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Attorneys for Plaintiffs BTG International Ltd., Janssen Biotech, Inc., Janssen Oncology, Inc., and Janssen Research & Development, LLC.

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

BTG INTERNATIONAL LIMITED, JANSSEN BIOTECH, INC., JANSSEN ONCOLOGY, INC., JANSSEN RESEARCH & DEVELOPMENT, LLC, Plaintiffs, v. TEVA PHARMACEUTICALS USA, INC. and TEVA PHARMACEUTICALS INDUSTRIES, LTD., Defendants.	)	Civil Action No.: _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs BTG International Limited ("BTG"), Janssen Biotech, Inc. ("Janssen Biotech"), Janssen Oncology, Inc. ("Janssen Oncology"), and Janssen Research & Development, LLC ("Janssen R&D"),[1] for their Complaint against Defendants Teva Pharmaceuticals USA, Inc.

[1] Janssen Biotech, Janssen Oncology, and Janssen R & D hereinafter are collectively referred to as "Janssen." BTG and Janssen hereinafter are referred to collectively as "Plaintiffs."

("Teva Pharms. USA") and Teva Pharmaceuticals Industries, Ltd. ("Teva Pharms. Indus. Ltd."),[2] to the best of their knowledge, information and belief, hereby allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, § 100 *et seq*. This action relates to the submission of an Abbreviated New Drug Application ("ANDA") by Defendant Teva to the United States Food and Drug Administration (the "FDA") seeking approval to market a generic version of Janssen's ZYTIGA® (abiraterone acetate) Tablets 500 mg ("ZYTIGA® (abiraterone acetate)") drug product prior to the expiration of United States Patent No. 8,822,438 ("the '438 patent").

THE PARTIES

2. Plaintiff BTG is a company organized and existing under the laws of the United Kingdom, with its principal place of business at 5 Fleet Place, London, EC4M 7RD United Kingdom.

3. Plaintiff Janssen Biotech is a corporation organized and existing under the laws of Pennsylvania, with its principal place of business at 800/850 Ridgeview Drive, Horsham, PA 19044.

4. Plaintiff Janssen Oncology is a corporation organized and existing under the laws of Delaware, with its principal place of business at 10990 Wilshire Blvd., Los Angeles, CA 90024.

[2] Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals Industries, Ltd. are herein after referred to as "Teva."

5. Plaintiff Janssen R&D is a limited liability company organized and existing under the laws of New Jersey, with its principal place of business at 920 Route 202 South, Raritan, NJ 08869.

6. Upon information and belief, Defendant Teva Pharms. USA is a corporation organized and existing under the laws of Delaware, having a principal place of business at 1090 Horsham Road, North Wales, PA 19454. Upon information and belief, Teva Pharms. USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0100250184, and has appointed Corporate Creations Network Inc., 811 Church Road Suite 105, Cherry Hill, NJ, 08002, as its registered agent for service of process in New Jersey. Upon information and belief, Teva Pharms. USA is registered with the State of New Jersey's Department of Health as a drug Manufacturer and Wholesaler, under Registration No. 5000583 and as a drug Wholesaler, under Registration No. 5003436.

7. Upon information and belief, Defendant Teva Pharms. Indus. Ltd. is a company organized and existing under the laws of Israel, having a principal place of business at 5 Basel Street, Petach Tikva 49131 Israel.

8. Upon information and belief, Teva Pharms. USA is a wholly-owned subsidiary of Teva Pharms. Indus. Ltd.

9. Upon information and belief, Teva Pharms. USA is acting on behalf of Teva Pharms. Indus. Ltd. with respect to Teva's ANDA No. 210726.

THE PATENT-IN-SUIT

10. The ’438 patent, entitled “Methods and Compositions for Treating Cancer,” was duly issued by the USPTO on September 2, 2014, naming as inventors Alan H. Auerbach and Arie S. Belldegrun. A copy of the ’438 patent is attached hereto as **Exhibit A**.

11. Plaintiff Janssen Oncology is a lawful co-owner of the ’438 patent, with the right to sue and to recover for past infringement.

12. On January 24, 2017, in *BTG International et al. v. Actavis et al.*, No. 2:15-cv-05909 (DNJ), the Court granted Plaintiff Janssen’s Motion to Set a Hearing and Correct Inventorship of U.S. Patent No. 8,822,438 Pursuant to 35 U.S.C. § 256 and directed the U.S. Patent and Trademark Office to issue a certificate of correction adding Dr. Johann S. de Bono as an inventor of the ’438 patent.

