IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ELI LILLY AND COMPANY, Plaintiff, v. SUN PHARMACEUTICAL INDUSTRIES LTD. AND SUN PHARMACEUTICAL INDUSTRIES, INC. Defendants.	)	C. A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

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

NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent No. 7,517,334 ("the '334 patent"). This action relates to Sun's submission of Abbreviated New Drug Application ("ANDA") No. 215424 to the U.S. Food and Drug Administration ("FDA") for approval to market a generic version of Lilly's Forteo® (teriparatide [rDNA origin] injection) product, constituting an act of infringement under the patent laws of the United States, Title 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(e)(2).

THE PARTIES

2. Lilly is a corporation organized and existing under the laws of Indiana with its corporate offices and principal place of business at Lilly Corporate Center, Indianapolis, Indiana

46285. Lilly is engaged in the business of research, development, manufacture, and sale of innovative pharmaceutical products throughout the world.

3. On information and belief, Sun Ltd. is a foreign entity organized and existing under the laws of India with its corporate offices and principal place of business at SUN HOUSE, Plot No. 201 B/1, Western Express Highway, Goregaon (E), Mumbai, Maharashtra, India, 400063.

4. On information and belief, Sun Ltd. operates in the United States through its wholly owned subsidiary Sun Inc., to develop, manufacture, market, sell, and distribute generic pharmaceutical products in the State of Delaware and throughout the United States. On information and belief, Sun Ltd. controls and directs Sun Inc.

5. On information and belief, Sun Inc. is a corporation organized and existing under the laws of Delaware with offices at 2 Independence Way, Princeton, NJ 08540.

6. On information and belief, Sun Ltd. acted in concert with Sun Inc. to prepare and submit ANDA No. 215424 ("Sun's ANDA") for Sun's generic version of Lilly's Forteo® (teriparatide [rDNA origin] injection) product, and the acts of Sun Ltd. complained of herein were done with the cooperation, participation, and assistance of Sun Inc.

JURISDICTION AND VENUE

7. This action arises under the patent laws of the United States, including 35 U.S.C. § 271.

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

9. Venue is proper in this Court because, among other things, Sun Inc. resides in this judicial district and Sun Ltd. is a foreign entity not residing in any United States judicial district, which may be sued in any judicial district. 28 U.S.C. §§ 1391(c), 1400(b). Moreover, both

Sun Ltd. and Sun Inc. have previously litigated Hatch-Waxman patent infringement disputes in the District of Delaware.

10. This Court has personal jurisdiction over Sun Inc. because it is a Delaware corporation and is "at home" in this District. Further, Sun Inc. regularly does or solicits business, or engages in a persistent course of conduct in this District, or derives substantial revenue from things used or consumed in this District.

11. On information and belief, Sun Inc. and Sun Ltd. maintain continuous and systematic contacts with the State of Delaware so as to reasonably allow jurisdiction to be exercised over Sun Inc. and Sun Ltd. On information and belief, Sun Inc. and Sun Ltd.—either directly, or indirectly through its subsidiary Sun Inc.—develops, manufactures, markets, and sells pharmaceutical products throughout the United States, including the State of Delaware. On information and belief, Sun Inc. and Sun Ltd.—either directly or through its subsidiaries and affiliates—currently sells significant quantities of generic drug products in the United States and in the State of Delaware. These products include, for example, generic versions of Cialis®, Lyrica®, Claritin®, Letairis®, and Zyprexa®.

12. On information and belief, Sun Ltd. has not contested jurisdiction in Delaware in prior cases arising out of the filing of its ANDAs. *See, e.g., Pfizer Inc. et al. v. Sun Pharmaceutical Industries Ltd. et al.*, C.A. No. 21-0285-CFC (D. Del.); *Boehringer Ingelheim Pharm. Inc. v. Sun Pharm. Indus. Ltd.*, C.A. No. 21-0356-CFC (D. Del.); *Boehringer Ingelheim Pharm. Inc. v. Sun Pharm. Indus. Ltd.*, C.A. No. 20-1585-CFC (D. Del.). Sun Ltd. has also filed counterclaims in these and other cases. *See*, *e.g.*, *id*.

13. Alternatively, this Court may exercise jurisdiction over Sun Ltd. pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiff's claims arise under federal law; (b) Sun Ltd. would

be a foreign defendant not subject to personal jurisdiction in the courts of any state; and (c) Sun Ltd. has sufficient contacts with the United States as a whole, including, but not limited to, filing ANDAs with the FDA and manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Sun Ltd. satisfies due process.

