IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAYER INTELLECTUAL PROPERTY GMBH, BAYER PHARMA AG, and JANSSEN PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
AUROBINDO PHARMA LIMITED, AUROBINDO PHARMA USA, INC., BRECKENRIDGE PHARMACEUTICAL, INC., MICRO LABS LTD., MICRO LABS USA INC., MYLAN PHARMACEUTICALS INC., MYLAN INC., PRINSTON PHARMACEUTICAL INC., SIGMAPHARM LABORATORIES, LLC, TORRENT PHARMACEUTICALS, LIMITED, and TORRENT PHARMA INC.	)	
Defendants.	)	

COMPLAINT

Plaintiffs Bayer Intellectual Property GmbH ("BIP"), Bayer Pharma AG ("Bayer Pharma") (Bayer Pharma and BIP are collectively referred to herein as "Bayer"), and Janssen Pharmaceuticals, Inc. ("Janssen") (Bayer and Janssen are collectively referred to herein as "Plaintiffs"), by their attorneys, for their Complaint, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement under the patent laws of the United States, Title 35, United States Code, that arises out of the filing by various defendants of Abbreviated New Drug Applications ("ANDA") with the U.S. Food and Drug Administration ("FDA") seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of Plaintiffs' XARELTO® products prior to the expiration

of one or more of U.S. Patent Nos. 7,157,456 ("the '456 patent"), 7,585,860 ("the '860 patent"), and 7,592,339 ("the '339 patent").

THE PARTIES

Plaintiffs

2. Plaintiff Bayer Intellectual Property GmbH is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Alfred-Nobel-Strasse 10, 40789 Monheim am Rhein, Germany.

3. Plaintiff Bayer Pharma AG is a corporation organized and existing under the laws of the Federal Republic of Germany, with a place of business at Müllerstrasse 178, 13353 Berlin, Germany.

4. Plaintiff Janssen Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey.

Aurobindo

5. On information and belief, Defendant Aurobindo Pharma Limited is a company organized and existing under the laws of India, with a place of business at Plot #2, Maitri Vihar, Ameerpet, Hyderabad – 500 038, Andhra Pradesh, India.

6. On information and belief, Defendant Aurobindo Pharma USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 6 Wheeling Road, Dayton, New Jersey.

7. On information and belief, Aurobindo Pharma USA, Inc. is a wholly-owned subsidiary of Aurobindo Pharma Limited, and is controlled and dominated by Aurobindo Pharma Limited.

8. On information and belief, Aurobindo Pharma Limited is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Aurobindo Pharma Limited, acting in concert with Aurobindo Pharma USA, Inc., files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. On information and belief, as part of these ANDAs, Aurobindo Pharma Limited, acting in concert with Aurobindo Pharma USA, Inc., files certifications of the type described in Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug, and Cosmetic Act ("Paragraph IV Certifications") to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

9. On information and belief, and consistent with their practice with respect to other generic products, Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. acted in concert to prepare and submit ANDA No. 208544 for Aurobindo Pharma Limited's 10 mg, 15 mg, and 20 mg rivaroxaban tablets ("Aurobindo's ANDA Products"), which was done at the direction of, under the control of, and for the direct benefit of Aurobindo Pharma Limited.

10. On information and belief, Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into Delaware, and including with respect to the infringing Aurobindo's ANDA Products at issue.

11. On information and belief, following any FDA approval of ANDA No. 208544, Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. will act in concert to market, distribute, offer for sale, and sell Aurobindo's ANDA Products throughout the United States and within Delaware. These two entities are hereafter collectively referred to as "Aurobindo."

12. On information and belief, following any FDA approval of ANDA No. 208544, Aurobindo knows and intends that its ANDA Products will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

Breckenridge

13. On information and belief, Defendant Breckenridge Pharmaceutical, Inc. ("Breckenridge") is a corporation organized and existing under the laws of the State of Florida, with a place of business at 6111 Broken Sound Parkway, NW, Suite 170, Boca Raton, Florida.

14. On information and belief, Breckenridge is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Breckenridge files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. On information and belief, as part of these ANDAs, Breckenridge files Paragraph IV Certifications to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

15. On information and belief, Breckenridge prepared and submitted ANDA No. 208220 for Breckenridge's 10 mg, 15 mg, and 20 mg rivaroxaban tablets, oral ("Breckenridge's ANDA Products").

16. On information and belief, following any FDA approval of ANDA No. 208220, Breckenridge will market, distribute, offer for sale, and sell Breckendridge's ANDA Products throughout the United States and within Delaware.

17. On information and belief, following any FDA approval of ANDA No. 208220, Breckenridge knows and intends that its ANDA Products will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

Micro Labs

18. On information and belief, Defendant Micro Labs Ltd. is a corporation organized and existing under the laws of India, with a place of business at 27 Race Course Road, Bangalore 560 001, India.

19. On information and belief, Defendant Micro Labs USA Inc. is a corporation organized and existing under the laws of the State of New Jersey, with a place of business at 104 Carnegie Ctr., Suite 216, Princeton, New Jersey.

20. On information and belief, Defendant Micro Labs USA Inc. is a wholly-owned subsidiary of Micro Labs Ltd., and is controlled and dominated by Micro Labs Ltd.

21. On information and belief, Micro Labs Ltd. is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Micro Labs Ltd., acting in concert with Micro Labs USA Inc., files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of

drug products that are covered by United States patents. On information and belief, as part of these ANDAs, Micro Labs Ltd., acting in concert with Micro Labs USA Inc., files Paragraph IV Certifications to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

22. On information and belief, and consistent with their practice with respect to other generic products, Micro Labs Ltd. and Micro Labs USA Inc. acted in concert to prepare and submit ANDA No. 208334 for Micro Labs Ltd.'s 10 mg, 15 mg, and 20 mg rivaroxaban tablets ("Micro Labs' ANDA Products"), which was done at the direction of, under the control of, and for the direct benefit of Micro Labs Ltd.

23. On information and belief, Micro Labs Ltd. and Micro Labs USA Inc. are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into Delaware, and including with respect to the infringing Micro Labs' ANDA Products at issue.

24. On information and belief, following any FDA approval of ANDA No. 208334, Micro Labs Ltd. and Micro Labs USA Inc. will act in concert to market, distribute, offer for sale, and sell Micro Labs' ANDA Products throughout the United States and within Delaware. These two entities are hereafter collectively referred to as "Micro Labs."

25. On information and belief, following any FDA approval of ANDA No. 208334, Micro Labs knows and intends that its ANDA Products will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

Mylan

26. On information and belief, Defendant Mylan Pharmaceuticals Inc. is a corporation organized and existing under the laws of the State of West Virginia, with a place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia.

27. On information and belief, Defendant Mylan Inc. is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, with a place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania.

28. On information and belief, Defendant Mylan Pharmaceuticals Inc. is a wholly-owned subsidiary of Mylan Inc., and is controlled and dominated by Mylan Inc.

29. On information and belief, Mylan Inc. is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Mylan Pharmaceuticals Inc., acting in concert with Mylan Inc., files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. On information and belief, as part of these ANDAs, Mylan Pharmaceuticals Inc., acting in concert with Mylan Inc., files Paragraph IV Certifications to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

30. On information and belief, and consistent with their practice with respect to other generic products, Mylan Inc. and Mylan Pharmaceuticals Inc. acted in concert to prepare and submit ANDA No. 208561 for Mylan Pharmaceutical Inc.'s 10 mg, 15 mg, and 20 mg

rivaroxaban tablets ("Mylan's ANDA Products"), which was done at the direction of, under the control of, and for the direct benefit of Mylan Inc.

31. On information and belief, Mylan Pharmaceuticals Inc. and Mylan Inc. are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into Delaware, and including with respect to the infringing Mylan ANDA Products at issue.

32. On information and belief, following any FDA approval of ANDA No. 208561, Mylan Pharmaceuticals Inc. and Mylan Inc. will act in concert to market, distribute, offer for sale, and sell Mylan's ANDA Products throughout the United States and within Delaware. These two entities are hereafter collectively referred to as "Mylan."

33. On information and belief, following any FDA approval of ANDA No. 208561, Mylan knows and intends that its ANDA Products will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

Prinston

34. On information and belief, Defendant Prinston Pharmaceutical Inc. ("Prinston") is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 2002 Eastpark Blvd, Cranbury, New Jersey.

35. On information and belief, Prinston is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Prinston files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or

importation of generic versions of drug products that are covered by United States patents. On information and belief, as part of these ANDAs, Prinston files Paragraph IV Certifications to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

36. On information and belief, Prinston prepared and submitted ANDA No. 208549 for Prinston's 10 mg, 15 mg, and 20 mg rivaroxaban tablets ("Prinston's ANDA Products").

