IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SUN PHARMA GLOBAL FZE and SUN PHARMACEUTICAL INDUSTRIES, INC., Plaintiffs, v. TEVA PHARMACEUTICAL INDUSTRIES LIMITED and TEVA PHARMACEUTICALS USA, INC., Defendants.	C.A. No._____ JURY TRIAL REQUESTED

PLAINTIFFS SUN PHARMA GLOBAL FZE'S AND SUN PHARMACEUTICAL INDUSTRIES, INC.'S COMPLAINT AGAINST TEVA PHARMACEUTICAL INDUSTRIES LIMITED and TEVA PHARMACEUTICALS USA, INC.

Plaintiffs, Sun Pharma Global FZE and Sun Pharmaceutical Industries, Inc. (collectively, "Sun" or "Plaintiffs"), for their complaint against defendants, Teva Pharmaceuticals Industries Limited ("Teva Ltd.") and Teva Pharmaceuticals USA, Inc. ("Teva USA") (collectively, "Teva" or "Defendants"), to the best of their knowledge, information and belief, allege as follows:

NATURE OF THE ACTION

1. This is an action for infringement of United States Patent No. 9,889,144 ("the '144 patent") under 35 U.S.C. § 271(e)(2) and for a declaratory judgment of infringement of said patent under 35 U.S.C. § 271(a) and 28 U.S.C. §§ 2201-02. The '144 patent covers Sun's commercially successful product, Yonsa® (Abiraterone Acetate Tablets) used to treat metastatic castration-resistant prostate cancer. This action arises from Teva's submission of an Abbreviated New Drug Application ("ANDA") to the United States Food and Drug Administration ("FDA") seeking FDA approval to market a generic version of Yonsa® prior to the expiration of the '144 patent.

THE PARTIES

2. Sun Pharma Global FZE is a corporation organized existing under the laws of the United Arab Emirates with a principal place of business at Office #43, Block Y, SAIF Zone, P.O. Box 122304, Sharjah, United Arab Emirates.

3. Sun Pharmaceutical Industries, Inc. is a corporation organized and existing under the laws of Michigan with a principal place of business at 270 Prospect Plains Road, Cranbury, New Jersey 08512, USA. Sun Pharmaceutical Industries, Inc. is the exclusive distributor for Yonsa® manufactured for Sun Pharma Global FZE in the United States.

4. Upon information and belief, Teva Ltd. is a corporation organization and existing under the laws of Israel with a principal place of business at 5 Basel Street, P.O. Box 3190, Petach Tiva, 4951033, Israel.

5. Teva Ltd. is the largest generic drug maker in the world in terms of annual revenue. Upon information and belief, it operates through a global network of subsidiaries that it directly or indirectly owns and controls, including Teva USA.

6. Upon information and belief, Teva USA is a corporation organized and existing under the laws of Delaware with a principal place of business at 1090 Horsham Road, North Wales, Pennsylvania 19454.

7. Upon information and belief, Teva USA is a wholly-owned subsidiary of Teva Ltd. and acts at the direction of, under the control of, and for the direct benefit of Teva Ltd.

8. Teva Ltd and Teva USA act as one entity. In Teva Ltd.'s annual report (Form 10-K submission to the SEC for the fiscal year ending December 31, 2017), Teva Ltd. repeatedly stated that it and its subsidiaries act in unison. Indeed, in the report, Teva, Ltd. stated that all references to "we" or "our" or "Teva" refer to Teva Ltd. "and its subsidiaries." *Id.* at 1. In this

regard, Teva stated: "We are a global pharmaceutical company . . . We operate worldwide, with headquarters in Israel and a significant presence in the United States. . . . " *Id.* at 2.

9. As to its present market dominance and efforts to maintain same, Teva stated:

> We are the leading generic company in the United States. We market over 500 generic prescription and OTC products in more than 1,800 dosage strengths and packaging sizes." Furthermore, "[w]e will continue our efforts in the United States in maintaining our position as an industry leader in introducing new generic equivalents for brand-name products on a timely basis. . . .

Id. at 5, 6.

