IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

APOTEX INC. and APOTEX CORP., Plaintiffs, v. ELI LILLY & COMPANY, Defendant.	C.A. No. 1:22-cv-2342

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiffs Apotex Inc. and Apotex Corp. (collectively, "Apotex") bring this Complaint against Eli Lilly & Company ("Lilly") seeking a declaration that Apotex has not infringed, does not infringe, and will not infringe any claim of U.S. Patent No. 7,517,334 ("the '334 patent"). Apotex brings this suit to ensure that final FDA approval for Abbreviated New Drug Application ("ANDA") No. 211097 for teriparatide injection, 20 mcg/dose (600 mcg/2.4 mL) is not delayed, and is granted final approval at the earliest possible date pursuant to 21 U.S.C. § 355(j)(5)(D)(i)(I).

NATURE OF THE ACTION

1. This action arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the Hatch-Waxman Act, 21 U.S.C. § 355(j) *et seq*.

THE PARTIES

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

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

4. Upon information and belief, Lilly is an Indiana corporation having corporate offices and its 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.

5. Based on publicly available information, Lilly is the owner and assignee of record with the United States Patent and Trademark Office ("USPTO") of the '334 patent.

JURISDICTION AND VENUE

6. This is a Complaint for a declaratory judgment that Apotex has not, does not, and will not infringe the claims of the '334 patent, which arises under the patent laws of the United States, 35 U.S.C. §§ 1 et seq.; the Hatch-Waxman Act, 21 U.S.C. §§ 355(j) et seq.; and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

7. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this action involves substantial claims arising under the United States Patent Act (35 U.S.C. §§ 1 *et seq*.), the Declaratory Judgment Act (28 U.S.C. §§ 2201 & 2202), 21 U.S.C. § 355(j)(5)(C), and 35 U.S.C. § 271(e)(5).

8. An actual controversy exists between Apotex and Lilly by virtue of Lilly's listing and maintenance of the '334 patent in FDA's *Orange Book* for Forteo®, and Apotex's filing of ANDA No. 211097 with the FDA under § 505(j) of the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 355(j), for generic versions of teriparatide injection, 20 mcg/dose (600 mcg/2.4 mL) prefilled pens that are bioequivalent to Lilly's drug Forteo® ("Apotex's ANDA Product"). Additionally, another applicant was the first to submit an ANDA referencing the

600 mcg/2.4 mL (250 mcg/mL) strength of Forteo®, and therefore retains eligibility for 180-day marketing exclusivity, which indefinitely blocks approval of any subsequently filed ANDA, such as Apotex's ANDA. Only a final decision of non-infringement or invalidity of the '334 patent will lift that regulatory block. *See Apotex, Inc. v. Daiichi Sankyo, Inc*., 781 F.3d 1356, 1368-69 (Fed. Cir. 2015).

9. Apotex contends that it has a right to engage in making, using, offering to sell, and selling their products described in Apotex's ANDA, without license from Lilly.

10. This Court has personal jurisdiction over Lilly because, *inter alia*, Lilly is a corporation existing under the laws of the State of Indiana and/or having a principal place of business in Indiana.

11. This Court also has personal jurisdiction over Lilly because Lilly transacts business in the State of Indiana and has purposefully availed itself of the privileges of doing business in Indiana.

12. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b), (c) and 1400(b), because the Southern District of Indiana is the judicial district where Lilly resides and/or because the Southern District of Indiana is a judicial district where Lilly has committed acts that give rise to Apotex's declaratory judgment claims as alleged in this Complaint, and where Lilly has a regular and established place of business, e.g., its headquarters in Indianapolis, Indiana.

THE HATCH-WAXMAN ACT

13. In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Act. *See* 21 U.S.C. § 355 and 35 U.S.C. §§ 156 and 271(e). The Hatch-Waxman Act was intended to encourage generic drug

competition while leaving intact incentives for research and development of new drugs by branded drug companies. *See* H.R. Rep. No. 98-857, pt. I at 14-15 (1984). The Hatch-Waxman Act was designed to stem the rising cost of prescription drugs by bringing less expensive generic drugs to market faster.

14. To establish this goal, the Hatch-Waxman Act established a framework with five elements that are relevant here.

15. *First*, a company seeking FDA approval of a new drug must submit a New Drug Application ("NDA") to the FDA. *See* 21 U.S.C. § 355. A brand-name drug sponsor must also inform the FDA of every patent that claims the "drug" or "method of using [the] drug" for which a claim of patent infringement could reasonably be asserted against unlicensed manufacture, use, or sale of that drug product. *See* 21 U.S.C. § 355(b)(1); 21 U.S.C. § 355(c)(2); 21 C.F.R. § 314.53(b), (c)(2). Upon approval of the NDA, the FDA publishes a listing of patent information for the approved drug in a document referred to as the *Orange Book*. *See* 21 U.S.C. § 355(b)(1). The new FDA-approved drug is known as the "reference-listed drug" or "RLD."

