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

ORBICULAR PHARMACEUTICAL TECHNOLOGIES PRIVATE LIMITED, and CIPLA USA, INC., Plaintiffs, v. ELI LILLY AND COMPANY, Defendant.	Civil Action No. 1:22-cv-1130 **COMPAINT FOR DECLARATORY JUDGMENT** **CONFIDENTIAL VERSION**

Plaintiffs Orbicular Pharmaceutical Technologies Private Limited ("Orbicular") and Cipla USA, Inc. ("Cipla"), collectively, "Plaintiffs", bring this Complaint against Eli Lilly and Company ("Defendant" or "Lilly") seeking a declaration that Plaintiffs have not infringed, do not infringe, and will not infringe any claim of U.S. Patent No. 7,517,334 ("the '334 Patent"). Plaintiffs bring this suit to obtain patent certainty under 21 U.S.C. § 355(j)(5)(C)(i)(I) and to obtain final FDA approval to market a generic teriparatide injection product (the "ANDA Product") 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 Hatch-Waxman Act governs approvals by the U.S. Food and Drug

Administration ("FDA") of drugs. Orbicular and Cipla are parties to a 2019 Development, Manufacture, License, Supply, and Distribution Agreement. Under that agreement, Orbicular seeks FDA approval for commercial manufacture, use, importation, offer for sale, and sale of a generic version of Forteo® (Teriparatide Injection USP) 600mcg/2.4mL (250 mcg/mL) prefilled pens as described in Plaintiffs' Abbreviated New Drug Application ("ANDA") No. 215844 ("Plaintiffs' ANDA"), and Cipla holds the exclusive right to market the ANDA Product. The ANDA contains a certification pursuant to 21 U.S.C.§ 355(j)(2)(A)(vii)(IV) with respect to the '334 Patent.

2. In accordance with 21 U.S.C. § 355(j)(2)(B) and 21 C.F.R. § 314.95, Plaintiffs sent notice to Lilly of the Paragraph IV certification as to the '334 Patent, and provided an Offer of Confidential Access to Plaintiffs' ANDA No. 215844. According to the terms of the Offer of Confidential Access, Lilly reviewed agreed-upon sections of the ANDA and certain other documents provided by Orbicular, but did not bring a suit for patent infringement within 45 days of receiving notice of the Paragraph IV certification, even though it had an opportunity to bring one. *See* 21 U.S.C. § 355(j)(5)(C).

3. The Hatch-Waxman Act provides for a "civil action to obtain patent certainty" when a generic applicant makes such certifications, and the patent owner does not bring an action within 45 days of receiving notice of the Paragraph IV certification. *See* 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa)-(cc). This declaratory judgment provision in the Hatch-Waxman Act aims to encourage early resolution of patent disputes, and prevent brand-name drug companies from using tactics that forestall the competing generic drug makers from entering the market. *See Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1285 (Fed. Cir. 2008).

4. The Medicare Modernization Act of 2003 ("MMA") sets forth certain provisions

by which the first applicant(s) to file an ANDA with a Paragraph IV certification as to a drug (a "first ANDA filer") would forfeit the generic exclusivity which the Hatch-Waxman provides to first ANDA filers. For example, the entry of a final judgment of non-infringement with respect to the patents against which a first ANDA filer submitted Paragraph IV certifications, regardless of whether or not those patents are asserted against subsequent ANDA filers, will cause the first ANDA filer to forfeit its exclusivity. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA).

5. Plaintiffs' complaint seeks a judgment to obtain patent certainty that Plaintiffs' 600mcg/2.4mL (250 mcg/mL) prefilled teriparatide pens do not infringe any claim of the '334 Patent. Such judgment triggers forfeiture of the first ANDA applicant's 180-day exclusivity, which otherwise blocks the FDA from approving Orbicular's ANDA, so as to enable Plaintiffs to bring their prefilled teriparatide pens to market at the earliest possible date allowed under applicable statutory and FDA regulatory provisions. Moreover, in the absence of a declaratory judgment, Lilly could sue Plaintiffs at any time, whether before or after Plaintiffs enter the market, and could potentially seek an injunction that could have the effect of delaying Plaintiffs' market entry even beyond the expiration of the first-filer's exclusivity.

THE PARTIES

6. Plaintiff Orbicular Pharmaceutical Technologies Private Limited ("Orbicular") is a corporation organized and existing under the laws of India and having a principal place of business at P. No. 53, ALEAP Industrial Estate, Behind Pragati Nagar, Kukatpally, Hyderabad 500 090 Telangana, India.

7. Plaintiff Cipla USA, Inc. ("Cipla") is a corporation organized and existing under the laws of Delaware and having a principal place of business at 919 North Market Street, Suite 950, Wilmington, Delaware 19801.

8. Defendant Eli Lilly and Company is a corporation organized and existing under the laws of Indiana and having its principal place of business at Lilly Corporate Center, 893 Delaware Street, Indianapolis, Indiana 46285.

9. 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

10. This is a Complaint for a declaratory judgment that Plaintiffs have not, do 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.

11. 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 and 2202), 21 U.S.C. § 355(j)(5)(C), and 35 U.S.C. § 271(e)(5).

12. An actual controversy exists between Plaintiffs and Lilly by virtue of Lilly's listing of the '334 Patent in the Orange Book for Forteo®, Plaintiffs' filing of ANDA No. 215844 with the FDA under § 505(j) of the Federal Food Drug and Cosmetic Act, 21 U.S.C. § 355(j), for generic versions of 600mcg/2.4mL (250 mcg/mL) prefilled teriparatide pens that are bioequivalent to Lilly's drug Forteo® ("Plaintiffs' ANDA Product"), and Lilly's failure to bring suit against Plaintiffs in connection with Plaintiffs' filing of ANDA No. 215844 or any product described therein. Additionally, another applicant was the first to submit an ANDA referencing the 600mcg/2.4mL (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 Plaintiffs' ANDA. Only a final decision of noninfringement 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).

