IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SUMITOMO PHARMA SWITZERLAND GMBH, SUMITOMO PHARMA AMERICA, INC., TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS INTERNATIONAL AG, and PFIZER INC., *Plaintiffs,* v. APOTEX INC., APOTEX CORP., BDR PHARMACEUTICALS INTERNATIONAL PVT. LTD., and BDR LIFESCIENCES PVT. LTD., *Defendants*.	)	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §§ 100 et. seq., as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, against Defendants Apotex Inc. and Apotex Corp. (together, "Apotex") and Defendants BDR Pharmaceuticals International Private Limited and BDR Lifesciences Private Limited (together, "BDR") (collectively, "Defendants"). This action arises out of the submission by Apotex and BDR of Abbreviated New Drug Application ("ANDA") No. 219793 (the "Apotex/BDR ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell 120 mg tablets of relugolix, a generic version of Orgovyx® (the "ANDA Product"), prior to the expiration of U.S. Patent Nos. 11,795,178, 12,097,198, and 12,144,809 (collectively, the "Patents-in-Suit").

PARTIES

1. Plaintiff Sumitomo Pharma Switzerland GmbH ("SMPS") is a corporation organized and existing under the laws of Switzerland, with its principal place of business at Aeschengraben 27, 4051 Basel, Switzerland.

2. Plaintiff Sumitomo Pharma America, Inc. ("SMPA") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 84 Waterford Drive, Marlborough, MA 01752.

3. Plaintiff Takeda Pharmaceutical Company Limited ("Takeda") is a corporation organized and existing under the laws of Japan, with its principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, Japan.

4. Plaintiff Takeda Pharmaceuticals International AG ("Takeda International") is a corporation organized and existing under the laws of Switzerland, with its principal place of business at Thurgauerstrasse 130, Glattpark-Opfikon, Zurich, 8152, Switzerland.

5. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and having a place of business at 66 Hudson Boulevard East, New York, New York 10001.

6. Plaintiffs SMPS, SMPA, Takeda, Takeda International, and Pfizer are referred to collectively herein as "Plaintiffs."

7. Upon information and belief, Apotex Inc. is a corporation organized and existing under the laws of Canada, with its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

8. Upon information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 2400 N. Commerce

Parkway Suite 400, Weston, FL 33326.

9. Upon information and belief, Apotex Inc., itself and through its subsidiaries and agents, including Apotex Corp., develops, manufactures, markets, distributes, and/or imports pharmaceutical products for sale and use throughout the United States, including in Delaware.

10. Upon information and belief, Apotex Corp. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market, including in Delaware.

11. Upon information and belief, Apotex Corp. is the U.S. agent for Apotex Inc. with the FDA with respect to the Apotex/BDR ANDA.

12. Upon information and belief, Apotex Corp. has been designated as the U.S. agent for Apotex Inc. in accordance with 21 C.F.R. § 314.50(a) in connection with one or more ANDAs.

13. Upon information and belief, BDR Lifesciences Private Limited is the holder of relugolix Drug Master File ("DMF") No. 40209.

14. Upon information and belief, following any FDA approval of the Apotex/BDR ANDA, Apotex will make, use, offer to sell, and/or sell the ANDA Product that is the subject of the Apotex/BDR ANDA throughout the United States, including in Delaware, and/or import such generic products into the United States, including into Delaware.

15. Upon information and belief, BDR Pharmaceuticals International Private Limited is a corporation organized and existing under the laws of India, having its principal place of business at 407/408, Sharda Chambers, New Marine Lines, Mumbai 400020, India.

16. Upon information and belief, BDR Lifesciences Private Limited is a corporation organized and existing under the laws of India, having its principal place of business at RS No. 578, Near Effluent Channel, Luna Village, Padra Taluka, Vadodara District, Gujarat – 391440, India.

17. Upon information and belief, BDR Lifesciences Private Limited is a subsidiary and/or affiliate of BDR Pharmaceuticals International Private Limited.

18. Upon information and belief, BDR Pharmaceuticals International Private Limited and BDR Lifesciences Private Limited participated in the preparation and submission of the Apotex/BDR ANDA.

JURISDICTION AND VENUE

19. This case arises under the patent laws of the United States of America, 35 U.S.C. §§ 100 et. seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

20. This Court has personal jurisdiction over Apotex Corp. at least because Apotex Corp. is a corporation organized and existing under the laws of Delaware.

