Donald A. Robinson
Keith J. Miller
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. QILU PHARMACEUTICAL CO., LTD. and QILU PHARMA, INC., 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 Qilu Pharmaceutical Co, Ltd., ("Qilu

[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."

Pharma Ltd.") and Qilu Pharma, Inc.,[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 an Abbreviated New Drug Application ("ANDA") by Defendant Qilu to the United States Food and Drug Administration (the "FDA") seeking approval to market a generic version of Janssen's ZYTIGA® (abiraterone acetate) Tablets 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] Qilu Pharmaceutical Co., Ltd. and Qilu Pharma Inc. are hereinafter referred to collectively as "Qilu."

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 Qilu Pharmaceuticals, Co., Ltd. is a Chinese company located at 243 Gong Ye Bei Road, Jinan, Shandong 250100, China, having a United States subsidiary/agent, Qilu Pharma, Inc.

7. Upon information and belief, Qilu Pharma, Inc. is a corporation organized and existing under the laws of the State of Pennsylvania, under the business entity identification number 3800476, with its principal place of business at 101 Lindenwood Drive Suite 225, Malvern, PA 19355.

8. Upon information and belief, Qilu Pharma, Inc., has an active business entity status registered with the New Jersey Department of Treasury under the business entity identification number 0400704255, and maintains a business address at 104 Carnegie Center, Suite 212, Princeton, NJ 08540, and a corporate agent for service of process at 820 Bear Tavern Road, West Trenton, NJ, 08626.

9. Upon information and belief, Qilu Pharma, Inc. is the US agent of, and is acting on behalf of, Qilu Pharmaceutical Co., Ltd.with respect to Qilu's ANDA No. 212462.

10. Upon information and belief, Qilu develops, manufactures, imports, markets, distributes, and/or sells generic pharmaceutical versions of branded products for sale and use throughout the United States, including in the State of New Jersey.

THE PATENTS-IN-SUIT

11. The '438 patent, entitled "Methods and Compositions for Treating Cancer," was duly issued by the U.S. Patent and Trademark Office ("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**.

12. Plaintiff Janssen Oncology lawfully owns all right, title and interest in the ’438 patent, including the right to sue and to recover for past infringement.

‘438 PATENT DISTRICT of NEW JERSEY LITIGATION

13. The ’438 patent has been the subject of previous District Court litigation in which it was found infringed by generic drug manufacturers’ proposed labeling that, upon information and belief, are substantially similar to the proposed labeling to be distributed with the proposed Qilu abiraterone acetate product. The ’438 patent was also found invalid for obviousness, a judgment that is currently being appealed.

14. On July 31, 2015 and September 28, 2015, Plaintiffs filed suit against Actavis Laboratories Fl, Inc., Actavis Pharm, Inc. Actavis, Inc., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals of New York, LLC, Apotex Corp., Apotex Inc., Citron Pharma LLC, Dr. Reddy’s Laboratories, Inc., Dr. Reddy’s Laboratories, Ltd., Mylan Pharmaceuticals Inc., Mylan Inc., Par Pharamceutical, Inc., Par Pharmaceutical Companies, Inc., Sun Pharamceuticals Industries, Ltd., Sun Pharamceuticals Industries, Inc., Teva Pharmaceuticals USA, Inc., Teva Pharmaceuticals Industries Limited, West-Ward Pharmaceuticals Corp., Hikma Pharmaceuticals, LLC, The Arab Pharmaceutical Manufacturing Co., Hikma Pharmaceuticals, PLC, Wockhardt Bio AG, Wockhardt USA LLC, Wockhardt Ltd., Hetero USA Inc., Hetero Labs Limited Unit-V, and Hetero Labs Limited in this Court, Civil Action No. 15-cv-05909 alleging infringement of the ’438 patent (the “Lead Action”).

15. On May 2, 2016, Plaintiffs filed a separate action against Amerigen Pharmaceuticals, Inc. and Amerigen Pharmaceuticals, Ltd. in this Court, Civil Action No. 16-cv-02449 asserting infringement of the ’438 patent (the “Amerigen Action”). On July 29, 2016, the Amerigen Action was consolidated with the Lead Action for discovery purposes.

16. On August 25, 2017, Plaintiffs filed a separate action against Teva Pharmaceuticals USA, Inc. and Teva Pharmaceuticals Industries Limited in this Court, Civil Action No. 17-cv-06435 alleging infringement of the ’438 patent (the “Teva Action”). On January 8, 2018, the Court entered a stipulation consolidating the Teva Action with the Lead Action for all purposes pursuant to Federal Rule of Civil Procedure 42(a).