13. Plaintiffs contend that they have a right to engage in making, using, offering to sell, and selling their products described in Plaintiffs' ANDA, without license from Lilly.

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

15. 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.

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

OVERVIEW OF RELEVANT PORTIONS OF THE HATCH-WAXMAN ACT

17. In 1984, the Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Act, was enacted. *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.

18. To accomplish this goal, the Hatch-Waxman Act established a framework with five elements that are pertinent here.

19. 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)(I). The new FDA-approved drug is known as the "reference-listed drug."

20. 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).

21. An ANDA must also contain one of four certifications for each patent listed in the Orange Book: (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) that 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."

22. 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. *See* 21 U.S.C. § 355(j)(2)(B)(i).

23. The Hatch-Waxman Act encourages prompt resolution of patent disputes by authorizing a patent owner to sue an ANDA applicant for patent infringement if a Paragraph IV certification has been made. *See* 35 U.S.C. § 271(e)(2). By statute, if the patent owner brings suit within 45-days of receiving notice of the Paragraph IV certification, the suit will trigger an automatic statutory 30-month stay of approval by the FDA of the ANDA to allow parties time to adjudicate the merits of the infringement action before the generic company launches its product. *See* 21 U.S.C. § 355(j)(5)(B)(iii).

24. To encourage prompt generic-market entry, the Hatch-Waxman Act grants the first generic applicant to file a substantially complete ANDA containing a Paragraph IV certification ("first-filer") to an Orange-Book-listed patent a 180-day period of marketing exclusivity that begins upon the date it begins commercial marketing of its generic-drug product. During this 180-day period of exclusivity, the FDA may not approve ANDAs filed subsequent to the first filed ANDA.

25. To curb abuses of the 180-day exclusivity by patent owners and first-filers, whereby the 180-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, which provided for various conditions under which a first-filer would forfeit

its 180-day eligibility. *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 eligibility will be forfeited if a subsequent ANDA filer obtains a judgment of noninfringement as to the patent(s) that confer exclusivity. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA); *see also Daiichi Sankyo,* 781 F.3d at 1360. As part of that remedy, the Hatch-Waxman Act allows ANDA applicants to bring declaratory-judgment actions asserting noninfringement against any relevant Orange-Book-listed patent if (1) neither the patent owner nor the NDA holder brought an action against the ANDA applicant for infringement of the patent within the 45-day period; and (2) the ANDA applicant's notice of Paragraph IV certification included an offer of confidential access to the ANDA. 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa)-(cc).

26. If the first-filer does not commercially market the generic drug and none of the MMA forfeiture provisions are triggered (including the entry of a final judgment of non-infringement or invalidity), the first-filer's 180-day exclusivity period will be delayed indefinitely, ultimately blocking final FDA approval of all subsequent ANDAs. This block is known as "bottlenecking" or the '"statutory block" of a subsequent ANDA.

27. 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' bottlenecked ANDAs.

28. 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).

LILLY BLOCKS PLAINTIFFS' GENERIC ENTRY

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

29. Lilly requested that the FDA list the '334 Patent in the Orange Book in connection with its Forteo® NDA as a patent to 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 600mcg/2.4mL (250 mcg/mL) teriparatide in a prefilled pen. 21 U.S.C.§ 355(b)(1), (c)(2).

30. Lilly is the holder of the approved Forteo® NDA 021318, and caused or authorized the '334 Patent to be listed in the Orange Book in connection with the Forteo® NDA.

31. The '334 Patent, entitled "Medication dispensing apparatus with spring-driven locking feature enabled by administration of final dose," issued on April 14, 2009. The 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.

32. The '334 Patent purports to claim a medication dispensing apparatus with specified elements.

33. At the time of Plaintiffs' ANDA filing, one patent was listed in FDA's Orange Book as covering Forteo®: the '334 Patent. Under the Hatch-Waxman statutory scheme, Plaintiffs

were required to submit patent certification to the '334 Patent.

34. Plaintiffs' ANDA contains a Paragraph IV certification that Plaintiffs' ANDA Product will not infringe the '334 Patent, which the Orange Book lists as having an expiration date of March 25, 2025. Through their Paragraph IV certification, Plaintiffs are seeking immediate approval of their ANDA, prior to expiration of the '334 Patent.

B. The First Paragraph IV Certification for Forteo®

35. The FDA maintains the identity of the first-filer(s) as confidential. However, the FDA publishes the date of submission of the first substantially complete ANDA containing a Paragraph IV certification for each drug. For Forteo®, the FDA identifies the date of submission of the first-filer(s) as July 27, 2015. *See* Exhibit B.

36. On information and belief, the first-filer submitted a substantially complete ANDA containing a Paragraph IV certification for 600mcg/2.4mL (250 mcg/mL, 2.4 mL) prefilled teriparatide pens on July 27, 2015, and thus holds eligibility for 180-day marketing exclusivity that prevents all subsequently filed ANDAs (including Plaintiffs' ANDA) from receiving final approval. However, absent a judgment by this Court on the '334 Patent, the first- filer(s) will retain eligibility for 180-days of marketing exclusivity indefinitely until (1) it launches its product or (2) upon expiration of the '334 Patent, thereby blocking Plaintiffs' market entry.

37. 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.

