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

ELI LILLY AND COMPANY and ICOS CORPORATION,	
Plaintiffs,	CIVIL ACTION NO. 2:16-cv-518
v.	
SUN PHARMACEUTICAL INDUSTRIES, LTD., SUN PHARMA GLOBAL FZE, and SUN PHARMACEUTICAL INDUSTRIES, INC.,	
Defendants.	

COMPLAINT

Plaintiffs Eli Lilly and Company ("Lilly") and ICOS Corporation ("ICOS") (collectively "Plaintiffs") file this Complaint for patent infringement against Sun Pharmaceutical Industries, Ltd. ("Sun Ltd."), Sun Pharma Global FZE ("Sun Global"), and Sun Pharmaceutical Industries, Inc. ("Sun Inc.") (collectively "Sun Pharma" 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 Sun Pharma. This action relates to Abbreviated New Drug Application No. 208934 ("tadalafil ANDA") submitted by Sun Pharma 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. Sun Pharma'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 Sun Pharma'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, Sun Ltd. is a company organized and existing under the laws of India, having a principal place of business at SUN HOUSE, CTS No. 201 B/1, Western Express Highway, Goregaon (E), 400 063, Mumbai, Maharushtra, India.

5. On information and belief, Sun Global is a limited liability company incorporated under the provisions of Sharjah's Emiri Decree Number (2) of 1995, having a place of business at Office # 43, Block Y, SAIF-Zone, P.O. Box #122304, Sharjah, United Arab Emirates. On information and belief, Sun Global is a wholly owned subsidiary of Sun Ltd.

6. On information and belief, Sun Inc. is a corporation organized and existing under the laws of the State of Michigan, having a principal place of business at 270 Prospect Plains Road, Cranbury, New Jersey 08512. On information and belief, Sun Inc. is a wholly owned subsidiary of Sun Ltd.

7. On information and belief, Sun Ltd., directly or through its subsidiaries Sun Global and Sun Inc., is in the business of manufacturing and selling generic pharmaceutical products that are distributed in the Eastern District of Virginia and throughout the United States.

8. On information and belief, as stated in its 2016 Annual Report, Sun Pharma together with its related corporate entities, is "5th largest generic pharmaceutical company in the US," "5th largest global generics player (for 12 months ended December 2014)," and "#1 US supplier of generic dermatology products." On information and belief, as stated in its 2016 Annual Report, Sun Pharma, along with its related corporate entities earned revenues of over $2 billion in 2015 from sales in the U.S. and U.S. sales represented 50% of its total revenue.

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, Sun Ltd., Sun Global, and Sun 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.

13. On information and belief, Sun Ltd., Sun Global, and Sun Inc., hold themselves out as a unitary entity for purposes of manufacturing, marketing, selling, and distributing generic products.

14. On information and belief, Sun Ltd., Sun Global, and Sun 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.

15. Sun 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, Sun Ltd., directly or through its subsidiaries Sun Global and Sun 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, Sun Ltd. purposefully has conducted and continues to conduct business, directly or through its subsidiaries Sun Global and Sun Inc., in the Eastern District of Virginia, and this Judicial District is a destination for Sun Ltd's generic products.

16. Sun Ltd's website states "We are present in the US directly, through Sun Pharmaceuticals, Inc. . . .[C]urrently over 147 filings await approval (March 2012). Our pipeline is a mix of simpler generic filings, complex filings like those for derma products, injectables or sprays and a few patent challenges." *See* http://www.sunpharma.com/node/92 (accessed August 19, 2016).

17. Sun Global 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, Sun Global, directly or through its parent Sun Ltd. and related entity Sun Inc., manufactures, markets, imports, and sells generic drugs throughout the United States and the Eastern District of Virginia. On information and belief, Sun Global purposefully has conducted and continues to conduct business, directly or through its parent Sun Ltd. and its related entity

Sun Inc., in the Eastern District of Virginia, and this Judicial District is a destination for Sun Global's generic products.

18. Sun 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, Sun Inc., directly or through its parent Sun Ltd. and related entity Sun Global, manufactures, markets, imports, and sells generic drugs throughout the United States and the Eastern District of Virginia. On information and belief, Sun Inc. purposefully has conducted and continues to conduct business, directly or through its parent Sun Ltd. and its related entity Sun Global, in the Eastern District of Virginia, and this Judicial District is a destination for Sun Inc.'s generic products.

19. Sun Inc.'s Consolidated Financial Statements state that Sun Inc. "develops, licenses, manufactures, markets and distributes generic, prescription and over-the-counter pharmaceuticals to the nation's largest wholesalers, distributors, warehousing and non-warehousing chain drugstores and managed care providers." As stated in the Financial Statements, "Sun distributes various products exclusively for Sun Pharmaceutical Industries Limited."

