IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

ELI LILLY AND COMPANY and ICOS CORPORATION,	)	
	)	CIVIL ACTION NO.
Plaintiffs,	)	
v.	)	
AJANTA PHARMA, LTD. and AJANTA PHARMA USA, INC.	)	
Defendants.	)	

COMPLAINT

Plaintiffs Eli Lilly and Company ("Lilly") and ICOS Corporation ("ICOS") (collectively "Plaintiffs") file this Complaint for patent infringement against Ajanta Pharma Ltd. and Ajanta Pharma USA, Inc. (collectively "Ajanta" 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 Ajanta. This action relates to Abbreviated New Drug Application No. 209654 ("tadalafil ANDA") submitted by Ajanta 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. Ajanta'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 Ajanta'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. On information and belief, Ajanta Pharma, Ltd. is an India corporation and has its principle place of business at Ajanta House, Charkop, Kandivili West, Mumbai 400 067 India.

5. Upon information and belief, Defendant Ajanta Pharma, Ltd. manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district, and including through its agent Ajanta Pharma USA, Inc.

6. On information and belief, Ajanta Pharma USA, Inc. is a corporation organized under the laws of the State of New Jersey and has its principal place of business at One Grande Commons, 440 US Highway 22 East, Suite 150, Bridgewater, NJ 08807.

7. Upon information and belief, Defendant Ajanta Pharma USA, Inc. manufactures and/or distributes numerous generic drugs for sale and use throughout the United States, including in this judicial district, and including as an agent of Ajanta Pharma, Ltd.

JURISDICTION AND VENUE

8. Each of the preceding paragraphs 1 to 7 is re-alleged and re-incorporated as if fully set forth herein.

9. 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.

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

11. On information and belief, Ajanta Pharma, Ltd. and Ajanta Pharma USA, Inc. 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 Eastern District of Virginia.

12. On information and belief, Ajanta Pharma, Ltd. and Ajanta Pharma USA, Inc. hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling, and distributing generic products.

13. On information and belief, Ajanta Pharma, Ltd. and Ajanta Pharma USA, Inc. work in concert with each other with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products in the Eastern District of Virginia and throughout the United States.

14. Ajanta Pharma, 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, Ajanta Pharma, Ltd., directly or through its affiliate Ajanta Pharma USA, Inc., manufactures, markets, imports, and sells generic drugs for distribution in the Eastern District of Virginia and throughout the United States. On information and belief, Ajanta Pharma, Ltd. purposefully has conducted and continues to conduct business, directly or through its affiliate Ajanta Pharma USA, Inc., in the Eastern District of Virginia, and this Judicial District is a destination for Ajanta Pharma, Ltd.'s generic products.

15. Ajanta Pharma USA, Inc. 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, Ajanta Pharma USA, Inc., directly or through its affiliate Ajanta Pharma, Ltd., manufactures, markets, imports, and sells generic drugs for distribution in the Eastern District of Virginia and throughout the United States. On information and belief, Ajanta Pharma USA, Inc. purposefully has conducted and continues to conduct business, directly or through its affiliate Ajanta Pharma, Ltd., in the Eastern District of Virginia, and this Judicial District is a destination for Ajanta Pharma USA, Inc.'s generic products.

16. Ajanta Pharma, Ltd.'s website states "[w]e have recently entered the Regulated Markets of USA with select product portfolio, which include complex technology products to get the competitive advantage in the market place. We expect US market to be our key growth driver in the coming years." *See* http://www.ajantapharma.com/overview.html (accessed December 8, 2016).

17. According to its website, Ajanta Pharma USA is a wholly owned subsidiary of Ajanta Pharma Ltd. and Ajanta Pharma USA provides "a dedicated front end sales and marketing team" in the United States marketplace. *See* http://ajantapharmausa.com/business-development.html. (accessed December 10, 2016).

18. Ajanta Pharma USA's website states that and Ajanta Pharma Ltd. is "a fully-integrated specialty pharmaceutical company" that has specifically developed a product portfolio for the United States market comprising "Immediate-Release, Extended-Release, Delayed-Release, Orally Disintegrating Tablets and Powders." *See* http://www.ajantapharmausa.com/overview.html (accessed December 10, 2016.)

19. Ajanta solicits customers in the Eastern District of Virginia using its website. Through Ajanta's website, customers and potential customers throughout the United States, including in the Eastern District of Virginia can, among other things: (1) search and download prescribing information for Ajanta's full US product line; (2) review press release documents for US launches of its generic products; and (3) contact Ajanta representatives regarding its US product line.

20. Ajanta 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).

21. As in *Acorda,* Ajanta "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.

22. Ajanta'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.

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

24. On information and belief, Ajanta will engage in marketing of its proposed tadalafil ANDA product in Virginia, including the Eastern District of Virginia, upon approval of its tadalafil ANDA.

25. Ajanta'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 Ajanta.

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

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

PATENT-IN-SUIT

28. 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.

29. 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®.

30. Plaintiffs are currently litigating infringement actions in this District against nine other generic drug companies that have sought FDA approval to market and sell generic versions of Cialis®. Plaintiffs would therefore be substantially burdened if forced to pursue parallel litigation in different districts.

INFRINGEMENT BY DEFENDANT

31. Each of the preceding paragraphs 1 to 30 is re-alleged and re-incorporated as if fully set forth herein.

32. In a letter dated December 5, 2016 ("the Notice Letter"), Ajanta notified ICOS and Lilly that Ajanta 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.

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

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

35. In the Notice Letter, Ajanta 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 Ajanta's proposed tadalafil ANDA product.

36. 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, Ajanta 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.

37. 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.

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

39. In its Notice Letter, Ajanta 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).

40. On information and belief, Ajanta 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®.

41. 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.

42. In its Notice Letter, Ajanta 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).

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

44. 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, Ajanta 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.

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

46. Claim 6 recites “[t]he method of claim 1 wherein the unit dose contains about 10 mg of the compound and is administered once per day.” Exhibit A, col. 16, lines 5-7.

47. In its Notice Letter, Ajanta admits that its proposed tadalafil ANDA product will contain tadalafil as an active ingredient in a 10 mg dosage strength, among others.

48. In its Notice Letter, Ajanta 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®.

49. On information and belief, Ajanta will market its proposed tadalafil ANDA product for once daily use, consistent with the FDA approved label for Cialis®.

50. 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, Ajanta admits that its proposed tadalafil ANDA product is a tablet product.

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

52. 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.

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

54. 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.

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

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

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

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

59. Each of the preceding paragraphs 1 to 58 is re-alleged and re-incorporated as if fully set forth herein.

60. 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).

61. 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.

62. 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 13, 2016

Respectfully submitted,

/s/ Yieyie Yang

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