16. *Second*, the Hatch-Waxman Act provides a streamlined process for approving generic drugs. Before marketing a generic version of an FDA-approved drug, a generic-drug manufacturer must submit an ANDA to the FDA. An ANDA is "abbreviated" because applicants are generally not required to include the extensive preclinical and clinical data that must be included in an NDA for a brand-name drug. Instead, the ANDA applicants can rely on the NDA's preclinical and clinical data if the proposed generic product is "bioequivalent" to the corresponding reference-listed drug. *See* 21 U.S.C. § 355(j)(4)(F).

17. With respect to any patents listed in the *Orange Book* for a reference-listed drug, an ANDA must contain one of four certifications: (i) that there are no patents listed in the

Orange Book; (ii) that any listed patent has expired; (iii) that the patent will expire before the generic manufacturer is seeking to market its generic product; or (iv) the patent is invalid, unenforceable or will not be infringed by the manufacture, use or sale of the generic drug for which the ANDA is submitted. *See* 21 U.S.C. §§ 355(j)(2)(A)(vii)(I)-(IV); 21 C.F.R. § 314.94(a)(12). The last of these is commonly referred to as a "Paragraph IV certification."

18. An applicant submitting an ANDA containing a Paragraph IV certification must provide formal written notice (i.e., "a notice letter") informing both the patent holder and the NDA holder of its Paragraph IV certification. 21 U.S.C. § 355(j)(2)(B)(i).

19. *Third*, the Hatch-Waxman Act encourages prompt resolution of patent disputes by authorizing a patent owner to bring an action for patent infringement against an ANDA applicant upon receipt of a notice letter (i.e., prior to FDA approval of the ANDA). 35 U.S.C. § 271(e)(2). By statute, if a patent owner brings an action within 45 days of receiving a notice letter, that triggers an automatic statutory 30-month stay of FDA-approval of the ANDA to allow parties time to adjudicate the merits of the infringement action prior to FDA approval of the ANDA. 21 U.S.C. § 355(j)(5)(B)(iii).

20. *Fourth*, to encourage generic applicants, the Hatch-Waxman Act grants the first applicant to file a substantially complete ANDA containing a Paragraph IV certification a 180-day period of marketing exclusivity, which begins on the date of first commercial marketing of the generic-drug product. During this 180-day exclusivity period, the FDA may not approve ANDAs filed subsequent to the first applicant's ANDA.

21. *Fifth*, to curb abuses of the 180-day exclusivity by patent owners and first-filers, whereby the 180-day exclusivity is used to block all subsequent ANDA filers from obtaining approval of their respective ANDAs, Congress enacted the Medicare Modernization

Amendments to the Hatch-Waxman Act (the "MMA"), which provided for various conditions under which a first-filer may forfeit its 180-day exclusivity. *See* 21 U.S.C. § 355(j)(5)(D). The first of the forfeiture provisions, known as the "Failure to Launch" provision, provides that 180-day exclusivity is forfeited if a subsequent ANDA filer obtains a judgment of non-infringement as to the patent(s) that confer(s) exclusivity. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA); *see also Daiichi Sankyo*, 781 F.3d at 1360.

22. If the first-filer does not commercially market its generic drug and none of the MMA forfeiture provisions are triggered (including entry of a final judgment of non-infringement or invalidity), then the first-filer's 180-day exclusivity period may be delayed indefinitely, ultimately blocking final FDA approval of all subsequent ANDAs.

23. By authorizing declaratory-judgment actions under these circumstances, Congress intended that full generic competition would not be delayed indefinitely, or blocked, by the first-filer's 180-day exclusivity. A declaratory-judgment action by a subsequent ANDA applicant could result in a court decision that triggers forfeiture of the first-filer's 180-day exclusivity under 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA), thereby clearing the way for approval of the subsequent-filers' ANDAs.

24. Congress explained the need for civil actions to obtain patent certainty:

> [W]hen generic applicants are blocked by a first generic applicant's 180-day exclusivity, the brand drug company could choose not to sue those other generic applicants so as to delay a final court decision that could . . . force the first generic to market. In . . . these . . . circumstances, generic applicants must be able to seek a resolution of disputes involving all patents listed in the Orange Book with respect to the drug.

Caraco, 527 F.3d at 1285 (quoting 149 Cong. Rec. S15885 (Nov. 25, 2003) (remarks of Sen. Kennedy, ranking member of U.S. Senate Committee on Health, Education, Labor, and Pensions)).