17. In response to the complaints alleging infringement of the ’438 patent filed in the Lead Action, Amerigen Action, and Teva Action, the defendants in each of those actions asserted , *inter alia*, that the ’438 patent was invalid.

18. 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 USPTO to issue a certificate of correction adding Dr. Johann S. de Bono as an inventor of the ’438 patent. The United States Patent and Trademark Office issued a Certificate of Correction to the ’438 patent on February 20, 2018. A copy of the ’438 patent Certificate of Correction is attached hereto as **Exhibit B**.

19. 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.

20. A nine-day bench trial relating to the ’438 patent infringement claims and defenses for the Lead Action, Amerigen Action, and Teva Action was held in July 2018.

21. On October 26, 2018, this Court (McNulty, J.) issued its Opinion (Dkt. 560) and Order (Dkt. 561) in the consolidated cases *BTG Int'l Ltd., et. al., v. Amneal Pharm. LLC., et. al.,* Civ. No. 15-cv-5909 (KM)(JBC), *BTG Int'l Ltd., et. al., v. Amerigen Pharm., Inc.,* Civ. No. 16-cv-2449 (KM)(JBC), and *BTG Int'l Ltd., et. al., v. Teva Pharm. USA., Inc.* Civ. No. 17-cv-6435 (KM)(JBC) (the "Consolidated D.N.J. Action"), finding: 1) the '438 patent invalid for obviousness; 2) the '438 patent to have an adequate written description; and 3) assuming validity of the '438 patent, the ANDA defendants' marketing of abiraterone would infringe the '438 patent, on either an induced infringement or contributory infringement theory. (Dkt. 560 at 3). This Court issued an amended Opinion on October 30, 2018 (Dkt. 571). The Court's findings with respect to validity and infringement were unchanged.

22. On October 26, 2018, this Court temporarily enjoined Defendants in the above captioned matters from launching their generic abiraterone acetate products, pending briefing and oral argument pursuant to Federal Rule of Civil Procedure 62(c). In that order, the Court acknowledged that "the merits of this case present a potentially appealable issue." (Dkt. 561 at 2 n.1.)

23. On October 30, 2018, this Court entered an order in the above captioned matters enjoining Defendants from commercial marketing and sale of any and all generic copies of ZYTIGA until midnight, November 9, 2018, or until the Federal Circuit rendered a decision on a stay pending appeal, whichever was sooner.

24. On October 31, 2018, the Court entered final judgment under rule 54(b) and Plaintiffs filed a notice of appeal appealing this Court's judgment of invalidity of the '438 patent in the Consolidated D.N.J. Action to the Court of Appeals for the Federal Circuit ("the Federal

Circuit"). Plaintiffs maintain that the district court erred in invalidating the claims of the '438 patent.

25. On November 1, 2018, Plaintiffs-Appellants filed an Emergency Motion under Fed. R. App. P. 8(a) for an Injunction Pending Appeal. On November 5, 2018, the CAFC entered an injunction to preserve the *status quo* until the court rendered a decision on Plaintiffs-Appellants' motion under Fed. R. App. P. 8 for an injunction pending a decision by the CAFC on the merits of the appeals ("CAFC Motion Pending Appeal"). The Federal Circuit injunction was modified on November 9, 2018, but the injunction to preserve the *status quo* until the court rendered a decision on the CAFC Motion for Injunction Pending Appeal remained intact. Plaintiffs-Appellants' Emergency Motion under Fed. R. App. P. 8(a) was denied on November 20, 2018 and the injunction was dissolved.

26. The Federal Circuit has issued a scheduling order for the Federal Circuit appeal on November 20, 2018. Plaintiffs-Appellants' principal brief is due on December 3, 2018; the response brief of Appellees and principal and response brief of Cross-Appellants is due December 26, 2018; Plaintiffs-Appellants' response and reply brief is due January 3, 2018; and Cross-Appellants' reply brief is due January 10, 2019. Among the issues on appeal is whether 35 U.S.C. §315(e)(2) precluded the District Court from reaching the obviousness issue, and if not, whether it should have entered an order, pursuant to 35 U.S.C. §271(e)(4), barring the FDA from granting final approval of any generic copy of Zytiga. Oral argument is scheduled for January 24, 2019.

