotex within 45 days of receiving the Notice Letter, suit would likely be brought in Indiana. As further evidence of personal jurisdiction over Apotex, Apotex has been sued for patent infringement in this district and has not contested personal jurisdiction. *See, e.g.*, *Eli Lilly and Company v. Apotex, Inc.*, No. 1:17-cv-02865-TWP-MPB, D.I. 28 (S.D. Ind. Nov. 21, 2017); *Eli Lilly and Company et al. v. Apotex Inc. & Apotex Corp.*, No. 1:16-cv-01512-WTL-DML, D.I. 32 (S.D. Ind. Oct. 31, 2016); *Eli Lilly and Company, et al. v. Apotex Corp. & Apotex Inc.*, No. 1:14-cv-00586-SEB-TAB, D.I. 40 (S.D. Ind. June 9, 2014); *Eli Lilly and Company v. Apotex Inc. & Apotex Corp.*, No. 1:12-cv-00499-TWP-DKL, D.I. 22 (S.D. Ind. June 8, 2012); *Alcon Mfg., Ltd. v. Apotex Inc. & Apotex Corp.*, No. 1:06-cv-01642-RLY-TAB, D.I. 21 (S.D. Ind. Dec. 13, 2006).

In addition, Apotex has purposefully availed itself of the rights and benefits of this Court by asserting counterclaims in lawsuits filed in this Court. *See, e.g.*, *Eli Lilly and Company v. Apotex, Inc.*, No. 1:17-cv-02865-TWP-MPB, D.I. 28 (S.D. Ind. Nov. 21, 2017); *Eli Lilly and Company et al. v. Apotex Inc. & Apotex Corp.*, No. 1:16-cv-01512-WTL-DML, D.I. 32 (S.D. Ind. Oct. 31, 2016); *Eli Lilly and Company, et al. v. Apotex Corp. & Apotex Inc.*, No. 1:14-cv-00586-SEB-TAB, D.I. 40 (S.D. Ind. June 9, 2014); *Eli Lilly and Company v. Apotex Inc. & Apotex Corp.*, No. 1:12-cv-00499-TWP-DKL, D.I. 22 (S.D. Ind. June 8, 2012); *Alcon Mfg., Ltd. v. Apotex Inc. & Apotex Corp.*, No. 1:06-cv-01642-RLY-TAB, D.I. 21 (S.D. Ind. Dec. 13, 2006).

21. In one of the above-cited matters, Defendants answered that: "Apotex Corp. is licensed as a Wholesale Drug Distributor in Indiana and that it provides pharmaceutical drug products some of which may be marketed and provided to residents of this State. . . . For purposes of this Action, Defendants Apotex Inc. and Apotex Corp. are not contesting personal jurisdiction in this District . . . ." *Eli Lilly and Company, et al. v. Apotex Corp. & Apotex Inc.*, No. 1:14-cv-00586-SEB-TAB, D.I. 40 at 5 (S.D. Ind. June 9, 2014).

22. In another of the above-cited matters, Apotex stated that: "Apotex . . . admits that it has a facility located at 2516 Airwest Blvd., Plainfield, IN 46168." *Eli Lilly and Company et al. v. Apotex Inc. & Apotex Corp.*, No. 1:16-cv-01512-WTL-DML, D.I. 32 at 7 (S.D. Ind. Oct. 31, 2016).

23. In another of the above-cited matters, Apotex stated that: "Apotex admits that jurisdiction is proper in this district"; "Apotex Inc. has caused product that was to be sold throughout the United States to be shipped to a facility in Indianapolis, Indiana," and "Apotex Corp. operates an operations and distribution center in Indianapolis through which it distributes

Apotex Inc. products for sale throughout the United States," *Alcon Mfg. Ltd., et al. v. Apotex Inc. & Apotex Corp.*, No. 1:06-cv-01642-RLY-TAB, D.I. 21 at 3 (S.D. Ind. Dec. 13, 2006).

24. Lilly and the State of Indiana have a substantial interest in resolving this suit in an Indiana forum. The Notice Letter was sent to Lilly in Indiana and, if Apotex's ANDA is approved, infringement would occur in, and Lilly would be injured in, the State of Indiana, its state of incorporation.