37. On information and belief, following any FDA approval of ANDA No. 208549, Prinston will market, distribute, offer for sale, and sell Prinston's ANDA Products throughout the United States and within Delaware.

38. On information and belief, following any FDA approval of ANDA No. 208549, Prinston knows and intends that its ANDA Products will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

Sigmapharm

39. On information and belief, Defendant Sigmapharm Laboratories, LLC ("Sigmapharm") is a limited liability company organized and existing under the laws of the Commonwealth of Pennsylvania, with a place of business at 3375 Progress Drive, Bensalem, Pennsylvania.

40. On information and belief, Sigmapharm is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Sigmapharm files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States

patents. On information and belief, as part of these ANDAs, Sigmapharm files Paragraph IV Certifications to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

41. On information and belief, Sigmapharm prepared and submitted ANDA No. 208546 for Sigmapharm's 10 mg, 15 mg, and 20 mg rivaroxaban tablets ("Sigmapharm's ANDA Products").

42. On information and belief, following any FDA approval of ANDA No. 208546, Sigmapharm will market, distribute, offer for sale, and sell Sigmapharm's ANDA Products throughout the United States and within Delaware.

43. On information and belief, following any FDA approval of ANDA No. 208546, Sigmapharm knows and intends that its ANDA Products will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

Torrent

44. On information and belief, Defendant Torrent Pharmaceuticals, Limited is a corporation organized and existing under the laws of India, with a place of business at Torrent House, Off Ashram Road, Ahmedabad – 380 009, India.

45. On information and belief, Defendant Torrent Pharma Inc. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 150 Allen Road, Suite 102, Basking Ridge, New Jersey.

46. On information and belief, Defendant Torrent Pharma Inc. is a wholly-owned subsidiary of Torrent Pharmaceuticals, Limited, and is controlled and dominated by Torrent Pharmaceuticals, Limited.

47. On information and belief, Torrent Pharmaceuticals, Limited is in the business of, among other things, manufacturing, marketing, distributing, offering for sale, and selling generic drug products. As a part of this business, on information and belief, Torrent Pharmaceuticals, Limited, acting in concert with Torrent Pharma Inc., files ANDAs with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic versions of drug products that are covered by United States patents. On information and belief, as part of these ANDAs, Torrent Pharmaceuticals, Limited, acting in concert with Torrent Pharma Inc., files Paragraph IV Certifications to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic drug products prior to the expiration of United States patents that cover such products.

48. On information and belief, and consistent with their practice with respect to other generic products, Torrent Pharmaceuticals, Limited and Torrent Pharma Inc. acted in concert to prepare and submit ANDA No. 208556 for Torrent Pharmaceuticals, Limited's 10 mg, 15 mg, and 20 mg rivaroxaban tablets ("Torrent's ANDA Products"), which was done at the direction of, under the control of, and for the direct benefit of Torrent Pharmaceuticals, Limited

49. On information and belief, Torrent Pharmaceuticals, Limited and Torrent Pharma Inc. are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and distribution of generic pharmaceutical products throughout the United States, including into Delaware, and including with respect to the infringing Torrent's ANDA Products at issue.

50. On information and belief, following any FDA approval of ANDA No. 208556, Torrent Pharmaceuticals, Limited and Torrent Pharma Inc. will act in concert to market,

distribute, offer for sale, and sell Torrent's ANDA Products throughout the United States and within Delaware. These two entities are hereafter collectively referred to as "Torrent."

51. On information and belief, following any FDA approval of ANDA No. 208556, Torrent knows and intends that its ANDA Products will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware.

JURISDICTION

52. Plaintiffs incorporate each of the preceding paragraphs as if each fully set forth herein.

53. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

54. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery if necessary, this Court has personal jurisdiction over each of the defendants.

Aurobindo

55. This Court has personal jurisdiction over Aurobindo Pharma USA, Inc. because, among other things, Aurobindo Pharma USA, Inc. is a corporation formed under the laws of the State of Delaware.

56. This Court has personal jurisdiction over Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. because, among other things, on information and belief: (1) Aurobindo Pharma Limited, acting in concert with Aurobindo Pharma USA, Inc., has filed an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Aurobindo's ANDA Products in the United States, including in Delaware; and (2) Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc., acting in

concert and/or as agents of one another, will market, distribute, offer for sale, and/or sell Aurobindo's ANDA Products in the United States, including in Delaware, upon approval of ANDA No. 208544, and will derive substantial revenue from the use or consumption of Aurobindo's ANDA Products in the State of Delaware. On information and belief, if ANDA No. 208544 is approved, the generic Aurobindo products charged with infringing the '456, '860, and '339 patents would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

57. Aurobindo Pharma Limited and Aurobindo Pharma USA, Inc. have consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of their ANDAs, and they have filed counterclaims in such cases.

58. Alternatively, if Aurobindo Pharma Limited's connections with Delaware, including its connections with Aurobindo Pharma USA, Inc., are found to be insufficient to confer personal jurisdiction, then, upon information and belief, Aurobindo Pharma Limited is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Aurobindo Pharma Limited in Delaware is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

Breckenridge

59. This Court has personal jurisdiction over Breckenridge because, on information and belief, Breckenridge has registered to do business in the State of Delaware and has appointed a registered agent in Delaware to accept service of process. Breckenridge has thus consented to personal jurisdiction in Delaware.

60. This Court also has personal jurisdiction over Breckenridge because, among other things, on information and belief: (1) Breckenridge has filed an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Breckenridge's ANDA Products in the United States, including in Delaware; and (2) Breckenridge will market, distribute, offer for sale, and/or sell Breckenridge's ANDA Products in the United States, including in Delaware, upon approval of ANDA No. 208220, and will derive substantial revenue from the use or consumption of Breckenridge's ANDA Products in the State of Delaware. On information and belief, if ANDA No. 208220 is approved, the generic Breckenridge products charged with infringing the '456 and '860 patents would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

61. Breckenridge has consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, and it has filed counterclaims in such cases.

62. In addition, Breckenridge, through its counsel, has represented that it will not contest personal jurisdiction in Delaware for purposes of this case.

Micro Labs

63. This Court has personal jurisdiction over Micro Labs Ltd. and Micro Labs USA Inc. because, among other things, on information and belief: (1) Micro Labs Ltd., acting in concert with Micro Labs USA Inc., has filed an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Micro Labs' ANDA Products in the United States, including in Delaware; and (2) Micro Labs Ltd. and

Micro Labs USA Inc., acting in concert and/or as agents of one another, will market, distribute, offer for sale, and/or sell Micro Labs' ANDA Products in the United States, including in Delaware, upon approval of ANDA No. 208334, and will derive substantial revenue from the use or consumption of Micro Labs' ANDA Products in the State of Delaware. On information and belief, if ANDA No. 208334 is approved, the generic Micro Labs products charged with infringing the '456 patent would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

64. Micro Labs Ltd. and Micro Labs USA Inc. have consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of their ANDAs, and they have filed counterclaims in such cases.

65. Alternatively, if Micro Labs Ltd.'s connections with Delaware are found to be insufficient to confer personal jurisdiction, then, upon information and belief, Micro Labs Ltd. is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Micro Labs Ltd. in Delaware is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

66. In addition, Micro Labs Ltd. and Micro Labs USA Inc., through their counsel, have represented that they will not contest personal jurisdiction in Delaware for purposes of this case.

Mylan

67. This Court has personal jurisdiction over Mylan Pharmaceuticals Inc. because, on information and belief, Mylan Pharmaceuticals Inc. has registered to do business in

the State of Delaware and has appointed a registered agent in Delaware to accept service of process. Mylan Pharmaceuticals Inc. has thus consented to jurisdiction in Delaware.

68. In addition, this Court also has personal jurisdiction over Mylan Pharmaceuticals Inc. and Mylan Inc. because, among other things, on information and belief: (1) Mylan Pharmaceuticals Inc., acting in concert with Mylan Inc., has filed an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Mylan's ANDA Products in the United States, including in Delaware; and (2) Mylan Pharmaceuticals Inc. and Mylan Inc., acting in concert and/or as agents of one another, will market, distribute, offer for sale, and/or sell Mylan's ANDA Products in the United States, including in Delaware, upon approval of ANDA No. 208561, and will derive substantial revenue from the use or consumption of Mylan's ANDA Products in the State of Delaware. On information and belief, if ANDA No. 208561 is approved, the generic Mylan products charged with infringing the '456, '860, and '339 patents would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

69. Mylan Pharmaceuticals Inc. is actively registered with the Delaware Board of Pharmacy, pursuant to Del. C. § 2540, as a licensed "Pharmacy – Wholesale Drug Distributor," and as a licensed "Distributor/Manufacturer CSR."