27. On November 21, 2018, Plaintiffs-Appellants filed an Emergency Application for Injunction Pending Appellate Review with the Supreme Court of the United States. The application is still pending.

’438 PATENT *INTER PARTES* REVIEW PROCEEDINGS

28. On December 4, 2015, Amerigen Pharmaceuticals, Ltd. filed a petition for *inter partes* review (IPR2016-00286) in the United States Patent and Trademark Office (“USPTO”) before the Patent Trial and Appeal Board (“PTAB”) seeking to invalidate Claims 1-20 of the ’438 patent, which was instituted on May 31, 2016. On June 29, 2016, Argentum Pharmaceuticals LLC filed a petition for *inter partes* review (IPR2016-01317) in the USPTO before the PTAB which was instituted and joined with IPR2016-00286 on September 19, 2016.

29. On June 30, 2016, Mylan Pharmaceuticals Inc. filed a petition for *inter partes* review (IPR2016-01332) in the USPTO before the PTAB seeking to invalidate Claims 1-20 of the ’438 patent, which was instituted on January 10, 2017. On February 8, 2017, Actavis Laboratories FL, Inc., Amneal Pharmaceuticals LLC, Amneal Pharmaceuticals of New York, LLC, Dr. Reddy’s Laboratories, Inc., Dr. Reddy’s Laboratories, Ltd., Sun Pharmaceuticals Industries, Ltd., Sun Pharmaceuticals Industries, Inc., Teva Pharmaceuticals USA, Inc., West-Ward Pharmaceuticals Corp., and Hikma Pharmaceuticals, LLC filed a petition for *inter partes* review (IPR2017-00853) in the USPTO before the PTAB seeking to invalidate Claims 1-20 of the ’438 patent, which was instituted and joined with IPR2016-01332 on April 12, 2017.

30. On August 10, 2016, Wockhardt Bio AG filed a petition for *inter partes* review (IPR2016-01582) in the USPTO before the PTAB seeking to invalidate Claims 1-20 of the ’438 patent, which was instituted on January 19, 2017.

31. On January 17, 2018, the Patent Trial and Appeal Board (“PTAB”) issued final written decisions in IPR2016-00286 (joined with IPR2016-01317), IPR2016-01332 (joined with IPR2017-00853), and IPR2016-001582, finding claims 1-20 of the ’438 patent unpatentable.

Plaintiffs have requested rehearing of the PTAB's decisions in IPR2016-00286, IPR2016-01332, and IPR2016-001582 which are still pending and will file an appeal with the Federal Circuit if necessary. The PTAB cannot issue a certificate cancelling the patent claims until after the termination of any appeal of the IPR decisions. 35 U.S.C. § 318(b).

JANSSEN'S ZYTIGA® (ABIRATERONE ACETATE) TABLETS

32. 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.

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

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

35. 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).

QILU'S ANDA SUBMISSION

36. By letter dated October 15, 2018 (the "Qilu Notice Letter"), Qilu notified Plaintiffs that it had submitted to the FDA ANDA No. 212462 ("Qilu ANDA") for Qilu's Abiraterone Acetate Tablets, a drug product that is a generic version of ZYTIGA® (abiraterone acetate) ("Qilu's ANDA Product").

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

38. In the Qilu Notice Letter, Qilu notified Plaintiffs that, as part of its ANDA, Qilu had filed certifications of the type described in Section 505(j)(1) and (2)(A) of the FDCA, 21 U.S.C. § 355(j)(1) and (2)(A), with respect to the '438 patent. Upon information and belief, Qilu submitted ANDA No. 212462 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 Qilu's ANDA Product.

39. The use of Qilu's ANDA Product is covered by one or more claims of the '438 patent.

40. Qilu had knowledge of the '438 patent when it submitted the Qilu ANDA.

THE FILING OF THIS SUIT

41. This action is being commenced before the expiration of forty-five days from the date Plaintiffs received the Qilu Notice letter, which Plaintiffs received on or about October 17, 2018.

42. Under 21 U.S.C. § 355(c)(3)(C), Plaintiffs have 45 days after receipt of Qilu's Notice Letter to sue for infringement of the '438 patent to trigger a 30-month stay during which the FDA cannot approve Qilu's ANDA. There is no mechanism in the statute by which, pending appeal, Plaintiffs can toll the statutory requirement that the suit be filed within 45 days of receipt of Qilu's Notice Letter in order for Plaintiffs to obtain such a stay, or to revive Plaintiffs' right to such a stay upon successful resolution of the appeal, if suit is not filed within 45 days.