21. This Court has personal jurisdiction over Apotex Inc. because, among other things, Apotex Inc. has committed, contributed to, and/or participated in an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends to engage in a future course of conduct that includes acts of patent infringement under 35 U.S.C. §§ 271(a), (b) and/or (c), including in Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs. For example, upon information and belief, following approval of the Apotex/BDR ANDA, Apotex Inc. either directly or indirectly through affiliated companies or agents, will make, use, import, sell, and/or offer for sale the ANDA Product in the United States, including in Delaware, prior to the expiration of the Patents-in-Suit.

22. The Court also has personal jurisdiction over Apotex Inc. because, among other things, this action arises from actions of Apotex Inc. directed toward Delaware, and because Apotex Inc. has purposefully availed itself of the rights and benefits of Delaware law by engaging

in systematic and continuous contacts with Delaware. Upon information and belief, Apotex Inc. regularly and continuously transacts business within Delaware, including by selling pharmaceutical products in Delaware either directly or indirectly through affiliated companies or agents. Upon information and belief, Apotex Inc. derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

23. The Court also has personal jurisdiction over Apotex Inc. pursuant to Federal Rule of Civil Procedure 4(k)(1) or 4(k)(2) because: (a) Apotex Inc. is subject to the general jurisdiction of the laws of Delaware; and (b) to the extent that Apotex Inc. is not subject to personal jurisdiction in the courts of any state, Plaintiffs' claims arise under federal law and Apotex Inc. has sufficient contacts with the United States as a whole, including but not limited to marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over Apotex Inc. satisfies due process.

24. In Apotex's Paragraph IV Notice Letter, dated January 29, 2025 ("Notice Letter"), Apotex Inc. stated that it does not contest personal jurisdiction in Delaware.

25. Apotex Inc. and Apotex Corp. have previously availed themselves of this forum for the purpose of litigating its patent infringement disputes. For example, Apotex Inc. and Apotex Corp. have affirmatively filed claims in this forum, including in:

- *Apotex Inc. v. Boehringer Ingelheim Pharms., Inc. et al.*, C.A. No. 24-577-MN (D. Del.)
- *Apotex Inc. v. Boehringer Ingelheim Pharms., Inc. et al.*, C.A. No. 23-704-MN (D. Del.)
- *Apotex Inc. & Apotex Corp. v. Symplmed Pharms., LLC et al.*, C.A. No. 17-276-CFC-MPT (D. Del.)

26. Apotex Inc. and Apotex Corp. have also previously availed themselves of this forum for the purpose of filing counterclaims in patent infringement disputes, including in:

- *Pfizer Inc. et al. v. Apotex Inc. & Apotex Corp.*, C.A. No. 24-621-CFC (D. Del.)
- *AstraZeneca AB v. Apotex Inc. & Apotex Corp.*, C.A. No. 24-551-RGA (D. Del.)
- *Mitsubishi Tanabe Pharma Corp. v. Apotex Inc. & Apotex Corp.*, C.A. No. 24-549-JLH (D. Del.)
- *Gilead Sciences, Inc. v. Apotex Inc. & Apotex Corp.*, C.A. No. 23-775-MN (D. Del.)
- *Boehringer Ingelheim Pharms. Inc. et al. v. Apotex Inc. & Apotex Corp.*, C.A. No. 23-685-CFC (D. Del.)
- *Bayer Pharma AG et al. v. Apotex Inc. & Apotex Corp.*, C.A. No. 23-327-RGA (D. Del.)
- *Vanda Pharms. Inc. v. Apotex Inc. & Apotex Corp.*, C.A. No. 23-153-CFC (D. Del.)
- *Novartis Pharms. Corp. v. Apotex Inc. & Apotex Corp.*, C.A. No. 18-1038-LPS (D. Del.)
- *Merck Sharp & Dohme Corp. v. Apotex Inc. & Apotex Corp.*, C.A. No. 19-313-RGA (D. Del.)
- *Genzyme Corp. et al v. Apotex Inc. & Apotex Corp.*, C.A. No. 18-1795-CFC (D. Del.)

27. This Court has personal jurisdiction over BDR Pharmaceuticals International Private Limited and BDR Lifesciences Private Limited because, among other things, BDR Pharmaceuticals International Private Limited and BDR Lifesciences Private Limited have committed, contributed, and/or participated in an act of patent infringement under 35 U.S.C. § 271(e)(2) and intend to engage in a future course of conduct that includes acts of patent infringement under 35 U.S.C. §§ 271(a), (b) and/or (c), including in Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs.

