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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ELI LILLY AND COMPANY and ICOS CORPORATION, Plaintiffs, v. QILU PHARMACEUTICAL CO., LTD., Defendant.	)	CIVIL ACTION NO.

COMPLAINT

Plaintiffs Eli Lilly and Company ("Lilly") and ICOS Corporation ("ICOS") (collectively, "Plaintiffs") file this Complaint for patent infringement against Defendant Qilu Pharmaceutical Co., Ltd., ("Qilu Ltd." or "Defendant") under 35 U.S.C. § 271(e)(2) for infringement of U.S. Patent No. 6,943,166 ("the '166 patent").

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against Defendant. This action relates to Abbreviated New Drug Application No. 210420 ("tadalafil ANDA") submitted by Defendant to the U.S. Food and

Drug Administration ("FDA") for approval to market a generic version of Lilly's Cialis® (tadalafil) tablets ("proposed tadalafil ANDA product") prior to the expiration of the '166 patent. Defendant's tadalafil ANDA includes a "Paragraph IV certification" asserting that the '166 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of Defendant's proposed tadalafil ANDA product, which constitutes an act of infringement under the United States Patent Laws, Title 35 U.S.C. § 100 *et seq.*, including 35 U.S.C. § 271(e)(2).

THE PARTIES

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

3. ICOS is a Delaware corporation having its corporate office at Lilly Corporate Center, Indianapolis, Indiana 46825. ICOS is a wholly owned subsidiary of Lilly.

4. Upon information and belief, Qilu Ltd. is a corporation organized under the laws of China, having its principal place of business at 243 Gong Ye Bei Road, Jinan, Shandong 250100, China.

5. Upon information and belief, Qilu Ltd. manufactures and/or distributes generic drugs for sale and use throughout the United States, including in the State of New Jersey.

JURISDICTION AND VENUE

6. Each of the preceding paragraphs 1 to 5 is re-alleged and re-incorporated as if fully set forth herein.

7. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, et seq., and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

8. Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

9. Qilu Ltd. is subject to personal jurisdiction in this District due, among other things, to its substantial, systematic, purposeful, and continuous contact in this District. On information and belief, Qilu Ltd., manufactures, markets, imports, and sells generic drugs for distribution in New Jersey and throughout the United States. On information and belief, Qilu Ltd. purposefully has conducted and continues to conduct business in New Jersey, and this Judicial District is a destination for Qilu Ltd.'s generic products.

10. On information and belief, Qilu Ltd. has previously availed itself of the jurisdiction of this court as a counterclaimant. *See, e.g., Helsinn Healthcare S.A. et al. v. Qilu Pharmaceutical Co., Ltd. et al.*, Civ. Action No. 2:15-cv-08132 (D.N.J.).

11. Defendant is subject to specific jurisdiction in this District based on the filing of its tadalafil ANDA with a Paragraph IV certification regarding the '166 patent. *See Acorda Therapeutics Inc. v. Mylan Pharm. Inc.*, 817 F.3d 755 (Fed. Cir. 2016).

12. As in *Acorda,* Defendant "has taken the costly, significant step of applying to the FDA for approval to engage in future activities—including the marketing of its generic drugs—that will be purposefully directed at," on information and belief, this District and elsewhere. *Acorda Therapeutics*, 817 F.3d at 759.

13. Defendant's "ANDA filings constitute formal acts that reliably indicate plans to engage in marketing of the proposed generic drugs." *Acorda Therapeutics*, 817 F.3d at 760.

14. As in *Acorda*, on information and belief Defendant "intends to direct sales of its drugs into [New Jersey], among other places, once it has the requested FDA approval to market them." *Acorda Therapeutics*, 817 F.3d at 758.

15. On information and belief, Defendant will engage in marketing of its proposed tadalafil ANDA product in New Jersey, upon approval of its tadalafil ANDA.

16. Defendant's ANDA filing, including its Paragraph IV certifications regarding the '166 patent at issue here, is suit-related and has a substantial connection with this District because it reliably, non-speculatively predicts activities in this District by Sunshine.

17. "[T]he minimum-contacts standard is satisfied by the particular actions [Defendant] has already taken—its ANDA filing[]—for the purpose of engaging in that injury-causing and allegedly wrongful marketing conduct in" this District. *Acorda Therapeutics*, 817 F.3d at 760.

18. Exercising personal jurisdiction over Defendant in this District would not be unreasonable given Defendant's contacts in this District, and the interest in this District of resolving disputes related to products to be sold herein.

PATENT-IN-SUIT

19. On September 13, 2005, the U.S. Patent and Trademark Office duly and legally issued the '166 patent entitled "Compositions Comprising Phosphodiesterase Inhibitors for the Treatment of Sexual Dysfunction." A true and correct copy of the '166 patent is attached hereto as Exhibit A. The claims of the '166 patent are valid and enforceable. At the time of its issue, the '166 patent was assigned to Lilly ICOS, LLC and it was subsequently assigned to ICOS which currently holds title.