70. Mylan Inc. and Mylan Pharmaceuticals Inc. have consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of their ANDAs, and they have filed counterclaims in such cases.

Prinston

71. This Court has personal jurisdiction over Prinston because, among other things, Prinston is a corporation formed under the laws of the State of Delaware.

72. This Court also has personal jurisdiction over Prinston because, among other things, on information and belief: (1) Prinston has filed an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Prinston's ANDA Products in the United States, including in Delaware; and (2) Prinston will market, distribute, offer for sale, and/or sell Prinston's ANDA Products in the United States, including in Delaware, upon approval of ANDA No. 208549, and will derive substantial revenue from the use or consumption of Prinston's ANDA Products in the State of Delaware. On information and belief, if ANDA No. 208549 is approved, the generic Prinston products charged with infringing the '456, '860, and '339 patents would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

73. Prinston has consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, and it has filed counterclaims in such cases.

Sigmapharm

74. This Court has personal jurisdiction over Sigmapharm because, among other things, on information and belief: (1) Sigmapharm has filed an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Sigmapharm's ANDA Products in the United States, including in Delaware; and (2) Sigmapharm will market, distribute, offer for sale, and/or sell Sigmapharm's ANDA Products

in the United States, including in Delaware, upon approval of ANDA No. 208546, and will derive substantial revenue from the use or consumption of Sigmapharm's ANDA Products in the State of Delaware. On information and belief, if ANDA No. 208546 is approved, the generic Sigmapharm products charged with infringing the '456, '860, and '339 patents would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

75. Sigmapharm has consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of its ANDAs, and it has filed counterclaims in such cases.

76. In addition, Sigmapharm, through its counsel, has represented that it will not contest personal jurisdiction in Delaware for purposes of this case.

Torrent

77. This Court has personal jurisdiction over Torrent Pharma Inc. because, among other things, Torrent Pharma Inc. is a corporation formed under the laws of the State of Delaware.

78. This Court has personal jurisdiction over Torrent Pharmaceuticals, Limited and Torrent Pharma Inc. because, among other things, on information and belief: (1) Torrent Pharmaceuticals, Limited, acting in concert with Torrent Pharma Inc., has filed an ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Torrent's ANDA Products in the United States, including in Delaware; and (2) Torrent Pharmaceuticals, Limited and Torrent Pharma Inc., acting in concert and/or as agents of one another, will market, distribute, offer for sale, and/or sell Torrent's ANDA Products in the United States, including in Delaware, upon approval of ANDA No.

208556, and will derive substantial revenue from the use or consumption of Torrent's ANDA Products in the State of Delaware. On information and belief, if ANDA No. 208556 is approved, the generic Torrent products charged with infringing the '456, '860, and '339 patents would, among other things, be marketed, distributed, offered for sale, and/or sold in Delaware, prescribed by physicians practicing in Delaware, and dispensed by pharmacies located within Delaware, and/or used by patients in Delaware, all of which would have a substantial effect on Delaware.

79. Torrent Pharmaceuticals, Limited and Torrent Pharma Inc. have consented to jurisdiction in Delaware in one or more prior cases arising out of the filing of their ANDAs, and they have filed counterclaims in such cases.

80. Alternatively, if Torrent Pharmaceuticals, Limited's connections with Delaware, including its connections with Torrent Pharma Inc., are found to be insufficient to confer personal jurisdiction, then, upon information and belief, Torrent Pharmaceuticals, Limited is not subject to jurisdiction in any state's courts of general jurisdiction, and exercising jurisdiction over Torrent Pharmaceuticals, Limited in Delaware is consistent with the United States Constitution and laws. *See* Fed. R. Civ. P. 4(k)(2).

VENUE

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

FACTUAL BACKGROUND

82. XARELTO® (active ingredient rivaroxaban) is a factor Xa inhibitor indicated: (i) to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; (ii) for the treatment of deep vein thrombosis (DVT), pulmonary embolism (PE), and for the reduction in the risk of recurrence of DVT and of PE; and (iii) for the

prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery. XARELTO® is available as tablets in 10 mg, 15 mg, and 20 mg dosage strengths.

83. Janssen is the holder of New Drug Application No. 022406 for XARELTO®, which has been approved by the FDA.

The '456 Patent

84. United States Patent No. 7,157,456 ("the '456 patent"), entitled "Substituted Oxazolidinones and Their Use in the Field of Blood Coagulation," was duly and legally issued on January 2, 2007. The '456 patent is attached as Exhibit A.

85. As set forth in greater detail in the '456 patent, the claims of the '456 patent, incorporated by reference herein, cover the compound rivaroxaban, pharmaceutical compositions containing rivaroxaban, methods of using rivaroxaban, and processes for preparing rivaroxaban.

86. BIP is the assignee of the '456 patent.

87. Bayer Pharma is an exclusive licensee under the '456 patent.

88. Janssen is an exclusive sublicensee under the '456 patent.

89. Pursuant to 21 U.S.C. § 355, the '456 patent is listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") in connection with XARELTO®.

The '860 Patent

90. United States Patent No. 7,585,860 ("the '860 patent"), entitled "Substituted Oxazolidinones and Their Use in the Field of Blood Coagulation", was duly and legally issued on September 8, 2009. The '860 patent is attached as Exhibit B.

91. As set forth in greater detail in the ’860 patent, the claims of the ’860 patent, incorporated by reference herein, cover the compound rivaroxaban and hydrates of rivaroxaban.

92. BIP is the assignee of the ’860 patent.

93. Bayer Pharma is an exclusive licensee under the ’860 patent.

94. Janssen is an exclusive sublicensee licensee under the ’860 patent.

95. Pursuant to 21 U.S.C. § 355, the ’860 patent is listed in the Orange Book in connection with XARELTO®.

The ’339 Patent

96. United States Patent No. 7,592,339 (“the ’339 patent”), entitled “Substituted Oxazolidinones and Their Use in the Field of Blood Coagulation,” was duly and legally issued on September 22, 2009. The ’339 patent is attached as Exhibit C.

97. As set forth in greater detail in the ’339 patent, the claims of the ’339 patent, incorporated by reference herein, cover methods of using rivaroxaban.

98. BIP is the assignee of the ’339 patent.

99. Bayer Pharma is an exclusive licensee under the ’339 patent.

100. Janssen is an exclusive sublicensee under the ’339 patent.

101. Pursuant to 21 U.S.C. § 355, the ’339 patent is listed in the Orange Book in connection with XARELTO®.

Infringement by Aurobindo

102. By letter dated September 24, 2015 (the “Aurobindo Notice Letter”), Aurobindo notified BIP and Janssen that Aurobindo had submitted to the FDA ANDA No. 208544 for Aurobindo’s ANDA Products. These products are generic versions of XARELTO®.

103. In the Aurobindo Notice Letter, Aurobindo stated that Aurobindo's ANDA Products contain rivaroxaban.

104. On information and belief, the proposed labeling for Aurobindo's ANDA Products directs the use of Aurobindo's ANDA Products for one or more of the following indications: (i) to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; (ii) for the treatment of deep vein thrombosis (DVT), pulmonary embolism (PE), and for the reduction in the risk of recurrence of DVT and of PE; and (iii) for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery.

105. On information and belief, the manufacture, use (including in accordance with and as directed by Aurobindo's proposed labeling for Aurobindo's ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products will infringe one or more claims of each of the '456, '860, and '339 patents.

106. In the Aurobindo Notice Letter, Aurobindo indicated that, in connection with its ANDA No. 208544, Aurobindo Pharma Limited had filed Paragraph IV Certifications with respect to each of the '456, '860, and '339 patents.

107. The purpose of ANDA No. 208544 was to obtain approval under the Federal Food, Drug, and Cosmetic Act ("FDCA") to engage in the commercial manufacture, use, offer for sale, and/or sale of Aurobindo's ANDA Products with their proposed labeling prior to the expiration of the '456, '860, and '339 patents.

108. Aurobindo intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products with their proposed

labeling immediately and imminently upon approval of ANDA No. 208544, *i.e.*, prior to the expiration of the '456, '860, and '339 patents.

109. Aurobindo has knowledge of the claims of the '456, '860, and '339 patents. Notwithstanding this knowledge, Aurobindo has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208544. On information and belief, by such activities, Aurobindo specifically intends infringement of the '456, '860, and '339 patents.

110. On information and belief, Aurobindo plans and intends to, and will, actively induce infringement of the '456, '860, and '339 patents when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

111. On information and belief, Aurobindo knows that Aurobindo's ANDA Products are especially made or adapted for use in infringing the '456 and '339 patents, and that Aurobindo's ANDA Products are not suitable for substantial noninfringing use. On information and belief, Aurobindo plans and intends to, and will, contribute to infringement of the '456 and '339 patents immediately and imminently upon approval of ANDA No. 208544.

112. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the '456, '860, and '339 patents, active inducement of infringement of the '456, '860, and '339 patents, and/or contribution to the infringement by others of the '456 and '339 patents.

113. An actual case or controversy exists between Plaintiffs and Aurobindo with respect to infringement of each of the '456, '860, and '339 patents.

114. This action is being commenced before the expiration of forty-five days from the date BIP and Janssen received the Aurobindo Notice Letter.

Infringement by Breckenridge

115. By letter dated September 15, 2015 (the "Breckenridge Notice Letter"), Breckenridge notified BIP and Janssen, among others, that Breckenridge had submitted to the FDA ANDA No. 208220 for Breckenridge's ANDA Products. These products are generic versions of XARELTO®.

116. In the Breckenridge Notice Letter, Breckenridge stated that Breckenridge's ANDA Products contain rivaroxaban.

117. On information and belief, the proposed labeling for Breckenridge's ANDA Products directs the use of Breckenridge's ANDA Products for one or more of the following indications: (i) to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; (ii) for the treatment of deep vein thrombosis (DVT), pulmonary embolism (PE), and for the reduction in the risk of recurrence of DVT and of PE; and (iii) for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery.

118. On information and belief, the manufacture, use (including in accordance with and as directed by Breckenridge's proposed labeling for Breckenridge's ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Breckenridge's ANDA Products will infringe one or more claims of each of the '456 and '860 patents.

119. In the Breckenridge Notice Letter, Breckenridge indicated that, in connection with its ANDA No. 208220, Breckenridge had filed Paragraph IV Certifications with respect to each of the '456 and '860 patents.

120. The purpose of ANDA No. 208220 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Breckenridge's ANDA Products with their proposed labeling prior to the expiration of the '456 and '860 patents.

121. Breckenridge intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Breckenridge's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208220, *i.e.*, prior to the expiration of the '456 and '860 patents.

122. Breckenridge has knowledge of the claims of the '456 and '860 patents. Notwithstanding this knowledge, Breckenridge has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Breckenridge's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208220. On information and belief, by such activities, Breckenridge specifically intends infringement of the '456 and '860 patents.

123. On information and belief, Breckenridge plans and intends to, and will, actively induce infringement of the '456 and '860 patents when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

124. On information and belief, Breckenridge knows that Breckenridge's ANDA Products are especially made or adapted for use in infringing the '456 patent, and that Breckenridge's ANDA Products are not suitable for substantial noninfringing use. On information and belief, Breckenridge plans and intends to, and will, contribute to infringement of the '456 patent immediately and imminently upon approval of ANDA No. 208220.

125. The foregoing actions by Breckenridge constitute and/or will constitute infringement of the ’456 and ’860 patents, active inducement of infringement of the ’456 and ’860 patents, and/or contribution to the infringement by others of the ’456 patent.

126. An actual case or controversy exists between Plaintiffs and Breckenridge with respect to infringement of each of the ’456 and ’860 patents.

127. This action is being commenced before the expiration of forty-five days from the date BIP and Janssen received the Breckenridge Notice Letter.

Infringement by Micro Labs

128. By letter dated September 11, 2015 (the “Micro Labs Notice Letter”), Micro Labs notified BIP and Janssen, among others, that Micro Labs had submitted to the FDA ANDA No. 208334 for Micro Labs’ ANDA Products. These products are generic versions of XARELTO®.

129. In the Micro Labs Notice Letter, Micro Labs stated that Micro Labs’ ANDA Products contain rivaroxaban.

130. On information and belief, the proposed labeling for Micro Labs’ ANDA Products directs the use of Micro Labs’ ANDA Products for one or more of the following indications: (i) to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; (ii) for the treatment of deep vein thrombosis (DVT), pulmonary embolism (PE), and for the reduction in the risk of recurrence of DVT and of PE; and (iii) for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery.

131. On information and belief, the manufacture, use (including in accordance with and as directed by Micro Labs’ proposed labeling for Micro Labs’ ANDA Products), offer

for sale, sale, marketing, distribution, and/or importation of Micro Labs' ANDA Products will infringe one or more claims of the '456 patent.

132. In the Micro Labs Notice Letter, Micro Labs indicated that, in connection with its ANDA No. 208334, Micro Labs Ltd. had filed a Paragraph IV Certification with respect to the '456 patent.

133. The purpose of ANDA No. 208334 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Micro Labs' ANDA Products with their proposed labeling prior to the expiration of the '456 patent.

134. Micro Labs intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Micro Labs' ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208334, *i.e.*, prior to the expiration of the '456 patent.

135. Micro Labs has knowledge of the claims of the '456 patent. Notwithstanding this knowledge, Micro Labs has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Micro Labs' ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208334. On information and belief, by such activities, Micro Labs specifically intends infringement of the '456 patent.

136. On information and belief, Micro Labs plans and intends to, and will, actively induce infringement of the '456 patent when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

137. On information and belief, Micro Labs knows that Micro Labs' ANDA Products are especially made or adapted for use in infringing the '456 patent, and that Micro

Labs' ANDA Products are not suitable for substantial noninfringing use. On information and belief, Micro Labs plans and intends to, and will, contribute to infringement of the '456 patent immediately and imminently upon approval of ANDA No. 208334.

138. The foregoing actions by Micro Labs constitute and/or will constitute infringement of the '456 patent, active inducement of infringement of the '456 patent, and/or contribution to the infringement by others of the '456 patent.

139. An actual case or controversy exists between Plaintiffs and Micro Labs with respect to infringement of the '456 patent.

140. This action is being commenced before the expiration of forty-five days from the date BIP and Janssen received the Micro Labs Notice Letter.

Infringement by Mylan

141. By letter dated September 15, 2015 (the "Mylan Notice Letter"), Mylan notified BIP and Janssen that Mylan had submitted to the FDA ANDA No. 208561 for Mylan's ANDA Products. These products are generic versions of XARELTO®.

142. In the Mylan Notice Letter, Mylan stated that Mylan's ANDA Products contain rivaroxaban.

143. On information and belief, the proposed labeling for Mylan's ANDA Products directs the use of Mylan's ANDA Products for one or more of the following indications: (i) to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; (ii) for the treatment of deep vein thrombosis (DVT), pulmonary embolism (PE), and for the reduction in the risk of recurrence of DVT and of PE; and (iii) for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery.

144. On information and belief, the manufacture, use (including in accordance with and as directed by Mylan's proposed labeling for Mylan's ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Products will infringe one or more claims of the '456, '860, or '339 patents.

145. In the Mylan Notice Letter, Mylan indicated that, in connection with its ANDA No. 208561, Mylan Pharmaceuticals Inc. had filed Paragraph IV Certifications with respect to each of the '456, '860, and '339 patents.

146. The purpose of ANDA No. 208561 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan's ANDA Products with their proposed labeling prior to the expiration of the '456, '860, and '339 patents.

147. Mylan intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208561, *i.e.*, prior to the expiration of the '456, '860, and '339 patents.

148. Mylan has knowledge of the claims of the '456, '860, and '339 patents. Notwithstanding this knowledge, Mylan has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208561. On information and belief, by such activities, Mylan specifically intends infringement of the '456, '860, and '339 patents.

149. On information and belief, Mylan plans and intends to, and will, actively induce infringement of the ’456, ’860, and ’339 patents when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

150. On information and belief, Mylan knows that Mylan’s ANDA Products are especially made or adapted for use in infringing the ’456 and ’339 patents, and that Mylan’s ANDA Products are not suitable for substantial noninfringing use. On information and belief, Mylan plans and intends to, and will, contribute to infringement of the ’456 and ’339 patents immediately and imminently upon approval of ANDA No. 208561.

151. The foregoing actions by Mylan constitute and/or will constitute infringement of the ’456, ’860, and ’339 patents, active inducement of infringement of the ’456, ’860, and ’339 patents, and/or contribution to the infringement by others of the ’456 and ’339 patents.

152. An actual case or controversy exists between Plaintiffs and Mylan with respect to infringement of each of the ’456, ’860, and ’339 patents.

153. This action is being commenced before the expiration of forty-five days from the date BIP and Janssen received the Mylan Notice Letter.

Infringement by Prinston

154. By letter dated September 15, 2015 (the “Prinston Notice Letter”), Prinston notified BIP and Janssen, among others, that Prinston had submitted to the FDA ANDA No. 208549 for Prinston’s ANDA Products. These products are generic versions of XARELTO®.

155. In the Prinston Notice Letter, Prinston stated that Prinston’s ANDA Products contain rivaroxaban.

156. On information and belief, the proposed labeling for Prinston's ANDA Products directs the use of Prinston's ANDA Products for one or more of the following indications: (i) to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; (ii) for the treatment of deep vein thrombosis (DVT), pulmonary embolism (PE), and for the reduction in the risk of recurrence of DVT and of PE; and (iii) for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery.