28. This Court has personal jurisdiction over BDR Pharmaceuticals International Private Limited pursuant to Federal Rule of Civil Procedure 4(k)(1) or 4(k)(2) because: (a) BDR

Pharmaceuticals International Private Limited is subject to the general jurisdiction of the laws of Delaware; and (b) to the extent that BDR Pharmaceuticals International Private Limited is not subject to personal jurisdiction in the courts of any state, Plaintiffs' claims arise under federal law and BDR Pharmaceuticals International Private Limited has sufficient contacts with the United States as a whole, including but not limited to having control and/or ownership over multiple DMFs registered with the FDA by and through its subsidiary and/or affiliate BDR Lifesciences Private Limited, such that this Court's exercise of jurisdiction over BDR Pharmaceuticals International Private Limited satisfies due process.

29. This Court has personal jurisdiction over BDR Lifesciences Private Limited pursuant to Federal Rule of Civil Procedure 4(k)(1) or 4(k)(2) because: (a) BDR Lifesciences Private Limited is subject to the general jurisdiction of laws of Delaware; and (b) to the extent that BDR Lifesciences Private Limited is a not subject to personal jurisdiction in the courts of any state, Plaintiffs' claims arise under federal law and BDR Lifesciences Private Limited has sufficient contacts with the United States as a whole, including but not limited to having ownership over multiple DMFs registered with the U.S. FDA, such that this Court's exercise of jurisdiction over BDR Lifesciences Private Limited satisfies due process.

30. Venue is proper in this Court as to Apotex Inc. under 28 U.S.C. § 1391(c)(3) because, upon information and belief, Apotex Inc. is a foreign corporation and may thus be sued in any judicial district.

31. Venue is proper in this court as to Apotex Corp. under 28 U.S.C. § 1400(b) because, *inter alia*, Apotex Corp. is incorporated in Delaware.

32. Venue is proper in this Court as to BDR Pharmaceuticals Private Limited under 28 U.S.C. § 1391(c)(3) because, upon information and belief, BDR Pharmaceuticals Private

Limited is a foreign corporation and may thus be sued in any judicial district.

33. Venue is proper in this Court as to BDR Lifesciences Private Limited under 28 U.S.C. § 1391(c)(3) because, upon information and belief, BDR Life Sciences Private Limited is a foreign corporation and may thus be sued in any judicial district.

BACKGROUND

34. Orgovyx® (relugolix) is a nonpeptide GnRH receptor antagonist, for oral administration, approved by the FDA for the treatment of adult patients with advanced prostate cancer. Orgovyx® is marketed in the United States pursuant to New Drug Application (NDA) No. 214621, which was approved by the FDA on December 18, 2020. SMPS holds the NDA for Orgovyx®.

35. The Patents-in-Suit cover Orgovyx® and/or its FDA-approved methods of use, and have been properly listed in connection with Orgovyx® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the "Orange Book."

36. U.S. Patent No. 11,795,178 (the "'178 Patent"), titled "Compositions of Thienopyrimidine Derivatives" (Ex. A), was duly and legally issued on October 24, 2023 and will expire on September 27, 2033. Takeda owns the '178 Patent.

37. U.S. Patent No. 12,097,198 (the "'198 Patent"), titled "Treatment of Prostate Cancer," (Ex. B), was duly and legally issued on September 24, 2024, and will expire on September 29, 2037. SMPS and Takeda jointly own the '198 Patent.

38. U.S. Patent No. 12,144,809 (the "'809 Patent"), titled "Treatment of Prostate Cancer," (Ex. C), was duly and legally issued on November 19, 2024, and will expire on September 29, 2037. SMPS and Takeda jointly own the '809 Patent.

39. Takeda International, SMPS, and Pfizer are exclusive licensees of the Patents-in-

Suit.

40. Orgovyx® is marketed and sold by SMPA and Pfizer throughout the United States, including in Delaware.

41. By letter dated January 29, 2025, Apotex notified SMPS, SMPA, and Takeda that BDR had submitted the Apotex/BDR ANDA to the FDA for approval of relugolix tablets, 120 mg, a generic version of Orgovyx®.

42. By submitting the Apotex/BDR ANDA, Apotex and BDR have represented to the FDA that the ANDA Product has the same active ingredient as Orgovyx®, has the same dosage form and strength as Orgovyx®, and is bioequivalent to Orgovyx®.