THE LISTING OF THE '334 PATENT ON FDA'S *ORANGE BOOK* BLOCKS APOTEX'S GENERIC ENTRY

A. The FDA's *Orange Book* Lists the '334 Patent

25. Lilly is the holder of approved NDA No. 021318 for Forteo® teriparatide solution, 0.6 mg/2.4 mL (0.25 mg/mL) prefilled pen, and Lilly caused or authorized FDA to list the '334 patent in connection with the Forteo® NDA as a patent for which "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug" product containing teriparatide solution, 0.6 mg/2.4 mL (0.25 mg/mL) in a prefilled pen. 21 U.S.C. §§ 355(b)(1), (c)(2).

26. The '334 patent, entitled "Medication dispensing apparatus with spring-driven locking feature enabled by administration of final dose," issued on April 14, 2009. The '334 patent names Alexander Thomas Jacobs, Jared Alden Judson, and Gordon Davidson Row as inventors, and identifies Lilly as the assignee of record. A true and correct copy of the '334 patent is attached hereto as Exhibit A.

27. The '334 patent purports to claim a medication dispensing apparatus with specified elements. According to FDA's *Orange Book*, the '334 patent expires on March 25, 2025.

28. Apotex's ANDA No. 211097 includes a Paragraph IV certification to the '334 patent. Through its Paragraph IV certification, Apotex is seeking immediate approval of its ANDA and prior to expiration of the '334 patent.

B. The First Paragraph IV Certification for Forteo®

29. The FDA publishes a list that provides the date on which the first substantially complete ANDA containing a Paragraph IV certification was received for a reference-listed drug, but does not disclose the identity of the first applicant(s). According to FDA, the first substantially complete ANDA containing a Paragraph IV certification for which 0.6 mg/2.4 mL (250 mcg/mL) teriparatide solution prefilled pens was received on July 27, 2015. *See* Exhibit B.

30. On information and believe, the first applicant submitted a substantially complete ANDA containing a Paragraph-IV certification to the '334 patent for teriparatide solution 0.6 mg/2.4 mL (0.25 mg/mL) prefilled pens on July 27, 2015. *Id*. On information and belief, the first applicant to file an ANDA for Teriparatide Injection USP, 600 mcg/2.4 mL (250 mcg/mL) prefilled pens, holds a 180-day exclusivity period, and no other applicant's ANDA can be made effective by FDA until the earlier of: (1) 180 days after the first applicant's first commercial marketing of its generic product, or (2) expiration of the '334 patent. *See* 21 U.S.C. §§ 355(j)(5)(B)(iv)(I)-(II).

31. A publicly available March 2021 investor presentation by Antares Pharma, a supplier of injection devices, indicates that the filer of an earlier teriparatide ANDA expects to receive 180-day exclusivity upon approval of their submission by the FDA. In that presentation, Antares states that Teva Pharmaceuticals is "awaiting approval for their ANDA for generic Forteo®" and "[e]xpect[s] six month exclusivity." *See* Exhibit C. A subsequent publicly available March 2022 investor presentation indicated "potential FDA approval" and "expect 6 month exclusivity." *See* Exhibit D.

C. Apotex Applies for FDA Approval of Its ANDA Product

32. Apotex submitted ANDA No. 211097 to the FDA seeking approval for the commercial manufacture, use, importation, offer for sale, and sale of a generic version of 600 mcg/2.4 mL (250 mcg/mL) Forteo® prefilled teriparatide pens. Apotex's ANDA contains a Paragraph IV certification that the '334 patent will not be infringed by the manufacture, use, or sale of Apotex's prefilled teriparatide pens. Apotex submitted its ANDA after July 27, 2015, and therefore is a "subsequent filer." As a subsequent filer, Apotex is blocked from marketing its 600 mcg/2.4 mL (250 mcg/mL) prefilled teriparatide pens by the first-applicant's exclusivity.

33. On or around February 22, 2018, and pursuant to 21 U.S.C. §§ 355(j)(2)(B)(i)-(iv), Apotex sent a notice to Lilly to inform Lilly of Apotex's Paragraph IV certification regarding the '334 patent, which included detailed factual and legal bases supporting Apotex's Paragraph IV certification to the '334 patent. Apotex's notice also included an Offer of Confidential Access ("OCA") to certain sections of Apotex's ANDA No. 211097 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

34. Lilly received Apotex's notice letter and OCA no later than February 23, 2018.

35. On April 4, 2018, Lilly filed a Complaint for infringement of the '334 patent against Apotex based on Apotex's ANDA.

36. On December 3, 2018, Lilly and Apotex filed a joint motion for dismissal of Lilly's Complaint and Apotex's Answer, affirmative defenses, and counterclaim pursuant to Rules 41(a)(1) and 41(c) of the Federal Rules of Civil Procedure. The dismissal was without prejudice.