C. Plaintiffs Apply for FDA Approval of Plaintiffs' 600mcg/2.4mL (250 mcg/mL, 2.4 mL) Prefilled Teriparatide Pens

38. Orbicular submitted ANDA No. 215844 to the FDA seeking approval for the commercial manufacture, use, importation, offer for sale, and sale of a generic version of 600mcg/2.4mL (250 mcg/mL) Forteo® prefilled teriparatide pens. This ANDA contains a Paragraph IV certification that the '334 Patent will not be infringed by the manufacture, use, or sale of Plaintiffs' prefilled teriparatide pens. Orbicular submitted its ANDA *after* July 27, 2015, and therefore is a "subsequent filer." As a subsequent filer, Cipla is blocked from marketing the ANDA Product by the first-filer's exclusivity.

39. On May 3, 2021, Orbicular sent notice to Lilly, as it was required by law, of Orbicular's Paragraph IV certification regarding the '334 Patent in the ANDA and provided an Offer of Confidential Access to its ANDA No. 215844 pursuant to 21 U.S.C. § 355(j)(5)(C) ("Notice Letter").

40. Lilly received the Notice Letter no later than May 4, 2021.

41. The Notice Letter provided Lilly a detailed factual and legal basis for the Paragraph IV certification to the '334 Patent, explaining why it would not be infringed by Plaintiffs' proposed generic version of 600mcg/2.4mL (250 mcg/mL) prefilled teriparatide pens. Lilly had a statutory right to bring suit against Plaintiffs if Lilly believed that Plaintiffs infringed the '334 Patent, but Lilly chose not to file suit. 21 U.S.C. § 355(j)(5)(B)(iii). Having failed to sue Plaintiffs within a 45-day period following receipt of the Notice Letter, the relevant statute provides Plaintiffs with a statutory right to bring the present declaratory judgment action for patent certainty. 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa)- (cc).

D. Plaintiffs' Approval is Blocked

42. Plaintiffs expect the FDA to promptly approve the ANDA; such approval could

be imminent, and is expected by no later than the end of 2022, and Plaintiffs will be prepared to begin commercial marketing of their prefilled teriparatide pens upon FDA marketing approval. Plaintiffs' prefilled teriparatide pens, however, will be blocked from receiving final approval and prevented from actually entering the market until the end of any first-filer exclusivity based on the '334 Patent.

43. As a consequence, absent a judgment from this Court declaring that the ANDA Product does not infringe the '334 Patent, Plaintiffs will be unable to sell the generic 600mcg/2.4mL (250 mcg/mL) prefilled teriparatide pens indefinitely, thereby injuring Plaintiffs by depriving them of sales revenue that they could earn for that period of time. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb).

AN ARTICLE III CASE OR CONTROVERSY EXISTS

44. There is an actual and ongoing controversy between Plaintiffs 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-filer's exclusivity, as Congress intended under 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb), thereby allowing Plaintiffs to bring their generic prefilled teriparatide pens to market at the earliest possible date, and enhancing generic competition.

45. The present dispute between Plaintiffs and Lilly presents a justiciable Article III controversy because Plaintiffs have standing and the issues raised are ripe for adjudication and Plaintiffs are seeking relief through the declaratory judgment mechanism established by Congress to obtain patent certainty. *See, e.g., Caraco,* 527 F.3d at 1278; 35 U.S.C. § 355(j)(5)(C).

46. 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.

47. Plaintiffs suffer an injury-in-fact from the ongoing listing of Defendants' '334 Patent in FDA's Orange Book. The '334 Patent confers 180-day exclusivity eligibility for the first-filer, which will preclude Plaintiffs from marketing their non-infringing generic prefilled teriparatide pens at the earliest possible date. Plaintiffs' 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 Plaintiffs' ANDA causing injury-in-fact to Orbicular. *Id.* Plaintiffs' injury is directly traceable to Lilly because Lilly listed the '334 Patent in the Orange Book and chose not to sue Plaintiffs after receiving a notice of Plaintiffs' Paragraph IV certification, so as to avoid an adverse judgment. 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.

48. But for Lilly's actions, final approval of Plaintiffs' ANDA would not be delayed by any first-filer's 180 day exclusivity. Lilly's actions cause injury to Plaintiffs by preventing Plaintiffs from rightfully marketing and earning revenue on a non-infringing product.

49. Plaintiffs' injury is redressable: judgment of non-infringement of the '334 Patent from this Court will activate forfeiture of the first-filer's exclusivity period as Congress intended, allowing Plaintiffs to enter the market at the earliest possible date and obtain patent certainty.

50. Accordingly, there is an actual, substantial and continuing justiciable case and

controversy between Plaintiffs and Lilly, over which this Court can and should exercise jurisdiction and declare the rights of the Parties. *Caraco*, 527 F.3d at 1278.

51. 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. Plaintiffs satisfy both prongs for ripeness. *First*, additional factual development would not advance the district court's ability to decide Plaintiffs' action because Orbicular's ANDA has all the necessary information to determine whether Plaintiffs' prefilled teriparatide pens infringe the '334 Patent. *Second*, Plaintiffs will not be able to obtain patent certainty or FDA approval to market their prefilled teriparatide pens at the earliest possible date without a declaratory judgment: a hardship that creates the potential for substantial lost revenue.

PLAINTIFFS' 600MCG/2.4ML (250 MCG/ML) PREFILLED TERIPARATIDE PENS

52. Orbicular submitted an ANDA to the FDA seeking approval to manufacture and sell a generic version of Lilly's Forteo® (Teriparatide Injection USP) 600mcg/2.4mL (250 mcg/mL) prefilled teriparatide pens as described in Orbicular's ANDA No. 215844.