25. This Court has personal jurisdiction over Defendants by virtue of, inter alia: (1) their course of conduct that is designed to cause the performance of tortious acts that will result in foreseeable harm in Indiana; (2) their presence in Indiana, including having a registered agent in Indiana, as well as operations and/or distribution facilities within the state; and (3) their prior purposeful availment of this forum for the purpose of litigating patent disputes.

## FACTUAL BACKGROUND

### A. Forteo®

26. Lilly is the holder of approved New Drug Application ("NDA") No. 021318 for the manufacture and sale of teriparatide [rDNA origin] injection, approved by the FDA for: (1) treatment of postmenopausal women with osteoporosis at high risk for fracture; (2) increase of bone mass in men with primary or hypogonadal osteoporosis at high risk for fracture; and (3) treatment of men and women with osteoporosis associated with sustained systemic glucocorticoid therapy at high risk for fracture. Lilly markets and sells teriparatide [rDNA origin] injection under the trade name Forteo®. Forteo® was approved by the FDA on November 26, 2002.

**B. The ’334 Patent**

27. The ’334 patent, titled “Medication Dispensing Apparatus with Spring-Driven Locking Feature Enabled by Administration of Final Dose,” and owned by Lilly, was duly and legally issued by the United States Patent and Trademark Office (“PTO”) on April 14, 2009, from U.S. Patent Application No. 10/598,987, filed as PCT Application No. PCT/US2005/010206 on March 25, 2005. The ’334 patent claims priority to U.S. Provisional Application No. 60/557,545, filed March 30, 2004, and U.S. Provisional Application No. 60/638,027, filed December 21, 2004. The ’334 patent claims, *inter alia*, a medication dispensing apparatus comprising: a housing, a drive member within said housing movable in a distal direction; a fluid container defining a medicine-filled reservoir with a movable piston at one end and an outlet at the other end; a plunger element; a gear set including first and second pinions; a first rack; a second rack; and a latching element including a latching lip and a skid. The ’334 patent is listed in the FDA publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the “Orange Book”) in connection with Forteo®. A true and correct copy of the ’334 patent is attached as ***Exhibit A***.

**C. Apotex’s ANDA No. 211097**

28. Apotex filed or caused to be filed with the FDA ANDA No. 211097 under 21 U.S.C. § 355(j) to obtain approval for the commercial manufacture, use, and sale of Teriparatide Injection USP, 600 mcg / 2.4 mL (250 mcg/mL) (“Apotex’s ANDA Product”) in the United States before the expiration of the ’334 patent.

29. Apotex’s ANDA No. 211097 contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (“paragraph IV certification”), alleging that the claims of the ’334 patent are invalid, unenforceable, and/or would not be infringed by Apotex’s ANDA Product.

30. Apotex sent or caused to be sent to Lilly a letter dated February 22, 2018 ("Notice Letter"), notifying Lilly that Apotex's ANDA No. 211097 includes a paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of Apotex's ANDA Product before the expiration of the '334 patent and providing information pursuant to 21 U.S.C. § 355(j)(2)(B). Apotex's Notice Letter states that "the FDA has received an [ANDA] from Apotex for Teriparatide Injection USP, 600 mcg / 2.4 mL (250 mcg/mL) ("the Apotex Product"). . . . The ANDA . . . contains a paragraph IV certification to obtain approval to engage in the commercial manufacture, use, sale, or importation of the Apotex Product before the expiration of the '334 patent . . . ."

31. The Notice Letter purported to include an "Offer of Confidential Access" to Lilly to ANDA No. 211097. On March 19, 2018, Lilly and Apotex executed an Offer of Confidential Access with revised terms. On March 19, 2018, pursuant to the Offer of Confidential Access, Apotex produced certain portions of ANDA No. 211097 to outside counsel for Lilly. In emails dated March 22 and 27, 2018, and April 2, 2018, outside counsel for Lilly reiterated an earlier request for a sample of the injection device for use with Apotex's ANDA Product for evaluation. In an April 2, 2018, email, outside counsel for Apotex notified outside counsel for Lilly that no actual samples of the injection device for use with Apotex's ANDA Product were available.