D. Apotex's Approval is Blocked By the First Applicant's 180-Day Exclusivity

37. Apotex is prepared to begin commercial marketing of its prefilled teriparatide pens immediately upon receiving final approval of Apotex's ANDA by FDA. Apotex's prefilled teriparatide pens, however, will be blocked from receiving final approval and prevented from actually entering the market until the end of any first-applicant's 180-day exclusivity based on the '334 patent.

38. As a consequence, absent a judgment from this Court declaring that Apotex's ANDA Product does not infringe the '334 Patent, Apotex will be unable to sell its generic 600 mcg/2.4 mL (250 mcg/mL) prefilled teriparatide pens indefinitely, thereby injuring Apotex by depriving it of sales revenue that it could earn for that period of time. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb). Were Apotex free to market its generic 600 mcg/2.4 mL (250 mcg/mL) prefilled teriparatide pens at the earliest possible date, it would earn substantial profits.

AN ARTICLE III CASE OR CONTROVERSY EXISTS

39. There is an actual and ongoing controversy between Apotex and Lilly with respect to infringement of the '334 Patent that can be resolved by a declaratory judgment from this Court. A judgment of non-infringement from this Court will trigger forfeiture of the first-exclusivity, as Congress intended under 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb), thereby allowing Apotex to obtain final FDA approval for ANDA No. 211097, and bring its generic prefilled teriparatide pens to market at the earliest possible date, thereby enhancing generic competition.

40. The present dispute between Apotex and Lilly presents a justiciable Article III controversy because Apotex has standing, and the issues raised are ripe for adjudication. *See, e.g., Caraco*, 527 F.3d at 1278; 35 U.S.C. § 355(j)(5)(C).

41. Standing requires three elements: (1) an alleged injury in fact—"a harm suffered by the plaintiff that is 'concrete' and actual or imminent, not 'conjectural' or 'hypothetical'"; (2) causation—"a fairly traceable connection between the plaintiff's injury and the complained-of conduct of the defendant"; and (3) redressability—"a likelihood that the requested relief will redress the alleged injury." *Caraco*, 527 F.3d at 1291.

42. Apotex suffers an injury-in-fact from the ongoing listing of the '334 Patent in FDA's Orange Book. The '334 Patent confers 180-day exclusivity eligibility upon the first applicant, which will preclude Apotex from marketing its non-infringing generic prefilled teriparatide pens at the earliest possible date. Apotex's injury is unique to the Hatch-Waxman context as compared to ordinary infringement action: "Ordinarily, a potential competitor in other fields is legally free to market its product in the face of an adversely-held patent. In contrast, under the Hatch-Waxman Act, an ANDA filer is not legally free to enter the market without FDA approval." *Caraco*, 527 F.3d at 1291. Lilly's listing of the '334 Patent in the Orange Book creates the bottleneck to Apotex's ANDA causing injury-in-fact to Apotex. *Id*.

43. Lilly benefits financially from the ANDA approval "bottleneck" it has created, because this bottleneck lengthens the duration of Lilly's monopoly over teriparatide prefilled pens. But for Lilly's listing of the '334 patent on FDA's Orange Book, final approval of Apotex's ANDA would not be delayed by any first-applicant's 180 day exclusivity. Lilly's actions cause injury to Apotex by preventing Apotex from marketing and earning revenue on a non-infringing product.

44. Apotex's injury is redressable: judgment of non-infringement of the '334 Patent from this Court will activate forfeiture of the first-applicant's exclusivity period as Congress intended, allowing Apotex to enter the market at the earliest possible date.

45. Accordingly, there is an actual, substantial and continuing justiciable case and controversy between Apotex and Lilly, over which this Court can and should exercise jurisdiction and declare the rights of the parties. *Caraco*, 527 F.3d at 1278.

46. Whether an action is "ripe" requires an evaluation of "both the fitness of the issues for judicial decision and the hardship to the parties of withholding court consideration." *Id.* at 1294. Apotex satisfies both prongs for ripeness. First, whether Apotex's ANDA infringes any claim of the '334 patent is an appropriate issue for judicial review. Second, withholding court consideration of the question of infringement would cause substantial hardship to Apotex because it would delay the marketing of Apotex's non-infringing product.

