UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

SUN PHARMACEUTICAL INDUSTRIES LTD., and SUN PHARMACEUTICAL INDUSTRIES, INC., Plaintiffs, v. ELI LILLY AND COMPANY, Defendant.	Case No.: 1:21-cv-2971

COMPLAINT

Plaintiffs Sun Pharmaceutical Industries Ltd. and Sun Pharmaceutical Industries Inc. (collectively, "Plaintiffs" or "Sun"), bring this Complaint against Eli Lilly and Company ("Defendant" or "Lilly") seeking a declaration that Sun has not infringed, does not infringe, and will not infringe any valid claim of U.S. Patent No. 7,517,334 ("the '334 patent"). Sun brings this suit to obtain patent certainty under 21 U.S.C. § 355(j)(5)(C)(i) and to ensure its final FDA approval to market its teriparatide injection product as described in Abbreviated New Drug Application No. 215424 is not delayed and is approved at the earliest possible date pursuant to 21 U.S.C. § 355 (j)(5)(D)(i)(I).

NATURE OF THE ACTION

1. The Hatch-Waxman Act governs the U.S. Food and Drug Administration's ("FDA") approval of both new and generic drugs. Sun seeks FDA approval for the

commercial manufacture, use, importation, offer for sale, and sale of a version of Forteo® (Teriparatide Injection USP) 600mcg/2.4mL (250 mcg/mL) prefilled pens ("Sun's ANDA Product") as described in Sun's Abbreviated New Drug Application ("ANDA") No. 215424 ("Sun's ANDA"). Sun's 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, Sun sent notice to Lilly of Sun's Paragraph IV certification to the '334 patent and provided an Offer of Confidential Access ("OCA") to its ANDA No. 215424.

3. The Hatch-Waxman Act provides for a "[c]ivil 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). The Hatch-Waxman Act further provides that a generic applicant may further "bring a civil action under such section" if a patent owner files a civil action and then dismisses it without prejudice. *See* 21 U.S.C. § 355(j)(5)(C)(i)(II). 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. Sun's Complaint seeks a judgment to obtain patent certainty that Sun's ANDA and Sun's ANDA Product do not infringe any valid and enforceable claim of the '334 patent.

In the absence of a declaratory judgment, Lilly could sue Sun at any time, whether before or after Sun enters the market. *See Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330, 1345 (Fed. Cir. 2007).

5. Sun therefore is under a cloud of litigation uncertainty with respect to its ANDA and ANDA Product, which may impact Sun's ANDA approval and Sun's business decisions. Sun is entitled to and seeks to lift this cloud of uncertainty under 21 U.S.C. § 355(j)(5)(C)(i).

THE PARTIES

6. Plaintiff Sun Pharmaceutical Industries Ltd. is a corporation organized and existing under the laws of the Republic of India with its place of business at Sun House, CTS No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai 400063, India.

7. Plaintiff Sun Pharmaceutical Industries, Inc. is a corporation organized and existing under the laws of the State of Delaware with its place of business at 2 Independence Way, Princeton, NJ 08540.

8. Upon information and belief, 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") for the '334 patent.

JURISDICTION AND VENUE

10. This is a Complaint for a declaratory judgment that Sun 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.

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

12. An actual controversy exists between Sun and Lilly by virtue of Lilly's listing and maintenance of the '334 patent in the Orange Book for Forteo®, Sun's filing of Sun's ANDA seeking approval for Sun's ANDA Product, Lilly's decision to file a lawsuit against Sun in connection with Sun's ANDA and then dismissing it without prejudice, Lilly's refusal to grant Sun a covenant not to sue with respect to the '334 patent and Sun's ANDA (without demanding material conditions), and Lilly's failure to disavow the allegations set forth in its lawsuit relating to Sun's alleged infringement of the '334 patent.

13. 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. Lilly transacts business in the State of Indiana and has purposefully availed itself of the privileges of doing business in Indiana.

14. 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 Sun'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.

HATCH-WAXMAN ACT OVERVIEW

15. 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.

16. To accomplish this goal, the Hatch-Waxman Act established a framework with four elements relevant here.

17. 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."

18. 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).

19. An ANDA must also contain one of four certifications for each patent listed in the Orange Book that: (i) there are no patents listed in the Orange Book; (ii) any listed patent has expired; (iii) 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" or "PIV certification."