20. Since at least 2009, Sun Pharma has maintained an active license with the Virginia Department of Health Professions as a "Non-Resident Wholesale Distributor," which permits Sun Pharma to directly distribute prescription drugs to pharmacies, physicians, and other retail entities throughout the Commonwealth of Virginia. On information and belief, pursuant to the Non-Resident Wholesale Distributer license, Sun Pharma distributes prescription drugs in this District.

21. Sun Pharma is a pharmaceutical vendor for the Minnesota Multistate Contracting Alliance for Pharmacy (MMCAP) which sells pharmaceuticals in the Eastern District of Virginia and in a number of states.

22. Sun Pharma solicits customers in Virginia using its website. Through Sun Pharma's interactive website, customers and potential customers throughout the United States, including in the Eastern District of Virginia can, among other things, search Sun Pharma's full product line and access medication guides for specific Sun Pharma products.

23. Sun Pharma is also 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).

24. As in *Acorda,* Sun Pharma "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.

25. Sun Pharma'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.

26. As in *Acorda*, on information and belief Sun Pharma "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.

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

28. Sun Pharma'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 Sun Pharma.

29. "[T]he minimum-contacts standard is satisfied by the particular actions [Sun Pharma] 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.

30. Exercising personal jurisdiction over Sun Pharma in this District would not be unreasonable given its size, contacts in this District, and the interest in this District of resolving disputes related to products to be sold herein.

PATENT-IN-SUIT

31. 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.

32. 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

33. Each of the preceding paragraphs 1 to 32 is re-alleged and re-incorporated as if fully set forth herein.

34. In a letter dated January 22, 2016 ("the Notice Letter"), Sun Pharma notified ICOS and Lilly that Sun Pharma 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.

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

36. In the Notice Letter, Sun Pharma 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 Sun Pharma's proposed tadalafil ANDA product.

37. 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, Sun Pharma does not deny that the commercial manufacture, use, offer to sell, or sale of its proposed tadalafil ANDA product will infringe claims 1, 2, 4-10, 12, if these claims are found valid.

38. 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.

39. In its Notice Letter, Sun Pharma admits that its proposed tadalafil ANDA product will be orally administered and that it will contain tadalafil as an active ingredient in 2.5 mg, 5 mg, 10 mg, and 20 mg dosage strengths.

40. In its Notice Letter, Sun Pharma admits that its proposed tadalafil ANDA product "will be marketed with prescribing instructions identical to those of CIALIS®," which includes, among other things, treatment of male erectile dysfunction as reflected in 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, Sun Pharma admits that its proposed tadalafil ANDA product "will be marketed with prescribing instructions identical to those of CIALIS®," which includes, among other things, treatment of male erectile dysfunction as reflected in the FDA approved label for CIALIS®.

43. 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, Sun Pharma 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.

44. 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, Sun Pharma admits that its

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

45. 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.

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

47. In its Notice Letter, Sun Pharma admits that its proposed tadalafil ANDA product "will be marketed with prescribing instructions identical to those of CIALIS®," which includes, among other things, treatment of male erectile dysfunction by administration "once per day" as reflected in the FDA approved label for CIALIS®.

48. 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, Sun Pharma admits that its proposed tadalafil ANDA product is a tablet product.

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

50. 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.

51. In its Notice Letter, Sun Pharma admits that its proposed tadalafil ANDA product "will be marketed with prescribing instructions identical to those of CIALIS®," which includes,

among other things, treatment of male erectile dysfunction by administration "once per day" as reflected in the FDA approved label for CIALIS®.

52. 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.

53. In its Notice Letter, Sun Pharma admits that its proposed tadalafil ANDA product "will be marketed with prescribing instructions identical to those of CIALIS®," which includes, among other things, treatment of male erectile dysfunction by administration "once per day" as reflected in the FDA approved label for CIALIS®.

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

55. Each of the preceding paragraphs 1 to 54 is re-alleged and re-incorporated as if fully set forth herein.

56. 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).

57. 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.

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

Dated: September 2, 2016

Respectfully submitted,

/s/ Laura Masurovsky
Laura Masurovsky (VA Bar # 32379)
laura.masurovsky@finnegan.com
Mark J. Feldstein (*pro hac vice* to be filed)
mark.feldstein@finnegan.com
John M. Williamson (*pro hac vice* to be filed)
john.williamson@finnegan.com
Danielle A. Duszczyszyn (*pro hac vice* to be filed)
danielle.duszczyszyn@finnegan.com
Yieyie Yang (VA Bar # 88134)
yieyie.yang@finnegan.com
Emily R. Gabranski (*pro hac vice* to be filed)
emily.gabranski@finnegan.com
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
901 New York Avenue, N.W.
Washington, D.C. 20001-4413
Phone: (202) 408-4000
Fax: (202) 408-4400

Charles E. Lipsey (VA Bar # 17251)
charles.lipsey@finnegan.com
FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, LLP
Two Freedom Square
11955 Freedom Drive
Reston, Virginia 20190-5675
Phone: (571) 203-2700
Fax: (202) 408-4400

Attorneys for Plaintiffs Eli Lilly and Company and ICOS Corporation