10. As pertinent to patent litigation, Teva stated:

> When considering whether to develop a generic medicine, we take into account a number of factors, including our overall strategy, regional and local patient and customer needs, R&D and manufacturing capabilities, regulatory considerations, commercial factors and the intellectual property landscape. We will challenge patents when appropriate if we believe they are either invalid or would not be infringed by our generic version. We may seek alliances to acquire rights to products we do not have in our portfolio or to otherwise share development costs or litigation risks, or to resolve patent and regulatory barriers to entry.

Id. at 5, 6.

* * *

> We may elect to sell a product even through patent litigation is still pending and either before any court decision is rendered or while on appeal of a lower court decision is pending.

Id. at 46.

11. Teva's marketing efforts have been successful because "[i]n 2017, [Teva] led the U.S. generic market in total prescriptions and new prescriptions, with approximately 583 million

in total prescriptions representing 15.2% of total U.S. generic prescriptions, accounting to IQVIA data." *Id.* at 62.

12. Upon information and belief, Teva Ltd. is in the business of, *inter alia*: (i) the development and manufacture of generic pharmaceutical products for sale throughout the world, including the United States and, more specifically, throughout Delaware; (ii) in concert with and/or through its various subsidiaries including Teva USA, the preparation, submission, and filing of ANDAs seeking FDA approval to market generic pharmaceutical products throughout the United States, including Delaware; and (iii) in concert with and/or through its various subsidiaries including Teva USA, the distribution of generic pharmaceutical products for sale throughout the United States, including Delaware.

13. Upon information and belief, Teva USA is in the business of, inter alia: (i) the development and manufacture of generic pharmaceutical products for sale throughout the United States, including Delaware; (ii) alone or in concert with and/or through Teva Ltd., the preparation, submission, and filing of ANDAs seeking FDA approval to market generic pharmaceutical products throughout the United States, including Delaware; and (iii) alone or in concert with and/or through Teva Ltd. and/or various Teva subsidiaries, the distribution of generic pharmaceutical products for sale throughout the United States, including Delaware.

14. Upon information and belief, and as shown in Teva Ltd.'s 2017 annual report, Teva Ltd. and Teva USA work in concert in the manufacture, sale, and distribution of generic versions of branded pharmaceutical products in the United States including Delaware.

15. Upon information and belief, Teva USA holds an active pharmacy wholesale license for the State of Delaware under License Nos. A4-0001468 and A4-0001447 and is an active

distributor/manufacturer licensee for controlled substances for the State of Delaware under License Nos. DM-0006546 and DM-0007115.

JURISDICTION AND VENUE

16. This action arises under the patent laws of the United States of America, United States Code, Title 35, section 1, et seq., including §§ 271(e)(2), 271(a) and 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338.

17. This Court has personal jurisdiction over Teva Ltd. because, on information and belief, Teva Ltd. has committed, or aided, abetted, contributed to, and/or participated in the commission of the tortious act of patent infringement that has led to foreseeable harm and injury to Sun, who conducts business in Delaware and derives substantial revenue therefrom.

18. This Court also has personal jurisdiction over Teva Ltd. because, upon information and belief, Teva Ltd. regularly does business in Delaware and has engaged in a persistent course of purposeful conduct in Delaware by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical products in Delaware.

19. This Court also has personal jurisdiction over Teva Ltd. because, on information and belief, Teva Ltd., acting in concert with Teva USA, has engaged in conduct that reliably predicts its future activities in Delaware. On information and belief, Teva Ltd., by acting in concert with Teva USA and submitting ANDA No. 212206, has taken the significant step of applying to the FDA for approval to engage in future activities, including the wrongful marketing of its generic abiraterone acetate tablets before the expiration of the ’144 patent where such conduct will be purposefully directed at Delaware.