APOTEX'S 600 mcg/2.4 mL (250 mcg/mL) PREFILLED TERIPARATIDE PENS

47. Apotex submitted an ANDA to the FDA seeking approval to manufacture and sell a generic version of Lilly's Forteo® (Teriparatide Injection USP) 600 mcg/2.4 mL (250 mcg/mL) prefilled teriparatide pens as described in Apotex's ANDA No. 211097.

48. Apotex's generic version of Lilly's Forteo® (Teriparatide Injection USP) 600 mcg/2.4 mL (250 mcg/mL) prefilled teriparatide pens as described in Apotex's ANDA No. 211097 is a simple, multiple-dose, fixed-dose, pre-filled disposable pen designed for manual insertion of the needle and manual injection and delivery of liquid drug into the subcutaneous tissue of the patient from a pre-filled 3 mL glass cartridges.

NON-INFRINGEMENT OF THE '334 PATENT

49. Infringement of a patent under 35 U.S.C. § 271(e)(2) requires a comparison between the patent claims and the ANDA applicant's proposed generic drug. If any claim limitation is absent from the ANDA applicant's proposed generic drug, there is no infringement

as a matter of law. *Bayer AG v. Elan Pharm. Research Corp*., 212 F.3d 1241, 1247-48 (Fed. Cir. 2000); *Glaxo, Inc. v. Novopharm, Ltd*., 110 F.3d 1562, 1569 (Fed. Cir. 1997).

A. The Claims of the '334 Patent

50. The '334 patent contains one independent claim. Claim 1 reads:

> 1. A medication dispensing apparatus comprising:
> a housing;
> a drive member within said housing and 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, said piston engageable by said drive member to be advanced toward said outlet a distance equal to a distal movement of said drive member when said drive member is moved distally:
> a plunger element;
> a gear set including first and second pinions, said gear set pivotal on said plunger element and shiftable proximally and distally with the plunger element;
> a first rack engaged with said first pinion and axially stationary within said housing:
> a second rack engaged with said second pinion and movable within said housing on a piece clutchably connected to said drive member;
> a latching element including a latching lip and a skid; said drive member including an axially extending, skid-engaging surface along which said skid is slidable as said drive member passes distally during advancement during plunger element shifting in the distal direction, said skid-engaging surface having an axial length and a proximal end, said drive member along said axial length structured and arranged with said skid so as to maintain said latching lip against a spring force in a first position free of a latchable element disposed on said plunger element during dose preparing and injecting prior to a final dose administration; and
> wherein said skid-engaging surface shifts distally of said skid such that said skid passes beyond the proximal end upon administration of a final dose allowing said latching lip to be urged by said spring force from said first position to a second position for engagement with said latchable element to physically lock said plunger element to prevent further dose preparing and injecting.

Exhibit A, '334 patent, cl. 1.

51. The dependent claims of the '334 patent are as follows:

> 2. The medication dispensing apparatus of claim 1 wherein said proximal end of said skid-engaging surface comprises a proximal end of said drive member.
>
> 3. The medication dispensing apparatus of claim 1 wherein said skid is disposed distally of said latching lip.
>
> 4. The medication dispensing apparatus of claim 1 wherein said skid comprises a blade shape member that extends axially, and wherein said latching lip comprises a transversely extending flange.
>
> 5. The medication dispensing apparatus of claim 1 wherein said latchable element comprises a ramped distal face over which said latching lip is cammable to reach a latching engagement with said latchable element.
>
> 6. The medication dispensing apparatus of claim 1 wherein said latching element is axially fixed to said housing by at least one flange fit into a slot provided in said housing.
>
> 7. The medication dispensing apparatus of claim 1 wherein said spring force acting on said latching element comprises a resiliency of said latching element tending to return said latching lip to a neutral arrangement.
>
> 8. The medication dispensing apparatus of claim 7 wherein said latching element comprises a one piece metal stamping.
>
> 9. The medication dispensing apparatus of claim 1 wherein said skid-engaging surface is smooth.
>
> 10. The medication dispensing apparatus of claim 1 wherein said latching lip comprises a rim along an opening through which latchable element extends to reach a latching engagement with said latching element.

Exhibit A, ’334 Patent, cl. 2-10.

B. Apotex’s Prefilled Teriparatide Pens Do Not Infringe Independent Claim 1 of the ’334 Patent, Either Literally or Under the Doctrine of Equivalents

52. Independent Claim 1 is directed to a medication dispensing apparatus comprising a number of different elements. Claim 1 contains several limitations that are directed to the medication dispensing apparatus utilizing a gear set, pinions, racks, and a latching element. To

literally infringe, Apotex's ANDA Product must include each of these limitations. Specifically, the relevant claim limitations read:

> 1. A medication dispensing apparatus comprising:
>
> **a gear set including first and second pinions**, said gear set pivotal on said plunger element and shiftable proximally and distally with the plunger element;
> **a first rack engaged with said first pinion and axially stationary within said housing;**
> **a second rack engaged with said second pinion and movable within said housing on a piece clutchably connected to said drive member;**
> **a latching element including a latching lip and a skid;**

Exhibit A, '334 patent at 9:56-10:13 (claim 1) (emphasis added).

