Donald A. Robinson
Keith J. Miller
Justin T. Quinn
ROBINSON MILLER LLC
One Newark Center, 19th Floor
Newark, New Jersey 07102
(973) 690-5400 (Telephone)
(973) 466-2760 (Facsimile)

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. AMERIGEN PHARMACEUTICALS, INC., and AMERIGEN 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 Amerigen Pharmaceuticals, 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."

("Amerigen Pharms., Inc.") and Amerigen Pharmaceuticals Ltd. ("Amerigen Pharms. 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, in response to the submission of Abbreviated New Drug Applications ("ANDAs") by Defendant Amerigen 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.

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

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, New Jersey 08869.

6. Upon information and belief, Defendant Amerigen Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware, having principal places of business at 9 Polito Avenue, Suite 900, Lyndhurst, New Jersey, 07071 and 197 State Rte 18, East Brunswick, New Jersey 08816.

7. Upon information and belief, Defendant Amerigen Pharmaceuticals Ltd. is a corporation organized and existing under the laws of the Cayman Islands, having a principal place of business at No. 58, Qunxing Yi Road, Suzhou Industrial Park, Suzhou, Jiangsu Province, China, 215006.

8. Upon information and belief, Amerigen Pharmaceuticals, Inc. is a wholly-owned subsidiary of Amerigen Pharmaceuticals Ltd.

THE PATENT-IN-SUIT

9. 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**.

10. 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.

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. Plaintiff BTG is 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

13. 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.

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

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

16. 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).

AMERIGEN'S ANDA SUBMISSION

17. By letter dated March 24, 2016 (the "Amerigen Notice Letter"), Amerigen notified Plaintiffs that it had submitted to the FDA ANDA No. 208027 ("Amerigen ANDA") for Amerigen's Abiraterone Acetate Tablets, a drug product that is a generic version of ZYTIGA® (abiraterone acetate) ("Amerigen's ANDA Product").

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

19. In the Amerigen Notice Letter, Amerigen notified Plaintiffs that, as part of its ANDA, Amerigen 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, Amerigen submitted ANDA No. 208027 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 Amerigen's ANDA Product.

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

21. Amerigen had knowledge of the '438 patent when it submitted the Amerigen ANDA.

22. This action is being commenced before the expiration of forty-five days from the date Plaintiffs received the Amerigen Notice letter, which Plaintiffs received on or about March 24, 2016.

SUBJECT MATTER JURISDICTION AND VENUE

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

24. 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.

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

PERSONAL JURISDICTION

26. By email dated April 8, 2016, through its counsel, Amerigen stated that "Amerigen will consent to jurisdiction in New Jersey."

27. Upon information and belief, Amerigen Pharmaceuticals, Inc. 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.

28. This Court has personal jurisdiction over Amerigen Pharmaceuticals, Inc. by virtue of the fact that, *inter alia*, Amerigen Pharmaceuticals, Inc. 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. 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, Amerigen Pharmaceuticals, Inc. is actively preparing to make the proposed generic copies of ZYTIGA® (abiraterone acetate) that are the subject of Amerigen's ANDA No. 208027, and to use, sell, and offer for sale such generic copies in this State and this judicial district.

29. Upon information and belief, Amerigen Pharmaceuticals, Inc. has substantial, continuous and systematic contacts with New Jersey, including, *inter alia*, having principal places of business in Lyndhurst, New Jersey and East Brunswick, New Jersey, and being registered as a drug manufacturer and wholesaler in New Jersey.

30. Upon information and belief, Amerigen Pharmaceuticals Ltd. is pharmaceutical company engaged "in all phases of the generic pharmaceutical business"[3] including "developing, manufacturing and marketing high quality generic pharmaceuticals"[4] with a focus on "orally delivered products that are challenging to develop…and present the opportunity for our experts to navigate complex regulatory and intellectual property obstacles to bring to market"[5] including products made by Amerigen Pharmaceuticals, Inc., in New Jersey and throughout the United States.

31. Upon information and belief, Amerigen Pharmaceuticals Ltd. has substantial, continuous and systematic contacts with New Jersey, directly or through its wholly-owned subsidiary Amerigen Pharmaceuticals, Inc.

32. Upon information and belief, Amerigen Pharmaceuticals Ltd. has previously submitted to the jurisdiction of this Court. *See, e.g.*, *Shire LLC v. Amerigen Pharmaceuticals Ltd*, No. 14-cv-6095.