20. This Court also has personal jurisdiction over Teva Ltd. because it has previously been sued in this district and has not challenged personal jurisdiction, and furthermore, it has affirmatively availed itself of the jurisdiction of this Court by asserting counterclaims in actions filed in this district. *See, e.g., Insys Therapeutics, Inc., et al. v. Teva Pharmaceuticals USA, Inc., et al.,* Civil Action No. 1:17-cv-01303 D.I. 10 (D. Del. Jan. 15, 2018); *Shire LLC, et al. v. Teva Pharmaceuticals, USA Inc. et al.*, Civil Action No. 1:10-cv-00329 D.I. 20 (D. Del. Aug. 30, 2010); *UCB Inc., et al. v. Teva Pharmaceuticals USA Inc., et al.,* Civil Action No: 1:13-cv-01148 D.I. 11 (D. Del. Sept. 9, 2013). Upon information and belief, Teva Ltd. has also availed itself of the legal protections of Delaware by filing suit in this jurisdiction. *See, e.g., Teva Pharmaceuticals USA, Inc., et al. v. Amneal Pharmaceuticals LLC, et al.,* Civil Action No. 1:17-00992 D.I 1 (D. Del. Jan 1, 2017); *Teva Pharmaceuticals USA, Inc., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 1:17-cv-00693 D.I. 1 (D. Del. Jun 7, 2017); *Teva Pharmaceuticals USA Inc., et al. v. Amneal Pharmaceuticals LLC*, Civil Action No. 1:15-cv- 00124 D.I. 1 (D. Del. Feb 3, 2015).

21. This Court has personal jurisdiction over Teva USA as it is incorporated in Delaware. As a domestic corporation, Teva USA is registered to do business with the Delaware Department of State, Division of Corporations. This Court also has personal jurisdiction over Teva USA because it has committed, or aided, abetted, contributed to, and/or participated in the commission of the tortious act of patent infringement that has led to foreseeable harm and injury to Sun in Delaware.

22. This Court also has personal jurisdiction over Teva USA because, upon information and belief, Teva USA regularly does business in Delaware and has engaged in a persistent course of conduct within Delaware by continuously and systematically placing goods into the stream of

commerce for distribution throughout the United States, including Delaware, and/or by directly selling pharmaceutical products in Delaware.

23. Upon information and belief, Teva USA holds an active pharmacy wholesale license for Delaware under License Nos. A4-0001468 and A4-0001447 and is an active distributor/manufacturer licensee for controlled substances for Delaware under License Nos. DM-0006546 and DM-0007115.

24. This Court also has personal jurisdiction over Teva USA because, on information and belief, Teva USA, acting in concert with Teva Ltd., has engaged in conduct that reliably predicts its future activities in Delaware. On information and belief, Teva USA, by acting in concert with Teva Ltd. and submitting ANDA No. 212206, has taken the significant step of applying to the FDA for approval to engage in future activities, including wrongful marketing of its generic abiraterone acetate tablets before the expiration of the '144 patent, where such conduct will be purposefully directed at Delaware.

25. The Court also has personal jurisdiction over Teva USA because it has previously been sued in this district and has not challenged personal jurisdiction, and furthermore, it has affirmatively availed itself of the jurisdiction of this Court by asserting counterclaims in actions filed in this district. *See, e.g., Insys Therapeutics, Inc., et al. v. Teva Pharmaceuticals USA, Inc., et al.,* Civil Action No. 1:17-cv-01303 D.I. 10 (D. Del. Jan. 15, 2018); *Shire LLC, et al. v. Teva Pharmaceuticals USA Inc., et al.,* Civil Action No: 1:10-cv-00329 D.I. 20 (D. Del. Aug. 30, 2010); *UCB Inc., et al. v. Teva Pharmaceuticals USA Inc*., *et al*., Civil Action No. 1:13-cv-01148 D.I. 11 (D. Del. Sept. 9, 2013). Upon information and belief, Teva USA has also availed itself of the legal protections of Delaware by filing suit in this jurisdiction. *See, e.g., Teva Pharmaceuticals USA, Inc., et al. v. Amneal Pharmaceuticals LLC, et al.,* Civil Action No. 1:17-00992 D.I 1 (D. Del. Jan

1, 2017); *Teva Pharmaceuticals USA, Inc., et al. v. Dr. Reddy's Laboratories, Ltd., et al.*, Civil Action No. 1:17-cv-00693 D.I. 1 (D. Del. Jun 7, 2017); *Teva Pharmaceuticals USA Inc., et al. v. Amneal Pharmaceuticals LLC*, Civil Action No. 1:15-cv- 00124 D.I. 1 (D. Del. Feb 3, 2015).

26. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391(c)(3) as to Teva Ltd. and § 1400(b) as to Teva USA.