157. On information and belief, the manufacture, use (including in accordance with and as directed by Prinston's proposed labeling for Prinston's ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Prinston's ANDA Products will infringe one or more claims of the '456, '860, or '339 patents.

158. In the Prinston Notice Letter, Prinston indicated that, in connection with its ANDA No. 208549, Prinston had filed Paragraph IV Certifications with respect to each of the '456, '860, and '339 patents.

159. The purpose of ANDA No. 208549 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Prinston's ANDA Products with their proposed labeling prior to the expiration of the '456, '860, and '339 patents.

160. Prinston intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Prinston's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208549, *i.e.*, prior to the expiration of the '456, '860, and '339 patents.

161. Prinston has knowledge of the claims of the ’456, ’860, and ’339 patents. Notwithstanding this knowledge, Prinston has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Prinston’s ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208549. On information and belief, by such activities, Prinston specifically intends infringement of the ’456, ’860, and ’339 patents.

162. On information and belief, Prinston plans and intends to, and will, actively induce infringement of the ’456, ’860, and ’339 patents when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

163. On information and belief, Prinston knows that Prinston’s ANDA Products are especially made or adapted for use in infringing the ’456 and ’339 patents, and that Prinston’s ANDA Products are not suitable for substantial noninfringing use. On information and belief, Prinston plans and intends to, and will, contribute to infringement of the ’456 and ’339 patents immediately and imminently upon approval of ANDA No. 208549.

164. The foregoing actions by Prinston constitute and/or will constitute infringement of the ’456, ’860, and ’339 patents, active inducement of infringement of the ’456, ’860, and ’339 patents, and/or contribution to the infringement by others of the ’456 and ’339 patents.

165. An actual case or controversy exists between Plaintiffs and Prinston with respect to infringement of each of the ’456, ’860, and ’339 patents.

166. This action is being commenced before the expiration of forty-five days from the date BIP and Janssen received the Prinston Notice Letter.

Infringement by Sigmapharm

167. By letter dated August 31, 2015 (the "Sigmapharm Notice Letter"), Sigmapharm notified BIP and Janssen, among others, that Sigmapharm had submitted to the FDA ANDA No. 208546 for Sigmapharm's ANDA Products. These products are generic versions of XARELTO®.

168. In the Sigmapharm Notice Letter, Sigmapharm stated that Sigmapharm's ANDA Products contain rivaroxaban.

169. On information and belief, the proposed labeling for Sigmapharm's ANDA Products directs the use of Sigmapharm's ANDA Products for one or more of the following indications: (i) to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; (ii) for the treatment of deep vein thrombosis (DVT), pulmonary embolism (PE), and for the reduction in the risk of recurrence of DVT and of PE; and (iii) for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery.

170. On information and belief, the manufacture, use (including in accordance with and as directed by Sigmapharm's proposed labeling for Sigmapharm's ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Sigmapharm's ANDA Products will infringe one or more claims of the '456, '860, or '339 patents.

171. In the Sigmapharm Notice Letter, Sigmapharm indicated that, in connection with its ANDA No. 208546, Sigmapharm had filed Paragraph IV Certifications with respect to each of the '456, '860, and '339 patents.

172. The purpose of ANDA No. 208546 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of

Sigmapharm's ANDA Products with their proposed labeling prior to the expiration of the '456, '860, and '339 patents.

173. Sigmapharm intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sigmapharm's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208546, *i.e.*, prior to the expiration of the '456, '860, and '339 patents.

174. Sigmapharm has knowledge of the claims of the '456, '860, and '339 patents. Notwithstanding this knowledge, Sigmapharm has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sigmapharm's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208546. On information and belief, by such activities, Sigmapharm specifically intends infringement of the '456, '860, and '339 patents.

175. On information and belief, Sigmapharm plans and intends to, and will, actively induce infringement of the '456, '860, and '339 patents when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

176. On information and belief, Sigmapharm knows that Sigmapharm's ANDA Products are especially made or adapted for use in infringing the '456 and '339 patents, and that Sigmapharm's ANDA Products are not suitable for substantial noninfringing use. On information and belief, Sigmapharm plans and intends to, and will, contribute to infringement of the '456 and '339 patents immediately and imminently upon approval of ANDA No. 208546.

177. The foregoing actions by Sigmapharm constitute and/or will constitute infringement of the '456, '860, and '339 patents, active inducement of infringement of the '456,

'860, and '339 patents, and/or contribution to the infringement by others of the '456 and '339 patents.

178. An actual case or controversy exists between Plaintiffs and Sigmapharm with respect to infringement of each of the '456, '860, and '339 patents.

179. This action is being commenced before the expiration of forty-five days from the date BIP and Janssen received the Sigmapharm Notice Letter.

Infringement by Torrent

180. By letter dated August 31, 2015 (the "Torrent Notice Letter"), Torrent notified BIP and Janssen that Torrent had submitted to the FDA ANDA No. 208556 for Torrent's ANDA Products. These products are generic versions of XARELTO®.

181. In the Torrent Notice Letter, Torrent stated that Torrent's ANDA Products contain rivaroxaban.

182. On information and belief, the proposed labeling for Torrent's ANDA Products directs the use of Torrent's ANDA Products for one or more of the following indications: (i) to reduce the risk of stroke and systemic embolism in patients with nonvalvular atrial fibrillation; (ii) for the treatment of deep vein thrombosis (DVT), pulmonary embolism (PE), and for the reduction in the risk of recurrence of DVT and of PE; and (iii) for the prophylaxis of DVT, which may lead to PE in patients undergoing knee or hip replacement surgery.

183. On information and belief, the manufacture, use (including in accordance with and as directed by Torrent's proposed labeling for Torrent's ANDA Products), offer for sale, sale, marketing, distribution, and/or importation of Torrent's ANDA Products will infringe one or more claims of the '456, '860, or '339 patents.

184. In the Torrent Notice Letter, Torrent indicated that, in connection with its ANDA No. 208556, Torrent Pharmaceuticals, Limited had filed Paragraph IV Certifications with respect to each of the '456, '860, and '339 patents.

185. The purpose of ANDA No. 208556 was to obtain approval under the FDCA to engage in the commercial manufacture, use, offer for sale, and/or sale of Torrent's ANDA Products with their proposed labeling prior to the expiration of the '456, '860, and '339 patents.

186. Torrent intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Torrent's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208556, *i.e.*, prior to the expiration of the '456, '860, and '339 patents.

187. Torrent has knowledge of the claims of the '456, '860, and '339 patents. Notwithstanding this knowledge, Torrent has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Torrent's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208556. On information and belief, by such activities, Torrent specifically intends infringement of the '456, '860, and '339 patents.

188. On information and belief, Torrent plans and intends to, and will, actively induce infringement of the '456, '860, and '339 patents when its ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

189. On information and belief, Torrent knows that Torrent's ANDA Products are especially made or adapted for use in infringing the '456 and '339 patents, and that Torrent's ANDA Products are not suitable for substantial noninfringing use. On information and belief,

Torrent plans and intends to, and will, contribute to infringement of the ’456 and ’339 patents immediately and imminently upon approval of ANDA No. 208556.

190. The foregoing actions by Torrent constitute and/or will constitute infringement of the ’456, ’860, and ’339 patents, active inducement of infringement of the ’456, ’860, and ’339 patents, and/or contribution to the infringement by others of the ’456 and ’339 patents.

191. An actual case or controversy exists between Plaintiffs and Torrent with respect to infringement of each of the ’456, ’860, and ’339 patents.

192. This action is being commenced before the expiration of forty-five days from the date BIP and Janssen received the Torrent Notice Letter.

COUNT I
(Infringement of the ’456 Patent by Aurobindo)

193. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

194. Aurobindo’s submission of ANDA No. 208544 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Aurobindo’s ANDA Products was an act of infringement of the ’456 patent under 35 U.S.C. § 271(e)(2).

195. On information and belief, Aurobindo has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Aurobindo’s ANDA Products with their proposed labeling prior to the expiration of the ’456 patent.

196. Aurobindo intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo’s ANDA Products with their proposed

labeling immediately and imminently upon approval of ANDA No. 208544, *i.e.*, prior to the expiration of the ’456 patent.

197. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the ’456 patent, active inducement of infringement of the ’456 patent, and/or contribution to the infringement by others of the ’456 patent.

198. Unless Aurobindo is enjoined from infringing the ’456 patent, actively inducing infringement of the ’456 patent, and contributing to the infringement by others of the ’456 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II
(Infringement of the ’860 Patent by Aurobindo)

199. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

200. Aurobindo’s submission of ANDA No. 208544 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Aurobindo’s ANDA Products was an act of infringement of the ’860 patent under 35 U.S.C. § 271(e)(2).