20. 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).

21. Third, the Hatch-Waxman Act encourages prompt resolution of patent disputes by authorizing a patent owner to sue an ANDA applicant for patent infringement upon a Paragraph IV submission. 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. 21 U.S.C. § 355(j)(5)(B)(iii). By statute, the 30-month stay is extinguished if before the expiration of the period, (1) the district court decides that the patent is invalid or not infringed, (2) the district court decides that the patent has been infringed, (3) the court grants a preliminary injunction prohibiting the applicant from engaging in commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement, or (4) the court grants a preliminary injunction prohibiting the applicant from engaging in commercial manufacture or sale of the drug until the court decides the issues of patent validity and infringement and then the court decides such patent has been infringed. 21 U.S.C. §355(j)(5)(B)(iii)(I)-(IV).

22. Fourth, to curb abuses by patent owners and provide certainty to ANDA applicants, Congress extended federal court declaratory judgment jurisdiction to

Paragraph-IV disputes. 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 (or does so and dismisses the action without prejudice); and (2) the ANDA applicant's notice of Paragraph IV certification included an OCA to the ANDA. 21 U.S.C. § 355(j)(5)(C)(i)(I) and (II). If these conditions have been met, the ANDA applicant may, in accordance with Section 2201 of Title 28, bring a civil action against the patent owner or reference listed drug holder for a declaratory judgment. 21 U.S.C. § 355(j)(5)(C)(i)(II).

23. Congress explained the need for civil actions in order to permit ANDA filers to obtain patent certainty explaining that, even where no 30-month stay exists, "the brand company could sit back to create uncertainty and similarly delay generic entry by delaying resolution of those patents." S. Rep. No. 108-174, at S15885 (2003) (Conf. Rep.) (remarks of Sen. Kennedy, ranking member of the U.S. Senate Committee on Health, Education, Labor, and Pensions). Uncertainty could also permit the brand company to hold the "patents in reserve . . . that could discourage generic companies from devoting resources to bring the generic drug to market and that would give the brand drug company a second opportunity to delay generic competition by suing the generic company for infringement of the reserved patents after the resolution of the initial infringement." *Id*.

LILLY BLOCKS GENERIC ENTRY

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

24. 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. Lilly has not sought to delist the '334 patent from the Orange Book in connection with the Forteo® NDA. Lilly has maintained and continues to maintain the listing of '334 patent in the Orange Book with respect to Forteo®. Lilly's listing of the '334 patent in the Orange Book in connection with the Forteo® NDA means that, according to Lilly, it is 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).

25. 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**.

26. The '334 patent purports to claim a medication dispensing apparatus with specified elements.

27. At the time of Sun's ANDA filing, only the '334 patent was listed in the FDA's

Orange Book as covering Forteo®. Under the Hatch-Waxman Act, Sun was therefore required to submit a patent certification to the '334 patent.

B. Sun Applies for FDA Approval of Its ANDA Product

28. Sun submitted its ANDA seeking approval for its ANDA Product, along with a Paragraph IV certification that the '334 patent will not be infringed by the manufacture, use, or sale of Sun's ANDA Product. Through its Paragraph IV certification, Sun is seeking immediate approval of its ANDA and prior to expiration of the '334 patent.

29. On or around June 15, 2021, Sun sent notice to Lilly of Sun's Paragraph IV certification regarding the '334 patent in Sun's ANDA and provided an OCA to its ANDA pursuant to 21 U.S.C. § 355(j)(2)(B)(i).

30. In its notice letter, Sun provided to Lilly a detailed factual and legal basis for Sun's Paragraph IV certification to the '334 patent, including why Sun's ANDA Product would not infringe the '334 patent.

31. Lilly received Sun's notice letter and OCA no later than June 17, 2021.

C. Sun's OCA and Lilly's Complaint

32. On June 24, 2021, Lilly emailed Sun's counsel and proposed revisions to Sun's OCA.

33. On July 4, Sun sent a revised version of Sun's OCA to Lilly. On July 14, Lilly requested a phone call to discuss Sun's revisions. The parties conferred via telephone on

July 16. On July 20, Lilly provided additional revisions to Sun's OCA. Sun responded the same day asking for explanations for Lilly's changes and then sent another revised draft. On July 22, Lilly sent yet another revised OCA to Sun and asked Sun to execute it. Sun executed the revised OCA on July 23, 2021. Lilly refused to countersign. Instead, on July 26, 2021, after Sun requested the status of Lilly's countersignature, Lilly stated it would file a lawsuit against Sun and revised Sun's OCA to reflect that change. Both parties executed the OCA on July 28, 2021.