53. [redacted]

[redacted]

54. [redacted]

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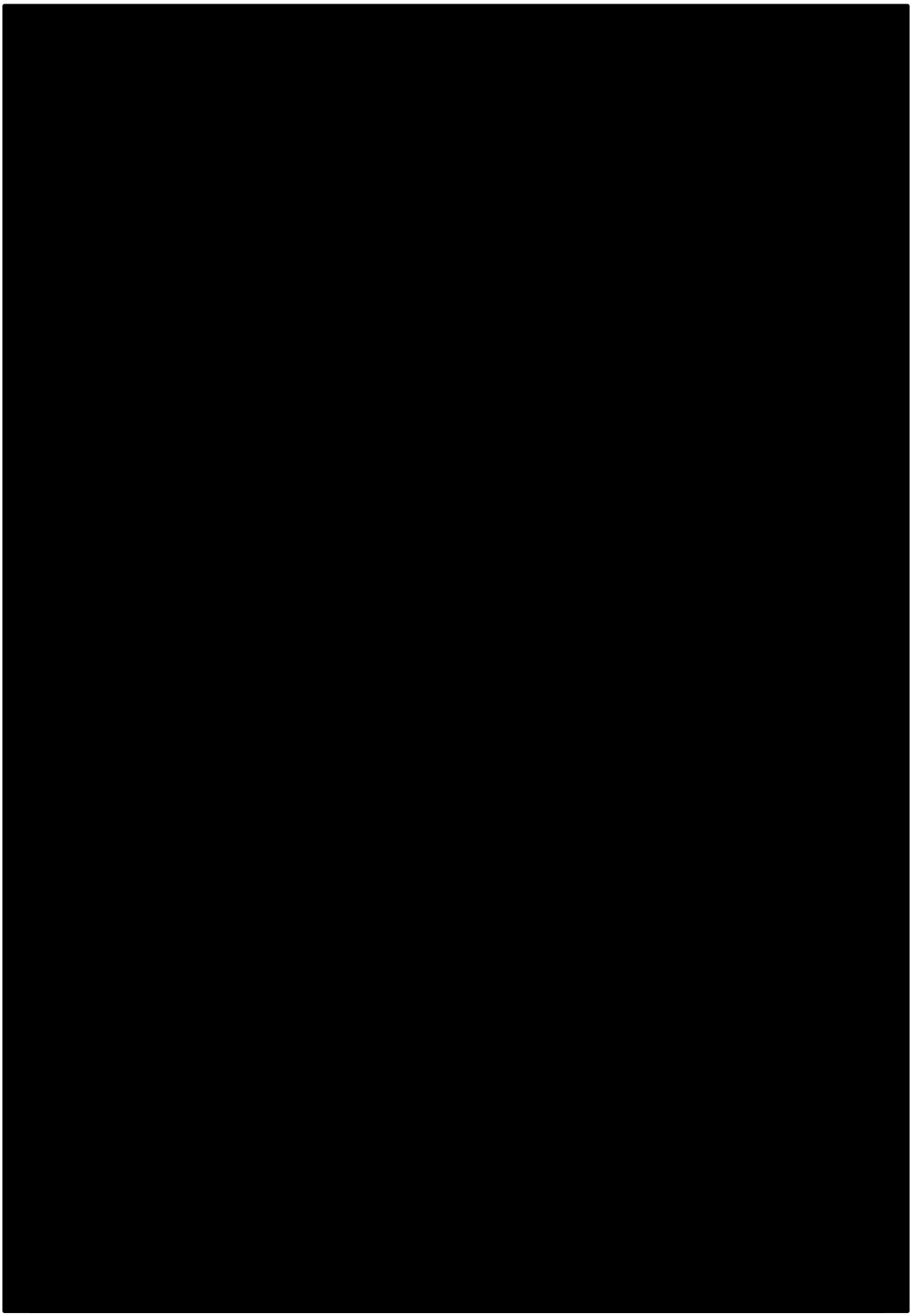

NON-INFRINGEMENT OF THE '334 PATENT

58. Patent infringement under 35 U.S.C. § 271(e)(2) requires a comparison between the patent claims and the proposed ANDA product. If any claim limitation is absent from the proposed ANDA product, 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

59. 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.

60. 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 a latchable element extends to reach a latching engagement with said latching element.

Exhibit A, '334 Patent, cl. 2-10.

B. Plaintiffs' Prefilled Teriparatide Pens Cannot Infringe Independent Claim 1 of the '334 Patent, Either Literally or Under the Doctrine of Equivalents

61. 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, Plaintiffs' 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 fust 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).

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

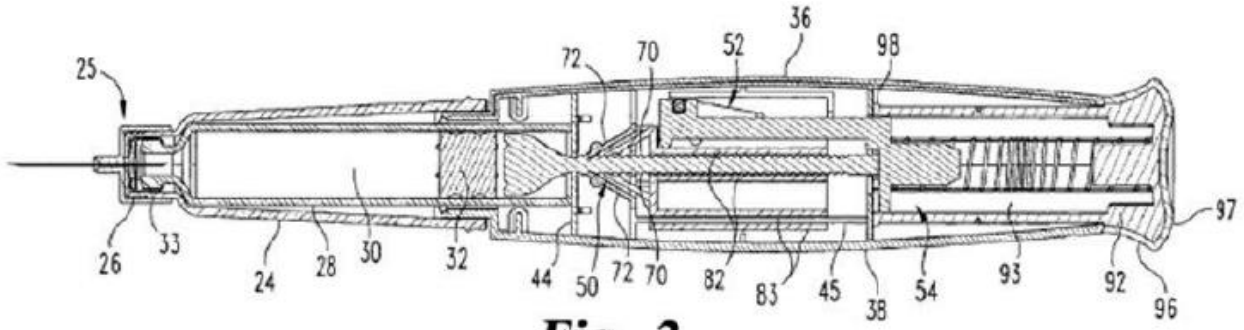

Fig. 2

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

63. 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):

