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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. GLENMARK PHARMACEUTICALS INC., USA, GLENMARK PHARMACEUTICALS SA, and GLENMARK PHARMACEUTICALS 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 Defendant Glenmark Pharmaceuticals, Inc. USA, Glenmark Pharmaceuticals SA and Glenmark Pharmaceuticals Ltd.,[2] to the best of their knowledge, information and belief, hereby allege as follows:

[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."

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

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, in response to the submission of Abbreviated New Drug Applications ("ANDAs") by Defendant Glenmark to the United States Food and Drug Administration (the "FDA") seeking approval to market a generic version of Janssen's ZYTIGA® (abiraterone acetate) Tablets ("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.

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 Glenmark Pharmaceuticals, Inc. USA is a corporation organized and existing under the laws of Delaware, having a principal place of business at 750 Corporate Drive, Mahwah, New Jersey 07430.

7. Upon information and belief, Defendant Glenmark Pharmaceuticals SA is a corporation organized and existing under the laws of Switzerland, having a principal place of business at Chemin de la Combeta 5, 2300 La Chaux-de-Fonds, Switzerland.

8. Upon information and belief, Glenmark Pharmaceuticals Ltd is a corporation organized and existing under the laws of India, having a principal place of business at Glenmark House, HDO-Corporate Building, Wing-A, B D S Marg, Chakala, Off Western Express Highway, Andheri (E), Mumbai 400099, India.

9. Upon information and belief, Glenmark Pharmaceuticals Inc, USA is a wholly owned subsidiary of Glenmark Pharmaceuticals Ltd.

10. Upon information and belief, Glenmark Pharmaceuticals SA is a wholly owned subsidiary of Glenmark Pharmaceuticals Ltd.

11. Upon information and belief, Glenmark Pharmaceuticals Inc., USA is acting on behalf of Glenmark Pharmaceuticals SA with respect to Glenmark's ANDA No. 209227.

12. Upon information and belief, Glenmark Pharmaceuticals Inc., USA and Glenmark Pharmaceuticals SA are acting on behalf of Glenmark Pharmaceuticals Ltd. with respect to Glenmark's ANDA No. 209227

THE PATENT-IN-SUIT

13. 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**.

14. On March 8, 2016, in *BTG International et al. v. Actavis et al.*, No. 2:15-cv-05909 (DNJ), Plaintiff Janssen filed a Motion to Set a Hearing and Correct Inventorship of U.S. Patent No. 8,822,438 Pursuant to 35 U.S.C. § 256, requesting that the Court issue an order

directing the U.S. Patent and Trademark Office ("USPTO") to issue a certificate of correction adding Dr. Johann S. de Bono as an inventor of the '438 patent.

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

16. 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

17. 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.

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

19. The FDA issues a publication entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (the "Orange Book").

20. 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).

GLENMARK'S ANDA SUBMISSION

21. By letter dated May 18, 2016 (the "Glenmark Notice Letter"), Glenmark notified Plaintiffs that it had submitted to the FDA ANDA No. 209227 ("Glenmark ANDA") for

Glenmark's Abiraterone Acetate Tablets, a drug product that is a generic version of ZYTIGA® (abiraterone acetate) ("Glenmark's ANDA Product").

22. Upon information and belief, the purpose of Glenmark'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 Glenmark's ANDA Product prior to the expiration of the '438 patent.

23. In the Glenmark Notice Letter, Glenmark notified Plaintiffs that, as part of its ANDA, Glenmark 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, Glenmark submitted ANDA No. 209227 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 Glenmark's ANDA Product.

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

25. Glenmark had knowledge of the '438 patent when it submitted the Glenmark ANDA.

26. This action is being commenced before the expiration of forty-five days from the date Plaintiffs received the Glenmark Notice letter, which Plaintiffs received on or about May 23, 2016.

SUBJECT MATTER JURISDICTION AND VENUE

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

28. 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.