201. On information and belief, Aurobindo has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Aurobindo’s ANDA Products with their proposed labeling prior to the expiration of the ’860 patent.

202. Aurobindo intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo’s ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208544, *i.e.*, prior to the expiration of the ’860 patent.

203. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the ’860 patent and/or active inducement of infringement of the ’860 patent.

204. Unless Aurobindo is enjoined from infringing the ’860 patent and actively inducing infringement of the ’860 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT III
(Infringement of the ’339 Patent by Aurobindo)

205. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

206. Aurobindo’s submission of ANDA No. 208544 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Aurobindo’s ANDA Products was an act of infringement of the ’339 patent under 35 U.S.C. § 271(e)(2).

207. On information and belief, Aurobindo has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Aurobindo’s ANDA Products with their proposed labeling prior to the expiration of the ’339 patent.

208. Aurobindo intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Aurobindo’s ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208544, *i.e.*, prior to the expiration of the ’339 patent.

209. The foregoing actions by Aurobindo constitute and/or will constitute infringement of the ’339 patent, active inducement of infringement of the ’339 patent, and/or contribution to the infringement by others of the ’339 patent.

210. Unless Aurobindo is enjoined from infringing the ’339 patent, actively inducing infringement of the ’339 patent, and contributing to the infringement by others of the ’339 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT IV
(Infringement of the ’456 Patent by Breckenridge)

211. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

212. Breckenridge’s submission of ANDA No. 208220 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Breckenridge’s ANDA Products was an act of infringement of the ’456 patent under 35 U.S.C. § 271(e)(2).

213. On information and belief, Breckenridge has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Breckenridge’s ANDA Products with their proposed labeling prior to the expiration of the ’456 patent.

214. Breckenridge intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Breckenridge’s ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208220, *i.e.*, prior to the expiration of the ’456 patent.

215. The foregoing actions by Breckenridge constitute and/or will constitute infringement of the ’456 patent, active inducement of infringement of the ’456 patent, and/or contribution to the infringement by others of the ’456 patent.

216. Unless Breckenridge is enjoined from infringing the ’456 patent, actively inducing infringement of the ’456 patent, and contributing to the infringement by others of the ’456 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT V
(Infringement of the ’860 Patent by Breckenridge)

217. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

218. Breckenridge’s submission of ANDA No. 208220 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Breckenridge’s ANDA Products was an act of infringement of the ’860 patent under 35 U.S.C. § 271(e)(2).

219. On information and belief, Breckenridge has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Breckenridge’s ANDA Products with their proposed labeling prior to the expiration of the ’860 patent.

220. Breckenridge intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Breckenridge’s ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208220, *i.e.*, prior to the expiration of the ’860 patent.

221. The foregoing actions by Breckenridge constitute and/or will constitute infringement of the ’860 patent and/or active inducement of infringement of the ’860 patent.

222. Unless Breckenridge is enjoined from infringing the ’860 patent and actively inducing infringement of the ’860 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT VI
(Infringement of the '456 Patent by Micro Labs)

223. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

224. Micro Labs' submission of ANDA No. 208334 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Micro Labs' ANDA Products was an act of infringement of the '456 patent under 35 U.S.C. § 271(e)(2).

225. On information and belief, Micro Labs has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Micro Labs' ANDA Products with their proposed labeling prior to the expiration of the '456 patent.

226. Micro Labs intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Micro Labs' ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208334, *i.e.*, prior to the expiration of the '456 patent.

227. The foregoing actions by Micro Labs constitute and/or will constitute infringement of the '456 patent, active inducement of infringement of the '456 patent, and/or contribution to the infringement by others of the '456 patent.

228. Unless Micro Labs is enjoined from infringing the '456 patent, actively inducing infringement of the '456 patent, and contributing to the infringement by others of the '456 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT VII
(Infringement of the ’456 Patent by Mylan)

229. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

230. Mylan’s submission of ANDA No. 208561 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan’s ANDA Products was an act of infringement of the ’456 patent under 35 U.S.C. § 271(e)(2).

231. On information and belief, Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Mylan’s ANDA Products with their proposed labeling prior to the expiration of the ’456 patent.

232. Mylan intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan’s ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208561, *i.e.*, prior to the expiration of the ’456 patent.

233. The foregoing actions by Mylan constitute and/or will constitute infringement of the ’456 patent, active inducement of infringement of the ’456 patent, and/or contribution to the infringement by others of the ’456 patent.

234. Unless Mylan is enjoined from infringing the ’456 patent, actively inducing infringement of the ’456 patent, and contributing to the infringement by others of the ’456 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT VIII
(Infringement of the ’860 Patent by Mylan)

235. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

236. Mylan's submission of ANDA No. 208561 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan's ANDA Products was an act of infringement of the '860 patent under 35 U.S.C. § 271(e)(2).

237. On information and belief, Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Mylan's ANDA Products with their proposed labeling prior to the expiration of the '860 patent.

238. Mylan intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208561, *i.e.*, prior to the expiration of the '860 patent.

239. The foregoing actions by Mylan constitute and/or will constitute infringement of the '860 patent and/or active inducement of infringement of the '860 patent.

240. Unless Mylan is enjoined from infringing the '860 patent and actively inducing infringement of the '860 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT IX
(Infringement of the '339 Patent by Mylan)

241. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

242. Mylan's submission of ANDA No. 208561 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Mylan's ANDA Products was an act of infringement of the '339 patent under 35 U.S.C. § 271(e)(2).

243. On information and belief, Mylan has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Mylan's ANDA Products with their proposed labeling prior to the expiration of the '339 patent.

244. Mylan intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Mylan's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208561, *i.e.*, prior to the expiration of the '339 patent.

245. The foregoing actions by Mylan constitute and/or will constitute infringement of the '339 patent, active inducement of infringement of the '339 patent, and/or contribution to the infringement by others of the '339 patent.

246. Unless Mylan is enjoined from infringing the '339 patent, actively inducing infringement of the '339 patent, and contributing to the infringement by others of the '339 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT X
(Infringement of the '456 Patent by Prinston)

247. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

248. Prinston's submission of ANDA No. 208549 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Prinston's ANDA Products was an act of infringement of the '456 patent under 35 U.S.C. § 271(e)(2).

249. On information and belief, Prinston has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Prinston's ANDA Products with their proposed labeling prior to the expiration of the '456 patent.

250. Prinston intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Prinston's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208549, *i.e.*, prior to the expiration of the '456 patent.

251. The foregoing actions by Prinston constitute and/or will constitute infringement of the '456 patent, active inducement of infringement of the '456 patent, and/or contribution to the infringement by others of the '456 patent.

252. Unless Prinston is enjoined from infringing the '456 patent, actively inducing infringement of the '456 patent, and contributing to the infringement by others of the '456 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT XI
(Infringement of the '860 Patent by Prinston)

253. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

254. Prinston's submission of ANDA No. 208549 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Prinston's ANDA Products was an act of infringement of the '860 patent under 35 U.S.C. § 271(e)(2).

255. On information and belief, Prinston has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Prinston's ANDA Products with their proposed labeling prior to the expiration of the '860 patent.

256. Prinston intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Prinston's ANDA Products with their proposed

labeling immediately and imminently upon approval of ANDA No. 208549, *i.e.*, prior to the expiration of the ’860 patent.

257. The foregoing actions by Prinston constitute and/or will constitute infringement of the ’860 patent and/or active inducement of infringement of the ’860 patent.

258. Unless Prinston is enjoined from infringing the ’860 patent and actively inducing infringement of the ’860 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT XII
(Infringement of the ’339 Patent by Prinston)

259. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

260. Prinston’s submission of ANDA No. 208549 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Prinston’s ANDA Products was an act of infringement of the ’339 patent under 35 U.S.C. § 271(e)(2).

261. On information and belief, Prinston has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Prinston’s ANDA Products with their proposed labeling prior to the expiration of the ’339 patent.

262. Prinston intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Prinston’s ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208549, *i.e.*, prior to the expiration of the ’339 patent.

263. The foregoing actions by Prinston constitute and/or will constitute infringement of the ’339 patent, active inducement of infringement of the ’339 patent, and/or contribution to the infringement by others of the ’339 patent.

264. Unless Prinston is enjoined from infringing the ’339 patent, actively inducing infringement of the ’339 patent, and contributing to the infringement by others of the ’339 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT XIII
(Infringement of the ’456 Patent by Sigmapharm)

265. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

266. Sigmapharm’s submission of ANDA No. 208546 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Sigmapharm’s ANDA Products was an act of infringement of the ’456 patent under 35 U.S.C. § 271(e)(2).

