IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS PHARMA INC., ASTELLAS IRELAND CO., LTD., and ASTELLAS PHARMA GLOBAL DEVELOPMENT, INC.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
LUPIN LTD. and LUPIN PHARMACEUTICALS, INC.	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Astellas Pharma Inc., Astellas Ireland Co., Ltd., and Astellas Pharma Global Development, Inc. (collectively, "Plaintiffs"), by their undersigned attorneys, for their Complaint against Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. (collectively "Lupin"), hereby allege as follows:

THE PARTIES

1. Plaintiff Astellas Pharma Inc. is a corporation organized and existing under the laws of Japan, having its principal place of business at 2-5-1, Nihonbashi-Honcho, Chuo-Ku, Tokyo 103-8411, Japan. Astellas Pharma Inc. was formed on April 1, 2005, from the merger of Yamanouchi Pharmaceutical Co., Ltd. and Fujisawa Pharmaceutical Co., Ltd.

2. Plaintiff Astellas Ireland Co., Ltd. ("AICL") is a corporation organized and existing under the laws of Ireland, having its principal place of business at Damastown Road, Damastown Industrial Park, Mulhuddart, Dublin 15, Ireland. AICL is a subsidiary of Plaintiff Astellas Pharma Inc.

3. Plaintiff Astellas Pharma Global Development, Inc. ("APGD") is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 1 Astellas Way, Northbrook, Illinois 60062. APGD is a subsidiary of Plaintiff Astellas Pharma Inc.

4. On information and belief, Defendant Lupin Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400051, Maharashtra, India. On information and belief, Lupin Ltd., by itself and/or through its affiliates and agents, is in the business, *inter alia*, of developing, manufacturing, and obtaining regulatory approval of generic copies of branded pharmaceutical products for distribution and sale throughout the United States, including within this Judicial District.

5. On information and belief, Defendant Lupin Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21292. On information and belief, Lupin Pharmaceuticals, Inc., by itself and/or through its affiliates and agents, is in the business, *inter alia*, of developing, manufacturing, and obtaining regulatory approval of generic copies of branded pharmaceutical products for distribution and sale throughout the United States, including within this Judicial District.

6. On information and belief, Lupin Pharmaceuticals, Inc. is a wholly-owned subsidiary of Lupin Ltd.

7. On information and belief, Defendants Lupin Ltd. and Lupin Pharmaceuticals, Inc. have cooperated and assisted in the preparation and filing of Lupin's Abbreviated New Drug

Application ("ANDA") No. 209485 and will be involved in the manufacture, importation, marketing and sale of the drug that is the subject of ANDA No. 209485 if it is approved.

NATURE OF ACTION

8. This is an action for patent infringement of United States Patent Nos. 7,342,117 ("the '117 patent"), 7,982,049 ("the '049 patent"), 8,835,474 ("the '474 patent"), and RE44,872 ("the '872 patent"), arising under the United States patent laws, Title 35, United States Code. This action relates to Lupin's filing of ANDA No. 209485 under Section 505(j) of the Federal Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking United States Food and Drug Administration ("FDA") approval to market generic pharmaceutical products.

JURISDICTION AND VENUE

9. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

10. This Court has personal jurisdiction over each Defendant for purposes of this civil action.

11. This Court has jurisdiction over Lupin Ltd. On information and belief, Lupin Ltd. is the parent corporation of Lupin Pharmaceuticals, Inc.

12. This Court has jurisdiction over Lupin Pharmaceuticals, Inc. On information and belief, Lupin Pharmaceuticals, Inc. is a Delaware company.

13. On information and belief, Lupin, directly or through its affiliates and agents, develops, formulates, manufactures, markets, and sells pharmaceutical drug products, including generic drug products, throughout the United States and in this Judicial District. On information and belief, Lupin has purposefully conducted and continues to conduct business in Delaware, and Delaware is a likely destination of Lupin's generic drug products. On

information and belief, Lupin has purposefully availed itself of the rights and benefits of the laws of the State of Delaware, having previously submitted to personal jurisdiction in this Court and having engaged in systematic and continuous contacts with the State of Delaware.

14. On information and belief, Lupin Pharmaceuticals, Inc. and Lupin Ltd. are agents of each other with respect to the development, regulatory approval, marketing, sale and/or distribution of generic drug products. On information and belief, the acts of Lupin Ltd. complained of herein were done with the cooperation, participation, and assistance of, and at least in part for the benefit of Lupin Pharmaceuticals, Inc.