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

PERSONAL JURISDICTION

30. By email dated June 7, 2016, through its counsel, Glenmark stated that "Glenmark Pharmaceuticals, Inc., USA, and Glenmark Pharmaceuticals SA consent to jurisdiction in New Jersey."

31. This Court has personal jurisdiction over Glenmark Pharmaceuticals Inc., USA, Glenmark Pharmaceuticals SA, and Glenmark Pharmaceuticals Ltd. by virtue of the fact that, *inter alia*, they have committed a tortious act of patent infringement under 35 U.S.C. § 271(e)(2), and intend a future course of conduct that includes acts of patent infringement in New Jersey. These acts have led and will lead to foreseeable harm and injury to Plaintiffs, including to Plaintiff Janssen R&D, a New Jersey resident corporation, in New Jersey. For example, upon information and belief, Glenmark Pharmaceuticals Inc., USA, Glenmark Pharmaceuticals SA, and Glenmark Pharmaceuticals Ltd. are actively preparing to make the proposed generic copies of ZYTIGA® (abiraterone acetate) that are the subject of Glenmark's ANDA No. 209227, and to use, sell, and offer for sale such generic copies in this State and this judicial district.

32. Upon information and belief, Glenmark Pharmaceuticals Inc., 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.

33. Upon information and belief, Glenmark Pharmaceuticals Inc., USA has substantial, continuous and systematic contacts with New Jersey, including, *inter alia*, having a

principal place of business in Mahwah, New Jersey, is registered to do business in New Jersey and has appointed a registered agent in New Jersey for receipt of service of process, and is registered as a drug wholesaler in New Jersey.

34. Upon information and belief, Glenmark Pharmaceuticals Inc., USA has previously submitted to the jurisdiction of this Court and has asserted counterclaims in this jurisdiction. *See, e.g., Schering Corp. et al. v. Glenmark Pharmaceuticals, Inc., USA et al.*, No. 2:07-cv-1334; *Eli Lilly and Company v. Actavis Elizabeth LLC et al.*, No. 2:07-cv-3770; *Symed Labs Limited et al v. Glenmark Pharmaceuticals Inc., USA*, No. 2:15-cv-8306; *Sanofi-Aventis U.S. LLC v. Glenmark Pharmaceuticals Inc., USA*, No. 3:15-cv-2523.

35. Upon information and belief, Glenmark Pharmaceuticals SA, directly or through it affiliate Glenmark Pharmaceuticals Inc., 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.

36. Upon information and belief, Glenmark Pharmaceuticals SA has substantial, continuous and systematic contacts with New Jersey, directly or through its affiliate Glenmark Pharmaceuticals Inc., USA.

37. Upon information and belief, Glenmark Pharmaceuticals Ltd, directly or through its wholly owned subsidiaries Glenmark Pharmaceuticals SA and Glenmark Pharmaceuticals Inc., USA, is in the business of formulating, manufacturing, marketing, and selling generic prescription drugs that it distributes in New Jersey and throughout the United States.

38. Upon information and belief, Glenmark Pharmaceuticals Ltd. has substantial, continuous and systematic contacts with New Jersey, including, *inter alia* the direction of

operations and management of Glenmark Pharmaceuticals SA and Glenmark Pharmaceuticals Inc., USA.

39. Upon information and belief, Glenmark Pharmaceuticals Ltd has previously submitted to the jurisdiction of this Court and has asserted counterclaims in this jurisdiction. *See, e.g.*, *Schering Corp. et al. v. Glenmark Pharmaceuticals, Inc., USA et al.*, No. 2:07-cv-1334; *Teva Pharmaceutical Industries Ltd. et al. v. Glenmark Generics Inc., USA et al.*, No. 3:08-cv-4355; *Sanofi-Aventis U.S. LLC v. Glenmark Pharmaceuticals Inc., USA*, No. 3:15-cv-2523.

40. Upon information and belief, Glenmark Pharmaceuticals Inc., USA, Glenmark Pharmaceuticals SA, and Glenmark Pharmaceuticals 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.