34. On July 28, 2021, Lilly filed a Complaint for infringement of the '334 patent against Sun based on Sun's ANDA. Lilly alleged two counts of patent infringement against Sun. First, Lilly alleged that, if Sun's ANDA is approved by the FDA, Sun's commercial manufacture, use, or sale of Sun's ANDA Product would directly infringe, either literally or under the doctrine of equivalents, at least claim 1 of the '334 patent. Second, Lilly alleged that Sun 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.

35. On August 9, 2021, according to the terms of Sun's OCA executed by the parties, Sun provided Lilly with agreed-upon sections of Sun's ANDA, [redacted], and related ANDA information.

36. Lilly filed a notice of voluntary dismissal on September 13, 2021, pursuant to Rule 41(a)(1)(A) of the Federal Rules of Civil Procedure. The dismissal was without prejudice. Lilly did not give Sun any notice that Lilly intended to dismiss its Complaint. Nor has Lilly

explained to Sun why it dismissed its Complaint. Lilly has not informed Sun that it no longer believes or otherwise expressly disavowed the infringement allegations it set forth in its Complaint.

D. Sun Requests a Covenant Not to Sue and Lilly Refuses

37. Three days after Lilly dismissed its Complaint, Sun sought to obtain certainty. On September 16, 2021, Sun requested Lilly issue a covenant not to sue with respect to the '334 patent as it relates to Sun's ANDA and Sun's ANDA Product.

38. Lilly refused to provide Sun a covenant not to sue.

39. On October 1, after multiple emails from Sun requesting a covenant not to sue, Lilly sent Sun a draft agreement that would provide Sun certain assurances relating to the '334 patent so long as Sun agreed to material obligations and conditions. For instance, irrespective of whether the law required Sun to do so, [redacted] Lilly's insistence that Sun engage in a bilateral agreement and undertake certain obligations in return for a covenant not to sue with respect to the '334 patent is improper unless Lilly believes it has a viable infringement claim. Otherwise, using the threat of a non-meritorious infringement claim to force a company to enter into a contract (or otherwise remain under a cloud of uncertainty) is

inappropriate.

40. Sun explained to Lilly after receiving its proposed agreement that Sun was entitled to certainty without obligations. Sun explained that Lilly had no good faith basis to sue Sun and that it is improper to keep Sun under a cloud of uncertainty. Sun reiterated its request that Lilly sign a covenant not to sue and sent proposed language. Lilly has not agreed to sign Sun's proposed covenant not to sue. Lilly has not proposed revised language for a covenant not to sue. Lilly has not represented to Sun that it will not sue Sun in the future based on Sun's ANDA or Sun's ANDA Product.

E. Sun Faces Ongoing Risks Absent a Declaratory Judgment of Non-Infringement

41. Sun is at risk of Lilly filing another Complaint against Sun's ANDA or ANDA Product sometime in the future, creating an ongoing threat of potential injunctive relief and/or damages. Sun needs certainty now so that it may make informed business decisions about its product pipeline and launch timetables.

42. Sun is also at risk of the FDA potentially delaying approval of Sun's ANDA due to Lilly's already-filed Complaint. Lilly filed its Complaint within 45-days. Based on prior experience in Hatch-Waxman cases, Lilly may have notified the FDA that it filed its Complaint against Sun within the 45-day period and triggered a 30-month stay pursuant to 21 U.S.C. §355(j)(5)(B)(iii). [redacted] But there is no

statute or regulation stating that the 30-month stay lifts when the patent-holder voluntarily dismisses its lawsuit without prejudice and without an order signed by the Court. *See* 21 U.S.C. §355(j)(5)(B)(iii)(I)-(IV); 21 CFR § 314.107(b)(3); see also *Endo Pharms. v. Mylan Techs*., 11-cv-220, 2013 U.S. Dist. LEXIS 32931, *13-17 (D. Del. March 11, 2013). Lilly has not informed Sun that it did not notify FDA of its Complaint filing within the 45-day window. Sun is entitled to certainty that approval of its ANDA will not be delayed because of Lilly's Complaint.