BACKGROUND

27. On February 13, 2018, the PTO duly and legally issued U.S. Patent No. 9,889,144 ("the '144 patent"), entitled "Abiraterone Acetate Formulation and Methods of Use" to inventors Maura Murphy, Paul Nemeth, H. William Bosch, Matthew Callahan, Satya Bhamidipati, Jason Coleman, and Marck Norett, each of whom assigned their interest in the '144 patent to iCeutica Inc., who in turn assigned its interest in the '144 patent to Churchill Intermediate, who, along with Churchill Pharmaceuticals, assigned its interest in the '144 patent to Sun Pharma Global FZE. Sun Pharma Global FZE is the lawful owner of all right, title and interest in and to the '144 patent. A true and correct copy of the '144 patent is attached hereto as **Exhibit A.**

28. On May 19, 2017, NDA No. 210308 was submitted to the FDA for Yonsa® (Abiraterone Acetate Tablets), which application was approved on May 22, 2018.

29. In conjunction with NDA No. 210308, the '144 patent was submitted to the FDA and was published in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the "Orange Book" for NDA No. 210308 covering Yonsa® (Abiraterone Acetate Tablets).

30. Sun Pharmaceutical Industries, Inc. is the exclusive distributor of Yonsa® in the United States.

31. Teva USA submitted ANDA No. 212206 under § 505(j) of the FFDCA (21 U.S.C. § 355(j)) seeking FDA approval to commercially manufacture, use, offer for sale, or sell a generic version of Yonsa® throughout the United States prior to the expiration of the '144 patent.

32. On information and belief, pursuant to § 505(j)(2)(A)(vii)(IV) of the FFDCA, on July 23, 2018 Teva submitted a Paragraph IV Certification in ANDA No. 212206 in which it alleged that all claims of the '144 patent are invalid and unenforceable, and that certain claims would not be infringed by its manufacture, use, or sale of its proposed generic abiraterone acetate tablets.

33. Teva's original written notification of the filing of ANDA No. 212206 and its accompanying certification was received by Sun on or about August 27, 2018 (the "August 27, 2018 Paragraph IV Notice").

34. On September 5, 2018, Sun Notified Teva that the August 27, 2018 Paragraph IV Notice did not comply with the applicable FDA requirements under various sections of 21 CFR 314.95(c) and was therefore deficient.

35. On September 6, 2018, Teva forwarded a new Paragraph IV Notice that, for the first time, complied with the applicable FDA requirements (the "September 6, 2018 Paragraph IV Notice"). The September 6, 2018 Paragraph IV Notice was received by Sun on September 7, 2018.

36. The September 6, 2018 Paragraph IV Notice stated that Teva had filed a Paragraph IV Certification with the FDA in conjunction with its ANDA No. 212206 in which it alleged that all claims of the '144 patent are invalid and unenforceable, and that certain claims would not be infringed by the manufacture, use or sale of its proposed generic abiraterone acetate tablets.

37. Teva has made and continues to make substantial preparation to manufacture, offer to sell, sell and/or import its proposed generic abiraterone acetate tablets in the United States prior to expiration of the '144 patent.

38. Teva's actions, including but not limited to the development of its proposed generic abiraterone acetate tablets and the filing of ANDA No. 212206 with a Paragraph IV Certification, indicate a continued course of conduct to seek FDA approval of ANDA No. 212206 and to manufacture, market, and sell its generic abiraterone acetate tablets before expiration of the '144 patent.

COUNT I

(Infringement of the '144 Patent Under 35 U.S.C. § 271(e)(2)(A) by Teva's ANDA Filing)

39. Sun incorporates each of the preceding paragraphs as if fully set forth herein..

40. Teva submitted ANDA No. 212206 to the FDA under section 505(j) of the FDCA to obtain approval to engage in the manufacture, use or sale throughout the United States of Teva's proposed generic abiraterone acetate tablets prior to the expiration of the '144 patent. By submitting ANDA No. 212206, Teva has committed an act of infringement of the '144 patent under 35 U.S.C. § 271(e)(2)(A).

41. The commercial manufacture, use, offer for sale, sale, and/or importation of Teva's proposed generic abiraterone acetate tablets in the United States prior to the expiration of the '144 patent will constitute an act of infringement of the '144 patent.