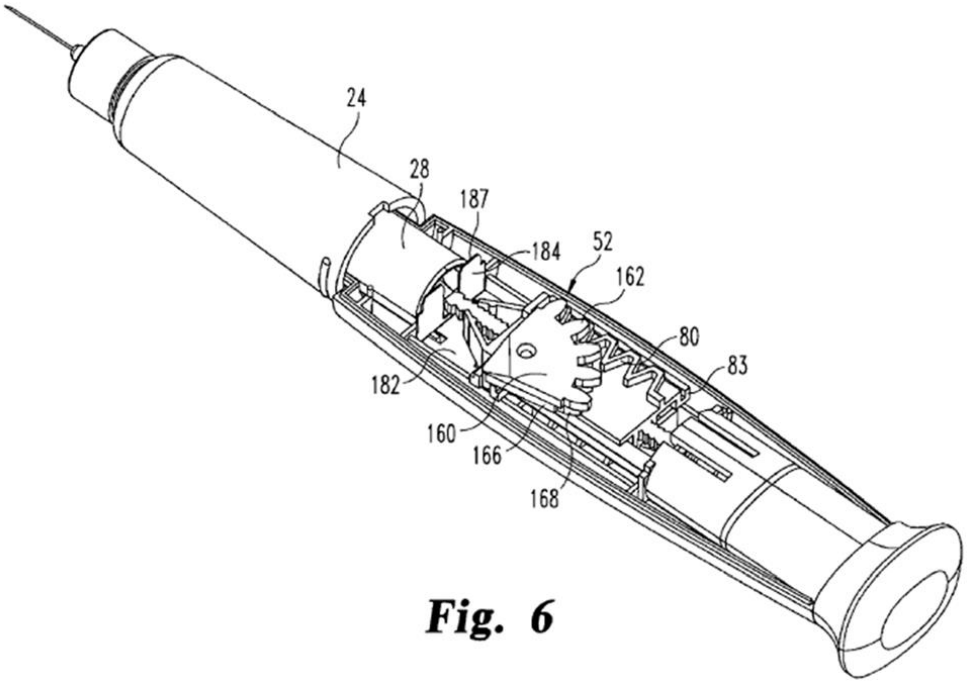
24
28
187
184
52
162
80
83
182
160
166
168