15. On information and belief, Lupin Ltd. filed an abbreviated new drug application seeking approval from the FDA to market and sell pharmaceutical products containing the compound mirabegron as active ingredient, for the treatment of overactive bladder, prior to the expiration of each of the '117, '049, '474, and '872 patents.

16. This lawsuit arises in part from Lupin Ltd. sending Plaintiffs, one of which is a Delaware corporate entity, a letter dated August 25, 2016 purporting to be a "Notice of Paragraph IV Certification Regarding NDA 202611 (Mirabegron) with respect to U.S. Patent Nos. 7,342,117; 7,982,049; 8,835,474; and RE44,872" ("Notice Letter"). The Notice Letter is signed by an attorney for Lupin Ltd.

17. When the Notice Letter was sent, Lupin knew or should have known that: (i) APGD is a Delaware corporation; and (ii) Plaintiffs would file suit against Lupin within 45 days of receiving the Notice Letter.

18. Alternatively, assuming that the above facts do not establish personal jurisdiction over Lupin Ltd., this Court may exercise jurisdiction over Lupin Ltd. pursuant to Federal Rule of Civil Procedure 4(k)(2) because (a) Plaintiffs' claims arise under federal law;

(b) Lupin Ltd. is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Lupin Ltd. has sufficient contacts with the United States as a whole, including but not limited to preparing and submitting an ANDA to the FDA and/or manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Lupin Ltd. satisfies due process

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

FACTUAL BACKGROUND

A. The '117 Patent

20. The PTO duly and legally issued the '117 patent, entitled "α-Form or β-Form Crystal of Acetanilide Derivative," on March 11, 2008. A true and correct copy of the '117 patent is attached as Exhibit A.

21. The '117 patent claims, *inter alia*, crystal forms of mirabegron.

22. The Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") lists the expiration date of the '117 patent as November 4, 2023.

B. The '049 Patent

23. The PTO duly and legally issued the '049 patent, entitled "α-Form or β-Form Crystal of Acetanilide Derivative," on July 19, 2011. A true and correct copy of the '049 patent is attached as Exhibit B.

24. The '049 patent claims, *inter alia*, pharmaceutical compositions comprising crystal forms of mirabegron and a pharmaceutically acceptable carrier.

25. The Orange Book lists the expiration date of the '049 patent as November 4, 2023.

C. The ’474 Patent

26. The PTO duly and legally issued the ’474 patent, entitled “Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative As The Active Ingredient,” on September 16, 2014. A true and correct copy of the ’474 patent is attached as Exhibit C.

27. The ’474 patent claims, *inter alia*, methods of treating overactive bladder by administering mirabegron.

28. The Orange Book lists the expiration date of the ’474 patent as November 4, 2023.

D. The ’872 Patent

29. The PTO duly and legally re-issued the ’872 patent, entitled “Remedy for Overactive Bladder Comprising Acetic Acid Anilide Derivative As The Active Ingredient,” on April 29, 2014. A true and correct copy of the ’872 patent is attached as Exhibit D.

30. The ’872 patent claims, *inter alia*, methods of treating overactive bladder by administering mirabegron to adult subjects.

31. The ’872 patent also claims, *inter alia*, methods of treating overactive bladder by administering mirabegron, to non-adult subjects that are not suffering from diabetes.

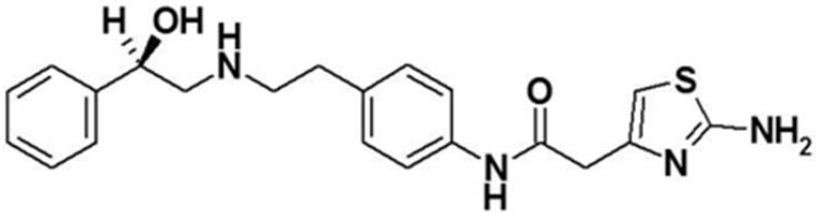
32. The Orange Book lists the expiration date of the ’872 patent as November 4, 2023.

E. Myrbetriq®

33. APGD holds approved New Drug Application (“NDA”) No. 202611 for Myrbetriq® extended-release tablets, 25 mg and 50 mg, which contain the active ingredient, mirabegron. The FDA approved NDA No. 202611 on June 28, 2012 for both the 25 mg and 50 mg extended-release Myrbetriq® tablets. In addition to the ’117, ’049, ’474 and ’872 patents, the Orange Book for NDA No. 202611 also lists, *inter alia*, U.S. Patent No. 6,346,532 (“the ’532

patent") covering the mirabegron compound and pharmaceutical compositions containing mirabegron.