13. Plaintiff BTG is the owner of Dr. de Bono’s inventions and a lawful co-owner of the ’438 patent, with the right to sue and to recover for past infringement.

JANSSEN’S ZYTIGA® (ABIRATERONE ACETATE) TABLETS

14. Janssen sells ZYTIGA® (abiraterone acetate) in the United States pursuant to a New Drug Application (“NDA”) No. 202379 that has been approved by the FDA. Janssen Biotech is the holder of NDA No. 202379. Janssen R&D works in collaboration with Janssen Biotech with respect to NDA No. 202379.

15. ZYTIGA® (abiraterone acetate) is indicated in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer.

16. The FDA issues a publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations” (the “Orange Book”).

17. In accordance with 21 U.S.C. § 355(b)(1), the ’438 patent is listed in the Orange Book in connection with NDA No. 202379 as a patent “with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug” ZYTIGA® (abiraterone acetate).

TEVA’S ANDA SUBMISSION

18. By letter dated July 24, 2017 (the “Teva Notice Letter”) Teva Pharms. USA notified Plaintiffs that it had submitted to the FDA ANDA No. 210726 (“Teva ANDA”) for Teva’s 500 mg Abiraterone Acetate Tablets, a drug product that purports to be a generic version of ZYTIGA® (abiraterone acetate) (“Teva’s ANDA Product”). The Teva Notice Letter stated that the ANDA was submitted under 21 U.S.C. §§ 355(j)(1) and 2(A). Teva sent similar Notice Letters on every business day after July 24, 2017 (“subsequent Notice Letters”).

19. Upon information and belief, the purpose of Teva’s ANDA was to obtain approval under the Federal Food, Drug, and Cosmetic Act (“FDCA”) to engage in the commercial manufacture, use, and/or sale of Teva’s ANDA Product prior to the expiration of the ’438 patent.

20. In the Teva Notice Letter and the subsequent Notice Letters, Teva Pharms. USA notified Plaintiffs that, as part of its ANDA, Teva had filed certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), with respect to the ’438 patent. Upon information and belief, Teva submitted ANDA No. 210726 to the FDA containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) asserting that the ’438 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, or sale of Teva’s ANDA Product.

21. The use of Teva's ANDA Product is covered by one or more claims of the '438 patent, including but not limited to Claims 1 and 12.

22. Teva had knowledge of the '438 patent when it submitted the Teva ANDA.

23. This action is being commenced before the expiration of forty-five days from the date Plaintiffs received the Teva Notice letter, which Plaintiffs received on or about July 25, 2017.

SUBJECT MATTER JURISDICTION AND VENUE

24. This action for patent infringement arises under 35 U.S.C. § 100 *et seq.* generally and 35 U.S.C. § 271(a), (b), (c), and (e)(2) specifically.

25. This Court has jurisdiction over the subject matter of this action pursuant to the provisions of 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

26. Venue is proper in this judicial district pursuant to the provisions of 28 U.S.C. §§ 1391 and 1400(b).

27. By email dated August 24, 2017, through its counsel, Teva stated that Teva Pharms. USA consents to venue in New Jersey "for purposes of the action concerning ANDA No. 210726."

PERSONAL JURISDICTION

28. By email dated August 24, 2017, through its counsel, Teva stated that Teva Pharms. USA "consents to jurisdiction and venue in New Jersey for purposes of the action concerning ANDA No. 210726."

29. Upon information and belief, Teva Pharms. USA is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

30. This Court has personal jurisdiction over Teva Pharms. USA by virtue of the fact that, *inter alia*, it has committed a tortious act of patent infringement under 35 U.S.C. § 271(e)(2), and intends a future course of conduct that includes acts of patent infringement in New Jersey under 35 U.S.C. §§ 271(a), (b), and (c). These acts have led and will lead to foreseeable harm and injury to Janssen, including to Plaintiff Janssen R&D, a New Jersey resident corporation, in New Jersey. For example, upon information and belief, Teva Pharms. USA is actively preparing to make the proposed generic copies of ZYTIGA® (abiraterone acetate) that are the subject of Teva's ANDA No. 210726, and to use, sell, and offer for sale such generic copies in this State and this judicial district.