267. On information and belief, Sigmapharm has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Sigmapharm’s ANDA Products with their proposed labeling prior to the expiration of the ’456 patent.

268. Sigmapharm intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sigmapharm’s ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208546, *i.e.*, prior to the expiration of the ’456 patent.

269. The foregoing actions by Sigmapharm constitute and/or will constitute infringement of the ’456 patent, active inducement of infringement of the ’456 patent, and/or contribution to the infringement by others of the ’456 patent.

270. Unless Sigmapharm is enjoined from infringing the ’456 patent, actively inducing infringement of the ’456 patent, and contributing to the infringement by others of the ’456 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT XIV
(Infringement of the ’860 Patent by Sigmapharm)

271. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

272. Sigmapharm’s submission of ANDA No. 208546 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Sigmapharm’s ANDA Products was an act of infringement of the ’860 patent under 35 U.S.C. § 271(e)(2).

273. On information and belief, Sigmapharm has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Sigmapharm’s ANDA Products with their proposed labeling prior to the expiration of the ’860 patent.

274. Sigmapharm intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sigmapharm’s ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208546, *i.e.*, prior to the expiration of the ’860 patent.

275. The foregoing actions by Sigmapharm constitute and/or will constitute infringement of the ’860 patent and/or active inducement of infringement of the ’860 patent.

276. Unless Sigmapharm is enjoined from infringing the ’860 patent and actively inducing infringement of the ’860 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT XV
(Infringement of the ’339 Patent by Sigmapharm)

277. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

278. Sigmapharm’s submission of ANDA No. 208546 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Sigmapharm’s ANDA Products was an act of infringement of the ’339 patent under 35 U.S.C. § 271(e)(2).

279. On information and belief, Sigmapharm has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Sigmapharm’s ANDA Products with their proposed labeling prior to the expiration of the ’339 patent.

280. Sigmapharm intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sigmapharm’s ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208546, *i.e.*, prior to the expiration of the ’339 patent.

281. The foregoing actions by Sigmapharm constitute and/or will constitute infringement of the ’339 patent, active inducement of infringement of the ’339 patent, and/or contribution to the infringement by others of the ’339 patent.

282. Unless Sigmapharm is enjoined from infringing the ’339 patent, actively inducing infringement of the ’339 patent, and contributing to the infringement by others of the ’339 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT XVI
(Infringement of the ’456 Patent by Torrent)

283. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

284. Torrent’s submission of ANDA No. 208556 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Torrent’s ANDA Products was an act of infringement of the ’456 patent under 35 U.S.C. § 271(e)(2).

285. On information and belief, Torrent has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Torrent’s ANDA Products with their proposed labeling prior to the expiration of the ’456 patent.

286. Torrent intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Torrent’s ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208556, *i.e.*, prior to the expiration of the ’456 patent.

287. The foregoing actions by Torrent constitute and/or will constitute infringement of the ’456 patent, active inducement of infringement of the ’456 patent, and/or contribution to the infringement by others of the ’456 patent.

288. Unless Torrent is enjoined from infringing the ’456 patent, actively inducing infringement of the ’456 patent, and contributing to the infringement by others of the ’456 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT XVII
(Infringement of the ’860 Patent by Torrent)

289. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

290. Torrent’s submission of ANDA No. 208556 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Torrent’s ANDA Products was an act of infringement of the ’860 patent under 35 U.S.C. § 271(e)(2).

291. On information and belief, Torrent has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Torrent’s ANDA Products with their proposed labeling prior to the expiration of the ’860 patent.

292. Torrent intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Torrent’s ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208556, *i.e.*, prior to the expiration of the ’860 patent.

293. The foregoing actions by Torrent constitute and/or will constitute infringement of the ’860 patent and/or active inducement of infringement of the ’860 patent.

294. Unless Torrent is enjoined from infringing the ’860 patent and actively inducing infringement of the ’860 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT XVIII
(Infringement of the ’339 Patent by Torrent)

295. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

296. Torrent's submission of ANDA No. 208556 for the purpose of obtaining approval to engage in the commercial manufacture, use, offer for sale, and/or sale of Torrent's ANDA Products was an act of infringement of the '339 patent under 35 U.S.C. § 271(e)(2).

297. On information and belief, Torrent has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, and/or import Torrent's ANDA Products with their proposed labeling prior to the expiration of the '339 patent.

298. Torrent intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Torrent's ANDA Products with their proposed labeling immediately and imminently upon approval of ANDA No. 208556, *i.e.*, prior to the expiration of the '339 patent.

299. The foregoing actions by Torrent constitute and/or will constitute infringement of the '339 patent, active inducement of infringement of the '339 patent, and/or contribution to the infringement by others of the '339 patent.

300. Unless Torrent is enjoined from infringing the '339 patent, actively inducing infringement of the '339 patent, and contributing to the infringement by others of the '339 patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

WHEREFORE, Plaintiffs request the following relief:

(a) A judgment that Aurobindo has infringed the '456 patent;

(b) A judgment that Aurobindo has infringed the '860 patent;

(c) A judgment that Aurobindo has infringed the '339 patent;

(d) A judgment that Breckenridge has infringed the '456 patent;

(e) A judgment that Breckenridge has infringed the '860 patent;

(f) A judgment that Micro Labs has infringed the ’456 patent;

(g) A judgment that Mylan has infringed the ’456 patent;

(h) A judgment that Mylan has infringed the ’860 patent;

(i) A judgment that Mylan has infringed the ’339 patent;

(j) A judgment that Prinston has infringed the ’456 patent;

(k) A judgment that Prinston has infringed the ’860 patent;

(l) A judgment that Prinston has infringed the ’339 patent;

(m) A judgment that Sigmapharm has infringed the ’456 patent;

(n) A judgment that Sigmapharm has infringed the ’860 patent;

(o) A judgment that Sigmapharm has infringed the ’339 patent;

(p) A judgment that Torrent has infringed the ’456 patent;

(q) A judgment that Torrent has infringed the ’860 patent;

(r) A judgment that Torrent has infringed the ’339 patent;

(s) A judgment ordering that the effective date of any FDA approval for Aurobindo to make, use, offer for sale, sell, market, distribute, or import Aurobindo’s ANDA Products, or any product or compound which infringes or the use of which infringes the ’456 patent, be no earlier than the expiration date of the ’456 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(t) A judgment ordering that the effective date of any FDA approval for Aurobindo to make, use, offer for sale, sell, market, distribute, or import Aurobindo’s ANDA Products, or any product or compound which infringes or the use of which infringes the ’860 patent, be no earlier than the expiration date of the ’860 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(u) A judgment ordering that the effective date of any FDA approval for Aurobindo to make, use, offer for sale, sell, market, distribute, or import Aurobindo's ANDA Products, or any product or compound the use of which infringes the '339 patent, be no earlier than the expiration date of the '339 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(v) A judgment ordering that the effective date of any FDA approval for Breckenridge to make, use, offer for sale, sell, market, distribute, or import Breckenridge's ANDA Products, or any product or compound which infringes or the use of which infringes the '456 patent, be no earlier than the expiration date of the '456 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(w) A judgment ordering that the effective date of any FDA approval for Breckenridge to make, use, offer for sale, sell, market, distribute, or import Breckenridge's ANDA Products, or any product or compound which infringes or the use of which infringes the '860 patent, be no earlier than the expiration date of the '860 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(x) A judgment ordering that the effective date of any FDA approval for Micro Labs to make, use, offer for sale, sell, market, distribute, or import Micro Labs' ANDA Products, or any product or compound which infringes or the use of which infringes the '456 patent, be no earlier than the expiration date of the '456 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(y) A judgment ordering that the effective date of any FDA approval for Mylan to make, use, offer for sale, sell, market, distribute, or import Mylan's ANDA Products, or any product or compound which infringes or the use of which infringes the '456 patent, be no

