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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. DR. REDDY'S LABORATORIES, INC. and DR. REDDY'S LABORATORIES, LTD. Defendants.	)	CIVIL ACTION NO.

COMPLAINT

Plaintiffs Eli Lilly and Company ("Lilly") and ICOS Corporation ("ICOS") (collectively "Plaintiffs") file this Complaint for patent infringement against Defendants Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. (collectively "DRL" 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 DRL. This action relates to Abbreviated New Drug Application No. 210069 ("tadalafil ANDA") submitted by DRL 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. DRL'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 DRL'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, Dr. Reddy's Laboratories, Inc. is a corporation organized under the laws of the State of New Jersey and has its principal place of business at 107 College Road East, Princeton, New Jersey 08540.

5. Upon information and belief, Dr. Reddy's Laboratories, Inc. manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in the State of New Jersey, and including as an agent of Dr. Reddy's Laboratories, Ltd.

6. Upon information and belief, Dr. Reddy's Laboratories, Inc. is a subsidiary of Dr. Reddy's Laboratories, Ltd.

7. Upon information and belief, Dr. Reddy's Laboratories, Ltd. is an India corporation and has its principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad 500 034, India.

8. Upon information and belief, Dr. Reddy's Laboratories, Ltd. manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in the State of New Jersey, and including through its agent Dr. Reddy's Laboratories, Inc.

JURISDICTION AND VENUE

9. Each of the preceding paragraphs 1 to 8 is re-alleged and re-incorporated as if fully set forth herein.

10. 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.

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

12. On information and belief, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. collaborate to develop, manufacture, import, market, and distribute, and/or sell pharmaceutical products, including generic drug products manufactured and sold pursuant to the tadalafil ANDA, throughout the United States and the State of New Jersey.

13. On information and belief, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling, and distributing generic products.

14. On information and belief, Dr. Reddy's Laboratories, Inc. and Dr. Reddy's Laboratories, Ltd. work in concert with each other with respect to the regulatory approval,

manufacturing, marketing, sale, and distribution of generic pharmaceutical products in the State of New Jersey and throughout the United States.

15. On information and belief, Dr. Reddy's Laboratories, Inc. is the agent of Dr. Reddy's Laboratories, Ltd. Upon information and belief, Dr. Reddy's Laboratories, Inc. is acting as the agent of Dr. Reddy's Laboratories, Ltd. with respect to ANDA No. 210069.

16. Dr. Reddy's Laboratories, Inc. is subject to personal jurisdiction in this District due, among other things, to its substantial, systematic, purposeful, and continuous contact in this District.

17. On information and belief, Dr. Reddy's Laboratories, Inc. has its principal place of business in New Jersey and has a registered agent for service of process in this Judicial District.

18. On information and belief, Dr. Reddy's Laboratories, Inc., directly or through its affiliate Dr. Reddy's Laboratories, Ltd., manufactures, markets, imports, and sells generic drugs for distribution in New Jersey and throughout the United States. On information and belief, Dr. Reddy's Laboratories, Inc. purposefully has conducted and continues to conduct business, directly or through its affiliate Dr. Reddy's Laboratories, Ltd., in New Jersey, and this Judicial District is a destination for Dr. Reddy's Laboratories, Inc.'s generic products.

19. On information and belief, Dr. Reddy's Laboratories, Inc. has previously consented to personal jurisdiction in this District. *See, e.g., AstraZeneca AB et al. v. v. Dr. Reddy's Laboratories, Ltd. et al.*, Civ. Action No. 3:15-cv-8267-MLC-TJB (D.N.J.)*; Helsinn Healthcare SA, et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, Civ. Action No. 3:15-cv-8662-MLC-DEA (D.N.J.).

20. On information and belief, Dr. Reddy's Laboratories, Inc. has availed itself of the jurisdiction of this court by initiating litigation in this district. *See, e.g., Dr. Reddy's*

Laboratories, Inc. et al. v. Purdue Pharmaceutical Products LP et al., Civ. Action No. 2:14-cv-3230-JLL-JAD (D.N.J.).

21. Dr. Reddy's Laboratories, 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, Dr. Reddy's Laboratories, Ltd., directly or through its agent Dr. Reddy's Laboratories, Inc., manufactures, markets, imports, and sells generic drugs for distribution in New Jersey and throughout the United States. On information and belief, Dr. Reddy's Laboratories, Ltd. purposefully has conducted and continues to conduct business, directly or through its agent Dr. Reddy's Laboratories, Inc., in New Jersey, and this Judicial District is a destination for Dr. Reddy's Laboratories, Ltd.'s generic products.

22. On information and belief, Dr. Reddy's Laboratories, Ltd. has previously consented to personal jurisdiction in this District. *See, e.g., AstraZeneca AB et al. v. v. Dr. Reddy's Laboratories, Ltd. et al.*, Civ. Action No. 3:15-cv-8267-MLC-TJB (D.N.J.)*; Helsinn Healthcare SA, et al. v. Dr. Reddy's Laboratories, Ltd. et al.*, Civ. Action No. 3:15-cv-8662-MLC-DEA (D.N.J.).