43. In the Notice Letter, Apotex stated that the Apotex/BDR ANDA included a paragraph IV certification pursuant to 21 U.S.C. § 355(j) with respect to the Patents-in-Suit, and alleged that the Patents-in-Suit are invalid or will not be infringed by the commercial manufacture, use, or sale of the ANDA Product. The Notice Letter further stated that Apotex is seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the ANDA Product before the Patents-in-Suit expire.

44. Upon information and belief, Apotex and BDR had knowledge of the Patents-in-Suit no later than when the Apotex/BDR ANDA was submitted to the FDA.

45. Upon information and belief, Apotex and BDR intend to engage in the manufacture, use, offer for sale, sale, and/or importation of the ANDA Product immediately and imminently upon approval of the Apotex/BDR ANDA.

46. Prior to filing this Complaint, Counsel for Plaintiffs obtained and reviewed portions of the Apotex/BDR ANDA produced by Apotex pursuant to an agreed Offer of Confidential Access.

47. This action is being commenced before the expiration of 45 days from the date of Plaintiffs' receipt of the Notice Letter.

CLAIMS FOR RELIEF

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 11,795,178

48. Plaintiffs incorporate each of the preceding paragraphs 1-47 as if fully set forth herein.

49. Apotex's and BDR's submission of the Apotex/BDR ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product before the expiration of the '178 Patent constituted an act of infringement of at least claims 1-6, 9-11, 14-16, 25-29, and 34-42 of the '178 Patent, under 35 U.S.C. § 271(e)(2)(A). In the Notice Letter, Apotex did not present any allegations that Apotex and BDR will not infringe claims 1-6, 9-11, 14-16, 25-29, and 34-42 of the '178 Patent.

50. Apotex's and BDR's commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product and/or its active ingredient prior to expiration of the '178 Patent, and Apotex's and BDR's inducement of and/or contribution to such conduct, would further infringe at least claims 1-6, 9-11, 14-16, 25-29, and 34-42 of the '178 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c).

51. Upon FDA approval of the Apotex/BDR ANDA, Apotex and BDR will infringe at least claims 1-6, 9-11, 14-16, 25-29, and 34-42 of the '178 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the ANDA Product and/or its active ingredient and/or by actively inducing and contributing to infringement of at least claims 1-6, 9-11, 14-16, 25-29, and 34-42 of the '178 Patent by others, including but not limited to healthcare providers and patients and including but not limited to Apotex as induced by

BDR, under 35 U.S.C. § 271(a), unless enjoined by the Court. Such infringement is imminent because, among other things, Apotex has notified Plaintiffs of the submission of Apotex's and BDR's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product before the expiration of the '178 Patent.

52. Upon information and belief, Apotex and BDR will actively induce infringement of at least claims 1-6, 9-11, 14-16, 25-29, and 34-42 of the '178 Patent under 35 U.S.C. § 271(b) by encouraging others, including but not limited to healthcare providers and patients and including but not limited to Apotex as induced by BDR, to make, use, offer for sale, sell, or import the ANDA Product in the United States. Upon information and belief, immediately and imminently upon FDA approval of the Apotex/BDR ANDA, Apotex and BDR will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients and including but not limited to Apotex as induced by BDR, with knowledge of the '178 Patent and with knowledge that its acts are encouraging infringement.

53. Unless enjoined by this Court, upon FDA approval of the Apotex/BDR ANDA, Apotex and BDR will contributorily infringe at least claims 1-6, 9-11, 14-16, 25-29, and 34-42 of the '178 Patent under 35 U.S.C. § 271(c) by offering to sell, selling, and/or importing the ANDA Product and/or its active ingredient in the United States. The ANDA Product and/or its active ingredient constitute a material part of the inventions of the claims of the '178 Patent. Upon information and belief, Apotex and BDR know that the ANDA Product and/or its active ingredient are especially made or adapted for use in infringing the '178 Patent, and that the ANDA Product and/or its active ingredient are not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Apotex and BDR plan and intend to, and will, contribute to the infringement of the '178 Patent immediately and imminently upon

approval of the Apotex/BDR ANDA.