31. Upon information and belief, Teva Pharms. USA employs people throughout New Jersey, including at least the following locations: 8 Gloria Ln, Fairfield, NJ 07004; 208 Passaic Avenue, Fairfield, NJ 07004; and 400 Chestnut Ridge Rd., Woodcliff Lake, NJ 07677.

32. Upon information and belief, Teva Pharms. USA has substantial, continuous and systematic contacts with New Jersey, and it has registered to do business in New Jersey, appointed a registered agent in New Jersey for receipt of service of process, and registered as a drug manufacturer and wholesaler in New Jersey.

33. Upon information and belief, Teva Pharms. Indus. Ltd., directly or through Teva Pharms. USA, is in the business of formulating, manufacturing, marketing, and selling generic prescription pharmaceutical drugs that it distributes in New Jersey and throughout the United States.

34. Upon information and belief, Teva Pharms. Indus. Ltd. has substantial, continuous and systematic contacts with New Jersey, including, but not limited to, the direction of the operations and management of Teva Pharms. USA.

35. Upon information and belief, Teva Pharms. USA and Teva Pharms. Indus. Ltd. hold themselves out as a single entity for the purposes of manufacturing, selling, marketing, distribution, and importation of generic drug products in New Jersey and throughout the United States.

36. On information and belief, Teva Pharms. USA and Teva Pharms. Indus. Ltd. are agents of each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products throughout the United States and will do the same with respect to Teva's ANDA Product for which they have sought approval from the FDA.

37. On information and belief, Teva Pharms. Indus. Ltd. and Teva Pharms. USA are acting in concert with each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products throughout the United States and will do the same with respect to Teva's ANDA Product for which they have sought approval from the FDA.

38. Upon information and belief, Teva Pharms. Indus. Ltd., together with its affiliate and/or agent, Teva Pharms. USA, filed the Teva ANDA with the FDA that is at issue in this patent infringement suit.

39. Upon information and belief, Teva Pharms. Indus. Ltd. alone and/or together with its affiliate and/or agent Teva Pharms. USA has committed, or aided, abetted, actively induced, contributed to, or participated in the commission of an act of patent infringement under 35 U.S.C. § 271(e)(2) that has led and/or will lead to foreseeable harm and injury to Janssen, including to Janssen R&D, which is a New Jersey company, in New Jersey.

40. This Court has personal jurisdiction over Teva Pharms. USA by virtue of, among other things, (1) its consent to jurisdiction in New Jersey by its express representation that it "consents to jurisdiction . . . in New Jersey for purposes of the action concerning ANDA No.

201726"; (2) its continuous and systematic contacts with New Jersey, including its facilities in Fairfield, New Jersey and Woodcliff Lake, New Jersey; (3) its registration to do business in New Jersey and appointment of registered agent in New Jersey for the receipt of service of process; (4) its registration as a drug manufacturer and wholesaler in New Jersey; (5) its tortious acts of patent infringement that will result in foreseeable harm in New Jersey; (6) its sale of a substantial volume of prescription drugs in New Jersey; and (7) its conduct by and through, and in concert with, Teva Pharms. Indus. Ltd.

41. This Court has personal jurisdiction over Teva Pharms. Indus. Ltd. by virtue of, among other things, (1) its continuous and systematic contacts with New Jersey; (2) its acts of tortious patent infringement that will result in foreseeable harm in New Jersey; (3) its sale of a substantial volume of prescription drugs in New Jersey; and (4) its conduct by and through, and in concert with, Teva Pharms. USA.

42. In the alternative, this Court has personal jurisdiction over Teva Pharms. Indus. Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met.

COUNT I: INFRINGEMENT OF THE '438 PATENT BY TEVA

43. Plaintiffs incorporate the preceding paragraphs as if fully set forth herein.

44. The use of Teva's ANDA Product is covered by one or more claims of the '438 patent, including but not limited to Claims 1 and 12.

45. The submission of Teva's ANDA No. 210726 with a Paragraph IV certification regarding the '438 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Teva's ANDA Product before the expiration of the '438 patent constitutes infringement of one or more of the claims of the '438 patent, including but not limited to Claims 1 and 12, under 35 U.S.C. § 271 (e)(2), and Teva intends a

future course of conduct that includes acts of patent infringement under 35 U.S.C. §§ 271(a), (b), and (c).

46. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Teva's ANDA Product before the expiration of the '438 patent would infringe one or more claims of the '438 patent, including but not limited to Claims 1 and 12, under 35 U.S.C. § 271.