F. An Article III Case or Controversy Exists

43. There is an actual and ongoing controversy between Sun and Lilly with respect to infringement of the '334 patent that can be resolved by a declaratory judgment from this Court. The act of submitting an ANDA with a paragraph IV certification is an act of infringement that created an immediate justiciable controversy. *See Teva Pharms. USA, Inc.*, 482 F.3d at 1342.

44. Sun has standing for this declaratory action. 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.

45. Sun has and continues to suffer an injury-in-fact from the ongoing listing of Lilly's

'334 patent in the FDA's Orange Book. As Congress explained when discussing the purpose of the declaratory judgment provision, there are "tactical reasons" why a patent owner or brand drug company might refrain from bringing suit on a patent within 45 days, or in this case, voluntarily dismissing the action prior to serving the Complaint. Congress explained that as a result:

> We believe there can be a case or controversy sufficient for courts to hear these cases merely because the patents at issue have been listed in the FDA Orange Book, and because the statutory scheme of the Hatch-Waxman Act relies on early resolution of patent disputes.

S. Rep. No. 108-174, at S15885 (2003) (Conf. Rep.) (remarks of Sen. Kennedy, ranking member of the U.S. Senate Committee on Health, Education, Labor, and Pensions).

46. Sun's injury is directly traceable to Lilly because Lilly (1) listed the '334 patent in the Orange Book; (2) filed a lawsuit wherein Lilly alleged Sun's ANDA Product infringed the '334 patent; (3) chose to dismiss its lawsuit without prejudice; (4) did not explain to Sun why it dismissed its lawsuit or expressly disavow its infringement allegations; and (5) refused to execute a covenant not to sue without forcing material conditions on Sun. Lilly's actions suggest it believes that it may assert the '334 patent again against Sun's ANDA and Sun's ANDA Product.

47. Sun's injury is redressable via a judgment of non-infringement of the '334 patent. Such a judgment will remove the cloud of uncertainty and confer the certainty Sun needs to proceed with its business. Accordingly, there is an actual, substantial, and continuing

justiciable case and controversy between Sun and Lilly.

48. 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." *Caraco*, 527 F.3d at 1294. Sun satisfies both prongs. First, additional factual development would not advance the district court's ability to determine infringement because Sun's ANDA and ANDA Product provide all necessary information. Second, without a declaratory judgment, Sun will not obtain patent certainty or potentially FDA approval for its ANDA Product, both of which could result in delays with respect to launching Sun's ANDA Product and related lost revenue.

SUN'S ANDA PRODUCT DOES NOT INFRINGE THE '334 PATENT

49. [redacted]

50. [redacted]

51. Patent infringement 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).

52. The '334 patent contains one independent claim, which recites:

> 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.

53. 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.

54. Claim 1 is directed to a medication dispensing apparatus comprising several different elements, including a plunger element, gear sets, pinions, and racks. Figure 2 of the '334 patent is a cross-sectional view of an embodiment containing a gear set (52):