53. Figure 2 of the '334 patent is a cross-sectional view of an embodiment containing a "gear set" (52):

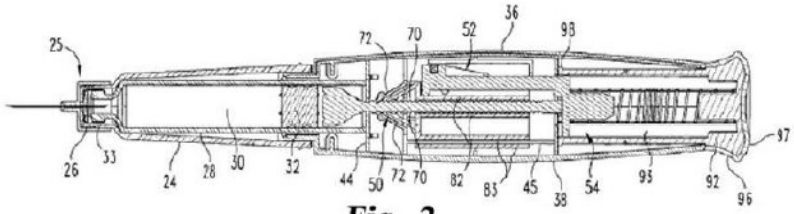

Fig. 2

See '334 patent at 2:44-45, 4:18-20, 6:50-55.

54. Figure 6, Figure 7, and Figure 8 of the '334 patent show sections of an embodiment containing a first "pinion" (160) and a second "pinion" (166):

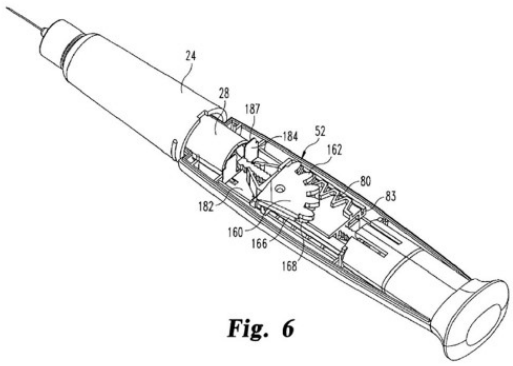

Fig. 6

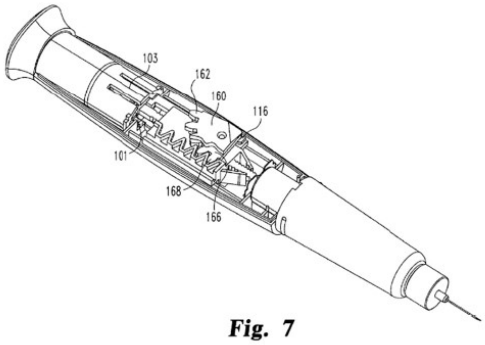

Fig. 7

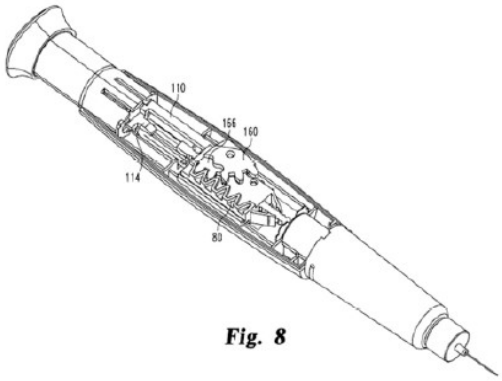

Fig. 8

See '334 patent at 2:54-67, 6:56-65.

55. Figure 4 of the '334 patent shows a first "rack" which is "fixed or axially stationary" (84):

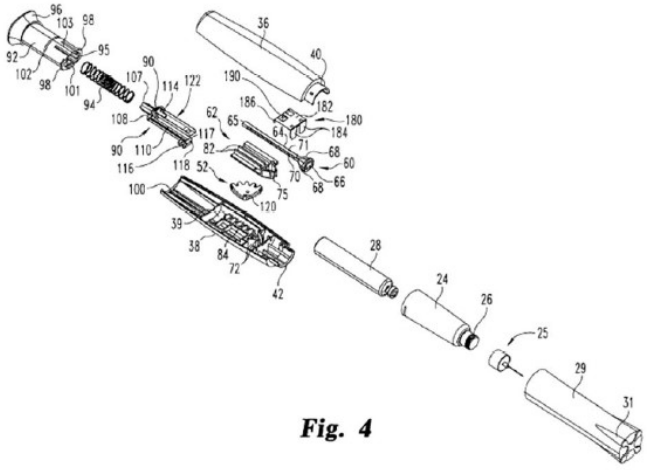

Fig. 4

See the '334 patent at 2:49-51, 5:1-3.