20. Lilly is the holder of NDA No. 021368 by which FDA granted approval for the marketing and selling of tadalafil tablets in 2.5 mg, 5 mg, 10 mg, and 20 mg dosage strengths for

the treatment of erectile dysfunction. Lilly markets tadalafil tablets in the United States under the name "Cialis®" in 2.5 mg, 5 mg, 10 mg, and 20 mg dosage strengths. The '166 patent is one of the patents listed in the FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly known as the Orange Book) as covering the approved indications for Cialis®.

INFRINGEMENT BY DEFENDANT

21. Each of the preceding paragraphs 1 to 20 is re-alleged and re-incorporated as if fully set forth herein.

22. In a "Notice Letter," dated November 4, 2018, Defendant notified Plaintiffs that Defendant had submitted its tadalafil ANDA to FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) to obtain approval to engage in the commercial manufacture, use or sale of its proposed tadalafil ANDA product in 2.5 mg, 5 mg, 10 mg, and 20 mg strengths.

23. This Complaint is being filed before the expiration of forty-five days from the date Lilly received the Notice Letter.

24. The Notice Letter states that Defendant is seeking approval from FDA to engage in the commercial manufacture, use, and sale of its proposed tadalafil ANDA product before the expiration of the '166 patent. On information and belief, Defendant intends to engage in the commercial manufacture, use, and sale of its generic tadalafil tablets after receiving FDA approval to do so.

25. In the Notice Letter, Defendant notified Plaintiffs that its ANDA contained a Paragraph IV certification asserting that the '166 patent is invalid, unenforceable, and/or will not

be infringed by the commercial manufacture, use, and sale of Defendant's proposed tadalafil ANDA product.

26. Pursuant to 21 U.S.C. 355(j)(2)(B)(ii), any notice letter containing a Paragraph IV certification must contain a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, is unenforceable, or will not be infringed." In Defendant's Notice Letter, Defendant does not deny that the commercial manufacture, use, offer to sell, or sale of its proposed tadalafil ANDA product will induce infringement of claims 1-2, 4, 5 and 7-12 of the '166 patent, if these claims are found valid.

27. Claim 1 of the '166 patent recites "a method of treating sexual dysfunction in a patient in need thereof comprising orally administering one or more unit dose containing about 1 to about 20 mg, up to a maximum total dose of 20 mg per day, of a compound having the structure [that is tadalafil]." Exhibit A, cols. 14-15, line 65-line 15.

28. In its Notice Letter, Defendant admits that its proposed tadalafil ANDA product will be a tablet for oral use, that it will contain tadalafil as an active ingredient in 2.5 mg, 5 mg, 10 mg, and 20 mg dosage strengths.

29. In its Notice Letter, Defendant does not provide any alleged "factual and legal basis" (21 U.S.C. 355(j)(2)(B)(ii)) that its proposed tadalafil ANDA product will not be marketed to treat "sexual dysfunction in a patient in need thereof comprising orally administering one or more unit dose containing about 1 to about 20 mg, up to a maximum total dose of 20 mg per day, of [tadalafil]," consistent with the FDA approved label for Cialis® which states that it is indicated for the treatment of male erectile dysfunction (ED).

30. On information and belief, Defendant will market its proposed tadalafil ANDA product to treat "sexual dysfunction in a patient in need thereof comprising orally administering

one or more unit dose containing about 1 to about 20 mg, up to a maximum total dose of 20 mg per day, of [tadalafil]," consistent with the FDA approved label for Cialis®.

31. Claim 2 of the '166 patent recites "[t]he method of claim 1 wherein the sexual dysfunction is male erectile dysfunction." Exhibit A, col. 15, lines 16-17.

32. In its Notice Letter, Defendant does not provide any alleged "factual and legal basis" (21 U.S.C. 355(j)(2)(B)(ii)) that its proposed tadalafil ANDA product will not be marketed to treat "male erectile dysfunction," consistent with the FDA approved label for Cialis® which states that it is indicated for the treatment of male erectile dysfunction (ED).

33. On information and belief, Defendant will market its proposed tadalafil ANDA product to treat male erectile sexual dysfunction, consistent with the FDA approved label for Cialis®.

34. Claim 4 recites "[t]he method of claim 1 wherein the unit dose contains about 2 to about 20 mg of the compound." Exhibit A, col. 15, lines 20-21. In its Notice Letter, Defendant admits that its proposed tadalafil ANDA product will contain tadalafil as an active ingredient in 2.5 mg, 5 mg, 10 mg, and 20 mg dosage strengths.