Fig. 6

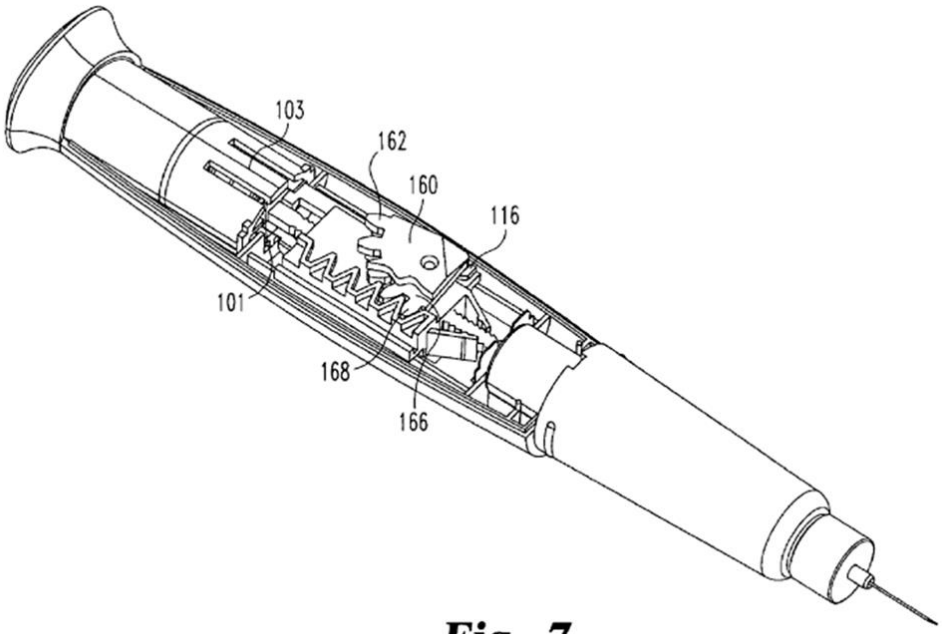
103
162
160
116
101
168
166

Fig. 7

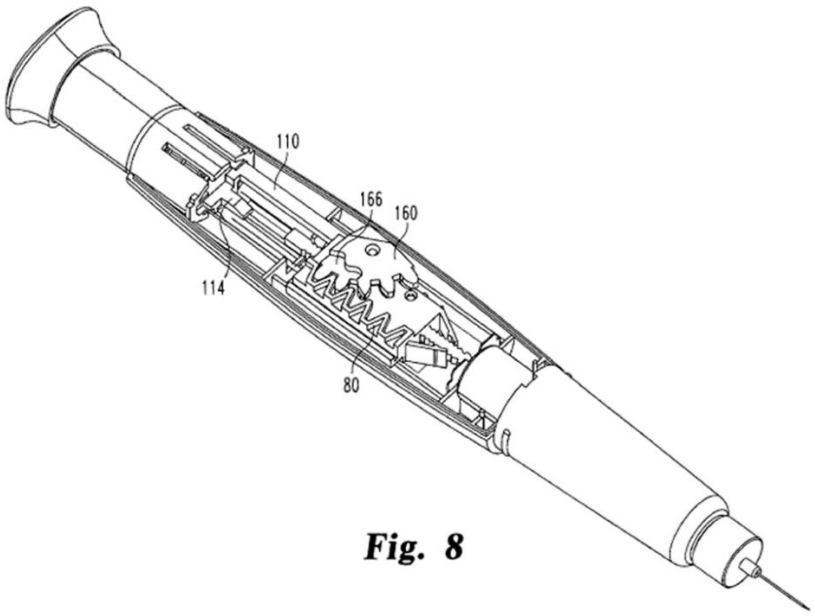

Fig. 8

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

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

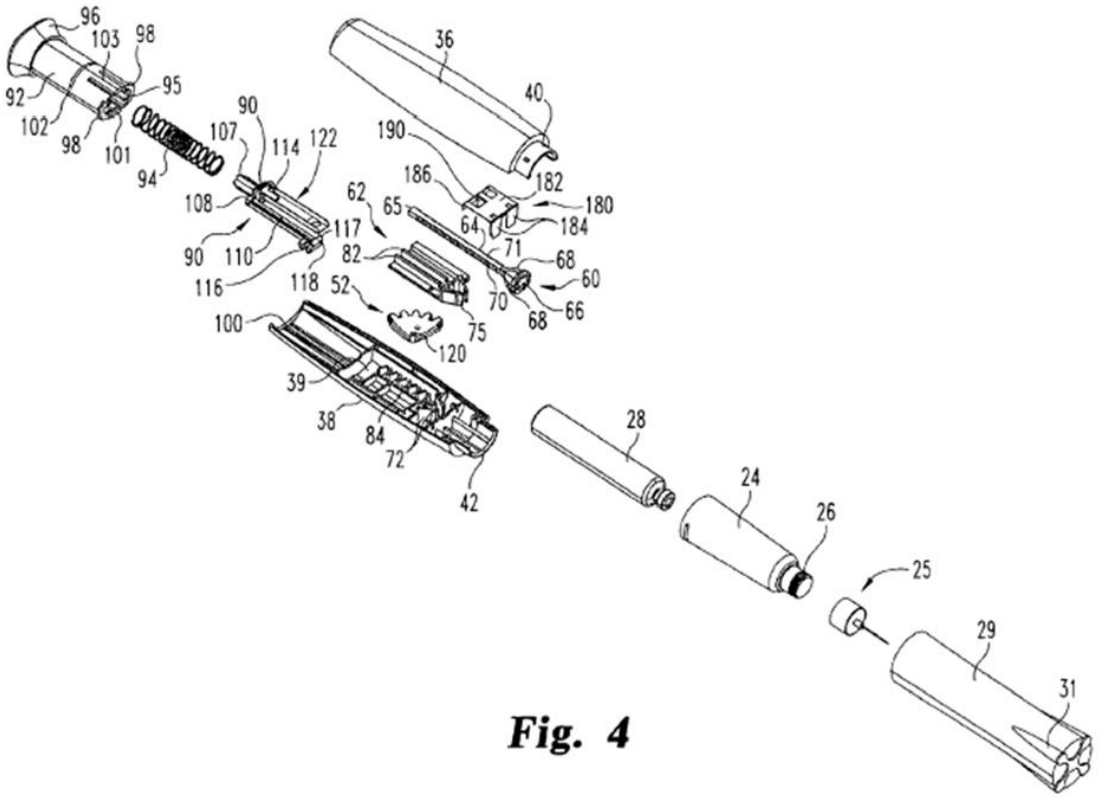

Fig. 4

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

65. Figure 8 of the '334 Patent (*supra* ¶ 64) 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* '334 Patent at 7:6-8, 7:19-28.

66. [redacted] "a gear set including first and second pinions"; "a first rack engaged with said fust 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"; or "[redacted]

67. [redacted]

68. [redacted]

69. [redacted]

[redacted]

70. Independent Claim 1 also provides that the claimed medication dispensing apparatus possess a latching element that includes a latching lip and skid. [redacted] 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, ’334 Patent, cl. 1.