34. Mirabegron has been referred to chemically as, *inter alia*, (R)-2-(2-aminothiazol-4-yl)-4'-[2-(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide, (R)-2-(2-aminothiazol-4-yl)-4'-[2-[(2-hydroxy-2-phenylethyl)amino]ethyl]acetanilide, and 2-(2-aminothiazol-4-yl)-N-[4-(2-{[(2R)-2-hydroxy-2-phenylethyl]amino}ethyl)phenyl]acetamide. Mirabegron can be depicted as, *inter alia*, the following formula:



35. Myrbetriq® extended-release tablets, 25 mg and 50 mg, are indicated for the treatment of overactive bladder (OAB) with symptoms of urge urinary incontinence, urgency, and urinary frequency.

36. Astellas Pharma Inc. is the record owner and assignee of the '532, '117, '049, '474 and '872 patents.

37. AICL is the exclusive licensee of the '532, '117, '049, '474 and '872 patents with the rights to develop, import, market, sell, distribute, and promote any and all pharmaceutical formulations in finished package forms which contain mirabegron as the active ingredient in the United States.

38. APGD has contracted with Astellas Pharma US, Inc., a subsidiary of Astellas Pharma Inc., to market and sell Myrbetriq® extended-release tablets, 25 mg and 50 mg, in the United States on its behalf.

F. Infringement by Lupin

39. On information and belief, Lupin submitted to the FDA ANDA No. 209485 under Section 505(j) of the Act, 21 U.S.C. § 355(j), seeking FDA approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of generic mirabegron extended-release tablets in 25 mg and 50 mg strengths ("ANDA Product"), as a pharmaceutical composition in an oral dosage form for the treatment of overactive bladder prior to the expiration of the '117, '049, '474 and '872 patents.

40. On information and belief, Lupin intends to engage in the commercial manufacture, use, offer for sale, sale, and/or importation into the United States of the ANDA Product if and when it receives FDA approval to do so.

41. The Notice Letter advised Plaintiffs that Lupin submitted ANDA No. 209485 to the FDA seeking approval to manufacture, use, offer to sell, sell, and/or import the ANDA Product prior to the expiration of the '117, '049, '474 and '872 patents. The Notice Letter advised Plaintiffs that Lupin's ANDA submission included a certification under 21 U.S.C. § 355(j)(2)(B)(iv) that, in Lupin's opinion, the claims of the '117, '049, '474 and '872 patents are invalid, unenforceable and/or not infringed.

42. The '532 patent is owned by Astellas Pharma Inc. and claims the compound mirabegron and compositions containing mirabegron, which is the active ingredient of Myrbetriq®. The ANDA Product is a composition that contains the compound mirabegron. Lupin made a "Paragraph III" certification with respect to the '532 patent, which includes certifying to the FDA that the '532 patent will expire on March 27, 2022, and that Lupin does not ask to have its ANDA approved before this date.

43. The submission of ANDA No. 209485 to the FDA constituted an act of infringement by Lupin of the '117, '049, '474 and '872 patents under 35 U.S.C. § 271(e)(2).

44. Plaintiffs are commencing this action within 45 days of receiving the Notice Letter pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

CLAIMS FOR RELIEF

COUNT I: DIRECT INFRINGEMENT OF THE '117 PATENT

45. Plaintiffs incorporate by reference and reallege paragraphs 1 through 44 above as though fully restated herein.

46. Pursuant to 35 U.S.C. § 271(e)(2), Lupin's submission of ANDA No. 209485 to the FDA seeking approval of the ANDA Product was an act of infringement by Lupin of at least claim 1 of the '117 patent, which claims a crystal form of mirabegron that is contained in the ANDA Product.

47. The ANDA Product and the use thereof would infringe the '117 patent under 35 U.S.C. § 271(a), including at least claim 1, which covers, *inter alia*, a crystal form of mirabegron.

48. Unless Lupin is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Lupin's infringement of the '117 patent. Plaintiffs do not have an adequate remedy at law.

COUNT II: DIRECT INFRINGEMENT OF THE '049 PATENT

49. Plaintiffs incorporate by reference and reallege paragraphs 1 through 48 above as though fully restated herein.

50. Pursuant to 35 U.S.C. § 271(e)(2), Lupin's submission of ANDA No. 209485 to the FDA seeking approval of the ANDA Product was an act of infringement by Lupin of at least claims 1, 5, 9 and 13 of the '049 patent which claim pharmaceutical compositions comprising a

crystal form of mirabegron and a pharmaceutically acceptable carrier contained in the ANDA Product.