43. Plaintiffs have a good faith belief that the Federal Circuit or United States Supreme Court will vacate and/or reverse the district court's determination of invalidity for obviousness of the '438 patent. Accordingly, the complaint is filed at this time to fully protect Plaintiffs' right to obtain the statutory 30-month stay of FDA approval of Qilu's ANDA provided by 21 U.S.C. § 355(c)(3)(C) if and when the Federal Circuit vacates or reverses the judgment of invalidity of the '438 patent in the Consolidated D.N.J. Action.

SUBJECT MATTER JURISDICTION AND VENUE

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

45. 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 and 35 U.S.C. § 271.

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

47. Venue is proper in this jurisdiction over Qilu Pharmaceutical Co., Ltd. pursuant to 28 U.S.C. § 1391. Upon information and belief, Qilu Pharmaceutical Co., Ltd. is not a resident in the United States, and therefore may be sued in any judicial district.

48. Venue is proper in this jurisdiction over Qilu Pharma, Inc. pursuant to 28 U.S.C. § 1400(b). Upon information and belief, Qilu Pharma, Inc. has and will commit acts of infringement in New Jersey, and has a regular and established place of business in this jurisdiction, as demonstrated by, *inter alia*, Qilu Pharma, Inc's, maintenance of a corporate agent for service of process and business address in New Jersey. (*See* ¶¶ 50-62).

49. Additionally, venue is proper in this jurisdiction because Qilu Pharmaceutical Co., Ltd. and Qilu Pharma, Inc. have consented to venue in New Jersey.

PERSONAL JURISDICTION

50. This Court has personal jurisdiction over Qilu Pharmaceuticals Co., Ltd. and Qilu Pharma, Inc. by virtue of the fact that, *inter alia*, Qilu Pharmaceuticals Co., Ltd. and Qilu Pharma, Inc. 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, Qilu Pharmaceuticals Co., Ltd. and Qilu Pharma, Inc. are actively preparing to make the proposed generic copies of ZYTIGA® (abiraterone acetate) that are the subject of Qilu's ANDA No. 212462, and to use, sell, and offer for sale such generic copies in this State and this judicial district.

51. Upon information and belief, Qilu Pharma, Inc. has continuous and systemic contacts with New Jersey. Qilu Pharma, Inc. has an active business entity status registered with the New Jersey Department of Treasury under the business entity identification number 0400704255, and maintains a business address at 104 Carnegie Center, Suite 212, Princeton, NJ 08540, and a corporate agent for service of process at 820 Bear Tavern Road, West Trenton, NJ, 08626.

52. Upon information and belief, Qilu Pharmaceutical Co., Ltd., directly or through its US agent Qilu Pharma, 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.

53. Upon information and belief, Qilu Pharmaceutical Co., Ltd. has substantial, continuous and systematic contacts with New Jersey, directly or through its US agent, Qilu Pharma Inc.

54. Upon information and belief, Qilu Pharmaceutical Co., Ltd. has previously submitted to the jurisdiction of this Court. *Helsinn Healthcare S.A. et al. v. Qilu Pharmaceutical Co., Ltd., et al.,* Civil Action No. 15-8132 (MLC)(DEA), D.I. 14 (Feb. 16, 2016).

55. Upon information and belief, Qilu Pharmaceutical Co., Ltd. and Qilu Pharma, Inc. 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.

56. On information and belief, Qilu Pharmaceutical Co., Ltd. and Qilu Pharma, Inc. are agents of each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products in New Jersey and throughout the United States and will do the same with respect to Qilu's ANDA Product for which they have sought approval from the FDA.

57. On information and belief, Qilu Pharmaceutical Co., Ltd., and Qilu Pharma, Inc. are acting in concert with each other with respect to formulating, manufacturing, packaging, marketing and/or selling pharmaceutical products in New Jersey and throughout the United States and will do the same with respect to Qilu's ANDA Product for which they have sought approval from the FDA.

58. Upon information and belief, Qilu Pharmaceutical Co., Ltd., together with its affiliate and/or agent, Qilu Pharma, Inc., filed the Qilu ANDA with the FDA that is at issue in this patent infringement suit.

59. Upon information and belief, Qilu Pharmaceutical Co., Ltd., alone and/or together with its affiliate and/or agent Qilu Pharma, Inc., have 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.