42. On information and belief, Teva became aware of the '144 patent no later than the date on which that patent was submitted to the FDA.

43. On information and belief, Teva knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its proposed generic abiraterone acetate

tablets will infringe claims of the ’144 patent, particularly those claims for which it did not deny infringement in its September 6, 2018 Paragraph IV Notice.

44. The commercial manufacture, use, offer for sale, sale and/or importation of Teva’s generic abiraterone acetate tablets in violation of Sun’s patent rights will cause harm to Sun for which damages are inadequate.

45. Sun does not have an adequate remedy at law and will be irreparably harmed by Teva’s infringing conduct unless such conduct is enjoined by this Court.

COUNT II

(Declaratory Judgment of Infringement of the ’144 Patent Under 35 U.S.C. § 271(a) by Teva’s Proposed Generic Abiraterone Acetate Tablets)

46. Sun incorporates each of the preceding paragraphs as if fully set forth herein.

47. This claim arises under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

48. An actual case or controversy exists between Sun and Teva such that the Court may entertain Sun’s request for declaratory relief consistent with Article III of the United States Constitution.

49. Teva has made and will continue to make substantial preparation to manufacture, sell, offer to sell and/or import its proposed generic abiraterone acetate tablets in the United States prior to the expiration of the ’144 patent.

50. Teva’s recent actions indicate that does not intend to alter its present and previous course of conduct.

51. Any manufacture, use, offer for sale, sale and/or importation of Teva’s proposed generic abiraterone acetate tablets in the United States prior to the expiration of the ’144 patent will directly infringe the ’144 patent. Indeed, Teva did not deny infringement of certain claims of the ’144 patent in its September 6, 2018 Paragraph IV Notice.

52. In view of the foregoing, Sun is entitled to a declaratory judgment that any manufacture, use, offer for sale, sale and/or importation of the proposed generic abiraterone acetate tablets in the United States by Teva prior to the expiration of the '144 patent will constitute infringement of said patent.

* * *

53. On information and belief, despite having actual notice of the '144 patent, Teva continues to willfully, wantonly, and deliberately prepare to infringe the '144 patent in disregard of Sun's rights, making this case exceptional and entitling Sun to reasonable attorneys' fees pursuant to 35 U.S.C. § 285.

JURY TRIAL DEMAND

Pursuant to Federal Rule of Civil Procedure 38(b), Plaintiffs hereby request a trial by jury of all issues so triable.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request:

a. That judgment be entered that Teva has infringed the '144 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 212206 to the FDA and that the commercial manufacture, use, offer for sale, sale in the United States and/or the importation into the United States of Teva's proposed generic abiraterone acetate tablets prior to the expiration of the '144 patent will constitute infringement of the said patent;

b. That an order be issued under 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 212206 shall be a date that is not earlier than the expiration date of the '144 patent, including any extensions or exclusivities;

c. That an injunction be issued under 35 U.S.C. § 271(e)(4)(B) and/or 35 U.S.C. § 283 permanently enjoining Teva, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in concert or participation with Teva or acting on Teva's behalf, from engaging in the commercial manufacture, use, offer to sale or sale in the United States or importation into the United States of any drug product covered by the '144 patent, including but not limited to Teva's proposed generic abiraterone acetate tablets, prior to the expiration date of said patent, including any extensions or exclusivities;

d. That a judgment be issued under 28 U.S.C. § 2201 that if Teva, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in concert or participation with Teva or acting on Teva's behalf, engage in the commercial manufacture, use, offer for sale, sale in the United States and/or importation into the United States of Teva's generic abiraterone acetate tablets prior to the expiration of the '144 patents, such conduct will constitute infringement of said patent;

e. That damages or other monetary relief be awarded to Sun under 35 U.S.C. § 271 (e)(4)(C) and/or 35 U.S.C. § 284 as appropriate, including an accounting;

f. That the Court find this is an exceptional case under 35 U.S.C. § 285, and that Sun be awarded reasonable attorneys' fees and costs; and

g. That this Court award Sun such other and further relief as it may deem just and proper.

Dated: October 9, 2018

Respectfully submitted,

FISH & RICHARDSON P.C.

By: */s/ Susan E. Morrison*

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