54. A substantial and justiciable controversy exists between the parties as to the infringement of the '178 Patent.

55. Pursuant to 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Apotex's and BDR's making, using, offering to sell, selling, and/or importing the ANDA Product will infringe the '178 Patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

56. Upon information and belief, Apotex and BDR acted, and upon FDA approval of the Apotex/BDR ANDA, will act, without a reasonable basis for believing that they would not be liable for directly and/or indirectly infringing the '178 Patent. This is an exceptional case.

57. Unless Apotex and BDR are enjoined from directly or indirectly infringing the '178 Patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 12,097,198

58. Plaintiffs incorporate each of the preceding paragraphs 1-57 as if fully set forth herein.

59. Apotex's and BDR's submission of the Apotex/BDR ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product before the expiration of the '198 Patent constituted an act of infringement at least claims 1-2, 4-6, and 10-12 of the '198 Patent, under 35 U.S.C. § 271(e)(2)(A). In the Notice Letter, Apotex did not present any allegations that Apotex and BDR will not indirectly infringe claims 4-5 and 10-11 of the '198 Patent.

60. Apotex's and BDR's commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product and/or its active ingredient prior to expiration of the '198 Patent, and Apotex's and BDR's inducement of and/or contribution to such conduct, would further

infringe at least claims 1-2, 4-6, and 10-12 of the '198 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c).

61. Upon FDA approval of the Apotex/BDR ANDA, Apotex and BDR will infringe at least claims 1-2, 4-6, and 10-12 of the '198 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the ANDA Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of the '198 Patent by others, including but not limited to healthcare providers and patients and including but not limited to Apotex as induced by BDR, under 35 U.S.C. § 271(a), unless enjoined by the Court. Such infringement is imminent because, among other things, Apotex has notified Plaintiffs of the submission of Apotex's and BDR's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product before the expiration of the '198 Patent.

62. Upon information and belief, Apotex and BDR will actively induce infringement of at least claims 1-2, 4-6, and 10-12 of the '198 Patent under 35 U.S.C. § 271(b) by encouraging others, including but not limited to healthcare providers and patients and including but not limited to Apotex as induced by BDR, to make, use, offer for sale, sell, or import the ANDA Product in the United States. Upon information and belief, immediately and imminently upon FDA approval of the Apotex/BDR ANDA, Apotex and BDR will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '198 Patent and with knowledge that its acts are encouraging infringement. For example, marketing the ANDA Product with its proposed labeling will induce healthcare providers and patients to practice the claimed methods of the '198 Patent.

63. Unless enjoined by this Court, upon FDA approval of the Apotex/BDR ANDA,

Apotex and BDR will contributorily infringe at least claims 1-2, 4-6, and 10-12 of the '198 Patent under 35 U.S.C. § 271(c) by offering to sell, selling, and/or importing the ANDA Product and its proposed labeling in the United States. The ANDA Product and its proposed labeling are materials for use in practicing methods claimed in the '198 Patent and constitute a material part of those claims' inventions. Upon information and belief, Apotex and BDR know that the ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '198 Patent, and that the ANDA Product and its proposed labeling are not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Apotex and BDR plan and intend to, and will, contribute to the infringement of the '198 Patent immediately and imminently upon approval of the Apotex/BDR ANDA.

64. A substantial and justiciable controversy exists between the parties as to the infringement of the '198 Patent.

65. Pursuant to 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Apotex's and BDR's making, using, offering to sell, selling, and/or importing the ANDA Product, inducement thereof or contribution thereto, will infringe the '198 Patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

66. Upon information and belief, Apotex and BDR acted, and upon FDA approval of the Apotex/BDR ANDA, will act, without a reasonable basis for believing that they would not be liable for directly and/or indirectly infringing the '198 Patent. This is an exceptional case.

67. Unless Apotex and BDR are enjoined from directly or indirectly infringing the '198 Patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 12,144,809

68. Plaintiffs incorporate each of the preceding paragraphs 1-67 as if fully set forth

herein.

69. Apotex's and BDR's submission of the Apotex/BDR ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product before the expiration of the '809 Patent constituted an act of infringement of at least claims 1, 3, 5, 9, 12, 19, and 23-29 of the '809 Patent, under 35 U.S.C. § 271(e)(2)(A).

70. Apotex's and BDR's commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product and/or its active ingredient prior to expiration of the '809 Patent, and Apotex's and BDR's inducement of and/or contribution to such conduct, would further infringe at least claims 1, 3, 5, 9, 12, 19, and 23-29 of the '809 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c).