71. Figure 9 of the ’334 Patent shows a “latch lip” (186) and an “upstanding lip” (117):

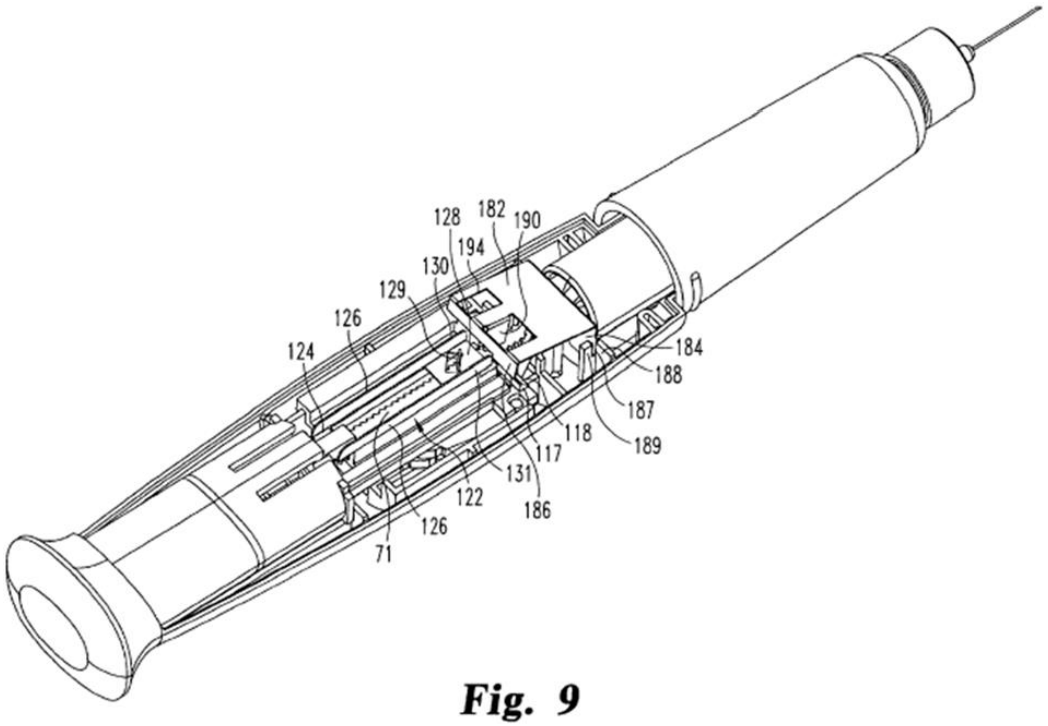

Fig. 9

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

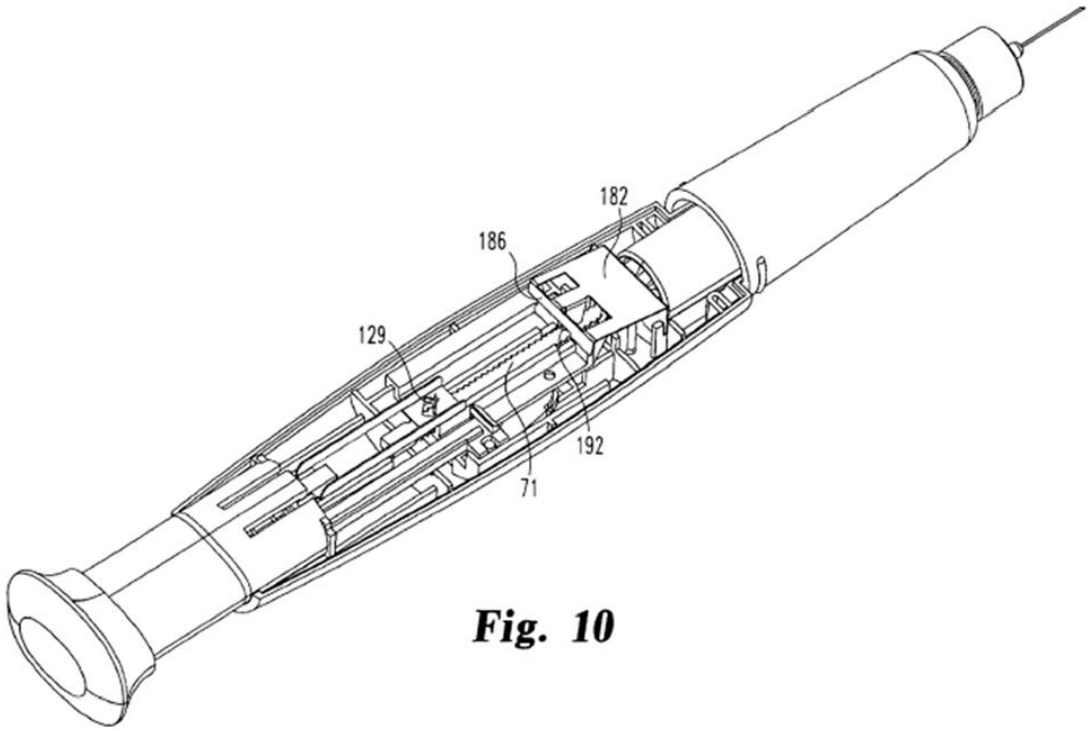

Fig. 10

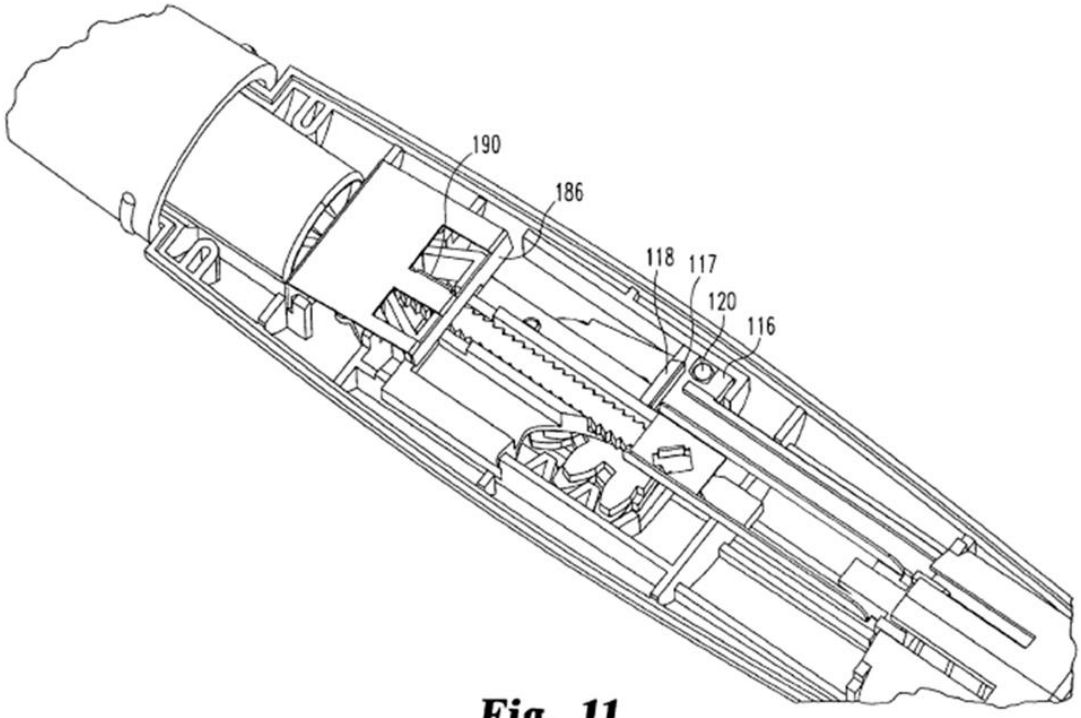

Fig. 11

See '344 patent at 7:35-8:56.