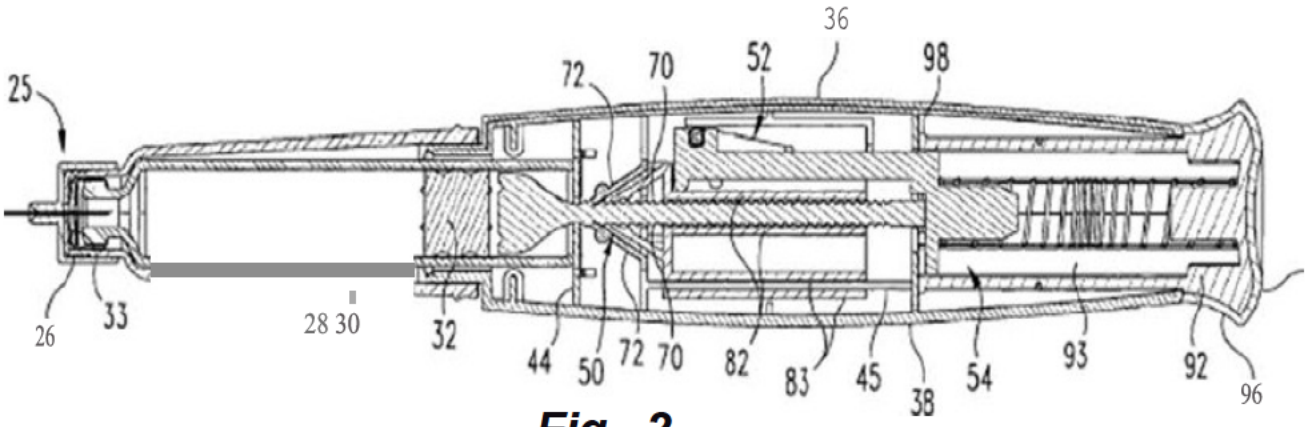

Fig. 2

See '334 patent at 2:41-45, 4:18-20, 6:50-55.

