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*Attorneys for Plaintiffs BTG International Ltd.,  
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Janssen Research & Development, LLC.*

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

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BTG INTERNATIONAL LIMITED, JANSSEN		)
BIOTECH, INC., JANSSEN ONCOLOGY, INC.,		)
JANSSEN RESEARCH & DEVELOPMENT, LLC,		)
		)
Plaintiffs,		)
		)
v.		)
	Civil Action No.:	)
	<hr/>	)
MSN PHARMACEUTICALS INC., MSN		)
LABORATORIES PRIVATE LIMITED		)
		)
Defendants.		)
<hr/>		)

**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”),<sup>1</sup> for their Complaint against Defendant MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited,<sup>2</sup> to the best of their knowledge, information and belief, hereby allege as follows:

<sup>1</sup> 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.”

<sup>2</sup> MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited are herein after referred to as “MSN.”

### **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 MSN to the United States Food and Drug Administration (the “FDA”) seeking approval to market a generic version of Janssen’s ZYTIGA® (abiraterone acetate) Tablets 250 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.

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 MSN Pharmaceuticals Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 343 Thornall Street, Suite 678, Edison, New Jersey, 08837.

7. Upon information and belief, Defendant MSN Laboratories Private Limited is a corporation organized and existing under the laws of India, having a principal place of business at MSN House Plot No. C-24, Industrial Estate, Sanathnagar, Hyderabad - 18, Telangana, India.

8. Upon information and belief, MSN Pharmaceuticals Inc. is a wholly owned subsidiary of MSN Laboratories Private Limited.

9. Upon information and belief, MSN Pharmaceuticals Inc. is acting on behalf of MSN Laboratories Private Limited with respect to MSN's ANDA No. 210686.

### **THE PATENT-IN-SUIT**

10. 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. Beldegrun. 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 USPTO 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.

14. On January 17, 2018, the Patent Trial and Appeal Board ("PTAB") issued final written decisions in several *inter partes* review ("IPR") proceedings—IPR2016-00286 (joined

with IPR2016-01317), IPR2016-01332 (joined with IPR2017-00853), and IPR2016-001582—finding that claims 1-20 of the '438 patent are unpatentable. 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). Plaintiffs intend to request rehearing of the PTAB's IPR decisions and file an appeal if necessary.

### **JANSSEN'S ZYTIGA® (ABIRATERONE ACETATE) TABLETS**

15. 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.

16. The indications for ZYTIGA® (abiraterone acetate) include in combination with prednisone for the treatment of patients with metastatic castration-resistant prostate cancer.

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

18. 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).

### **MSN'S ANDA SUBMISSION**

19. By letter dated January 9, 2018 (the "MSN Notice Letter"), MSN notified Plaintiffs that it had submitted to the FDA ANDA No. 210686 ("MSN ANDA") for MSN's 250 mg Abiraterone Acetate Tablets, a drug product that is a generic version of ZYTIGA® (abiraterone acetate) ("MSN's ANDA Product").

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

21. In the MSN Notice Letter, MSN notified Plaintiffs that, as part of its ANDA, MSN 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, MSN submitted ANDA No. 210686 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 MSN's ANDA Product.

22. The use of MSN'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.

23. MSN had knowledge of the '438 patent when it submitted the MSN ANDA.

24. This action is being commenced before the expiration of forty-five days from the date Plaintiffs received the MSN Notice letter, which Plaintiffs received on or about January 10, 2018.

#### **SUBJECT MATTER JURISDICTION**

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

26. 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.

**PERSONAL JURISDICTION AND VENUE**

27. By email dated February 15, 2018, through its counsel, MSN stated that “MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited consent to jurisdiction and venue in NJ for the purposes of this action.”

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

29. This Court has personal jurisdiction over MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited 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, MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited are actively preparing to make the proposed generic copies of ZYTIGA® (abiraterone acetate) that are the subject of MSN’s ANDA No. 210686, and to use, sell, and offer for sale such generic copies in this State and this judicial district.

30. Upon information and belief, MSN 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.

31. Upon information and belief, MSN Pharmaceuticals Inc. has substantial, continuous and systematic contacts with New Jersey, including, *inter alia*, having a principal place of business in Edison, 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.