56. Figure 8 of the ’334 patent (see ¶ 67 supra) shows a second “rack” (80), the “drive member rack 80, which rack is parallel to and disposed on the same side of the pinion axis as rack 84.” See Ex. A (the ’334 patent) at 7:6-8, 7:19-28.

57. Apotex’s ANDA Product does not include at least “a gear set including first and second pinions, said gear set pivotal on said plunger element and shiftable proximally and distally with the plunger element; a first rack engaged with said first pinion and axially stationary within said house; and second rack engaged with said second pinion and movable within said housing on a piece clutchably connected to said drive member;” as required by claim 1 of the ’334 patent.

58. Apotex’s ANDA Product does not literally infringe claim 1 of the ’334 patent.

59. Apotex’s ANDA Product does not infringe claim 1 of the ’334 patent under the doctrine of equivalents because the injection device for use with Apotex’s ANDA Product is not insubstantially different from the medication dispensing apparatus required by the ’334 patent. Specifically, the medication dispensing apparatus for use with Apotex’s ANDA Product does not include a dosing mechanism for delivering teriparatide in which the means for administering teriparatide operate with at least substantially the same functions or in substantially the same way as “a gear set including first and second pinions, said gear set pivotal on said plunger element and shiftable proximally and distally with the plunger element; a first rack engaged with said first pinion and axially stationary within said house; and second rack engaged with said second pinion and movable within said housing on a piece clutchably connected to said drive member;” as required by claim 1 of the ’334 patent.

60. Independent Claim 1 also provides that the claimed medication dispensing apparatus possess a latching element that includes a latching lip and skid. Specifically, the claim requires:

> 1. A medication dispensing apparatus comprising:
> **a latching element including a latching lip and a skid**;
> said drive member including an axially extending, skid-engaging surface along which said skid is slidable as said drive member passes distally during advancement during plunger element shifting in the distal direction, said skid-engaging surface having an axial length and a proximal end, said drive member along said axial length structured and **arranged with said skid so as to maintain said latching lip against a spring force** in a first position free of a latchable element disposed on said plunger element during dose preparing and injecting prior to a final dose administration; and
> wherein said skid-engaging surface shifts distally of said skid such that **said skid passes beyond the proximal end upon administration of a final dose allowing said latching lip to be urged by said spring force** from said first position to a second position for engagement with said latchable element to physically lock said plunger element to prevent further dose preparing and injecting.

Exhibit A, the '334 patent, cl. 1 (emphasis added).

61. Figure 9 of the '334 patent shows a "latch lip" (186) and an "upstanding lip" (117):

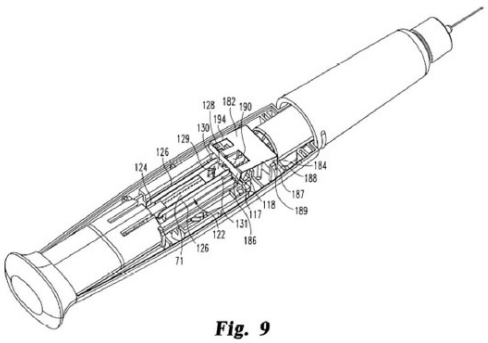

Fig. 9

62. Figure 10 and Figure 11 also show the "latch lip" (186):

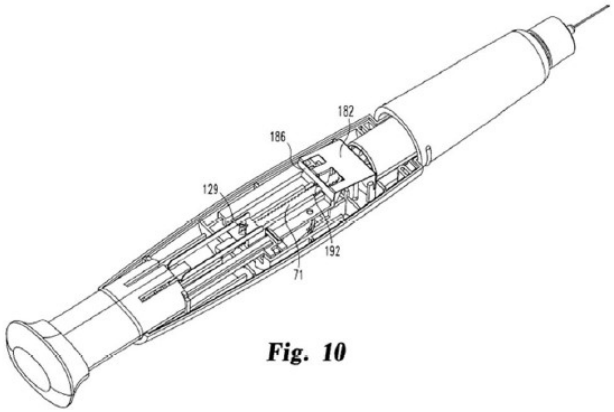

Fig. 10

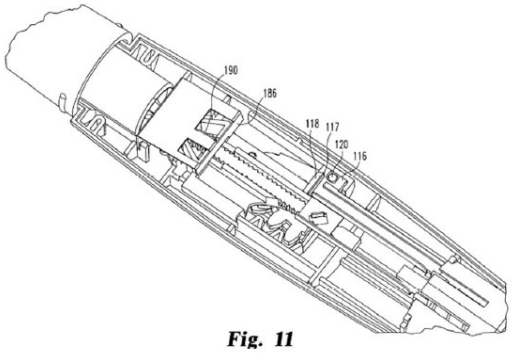

Fig. 11

See the '334 patent at 7:35-8:56.