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

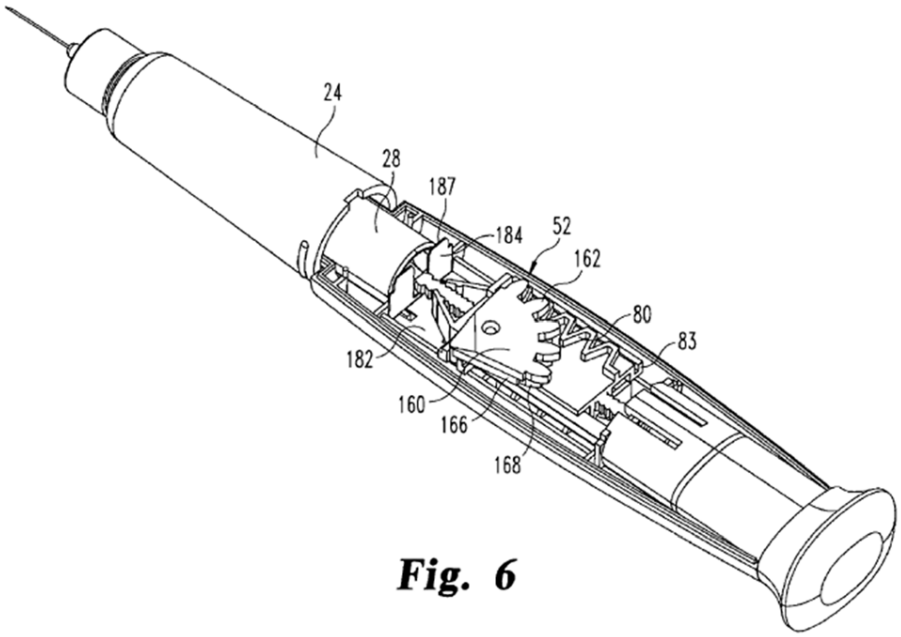

Fig. 6

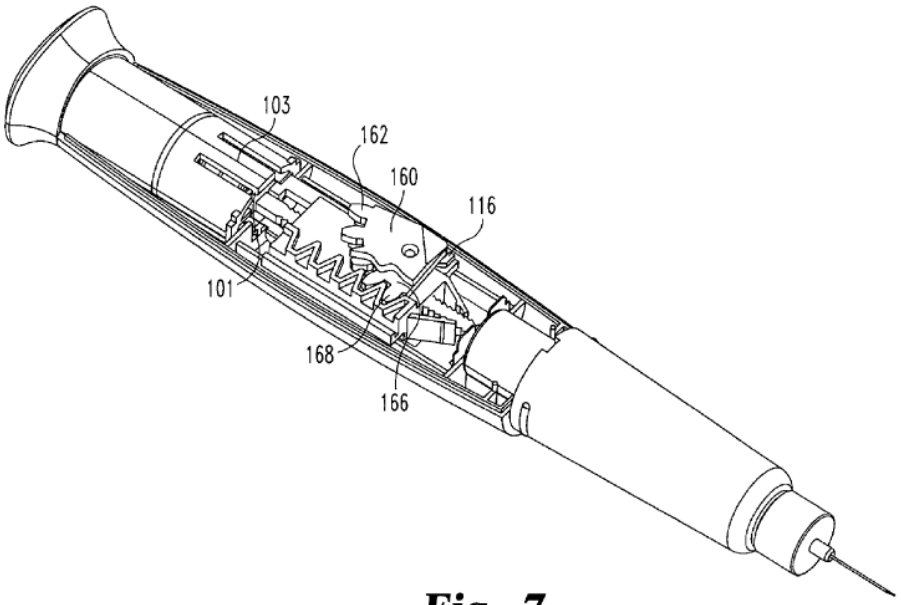

Fig. 7

56. Figure 8 of the '334 patent 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.

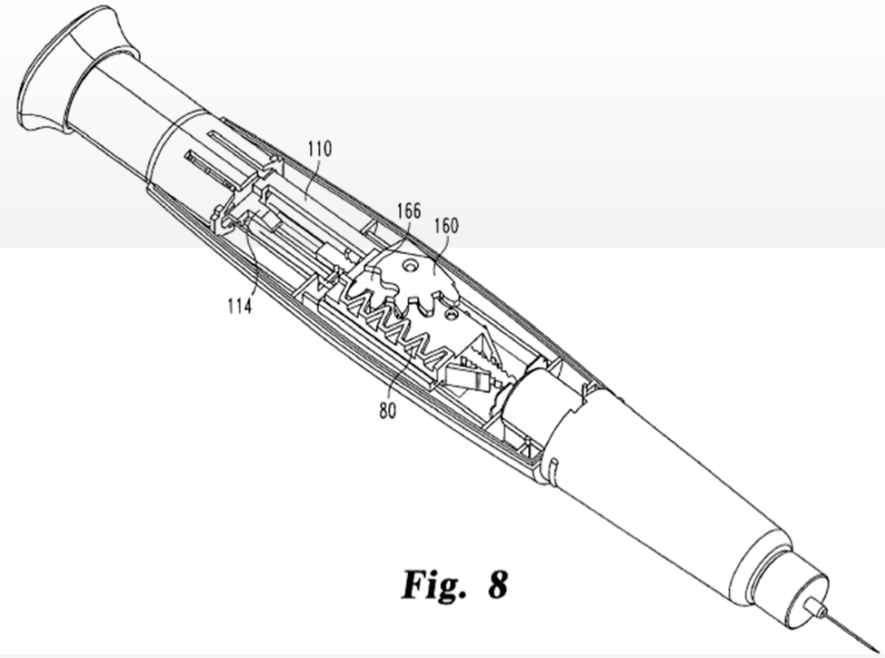

Fig. 8

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

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

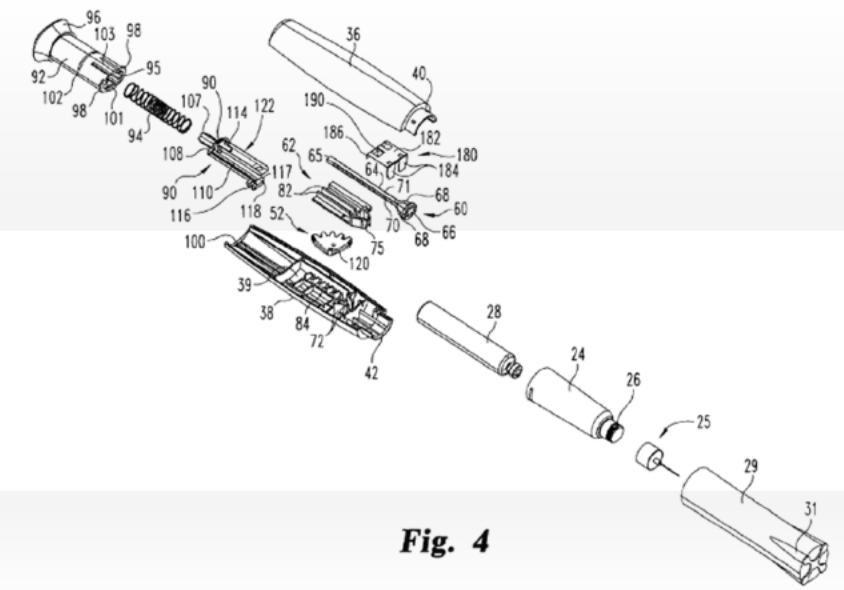

Fig. 4

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

58. [redacted]

59. Sun's ANDA Product does not literally infringe claim 1 of the '334 patent.

60. Sun's ANDA Product does not infringe claim 1 of the '334 patent under the doctrine of equivalents [redacted]

[redacted]

61. Claim 1 provides that the claimed medication dispensing apparatus possess a latching element that includes a latching lip and skid. Figure 9 of the '334 patent shows a latch lip (186) and an upstanding lip (117):