51. The ANDA Product and the use thereof would infringe the '049 patent under 35 U.S.C. § 271(a), including at least claims 1, 5, 9 and 13, which cover, *inter alia*, pharmaceutical compositions comprising a crystal form of mirabegron and a pharmaceutically acceptable carrier.

52. Unless Lupin is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Lupin's infringement of the '049 patent. Plaintiffs do not have an adequate remedy at law.

COUNT III: DIRECT INFRINGEMENT OF THE '474 PATENT

53. Plaintiffs incorporate by reference and reallege paragraphs 1 through 52 above as though fully restated herein.

54. Pursuant to 35 U.S.C. § 271(e)(2), Lupin's submission of ANDA No. 209485 to the FDA seeking approval of the ANDA Product was an act of infringement by Lupin of at least claims 1, 3-4, 6-7, 9-10 and 12 the '474 patent which cover the method of treating overactive bladder by administering mirabegron, the use for which Lupin seeks FDA approval in its ANDA.

55. Unless Lupin is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Lupin's infringement of the '474 patent. Plaintiffs do not have an adequate remedy at law.

COUNT IV: INDUCEMENT TO INFRINGE THE '474 PATENT

56. Plaintiffs incorporate by reference and reallege paragraphs 1 through 55 above as though fully restated herein.

57. Lupin has knowledge of the '474 patent.

58. If the ANDA Product is approved by the FDA and is sold by Lupin, its use by healthcare providers and/or patients will directly infringe one or more claims of the '474 patent, including at least claims 1, 3-4, 6-7, 9-10 and 12.

59. Lupin's proposed label for the ANDA Product explicitly instructs healthcare providers and/or patients to use the ANDA Product in a manner that will directly infringe one or more claims of the '474 patent, including at least claims 1, 3-4, 6-7, 9-10 and 12.

60. Any use of the ANDA Product by patients will be performed at the direction and control of healthcare providers treating overactive bladder, who in turn are instructed by Lupin in its proposed label for the ANDA Product.

61. If the ANDA Product is approved by the FDA, Lupin will actively induce others including, e.g., healthcare providers and/or patients, to directly infringe one or more claims of the '474 patent, including at least claims 1, 3-4, 6-7, 9-10 and 12. Lupin has acted with knowledge that the induced acts would constitute infringement of the '474 patent.

62. Lupin specifically intends to cause direct infringement by others, e.g., healthcare providers and/or patients.

63. If and when FDA approves ANDA No. 209485, Lupin will take affirmative steps to induce infringement by, among other things, instructing healthcare providers and/or patients, through Lupin's proposed label, to use the ANDA Product in a manner that directly infringes one or more claims of the '474 patent, including at least claims 1, 3-4, 6-7, 9-10 and 12. Thus, Lupin will aid, abet, urge, and/or encourage others including, e.g., healthcare providers and/or patients, to directly infringe one or more claims of the '474 patent, and Lupin will affirmatively and specifically intend to cause direct infringement.

64. Lupin's actions will constitute inducement of infringement of the '474 patent pursuant to 35 U.S.C § 271(b).

COUNT V: CONTRIBUTORY INFRINGEMENT OF THE '474 PATENT

65. Plaintiffs incorporate by reference and reallege paragraphs 1 through 64 above as though fully restated herein.

66. If ANDA No. 209485 is approved by the FDA, Lupin intends to and will offer to sell, sell, and/or import into the United States the ANDA Product.

67. The ANDA Product constitutes a material part of the inventions covered by the claims of the '474 patent and has no substantial non-infringing uses.

68. On information and belief, Lupin has had and continues to have knowledge that the ANDA Product is especially adapted for a use that infringes the '474 patent, including at least claims 1, 3-4, 6-7, 9-10 and 12.

69. On information and belief, Lupin has had and continues to have knowledge that there is no substantial non-infringing use for the ANDA Product.

70. Lupin's actions will constitute contributory infringement of the '474 patent pursuant to 35 U.S.C § 271(c).

COUNT VI: DIRECT INFRINGEMENT OF THE '872 PATENT

71. Plaintiffs incorporate by reference and reallege paragraphs 1 through 70 above as though fully restated herein.

72. Pursuant to 35 U.S.C. § 271(e)(2), Lupin's submission of ANDA No. 209485 to the FDA seeking approval of the ANDA Product was an act of infringement by Lupin of at least claims 1, 3-4, 6, 8-9 and 11-14 of the '872 patent which cover the method of treating overactive bladder by administering mirabegron, the use for which Lupin seeks FDA approval in its ANDA.

73. Unless Lupin is enjoined by the Court, Plaintiffs will be substantially and irreparably harmed by Lupin's infringement of the '872 patent. Plaintiffs do not have an adequate remedy at law.