FACTUAL BACKGROUND

A. Forteo®

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

B. The '334 Patent

15. The '334 patent, titled "Medication Dispensing Apparatus with Spring-Driven Locking Feature Enabled by Administration of Final Dose," and assigned to Lilly, was duly and legally issued by the United States Patent and Trademark Office ("PTO") on April 14, 2009, from U.S. Patent Application No. 10/598,987, filed as PCT Application No. PCT/US2005/010206 on March 25, 2005. The '334 patent claims priority to U.S. Provisional Application No. 60/557,545,

filed March 30, 2004, and U.S. Provisional Application No. 60/638,027, filed December 21, 2004. The '334 patent claims, *inter alia*, a medication dispensing apparatus comprising: a housing, a drive member within said housing movable in a distal direction; a fluid container defining a medicine-filled reservoir with a movable piston at one end and an outlet at the other end; a plunger element; a gear set including first and second pinions; a first rack; a second rack; and a latching element including a latching lip and a skid. The '334 patent is listed in the FDA publication titled *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the "Orange Book") in connection with Forteo®. A true and correct copy of the '334 patent is attached as ***Exhibit A***.

C. Sun's ANDA No. 215424

16. Sun filed or caused to be filed with the FDA ANDA No. 215424 under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use, or sale of Teriparatide Injection USP, 620 mcg / 2.48 mL (250 mcg/mL) single-use prefilled pens ("Sun's ANDA Product") in the United States before the expiration of the '334 patent.

17. Sun's ANDA contains a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("paragraph IV certification"), alleging that the claims of the '334 patent would not be infringed by Sun's ANDA Product.

18. Sun sent or caused to be sent to Lilly a Notice Letter dated June 15, 2021, notifying Lilly that Sun's ANDA includes a paragraph IV certification to FDA stating that Sun's ANDA does not infringe the claims of the '334 patent and providing information pursuant to 21 U.S.C. § 355(j)(2)(B).

19. The Notice Letter purported to include an Offer of Confidential Access ("OCA") to Lilly to ANDA No. 215424. Lilly has in good faith negotiated with counsel for Sun to obtain

detailed diagrams and samples of the injection device described in Sun's ANDA No. 215424 for evaluation and an OCA was executed between the parties on July 28, 2021. It is not feasible to complete an analysis of the ANDA documents, samples, and diagrams as needed prior to July 30, 2021.

20. On information and belief, the product described in Sun's ANDA is covered by one or more claims of the '334 patent.

21. On information and belief, the submission of Sun's ANDA constitutes infringement by Sun of the '334 patent under 35 U.S.C. § 271(e)(2). Moreover, any commercial manufacture, use, or sale of the product described in Sun's ANDA would infringe the '334 patent under 35 U.S.C. § 271(a), (b), and/or (c).

22. Sun knows and intends that physicians will prescribe, and patients will take, Sun's product for which approval is sought in Sun's ANDA. Sun had knowledge of the '334 patent and, by its proposed product for which approval is sought in Sun's ANDA, knows or should know that it will aid and abet in another's direct infringement of at least one of the claims of the '334 patent.

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

24. Lilly commenced this action within 45 days of receiving Sun's Notice Letter.

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

25. Lilly incorporates by reference and realleges Paragraphs 1–24 above as though fully restated herein.

26. Pursuant to 35 U.S.C. § 271(e)(2), Sun's ANDA submission to the FDA is an act of infringement of at least one claim of the '334 patent by Sun.

27. If Sun's ANDA is approved by the FDA, Sun's commercial manufacture, use, or sale of the product described in Sun's ANDA would directly infringe, either literally or under the doctrine of equivalents, at least claim 1 of the '334 patent under 35 U.S.C. § 271.

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

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

29. Lilly incorporates by reference and realleges Paragraphs 1–28 above as though fully restated herein.

30. Sun has knowledge of the '334 patent.

31. Upon FDA approval of Sun's ANDA, 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.

PRAYER FOR RELIEF

WHEREFORE, Lilly respectfully requests the following relief:

A. Under 35 U.S.C. § 271(e)(2)(A), a judgment that Sun has infringed U.S. Patent No. 7,517,334 by submitting its ANDA No. 215424 to the FDA seeking approval of its ANDA submission prior to expiration of U.S. Patent No. 7,517,334;

B. A judgment declaring that Sun's commercial manufacture, use, and/or sale of the product for which approval is sought in ANDA No. 215424 prior to expiration of U.S. Patent No. 7,517,334 would constitute infringement under 35 U.S.C. § 271(a) and/or (b);

C. A judgment and order that the effective date of any FDA approval of Sun's ANDA No. 215424 shall be no earlier than the expiration date of U.S. Patent No. 7,517,334 and any additional periods of exclusivity, in accordance with 35 U.S.C. § 271(e)(4)(A);

D. Entry of an injunction enjoining Sun, and all persons or entities acting in concert with Sun, from seeking, obtaining, or maintaining approval of Sun's ANDA No. 215424 and from commercially manufacturing, using, offering for sale, or selling Sun's ANDA Product within the United States, or importing Sun's ANDA Product into the United States until the expiration of U.S. Patent No. 7,517,334, in accordance with 35 U.S.C. §§ 271(e)(4)(B) and 283;

E. A finding that this is an exceptional case and an award of attorneys' fees pursuant to 35 U.S.C. § 285;

F. Costs and expenses in this action; and

G. Any further and additional relief that this Court deems just and proper.

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