32. Upon information and belief, MSN Pharmaceuticals Inc. has previously submitted to the jurisdiction of this Court and has asserted counterclaims in this jurisdiction. *See, e.g., Mitsubishi Tanabe Pharma Corp. et al. v. MSN Laboratories Private Ltd., et al.*, No. 3:17-cv-05302; *Forest Laboratories, LLC et al. v. MSN Laboratories Private Limited et al.*, No. 2:17-cv-10140.

33. Upon information and belief, MSN Laboratories Private Limited, directly or through its wholly owned subsidiary MSN Pharmaceuticals Inc., is in the business of formulating, manufacturing, marketing, and selling generic prescription drugs that it distributes in New Jersey and throughout the United States.

34. Upon information and belief, MSN Laboratories Private Limited has substantial, continuous and systematic contacts with New Jersey, including, *inter alia* the direction of operations and management of MSN Pharmaceuticals Inc.

35. Upon information and belief, MSN Laboratories Private Limited has previously submitted to the jurisdiction of this Court and has asserted counterclaims in this jurisdiction. *See, e.g., Mitsubishi Tanabe Pharma Corp. et al. v. MSN Laboratories Private Ltd., et al.*, No. 3:17-cv-05302; *Forest Laboratories, LLC et al. v. MSN Laboratories Private Limited et al.*, No. 2:17-cv-10140.

36. Upon information and belief, MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited 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.

37. On information and belief, MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited 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 MSN's ANDA Product for which they have sought approval from the FDA.

38. On information and belief, MSN Pharmaceuticals Inc. and MSN Laboratories Private Limited 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 MSN's ANDA Product for which they have sought approval from the FDA.

39. Upon information and belief, MSN Laboratories Private Limited, together with its affiliate and/or agent, MSN Pharmaceuticals Inc., filed the MSN ANDA with the FDA that is at issue in this patent infringement suit.

40. Upon information and belief, MSN Laboratories Private Limited, alone and/or together with its affiliate and/or agent MSN 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.

41. This Court has personal jurisdiction over MSN Pharmaceuticals Inc. by virtue of, among other things, (1) its express representation that MSN Pharmaceuticals Inc. consents to jurisdiction in New Jersey; (2) its continuous and systematic contacts with New Jersey, including its principal place of business in Edison, 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 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 MSN Laboratories Private Limited.

42. This Court has personal jurisdiction over MSN Laboratories Private Limited by virtue of, among other things, (1) its express representation that MSN Laboratories Private Limited 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 MSN Pharmaceuticals Inc.; and (5) its conduct by, through, and in concert with MSN Pharmaceuticals Inc.

43. In the alternative, this Court has personal jurisdiction over MSN Laboratories Private Limited and MSN Pharmaceuticals Inc. because the requirements of Federal Rule of Civil Procedure 4(k)(2)(A) are met.

**CLAIM: INFRINGEMENT OF THE '438 PATENT BY MSN**

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

45. The use of MSN'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.

46. The submission of MSN's ANDA No. 210686 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 MSN'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).

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

48. The use of MSN's ANDA Product in accordance with and as directed by MSN'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.

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

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

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

52. The foregoing actions by MSN 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).

53. MSN had knowledge of the '438 patent and is knowingly and willfully infringing the '438 patent.

54. MSN 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.

55. Unless MSN 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 permanent injunction should be entered preventing further infringement.

56. 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 MSN's ANDA No. 210686 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.

57. 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 MSN has infringed, literally or by the doctrine of equivalents, one or more claims of the '438 patent by the submission of ANDA No. 210686, and that the commercial manufacture, use, sale, offer for sale, marketing, distribution, or importation of MSN'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 MSN's ANDA No. 210686 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 permanent injunction, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., enjoining MSN, 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 MSN'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 MSN engages in the commercial manufacture, use, sale, offer to sell, marketing, distribution, or importation of MSN'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: February 20, 2018

Respectfully submitted,

s/Keith J. Miller

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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 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) and *BTG International Limited, et al., v. Amerigen Pharmaceuticals, Inc., et al.*, Docket No. 2:16-cv-2449 (KM/JBC) which involves the same plaintiffs and the same patent for the same drug product.

Respectfully submitted,

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