COUNT VII: INDUCEMENT TO INFRINGE THE '872 PATENT

74. Plaintiffs incorporate by reference and reallege paragraphs 1 through 73 above as though fully restated herein.

75. Lupin has knowledge of the '872 patent.

76. If the ANDA Product is approved by the FDA and is sold by Lupin, its use by healthcare providers and/or patients will directly infringe one or more claims of the '872 patent, including at least claims 1, 3-4, 6, 8-9 and 11-14.

77. Lupin's proposed label for the ANDA Product explicitly instructs healthcare providers and/or patients to use the ANDA Product in a manner that will directly infringe one or more claims of the '872 patent, including at least claims 1, 3-4, 6, 8-9 and 11-14.

78. Any use of the ANDA Product by patients will be performed at the direction and control of healthcare providers treating overactive bladder, who in turn are instructed by Lupin in its proposed label for the ANDA Product.

79. If the ANDA Product is approved by the FDA, Lupin will actively induce others including, e.g., healthcare providers and/or patients, to directly infringe one or more claims of the '872 patent, including at least claims 1, 3-4, 6, 8-9 and 11-14. Lupin has acted with knowledge that the induced acts would constitute infringement of the '872 patent.

80. Lupin specifically intends to cause direct infringement by others, e.g., healthcare providers and/or patients.

81. If and when FDA approves ANDA No. 209485, Lupin will take affirmative steps to induce infringement by, among other things, instructing healthcare providers and/or patients, through Lupin's proposed label, to use the ANDA Product in a manner that directly infringes one or more claims of the '872 patent, including at least claims 1, 3-4, 6, 8-9 and 11-14. Thus, Lupin will aid, abet, urge, and/or encourage others including, e.g., healthcare providers and/or patients, to directly infringe one or more claims of the '872 patent, and Lupin will affirmatively and specifically intend to cause direct infringement.

82. Lupin's actions will constitute inducement of infringement of the '872 patent pursuant to 35 U.S.C § 271(b).

COUNT VIII: CONTRIBUTORY INFRINGEMENT OF THE '872 PATENT

83. Plaintiffs incorporate by reference and reallege paragraphs 1 through 82 above as though fully restated herein.

84. If ANDA No. 209485 is approved by the FDA, Lupin intends to and will offer to sell, sell, and/or import into the United States the ANDA Product.

85. The ANDA Product constitutes a material part of the inventions covered by the claims of the '872 patent and has no substantial noninfringing uses.

86. On information and belief, Lupin has had and continues to have knowledge that the ANDA Product is especially adapted for a use that infringes the '872 patent, including at least claims 1, 3-4, 6, 8-9 and 11-14.

87. On information and belief, Lupin has had and continues to have knowledge that there is no substantial non-infringing use for the ANDA Product.

88. Lupin's actions will constitute contributory infringement of the '872 patent pursuant to 35 U.S.C § 271(c).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs Astellas Pharma Inc., AICL, and APGD, pray for a judgment in their favor and against Defendants Lupin, and respectfully request the following relief:

A. A judgment that, under 35 U.S.C. § 271(e)(2)(A), Lupin has infringed one or more claims of each of the '117, '049, '474 and '872 patents by Lupin's filing of ANDA No. 209485 seeking FDA approval for the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product before the expiration of those patents;

B. A judgment declaring that the manufacture, use, offer for sale, sale, and/or importation of the ANDA Product will infringe the '117, '049, '474 and '872 patents;

C. A judgment declaring that the '117, '049, '474 and '872 patents remain valid and enforceable;

D. A permanent injunction restraining and enjoining Lupin and its officers, agents, attorneys, and employees, and those acting in privity or concert therewith, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product, as claimed in the '117, '049, '474 and '872 patents, until the expiration of each of the '117, '049, '474 and '872 patents, or any later date of exclusivity to which Plaintiffs are or become entitled;

E. An order that the effective date of any approval of ANDA No. 209485 be a date that is not earlier than the expiration of the right of exclusivity under any of the '117, '049, '474 and '872 patents, or any later date of exclusivity to which Plaintiffs are or become entitled;

F. To the extent that Lupin has committed any acts with respect to the subject matter claimed in the '117, '049, '474 and/or '872 patents, other than those acts expressly exempted by 35 U.S.C. § 271(e)(1), an award of damages for such acts;

G. A determination that this case is "exceptional" under 35 U.S.C. § 285, and an award of attorney fees;

H. An award of Plaintiffs' costs and expenses in this action; and

I. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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