41. On information and belief, Glenmark Pharmaceuticals Inc., USA, Glenmark Pharmaceuticals SA, and Glenmark Pharmaceuticals 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 Glenmark's ANDA Product for which they have sought approval from the FDA.

42. On information and belief, Glenmark Pharmaceuticals Inc., USA, Glenmark Pharmaceuticals SA, and Glenmark Pharmaceuticals Ltd. 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 Glenmark's ANDA Product for which they have sought approval from the FDA.

43. Upon information and belief, Glenmark Pharmaceuticals SA together with its affiliate and/or agent, Glenmark Pharmaceuticals Inc., USA, filed the Glenmark ANDA with the FDA that is at issue in this patent infringement suit.

44. Upon information and belief, Glenmark Pharmaceuticals SA, alone and/or together with its affiliate and/or agent Glenmark Pharmaceuticals Inc. 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 Plaintiffs, including to Janssen R&D, which is a New Jersey company, in New Jersey.

45. This Court has personal jurisdiction over Glenmark Pharmaceuticals Inc., USA by virtue of, among other things, (1) its express representation that Glenmark Pharmaceuticals Inc., USA consents to jurisdiction in New Jersey; (2) its continuous and systematic contacts with New Jersey, including its principal place of business in Mahwah, New Jersey; (3) its consent to jurisdiction in New Jersey by its registration to do business in New Jersey and appointment of a registered agent in New Jersey for receipt of service of process; (4) its registration as a drug wholesaler in New Jersey; (5) its acts of tortious 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, through, and in concert with Glenmark Pharmaceuticals SA and Glenmark Pharmaceuticals Ltd.

46. This Court has personal jurisdiction over Glenmark Pharmaceuticals SA by virtue of, among other things, (1) its express representation that Glenmark Pharmaceuticals SA consents to jurisdiction in New Jersey; (2) its continuous and systematic contacts with New Jersey; (3) its acts of tortious patent infringement that will result in foreseeable harm in New

Jersey; (4) its sale of a substantial volume of prescription drugs in New Jersey, either directly or through Glenmark Pharmaceuticals Inc., USA; and (5) its conduct by, through, and in concert with Glenmark Pharmaceuticals Inc., USA and Glenmark Pharmaceuticals Ltd.

47. This Court has personal jurisdiction of Glenmark Pharmaceuticals 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, either directly or through Glenmark Pharmaceuticals Inc., USA and Glenmark Pharmaceuticals SA; and (4) its conduct by, through, and in concert with, Glenmark Pharmaceuticals Inc., USA and Glenmark Pharmaceuticals SA.

48. In the alternative, this Court has personal jurisdiction over Glenmark Pharmaceuticals SA and Glenmark Pharmaceuticals Ltd. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met.

CLAIM: INFRINGEMENT OF THE '438 PATENT BY GLENMARK

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

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

51. The submission of Glenmark's ANDA No. 209227 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 Glenmark'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).

52. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Glenmark'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.

53. The use of Glenmark's ANDA Product in accordance with and as directed by Glenmark'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.

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

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

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

57. The foregoing actions by Glenmark 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).

58. Glenmark had knowledge of the '438 patent and is knowingly and willfully infringing the '438 patent.

59. Glenmark 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.

60. Unless Glenmark 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.

61. 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 Glenmark's ANDA No. 209227 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.

62. 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 Glenmark has infringed, literally or by the doctrine of equivalents, one or more claims of the '438 patent by the submission of ANDA No. 209227, and that the commercial manufacture, use, sale, offer for sale, marketing, distribution, or importation of Glenmark'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;

(1) Judgment, pursuant to 35 U.S.C. §271(e)(4)(A), that the effective date of any FDA approval of Glenmark's ANDA No. 209227 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 Glenmark, 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 Glenmark'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 Glenmark engages in the commercial manufacture, use, sale, offer to sell, marketing, distribution, or importation of Glenmark'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: June 24, 2016

Respectfully submitted,

s/Donald A. Robinson

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