71. Upon FDA approval of the Apotex/BDR ANDA, Apotex and BDR will infringe at least claims 1, 3, 5, 9, 12, 19, and 23-29 of the '809 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the ANDA Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of the '809 Patent by others, including but not limited to healthcare providers and patients and including but not limited to Apotex as induced by BDR, under 35 U.S.C. § 271(a), unless enjoined by the Court. Such infringement is imminent because, among other things, Apotex has notified Plaintiffs of the submission of Apotex's and BDR's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product before the expiration of the '809 Patent.

72. Upon information and belief, Apotex and BDR will actively induce infringement of at least claims 1, 3, 5, 9, 12, 19, and 23-29 of the '809 Patent under 35 U.S.C. § 271(b) by encouraging others, including but not limited to healthcare providers and patients and including

but not limited to Apotex as induced by BDR, to make, use, offer for sale, sell, or import the ANDA Product in the United States. Upon information and belief, immediately and imminently upon FDA approval of the Apotex/BDR ANDA, Apotex and BDR will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients and including but not limited to Apotex as induced by BDR, with knowledge of the '809 Patent and with knowledge that its acts are encouraging infringement. For example, marketing the ANDA Product with its proposed labeling will induce healthcare providers and patients to practice the claimed methods of the '809 Patent.

73. Unless enjoined by this Court, upon FDA approval of the Apotex/BDR ANDA, Apotex and BDR will contributorily infringe at least claims 1, 3, 5, 9, 12, 19, and 23-29 of the '809 Patent under 35 U.S.C. § 271(c) by offering to sell, selling, and/or importing the ANDA Product and its proposed labeling in the United States. The ANDA Product and its proposed labeling are materials for use in practicing methods claimed in the '809 Patent and constitute a material part of those claims' inventions. Upon information and belief, Apotex and BDR know that the ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '809 Patent, and that the ANDA Product and its proposed labeling are not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Apotex and BDR plan and intend to, and will, contribute to the infringement of the '809 Patent immediately and imminently upon approval of the Apotex/BDR ANDA.

74. A substantial and justiciable controversy exists between the parties as to the infringement of the '809 Patent.

75. Pursuant to 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Apotex's and BDR's making, using, offering to sell, selling, and/or importing the ANDA Product,

inducement thereof or contribution thereto, will infringe the '809 Patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

76. Upon information and belief, Apotex and BDR acted, and upon FDA approval of the Apotex/BDR ANDA, will act, without a reasonable basis for believing that they would not be liable for directly and/or indirectly infringing the '809 Patent. This is an exceptional case.

77. Unless Apotex and BDR are enjoined from directly or indirectly infringing the '809 Patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs ask that this Court grant the following relief:

(a) A judgment that the claims of the '178 Patent, the '198 Patent, and the '809 Patent were infringed by Apotex's and BDR's submission of the Apotex/BDR ANDA under 35 U.S.C. § 271(e)(2)(A), and that Apotex's and BDR's manufacture, use, offer to sell, sale, or importation of the ANDA Product, inducement thereof or contribution thereto, prior to the expiration of the '178 Patent, the '198 Patent, and the '809 Patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled, will infringe the '178 Patent, the '198 Patent, and the '809 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c);

(b) A judgment that the claims of the '178 Patent, the '198 Patent, and the '809 Patent are not invalid;

(c) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Apotex/BDR ANDA shall not be earlier than the expiration of the '178 Patent, the '198 Patent, and the '809 Patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

(d) A declaratory judgment that Apotex's and BDR's manufacture, use, offer to sell, sale, or importation, including inducement thereof and contribution thereto, of the ANDA Product and/or its active ingredient prior to the expiration of the '178 Patent, the '198 Patent, and the '809 Patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled, would infringe the '178 Patent, the '198 Patent, and the '809 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c);

(e) An Order permanently enjoining Apotex and its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with Apotex, and BDR and its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with BDR, from making, using, offering to sell, selling, or importing the ANDA Product and/or its active ingredient until after the expiration of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

(f) Damages or other monetary relief, including costs, attorneys' fees, pre-judgement interest and post-judgment interest to Plaintiffs if Apotex and/or BDR engage in commercial manufacture, use, offers to sell, sale, or importation into the United States of the ANDA Product prior to the expiration of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

(g) Declaring this to be an exceptional case pursuant to 35 U.S.C. § 285 entitling Plaintiffs to their attorneys' fees and enhanced damages; and

(h) Such further and other relief as this Court deems proper and just.

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