earlier than the expiration date of the ’456 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(z) A judgment ordering that the effective date of any FDA approval for Mylan to make, use, offer for sale, sell, market, distribute, or import Mylan’s ANDA Products, or any product or compound which infringes or the use of which infringes the ’860 patent, be no earlier than the expiration date of the ’860 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(aa) A judgment ordering that the effective date of any FDA approval for Mylan to make, use, offer for sale, sell, market, distribute, or import Mylan’s ANDA Products, or any product or compound the use of which infringes the ’339 patent, be no earlier than the expiration date of the ’339 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(bb) A judgment ordering that the effective date of any FDA approval for Prinston to make, use, offer for sale, sell, market, distribute, or import Prinston’s ANDA Products, or any product or compound which infringes or the use of which infringes the ’456 patent, be no earlier than the expiration date of the ’456 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(cc) A judgment ordering that the effective date of any FDA approval for Prinston to make, use, offer for sale, sell, market, distribute, or import Prinston’s ANDA Products, or any product or compound which infringes or the use of which infringes the ’860 patent, be no earlier than the expiration date of the ’860 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(dd) A judgment ordering that the effective date of any FDA approval for Prinston to make, use, offer for sale, sell, market, distribute, or import Prinston's ANDA Products, or any product or compound the use of which infringes the '339 patent, be no earlier than the expiration date of the '339 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(ee) A judgment ordering that the effective date of any FDA approval for Sigmapharm to make, use, offer for sale, sell, market, distribute, or import Sigmapharm's ANDA Products, or any product or compound which infringes or the use of which infringes the '456 patent, be no earlier than the expiration date of the '456 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(ff) A judgment ordering that the effective date of any FDA approval for Sigmapharm to make, use, offer for sale, sell, market, distribute, or import Sigmapharm's ANDA Products, or any product or compound which infringes or the use of which infringes the '860 patent, be no earlier than the expiration date of the '860 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(gg) A judgment ordering that the effective date of any FDA approval for Sigmapharm to make, use, offer for sale, sell, market, distribute, or import Sigmapharm's ANDA Products, or any product or compound the use of which infringes the '339 patent, be no earlier than the expiration date of the '339 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(hh) A judgment ordering that the effective date of any FDA approval for Torrent to make, use, offer for sale, sell, market, distribute, or import Torrent's ANDA Products, or any product or compound which infringes or the use of which infringes the '456 patent, be no

earlier than the expiration date of the ’456 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(ii) A judgment ordering that the effective date of any FDA approval for Torrent to make, use, offer for sale, sell, market, distribute, or import Torrent’s ANDA Products, or any product or compound which infringes or the use of which infringes the ’860 patent, be no earlier than the expiration date of the ’860 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(jj) A judgment ordering that the effective date of any FDA approval for Torrent to make, use, offer for sale, sell, market, distribute, or import Torrent’s ANDA Products, or any product or compound the use of which infringes the ’339 patent, be no earlier than the expiration date of the ’339 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(kk) A preliminary and permanent injunction enjoining Aurobindo, and all persons acting in concert with Aurobindo, from making, using, selling, offering for sale, marketing, distributing, or importing Aurobindo’s ANDA Products, or any product or compound that infringes or the use of which infringes the ’456 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the ’456 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(ll) A preliminary and permanent injunction enjoining Aurobindo, and all persons acting in concert with Aurobindo, from making, using, selling, offering for sale, marketing, distributing, or importing Aurobindo’s ANDA Products, or any product or compound that infringes or the use of which infringes the ’860 patent, or the inducement of any of the

foregoing, prior to the expiration date of the ’860 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(mm) A preliminary and permanent injunction enjoining Aurobindo, and all persons acting in concert with Aurobindo, from making, using, selling, offering for sale, marketing, distributing, or importing Aurobindo’s ANDA Products, or any product or compound the use of which infringes the ’339 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the ’339 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(nn) A preliminary and permanent injunction enjoining Breckenridge, and all persons acting in concert with Breckenridge, from making, using, selling, offering for sale, marketing, distributing, or importing Breckenridge’s ANDA Products, or any product or compound that infringes or the use of which infringes the ’456 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the ’456 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(oo) A preliminary and permanent injunction enjoining Breckenridge, and all persons acting in concert with Breckenridge, from making, using, selling, offering for sale, marketing, distributing, or importing Breckenridge’s ANDA Products, or any product or compound that infringes or the use of which infringes the ’860 patent, or the inducement of any of the foregoing, prior to the expiration date of the ’860 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(pp) A preliminary and permanent injunction enjoining Micro Labs, and all persons acting in concert with Micro Labs, from making, using, selling, offering for sale, marketing, distributing, or importing Micro Labs’ ANDA Products, or any product or compound

that infringes or the use of which infringes the ’456 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the ’456 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(qq) A preliminary and permanent injunction enjoining Mylan, and all persons acting in concert with Mylan, from making, using, selling, offering for sale, marketing, distributing, or importing Mylan’s ANDA Products, or any product or compound that infringes or the use of which infringes the ’456 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the ’456 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(rr) A preliminary and permanent injunction enjoining Mylan, and all persons acting in concert with Mylan, from making, using, selling, offering for sale, marketing, distributing, or importing Mylan’s ANDA Products, or any product or compound that infringes or the use of which infringes the ’860 patent, or the inducement of any of the foregoing, prior to the expiration date of the ’860 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(ss) A preliminary and permanent injunction enjoining Mylan, and all persons acting in concert with Mylan, from making, using, selling, offering for sale, marketing, distributing, or importing Mylan’s ANDA Products, or any product or compound the use of which infringes the ’339 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the ’339 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(tt) A preliminary and permanent injunction enjoining Prinston, and all persons acting in concert with Prinston, from making, using, selling, offering for sale, marketing,

distributing, or importing Prinston's ANDA Products, or any product or compound that infringes or the use of which infringes the '456 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '456 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(uu) A preliminary and permanent injunction enjoining Prinston, and all persons acting in concert with Prinston, from making, using, selling, offering for sale, marketing, distributing, or importing Prinston's ANDA Products, or any product or compound that infringes or the use of which infringes the '860 patent, or the inducement of any of the foregoing, prior to the expiration date of the '860 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(vv) A preliminary and permanent injunction enjoining Prinston, and all persons acting in concert with Prinston, from making, using, selling, offering for sale, marketing, distributing, or importing Prinston's ANDA Products, or any product or compound the use of which infringes the '339 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '339 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(ww) A preliminary and permanent injunction enjoining Sigmapharm, and all persons acting in concert with Sigmapharm, from making, using, selling, offering for sale, marketing, distributing, or importing Sigmapharm's ANDA Products, or any product or compound that infringes or the use of which infringes the '456 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '456 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(xx) A preliminary and permanent injunction enjoining Sigmapharm, and all persons acting in concert with Sigmapharm, from making, using, selling, offering for sale, marketing, distributing, or importing Sigmapharm's ANDA Products, or any product or compound that infringes or the use of which infringes the '860 patent, or the inducement of any of the foregoing, prior to the expiration date of the '860 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(yy) A preliminary and permanent injunction enjoining Sigmapharm, and all persons acting in concert with Sigmapharm, from making, using, selling, offering for sale, marketing, distributing, or importing Sigmapharm's ANDA Products, or any product or compound the use of which infringes the '339 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '339 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(zz) A preliminary and permanent injunction enjoining Torrent, and all persons acting in concert with Torrent, from making, using, selling, offering for sale, marketing, distributing, or importing Torrent's ANDA Products, or any product or compound that infringes or the use of which infringes the '456 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the '456 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(aaa) A preliminary and permanent injunction enjoining Torrent, and all persons acting in concert with Torrent, from making, using, selling, offering for sale, marketing, distributing, or importing Torrent's ANDA Products, or any product or compound that infringes or the use of which infringes the '860 patent, or the inducement of any of the foregoing, prior to

the expiration date of the ’860 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(bbb) A preliminary and permanent injunction enjoining Torrent, and all persons acting in concert with Torrent, from making, using, selling, offering for sale, marketing, distributing, or importing Torrent’s ANDA Products, or any product or compound the use of which infringes the ’339 patent, or the inducement of or the contribution to any of the foregoing, prior to the expiration date of the ’339 patent, inclusive of any extension(s) and additional period(s) of exclusivity;

(ccc) A declaration that this is an exceptional case and an award of attorneys’ fees for Plaintiffs pursuant to 35 U.S.C. § 285;

(ddd) An award of Plaintiffs’ costs and expenses in this action; and

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

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Jack B. Blumenfeld

Jack B. Blumenfeld (#1014)
Rodger D. Smith (#3778)
Derek J. Fahnestock (#4705)
1201 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
rsmith@mnat.com
dfahnestock@mnat.com

Attorneys for Plaintiffs Bayer Intellectual Property GmbH, Bayer Pharma AG, and Janssen Pharmaceuticals, Inc.

OF COUNSEL:

Bruce R. Genderson
Adam L. Perlman
Dov P. Grossman
Steven M. Pyser
Alexander S. Zolan
Martha C. Kidd
WILLIAMS & CONNOLLY LLP
725 Twelfth Street NW
Washington, DC 20005
(202) 434-5000

Attorneys for Plaintiffs Bayer Intellectual Property GmbH and Bayer Pharma AG

David T. Pritikin
SIDLEY AUSTIN LLP
One South Dearborn
Chicago, IL 60603
(312) 853-7000

Bindu Donovan
S. Isaac Olson
SIDLEY AUSTIN LLP
787 Seventh Avenue
New York, NY 10019
(212) 839-5300

Attorneys for Plaintiff Janssen Pharmaceuticals, Inc.

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