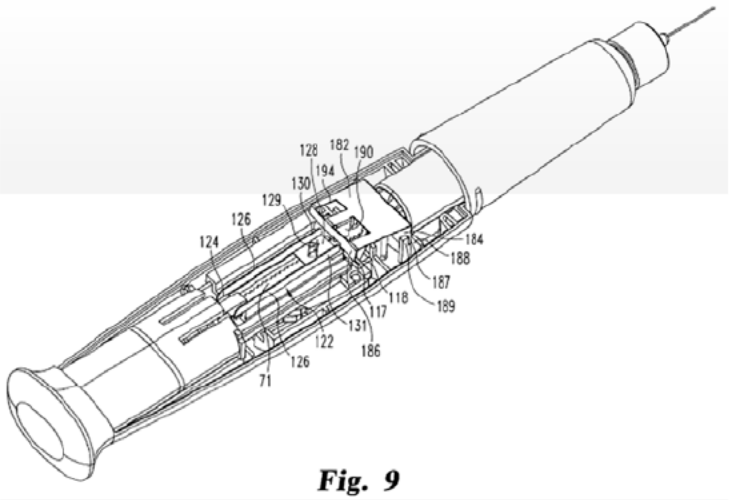

Fig. 9

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

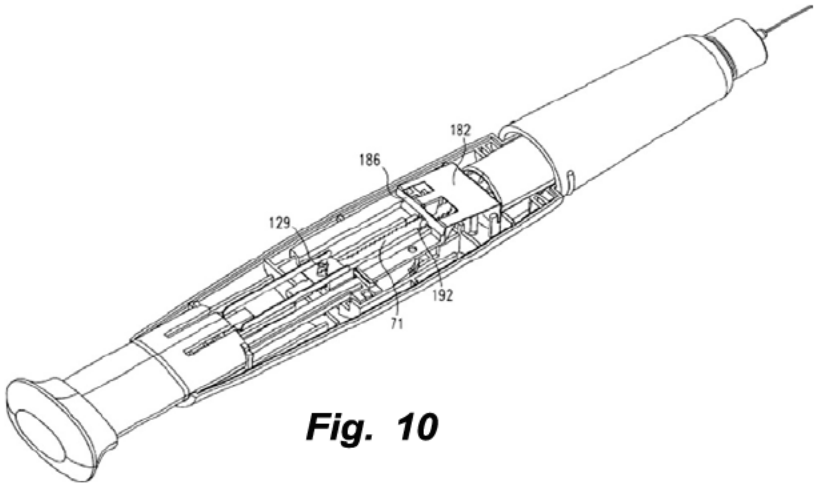

Fig. 10

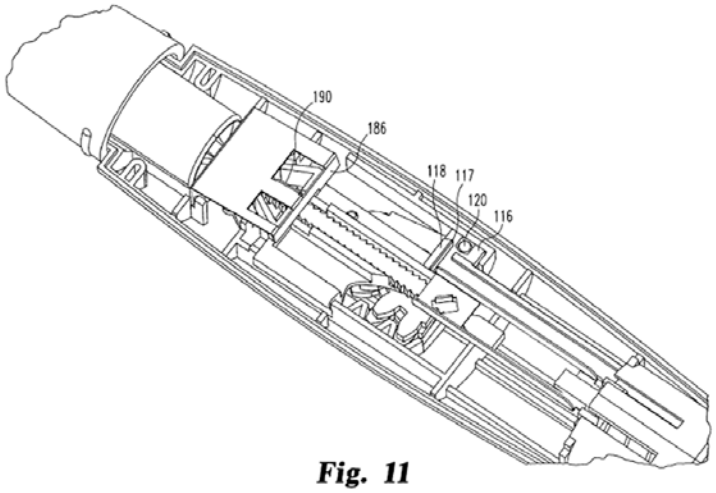

Fig. 11

See '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):