33. Upon information and belief, Amerigen Pharmaceuticals, Inc. and Amerigen 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.

34. On information and belief, Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals Ltd. are agents of each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products throughout the United States and

[3] *See* http://www.amerigenpharma.com/corporate-profile/ (last visited April 18, 2016).
[4] *See* http://www.amerigenpharma.com/our-mission-vision/ (last visited April 18, 2016).
[5] *See* http://www.amerigenpharma.com/product-focus/ (last visited April 18, 2016).

will do the same with respect to Amerigen's ANDA Product for which they have sought approval from the FDA.

35. On information and belief, Amerigen Pharmaceuticals, Inc. and Amerigen 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 Amerigen's ANDA Product for which they have sought approval from the FDA.

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

37. Upon information and belief, Amerigen Pharmaceuticals Ltd., alone and/or together with its affiliate and/or agent Amerigen Pharmaceuticals, Inc., 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.

38. This Court has personal jurisdiction over Amerigen Pharmaceuticals, Inc. by virtue of, among other things, (1) its consent to jurisdiction by its express representation that "Amerigen will consent to jurisdiction in New Jersey"; (2) its continuous and systematic contacts with New Jersey, including its principal place of business in Lyndhurst, New Jersey or East Brunswick, New Jersey; (3) its registration as a drug manufacturer and wholesaler in New Jersey; (4) its acts of tortious patent infringement that will result in foreseeable harm in New Jersey; (5) its sale of a substantial volume of prescription drugs in New Jersey; and (6) its conduct by, through, and in concert with Amerigen Pharmaceuticals Ltd.

39. This Court has personal jurisdiction over Amerigen Pharmaceuticals Ltd. by virtue of, among other things, (1) its consent to jurisdiction by its express representation that "Amerigen will consent to jurisdiction in New Jersey"; (2) its continuous and systematic contacts with New Jersey; (2) its tortious acts of 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, through, and in concert with Amerigen Pharmaceuticals, Inc.

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

CLAIM: INFRINGEMENT OF THE '438 PATENT BY AMERIGEN

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

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

43. The submission of Amerigen's ANDA No. 208027 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 Amerigen'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).

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

45. The use of Amerigen's ANDA Product in accordance with and as directed by Amerigen'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.

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

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

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

49. The foregoing actions by Amerigen 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).

50. Amerigen had knowledge of the '438 patent and is knowingly and willfully infringing the '438 patent.

51. Amerigen 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.

52. Unless Amerigen 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.

53. 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 Amerigen's ANDA No. 208027 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.

54. 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 Amerigen has infringed, literally or by the doctrine of equivalents, one or more claims of the '438 patent by the submission of ANDA No. 208027, and that the commercial manufacture, use, sale, offer for sale, marketing, distribution, or importation of Amerigen'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 Amerigen's ANDA No. 208027 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 Amerigen, 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 Amerigen'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 Amerigen engages in the commercial manufacture, use, sale, offer to sell, marketing, distribution, or importation of Amerigen'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: May 2, 2016

Respectfully submitted,

Donald A. Robinson
Donald A. Robinson (drobinson@rwmlegal.com)
Keith J. Miller (kmiller@rwmlegal.com)
Justin T. Quinn (jquinn@rwmlegal.com)
ROBINSON MILLER LLC
One Newark Center, 19th Floor
Newark, New Jersey 07102
(973) 690-5400 (Telephone)
(973) 466-2760 (Facsimile)

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

Of Counsel:

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

David T. Pritikin
SIDLEY AUSTIN LLP
1. S. Dearborn Street
Chicago, Illinois 60603
Tel: (312) 853-7000
Fax: (312) 853-7036
(dpritikin@sidley.com)

Bindu Donovan
SIDLEY AUSTIN LLP
787 Seventh Avenue
New York, New York 10019
Tel: (212) 839-5300
Fax: (212) 839-5599
(bdonovan@sidley.com)

Attorneys for Plaintiff BTG International Ltd.

Anthony C. Tridico
(anthony.tridico@finnegan.com)
Jennifer H. Roscetti
(jennifer.roscetti@finnegan.com)
FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, LLP
901 New York Avenue, N.W.
Washington D.C. 20001
Tel: (202) 408-4000
Fax: (202) 408-4400