47. The use of Teva's ANDA Product in accordance with and as directed by Teva's proposed labeling for that product before the expiration of the '438 patent would infringe one or more claims of the '438 patent, including but not limited to Claims 1 and 12, under 35 U.S.C. § 271.

48. Unless enjoined by this Court, Teva intends to, and will, engage in the manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of Teva's ANDA Product immediately and imminently upon approval of the Teva ANDA.

49. Unless enjoined by this Court, Teva intends to, and will, actively induce infringement of the '438 patent when the Teva ANDA is approved, and intends to, and will do so, immediately and imminently upon approval.

50. Teva knows that Teva's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '438 patent, and that Teva's ANDA Product and its proposed labeling are not suitable for substantial noninfringing use. Unless enjoined by this Court, Teva intends to, and will, contribute to the infringement of the '438 patent immediately and imminently upon approval of the Teva ANDA.

51. The foregoing actions by Teva prior to the expiration of the '438 patent constitute and/or will constitute infringement, active inducement of infringement, and/or contribution to the infringement by others under 35 U.S.C. §§ 271(a), (b) and/or (c).

52. Teva had knowledge of the '438 patent and is knowingly and willfully infringing the '438 patent.

53. Teva acted without a reasonable basis for believing that it would not be liable for infringing the '438 patent, actively inducing infringement of the '438 patent, and/or contributing to the infringement by others of the '438 patent.

54. Unless Teva is enjoined from infringing the '438 patent, actively inducing infringement of the '438 patent, and/or contributing to the infringement of the '438 patent, Plaintiffs will suffer irreparable injury for which they have no adequate remedy at law. Pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., a preliminary and permanent injunction should be entered preventing further infringement.

55. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court that the FDA set the effective date of approval for Teva's ANDA No. 210726 to be a date which is not earlier than the date on which the '438 patent expires or any later expiration of exclusivity to which Plaintiffs are or become entitled.

56. This case is "exceptional," as that term is used in 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request the following relief:

A. Judgment in favor of Plaintiffs and against Defendants.

B. Judgment that the '438 patent is valid and enforceable;

C. Judgment that by the submission of ANDA No. 210726, Teva has infringed, literally or by the doctrine of equivalents, one or more claims of the '438 patent under 35 U.S.C. § 271 (e) (2), and that the commercial manufacture, use, sale, offer for sale, marketing, distribution, or importation of Teva's ANDA Product, in the United States, will constitute infringement, contributory infringement, and actively inducing infringement of one or more claims of the '438 patent under 35 U.S.C. §§ 271 (a), (b), and (c);

(1) Judgment, pursuant to 35 U.S.C. §271(e)(4)(A), that the effective date of any FDA approval of Teva's ANDA No. 210726 shall be no earlier than the date of expiration of the '438 patent and any additional periods of exclusivity to which Plaintiffs are or become entitled;

(2) A preliminary and permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., enjoining Teva, its officers, partners, agents, servants, employees, parents, subsidiaries, affiliate corporations, other business entities and all other persons acting in concert, participation or privity with it, their successors and assigns, from making, using, selling, offering to sell, marketing, distributing, or importing into the United States Teva's ANDA Product and any product that is similar to or only colorably different from those products, and from infringing, contributorily infringing, or inducing others to infringe the '438 patent, before the expiration of the '438 patent and any additional periods of exclusivity;

(3) Damages or other monetary relief, including prejudgment and post-judgment interest, if Teva engages in the commercial manufacture, use, sale, offer to sell, marketing, distribution, or importation of Teva's ANDA Product, or any product or compound

that infringes the ’438 patent, or in inducement or contribution of the ’438 patent, before the expiration of the ’438 patent and any additional periods of exclusivity;

(4) A declaration that this is an exceptional case and an award of reasonable attorneys’ fees and expenses to Plaintiffs pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

(5) Plaintiffs’ reasonable costs of suit incurred in bringing and prosecuting this action; and

(6) Such further and other relief as this Court may deem just and proper.

Dated: August 25, 2017

Respectfully submitted,

s/Donald A. Robinson

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy in tis case is not the subject of any action pending in any court, or of any pending arbitration or administrative proceeding, except for *BTG International Limited, et al. v. Actavis Laboratories FL, Inc., et al.*, Docket No. 2:15-cv-5909 (KM/JBC) which involves the same plaintiffs and the same patent for a different dosage of the same drug product.

Dated: August 25, 2017

Respectfully submitted,

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