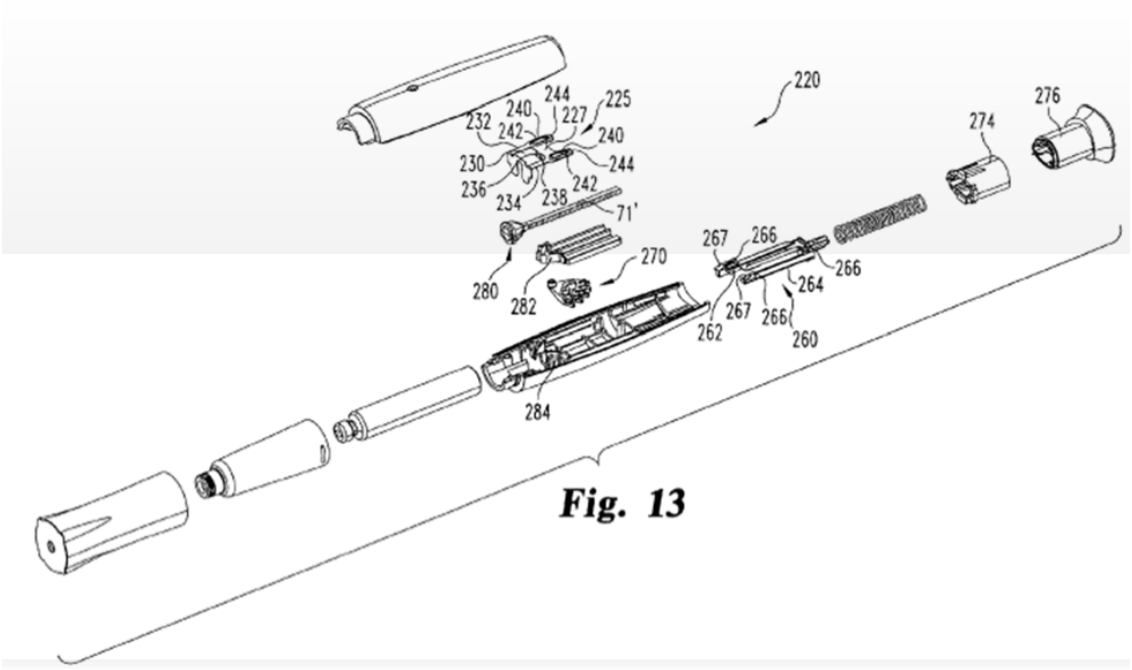

Fig. 13

'334 patent at 8:31-39.

64. [redacted]

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

66. Sun's ANDA Product does not infringe claim 1 of the '334 patent under the doctrine of equivalents [redacted]

67. Claims 2-10 depend from Claim 1. If an accused product does not infringe an independent claim, it does not infringe any claim that depends therefrom. For at least the reasons discussed with respect to Claim 1, Sun's ANDA Product does not 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 SUN'S ANDA PRODUCT

68. Sun hereby incorporates by reference its allegations contained in paragraphs 1 through 67 of this Complaint as though fully set forth herein.

69. Lilly lists the '334 patent in the Orange Book as covering its Forteo® 600mcg/2.4mL

(250 mcg/mL) prefilled teriparatide pens.

70. Sun filed its ANDA with a Paragraph IV certification stating the '334 patent is not and will not be infringed by Sun's ANDA Product.

71. Sun intends to sell Sun's ANDA Product once it obtains final FDA approval.

72. There is a real, actual and continuing justiciable case and controversy between Sun and Lilly regarding the infringement of the '334 patent.

73. The '334 patent will not be infringed by the filing of Sun's ANDA or the manufacture, use, offer for sale, sale, and/or importation of Sun's ANDA Product, either directly or indirectly, under 35 U.S.C. § 271.

74. Accordingly, Sun seeks and is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, and or importation of Sun's ANDA Product does not and will not infringe, directly or indirectly, any valid claim of the '334 patent.

PRAYER FOR RELIEF

WHEREFORE, Sun respectfully requests that this Court enter a judgment:

1. Declaring that:
    a. the '334 patent is not and will not be infringed by Sun's submission of ANDA No. 215424; and
    b. the manufacture, marketing, use, offer for sale, sale, and or importation of Sun's 600mcg/2.4mL (250 mcg/mL) prefilled teriparatide pens described in ANDA No. 215424 do not infringe and will not, if marketed, used,

offered for sale, or sold, infringe or induce or contribute to the infringement of any valid claim of the '334 patent.

2. Awarding Sun its costs, expenses and reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

3. Awarding Sun such other and further relief as the Court deems just and reasonable.

Dated: December 6, 2021

Respectfully submitted,

/s/ *Michael R. Limrick*

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