32. On information and belief, Apotex's ANDA Product is covered by one or more claims of the '334 patent.

33. The submission of ANDA No. 211097 to the FDA constitutes infringement by Apotex of the '334 patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, sale, offer for sale, or importation of Apotex's ANDA Product would infringe the '334 patent under 35 U.S.C. § 271(a), (b), and/or (c).

34. Apotex knows and intends that physicians will prescribe, and patients will take, Apotex's ANDA Product for which approval is sought in ANDA No. 211097. Apotex had knowledge of the '334 patent and, by its proposed ANDA Product, knows or should know that it will aid and abet in another's direct infringement of at least one of the claims of the '334 patent.

35. An actual case or controversy exists between Lilly and Apotex with respect to infringement of the '334 patent.

36. Lilly commenced this action within 45 days of receiving Apotex's Notice Letter.

**COUNT I FOR PATENT INFRINGEMENT**
**(DIRECT INFRINGEMENT OF U.S. PATENT NO. 7,517,334)**

37. Lilly incorporates by reference and realleges Paragraphs 1-36 above as though fully restated herein.

38. Pursuant to 35 U.S.C. § 271(e)(2), Apotex's submission of ANDA No. 211097 to the FDA seeking approval of Apotex's ANDA Product before expiration of the '334 patent was an act of infringement of at least claim 1 of the '334 patent by Apotex.

39. If ANDA No. 211097 is approved by the FDA, Apotex's commercial manufacture, use, offer to sell, sale in the United States, or importation into the United States of Apotex's ANDA Product would directly infringe, either literally or under the doctrine of equivalents, at least claim 1 of the '334 patent under 35 U.S.C. § 271.

40. Unless Apotex is enjoined by this Court, Lilly will be substantially and irreparably harmed by Apotex's infringement of the '334 patent. Lilly does not have an adequate remedy at law.

**COUNT II FOR PATENT INFRINGEMENT**
**(INDUCEMENT TO INFRINGE U.S. PATENT NO. 7,517,334)**

41. Lilly incorporates by reference and realleges Paragraphs 1-40 above as though fully restated herein.

42. Apotex has knowledge of the '334 patent.

43. Upon FDA approval of ANDA No. 211097, Apotex will intentionally encourage acts of direct infringement of at least claim 1 of the '334 patent by others, with knowledge that their acts are encouraging infringement.

**PRAYER FOR RELIEF**

Wherefore, Lilly respectfully requests that this Court enter judgment in its favor as follows:

A. U.S. Patent No. 7,517,334 is valid and enforceable;

B. Under 35 U.S.C. § 271(e)(2)(A), Defendants infringed U.S. Patent No. 7,517,334 by submitting ANDA No. 211097 to the FDA to obtain approval to commercially manufacture, use, offer for sale, sell, and/or import into the United States Apotex's ANDA Product prior to expiration of these patents;

C. Defendants' threatened acts of commercial manufacture, use, offer for sale, sale, and/or importation into the United States of Apotex's ANDA Product prior to expiration of U.S. Patent No. 7,517,334 would constitute infringement;

D. The effective date of any FDA approval of Apotex's ANDA Product shall be no earlier than the expiration date of U.S. Patent No. 7,517,334 and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

E. Defendants, and all persons acting in concert with Defendants, shall be enjoined from commercially manufacturing, using, offering for sale, or selling Apotex's ANDA Product

within the United States, or importing Apotex's ANDA Product into the United States, until the expiration of U.S. Patent No. 7,517,334 in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

F. This is an exceptional case, and Lilly should be awarded its costs, expenses, and disbursements in this action, including reasonable attorney fees, pursuant to 35 U.S.C. §§ 285 and 271(e)(4);

G. Lilly is entitled to any further appropriate relief under 35 U.S.C. § 271(e)(4); and

H. Lilly is entitled to any further and additional relief that this Court deems just and proper.

Dated: April 4, 2018

Respectfully submitted,

/s/ Anne N. DePrez

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