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

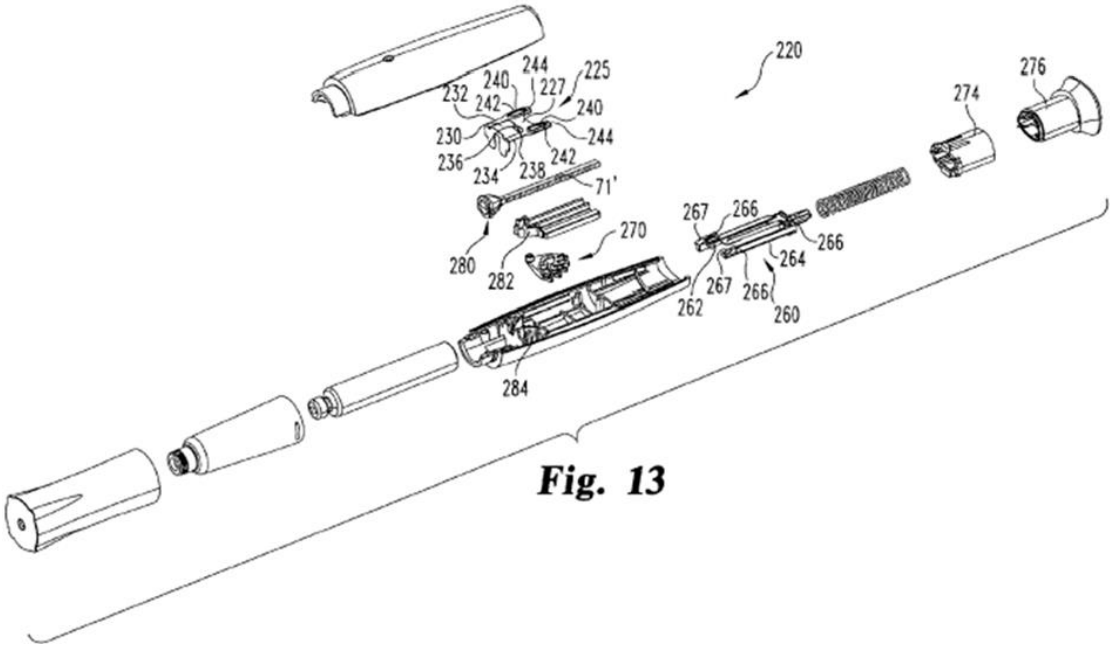

Fig. 13

'334 Patent at 8:31-39.

74. [redacted]

75. [redacted]

76. [redacted]

C. Claims 2-10

77. Each of dependent Claims 2-10 depends, either directly or indirectly, from independent Claim 1. As explained (*supra*, ¶¶ 60-77), Plaintiffs' ANDA Product does not infringe Claim 1 either literally or under the doctrine of equivalents.

78. If a claim does not infringe, either literally or under the doctrine of equivalents, all claims depending from the non-infringed claim are not infringed as a matter of law. *See Voter Verified, Inc. v. Premier Election Solutions, Inc.*, 698 F.3d 1374, 1383 (Fed. Cir. 2012). For at

least the reasons discussed with respect to Claim 1, Plaintiffs' ANDA Product cannot infringe any of Claims 2- 10, either literally or under the doctrine of equivalents.

CAUSES OF ACTION

COUNT I – DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF PLAINTIFFS' GENERIC 600MCG/2.4ML (250MCG/ML) PREFILLED TERIPARATIDE PENS

79. Plaintiffs hereby incorporate by reference their allegations contained in Paragraphs 1 through 78 of this Complaint as though fully set forth herein.

80. 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).

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

82. Orbicular filed an ANDA with a Paragraph IV certification stating the '334 Patent is not and will not be infringed by Plaintiffs' 600mcg/2.4mL (250 mcg/mL) prefilled teriparatide pens.

83. Cipla intends to sell the generic 600mcg/2.4mL (250 mcg/mL) prefilled teriparatide pens, as described in ANDA No. 215844, once Plaintiffs obtain final FDA approval.

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

85. The '334 Patent will not be infringed by the filing of ANDA No. 215844 or the manufacture, use, offer for sale, sale, and/or importation of Plaintiffs' generic 600mcg/2.4mL (250 mcg/mL) prefilled teriparatide pens that are described in ANDA No. 215844, either directly or indirectly under 35 U.S.C. § 271.

86. Accordingly, Plaintiffs seek and are entitled to a judicial declaration that the manufacture, use, offer for sale, sale, and or importation of Plaintiffs' 600mcg/2.4mL (250 mcg/mL) prefilled teriparatide pens, described in ANDA No. 215844, do not and will not infringe, directly or indirectly, any claim of the '334 Patent.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray 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 Plaintiffs' submission of ANDA No. 215844;

b. Judgment against Lilly declaring the manufacture, marketing, use, offer for sale, sale, and or importation of Plaintiffs' generic 600mcg/2.4mL (250 mcg/mL) prefilled teriparatide pens described in ANDA No. 215844 do not infringe and will not, if marketed, used, offered for sale, or sold, infringe or induce or contribute to the infringement of the '334 Patent;

c. Awarding Plaintiffs their costs, expenses and reasonable attorneys' fees pursuant to 35 U.S.C. § 285; and

d. Awarding Plaintiffs such other and further relief as the Court deems just and reasonable.

Dated: June 2, 2022.

Respectfully submitted,

/s/ James W. Riley, Jr.
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