23. On information and belief, Dr. Reddy's Laboratories, Ltd. has availed itself of the jurisdiction of this court by initiating litigation in this district. *See, e.g., Dr. Reddy's Laboratories, Inc. et al. v. Purdue Pharmaceutical Products LP et al.*, Civ. Action No. 2:14-cv-3230-JLL-JAD (D.N.J.).

24. DRL 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).

25. As in *Acorda*, DRL "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.

26. DRL'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.

27. As in *Acorda*, on information and belief DRL "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.

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

29. DRL'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 DRL.

30. "[T]he minimum-contacts standard is satisfied by the particular actions [DRL] 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.

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

PATENT-IN-SUIT

32. 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.

33. 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

34. Each of the preceding paragraphs 1 to 33 is re-alleged and re-incorporated as if fully set forth herein.

35. In a letter dated February 28, 2017 ("the Notice Letter"), DRL notified ICOS and Lilly that DRL 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.

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

37. The Notice Letter states that DRL 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, DRL intends to engage in the commercial manufacture, use, and sale of its generic tadalafil tablets after receiving FDA approval to do so.

38. In the Notice Letter, DRL notified Lilly 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 DRL's proposed tadalafil ANDA product.

39. 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, DRL 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, 4-12, if these claims are found valid.

40. 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.

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

42. In its Notice Letter, DRL 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).

43. On information and belief, DRL 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®.

44. 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. In its Notice Letter, DRL admits that its proposed tadalafil ANDA product will be marketed to treat erectile dysfunction.

45. 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, DRL 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.

46. 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, DRL admits that its proposed tadalafil ANDA product will contain tadalafil as an active ingredient in a 5 mg dosage strength, among others.

47. 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, DRL admits that its proposed tadalafil ANDA product is a tablet product.

48. 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, DRL admits that its proposed tadalafil ANDA product will contain tadalafil as an active ingredient in a 2.5 mg dosage strength, among others.

49. 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.

50. In its Notice Letter, DRL 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, DRL will market its proposed tadalafil ANDA product for once daily use, consistent with the FDA approved label for Cialis®.

51. 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.

52. In its Notice Letter, DRL 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, DRL will market its proposed tadalafil ANDA product for once daily use, consistent with the FDA approved label for Cialis®.

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

54. In its Notice Letter, DRL 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, DRL's proposed tadalafil ANDA product will contain tadalafil as a free drug.

55. Claim 12 recites "[t]he method of claim 1 wherein the unit dose contains about 20 mg of the compound." In its Notice Letter, DRL 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)

56. Each of the preceding paragraphs 1 to 55 is re-alleged and re-incorporated as if fully set forth herein.

57. 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).

58. 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.

59. 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: April 13, 2017

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. Hetero USA Inc., et al.*, Civil Action No. 2:17-cv-01951-KM-MAH (D.N.J.), and in the following actions that have been consolidated under the lead case *Eli Lilly and Company, et al., v. Actavis Laboratories UT, Inc.*, 1:16-cv-01119-AJT-MSN (E.D. Va.):

1. *Eli Lilly and Company, et al. v. Watson Laboratories, Inc.*, Pre-consolidated Docket No. 1:16-cv-1119-AJT-MSN

2. *Eli Lilly and Company, et al. v. Alembic Pharmaceuticals Ltd. and Alembic Pharmaceuticals, Inc.*, Pre-consolidated Docket No. 1:16-cv-1120-AJT-MSN

3. *Eli Lilly and Company, et al. v. Aurobindo Pharma Ltd. and Aurobindo Pharma USA, Inc.*, Pre-consolidated Docket No. 1:16-cv-1121-AJT-MSN

4. *Eli Lilly and Company, et al. v. Mylan Pharmaceuticals Inc.*, Pre-consolidated Docket No. 1:16-cv-1122-AJT-MSN

5. *Eli Lilly and Company, et al. v. Sun Pharma Global FZE and Sun Pharmaceutical Industries, Ltd.*, Pre-consolidated Docket No. 1:16-cv-1168-AJT-MSN

6. *Eli Lilly and Company, et al. v. Teva Pharmaceuticals USA Inc.*, Pre-consolidated Docket No. 1:16-cv-1169-AJT-MSN

7. *Eli Lilly and Company, et al. v. Zydus Pharmaceuticals (USA) Inc.*, Pre-consolidated Docket No. 1:16-cv-1170-AJT-MSN

8. *Eli Lilly and Company, et al. v. Cipla Limited and Cipla USA, Inc.*, Pre-consolidated Docket No. 1:16-cv-1208-AJT-MSN

9. *Eli Lilly and Company, et al. v. Accord Healthcare, Inc.*, Pre-consolidated Docket No. 1:16-cv-1352-AJT-MSN

10. *Eli Lilly and Company, et al. v. Ajanta Pharma Ltd. and Ajanta Pharma USA Inc.*, Pre-consolidated Docket No. 1:17-cv-00020-AJT-MSN

Dated: April 13, 2017

Respectfully submitted,

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