63. Figure 13 shows the "rims" (240) which "serve as a pair of latching lips" and the "skid" (236):

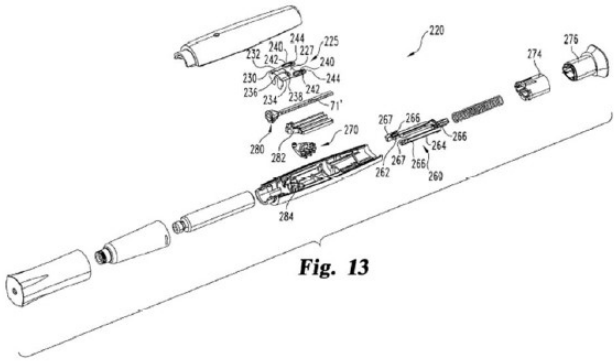

Fig. 13

See the '334 patent at 8:31-39.

64. Apotex's ANDA Product does not include at least "a latching element including a latching lip and a skid;" as required by claim 1 of the '334 patent.

65. Apotex's ANDA Product does not literally infringe claim 1 of the '334 patent.

66. Apotex's ANDA Product does not infringe claim 1 of the '334 patent under the doctrine of equivalents because the injection device for use with Apotex's ANDA Product is not insubstantially different from the medication dispensing apparatus required by the '334 patent. Specifically, the medication dispensing apparatus for use with Apotex's ANDA Product does not include a dosing mechanism for delivering teriparatide in which the means for administering teriparatide operate with at least substantially the same functions or in substantially the same way as "a latching element including a latching lip and a skid;" as required by claim 1 of the '334 patent.

C. Claims 2-10 of the '334 Patent

67. Claims 2-10 of the '334 patent depend from claim 1, and incorporate each and every limitation of claim 1. If an accused product does not infringe an independent claim, it does not infringe any claim that depends therefrom. 35 U.S.C. § 112(d). For at least the reasons discussed with respect to Claim 1, Apotex's ANDA Product cannot infringe any of claims 2-10 of the '334 patent, either literally or under the doctrine of equivalents.

CAUSES OF ACTION

COUNT I – DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF APOTEX'S GENERIC 600 mcg/2.4 mL (250 mcg/mL) PREFILLED TERIPARATIDE PENS

68. Apotex hereby incorporates by reference its allegations contained in paragraphs 1 through 80 of this Complaint as though fully set forth herein.

69. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*., the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Hatch-Waxman Act, 21 U.S.C. § 355(j)(5)(C).

70. Lilly listed the '334 patent in the Orange Book as covering its Forteo® 600 mcg/2.4 mL (250 mcg/mL) prefilled teriparatide pens.

71. Apotex filed an ANDA with a Paragraph IV certification stating the '334 patent is not and will not be infringed by Apotex's 600 mcg/2.4 mL (250 mcg/mL) prefilled teriparatide pens.

72. Apotex intends to sell its generic 600 mcg/2.4 mL (250 mcg/mL) prefilled teriparatide pens, as described in ANDA No. 211097 once it obtains final FDA approval.

73. There is a real, actual and continuing justiciable case and controversy between Apotex and Lilly regarding the infringement of the '334 patent by Apotex's generic 600 mcg/2.4 mL (250 mcg/mL) prefilled teriparatide pens.

74. The '334 patent will not be infringed by Apotex's filing of ANDA No. 211097 or the manufacture, use, offer for sale, sale, and/or importation of Apotex's generic 600 mcg/2.4 mL (250 mcg/mL) prefilled teriparatide pens that are described in ANDA No. 211097, either directly or indirectly under 35 U.S.C. § 271.

75. Accordingly, Apotex seeks and is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, and or importation of Apotex's 600 mcg/2.4 mL (250 mcg/mL) prefilled teriparatide pens described in ANDA No. 211097, do not and will not infringe, directly or indirectly, any claim of the '334 patent.

PRAYER FOR RELIEF

WHEREFORE, Apotex prays for a declaratory judgment against Lilly as follows:

a. Judgment against Lilly declaring that the '334 patent is not and will not be infringed by Apotex's submission of ANDA No. 211097.

b. Judgment against Lilly declaring the manufacture, use, offer for sale, sale, and or importation of Apotex's generic 600 mcg/2.4 mL (250 mcg/mL) prefilled teriparatide pens described in ANDA No. 211097 do not infringe and will not, if marked, used, offered for sale, or sold, infringe or induce or contribute to the infringement of the '334 patent; and

c. Awarding Apotex such other and further relief as the Court deems just and reasonable.

Date: December 6, 2022

Respectfully submitted,

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