35. Claim 5 recites "[t]he method of claim 1 wherein the unit dose contains about 5 mg of the compound. Exhibit A, col. 16, lines 3-4. In its Notice Letter, Defendant admits that its proposed tadalafil ANDA product will contain tadalafil as an active ingredient in a 5 mg dosage strength, among others.

36. Claim 7 recites "[t]he method of claim 1 wherein the unit dose is in a form selected from the group consisting of a liquid, a tablet, a capsule, and a gelcap." Exhibit A, col. 16, lines 8-9. In its Notice Letter, Defendant admits that its proposed tadalafil ANDA product is a tablet product.

37. Claim 8 recites "the method of claim 1 wherein the unit dose contains about 2.5 mg of the compound." Exhibit A, col. 16, lines 11-12. In its Notice Letter, Defendant admits that its proposed tadalafil ANDA product will contain tadalafil as an active ingredient in a 2.5 mg dosage strength, among others.

38. Claim 9 recites "[t]he method of claim 8 wherein the unit dose is administered once per day." Exhibit A, col. 16, lines 13-14.

39. In its Notice Letter, Defendant does not provide any alleged "factual and legal basis" (21 U.S.C. 355(j)(2)(B)(ii)) that its proposed tadalafil ANDA product will not be marketed to be "administered once per day," consistent with the FDA approved label for Cialis®. On information and belief, Defendant will market its proposed tadalafil ANDA product for once daily use, consistent with the FDA approved label for Cialis®.

40. Claim 10 recites "[t]he method of claim 5 wherein the unit dose is administered once per day." Exhibit A, col. 16, lines 13-14.

41. In its Notice Letter, Defendant does not provide any alleged "factual and legal basis" (21 U.S.C. 355(j)(2)(B)(ii)) that its proposed tadalafil ANDA product will not be marketed to be "administered once per day," consistent with the FDA approved label for Cialis®. On information and belief, Defendant will market its proposed tadalafil ANDA product for once daily use, consistent with the FDA approved label for Cialis®.

42. Claim 11 recites "[t]he method of claim 1 wherein the compound is administered as a free drug." Exhibit A, col 16, 15-16.

43. In its Notice Letter, Defendant does not provide any alleged "factual and legal basis" (21 U.S.C. 355(j)(2)(B)(ii)) that its proposed tadalafil ANDA product will not be "administered

as a free drug." On information and belief, Defendant's proposed tadalafil ANDA product will contain tadalafil as a free drug.

44. Claim 12 recites "[t]he method of claim 1 wherein the unit dose contains about 20 mg of the compound." In its Notice Letter, Defendant admits that its proposed tadalafil ANDA product will contain tadalafil as an active ingredient in a 20 mg dosage strength, among others.

COUNT I: INFRINGEMENT OF THE '166 PATENT
UNDER 35 U.S.C. § 271(e)(2)(A)

45. Each of the preceding paragraphs 1 to 44 is re-alleged and re-incorporated as if fully set forth herein.

46. Defendant's submission of its tadalafil ANDA to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of its proposed tadalafil ANDA product prior to the expiration of the '166 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

47. On information and belief, upon FDA approval of Defendant's tadalafil ANDA, Defendant will infringe at least one claim of the '166 patent by making, using, offering to sell, and selling its proposed tadalafil ANDA product in the United States and/or importing such tablets into the United States in violation of 35 U.S.C. §§ 271(a), 271(b), and/or 271(c) unless enjoined by the Court.

48. If Defendant's marketing and sale of its proposed tadalafil ANDA product prior to expiration of the '166 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

Wherefore, Plaintiffs demand judgment against Defendant and respectfully request that this Court grant the following relief:

A. A judgment that the claims of the ’166 patent are not invalid, not unenforceable, and are infringed by Defendant’s submission of its tadalafil ANDA, and that Defendant’s making, using, offering to sell, or selling in the United States, or importing into the United States Defendant’s proposed tadalafil ANDA product will infringe the ’166 patent.

B. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of Defendant’s tadalafil ANDA shall be a date which is not earlier than the latest expiration date of the ’166 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

C. An order permanently enjoining Defendant, its affiliates, subsidiaries, and each of its officers, agents, servants and employees, and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States, Defendant’s proposed tadalafil ANDA product until after the latest expiration date of the ’166 patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

D. An order that the effective date of any FDA approval of Defendant’s generic proposed tadalafil ANDA product shall be no earlier than thirty months from the date of the Notice Letter, in accordance with 21 U.S.C. § 355(j)(5)(B)(iii).

E. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

Dated: December 24, 2018

Respectfully submitted,

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CERTIFICATION PURSUANT TO L. CIV. R. 11.2

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is related to the subject matter in:

- *Eli Lilly and Company, et al. v. Umedica Laboratories Pvt., Ltd.*, Civil Action No. 2:18-cv-12385 (WHW)(CLW)

Dated: December 24, 2018

Respectfully submitted,

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