60. This Court has personal jurisdiction over Qilu Pharmaceutical Co., Ltd., by virtue of, among other things, (1) its consent to jurisdiction by its express representation that "Qilu will consent to both personal jurisdiction and venue in D.N.J."; (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; and (5) its conduct by, through, and in concert with Qilu Pharma, Inc.

61. This Court has personal jurisdiction over Qilu Pharma, Inc. by virtue of, among other things, (1) its consent to jurisdiction by its express representation that "Qilu will consent to both personal jurisdiction and venue in D.N.J."; (2) its continuous and systematic contacts with New Jersey, including its business address in Princeton, NJ; (3) its tortious acts of patent infringement that will result in foreseeable harm in New Jersey; (4) its sale of a substantial volume of prescription drugs in New Jersey; and (5) its conduct by, through, and in concert with Qilu Pharmaceutical Co., Ltd.

62. In the alternative, this Court has personal jurisdiction over Qilu Pharmaceutical Co., Ltd. and Qilu Pharma, Inc. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met.

CLAIM: INFRINGEMENT OF THE '438 PATENT BY QILU

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

64. The use of Qilu's ANDA Product is covered by one or more claims of the '438 patent, including but not limited to Claims 4, 11, 19, and 20.

65. The submission of Qilu's ANDA No. 212462 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 Qilu'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 4, 11, 19, and 20, under 35 U.S.C. § 271(e)(2).

66. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Qilu'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 4, 11, 19, and 20, under 35 U.S.C. § 271, either directly, through induced infringement or through contributory infringement.

67. The use of Qilu's ANDA Product in accordance with and as directed by Qilu'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 4, 11, 19, and 20, under 35 U.S.C. § 271.

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

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

70. Qilu knows that Qilu's ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '438 patent, and that Qilu's ANDA Product and its proposed labeling are not suitable for any substantial noninfringing use. Unless enjoined by this

Court, Qilu intends to, and will, contribute to the infringement of the ’438 patent immediately and imminently upon approval of the Qilu ANDA.

71. The foregoing actions by Qilu 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).

72. On information and belief, Qilu does not deny infringement of the ’438 patent separate and apart from asserting invalidity and therefore has not presented any legally cognizable defense against indirect infringement.

73. Qilu has knowledge of the ’438 patent and will be knowingly and willfully infringing the ’438 patent.

74. Unless Qilu 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.

75. 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 Qilu’s ANDA No. 212462 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.

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 Qilu has infringed, literally or by the doctrine of equivalents, the ’438 patent by the submission of ANDA No. 212462, and that the commercial manufacture, use, sale, offer for sale, marketing, distribution, or importation of Qilu’s ANDA Product, in the United States, will constitute infringement, contributory infringement, and actively inducing infringement 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 Qilu’s ANDA No. 212462 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 Qilu, 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, and their successors and assigns, from making, using, selling, offering to sell, marketing, distributing, or importing into the United States Qilu’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 Qilu engages in the commercial manufacture, use, sale, offer to sell, marketing, distribution, or importation of Qilu’s ANDA Product, or any product or compound that infringes the ’438 patent, or actions constituting inducement of infringement and/or

contributory infringement of the ’438 patent, before the expiration of the ’438 patent and any additional periods of exclusivity;

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

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

Dated: November 28, 2018

Respectfully submitted,

s/ Keith J. Miller

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
(dpritikin@sidley.com)
Thomas D. Rein
(trein@sidley.com)
SIDLEY AUSTIN LLP
1 S. Dearborn Street
Chicago, Illinois 60603
Tel: (312) 853-7000
Fax: (312) 853-7036

Paul Zegger
(pzegger@sidley.com)
SIDLEY AUSTIN LLP
1501 K Street, N.W.
Washington, D.C. 20005
Tel: (202) 736-8940
Fax: (202) 736-8711

Alyssa B. Monsen
(amonsen@sidley.com)
Amanda Potter

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

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

Andrew Langford
(alangford@sidley.com)
SIDLEY AUSTIN LLP
2021 McKinney Avenue
Suite 2000
Dallas, TX 75201
Tel: (214) 981-3300
Fax: (214) 981-3400

LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy in this 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), *BTG International Limited, et al., v. Amerigen Pharmaceuticals, Inc., et al.*, Docket No. 2:16-cv-2449 (KM/JBC) and *BTG International Limited, et al. v. MSN Pharmaceuticals, Inc., et al.*, Docket No. 2:18-cv-2372 (KM/JBC) which involves the same plaintiffs and the same patent for the same drug product.

Respectfully submitted,

s/Keith J. Miller
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.