IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FERRING PHARMACEUTICALS INC., FERRING INTERNATIONAL CENTER S.A., and FERRING B.V., Plaintiffs,	)	C.A. No. 19-cv-913-RGA
v.	)	
LUPIN INC., Defendant.	)	

AMENDED COMPLAINT

Plaintiffs Ferring Pharmaceuticals Inc. ("Ferring Pharma"), Ferring International Center S.A. ("FICSA"), and Ferring B.V. (collectively, "Ferring") bring this action against Defendant Lupin Inc., ("Lupin") and allege as follows:

PARTIES

1. Plaintiff FICSA is a Swiss private limited liability company having its offices at Ch. de la Vergognausaz 50, 1162 Saint-Prex, Switzerland.

2. Plaintiff Ferring Pharma is a private Delaware corporation having its principal place of business at 100 Interpace Parkway, Parsippany, New Jersey 07054.

3. Plaintiff Ferring B.V. is a Dutch private limited liability company having its offices at Polaris Avenue 144, Hoofddorp, 2132 JX, Netherlands.

4. On information and belief, Defendant Lupin Inc. is a corporation organized and existing under the laws of Delaware, having a principal place of business at 111 S. Calvert

Street, 21st Floor, Baltimore, MD 21202. Upon information and belief, Lupin Inc. is a wholly-owned subsidiary of Lupin Atlantis.

5. On information and belief, Lupin Atlantis Holdings SA ("Lupin Atlantis") is a corporation organized and existing under the laws of Switzerland, having a corporate headquarters at Landis & Gyr-Strasse 1, Zug, Switzerland 6300. Upon information and belief, Lupin Atlantis is a wholly-owned subsidiary of Lupin Ltd.

6. On information and belief, Lupin Ltd. is a corporation organized and existing under the laws of India, having a corporate headquarters at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (E), Mumbai 400 051.

7. On information and belief, Lupin Pharmaceuticals, Inc. ("Lupin Pharma") is a corporation organized and existing under the laws of Delaware, having a principal place of business at 111 S. Calvert Street, 21st Floor, Baltimore, MD 21202. Upon information and belief, Lupin Pharma is a subsidiary of Lupin Ltd. (3%) and Lupin Inc. (97%). (*See* https://www.lupin.com/pdf/annual-report/full-annual-report/lupin-annual-report-2018.pdf, last accessed on May 16, 2019.)

8. Lupin Atlantis, Lupin Ltd., and Lupin Pharma were originally named as Defendants in this litigation. (D.I. 1.)

9. On November 11, the parties filed a joint stipulation and order dismissing Lupin Atlantis, Lupin Ltd., and Lupin Pharma without prejudice, subject to the agreements made in the stipulation concerning Lupin Atlantis, Lupin Ltd., Lupin Pharma, and Novel Laboratories, Inc. ("Novel") (D.I. 55.)

10. The Court ordered the stipulation and order on November 12, 2019. (D.I. 56.)

NATURE OF THE ACTION

11. This is an action for infringement of United States Patent Number 9,827,231 ("the '231 patent"), United States Patent Number 9,669,110 (the '110 patent"), and United States Patent Number 10,624,879 ("the '879 patent") (collectively, the "patents in suit") arising under the Patent Laws of the United States, Title 35 of the United States Code, § 100 *et seq.*, including 35 U.S.C. §§ 271 and 281, and for declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202.

12. This action relates to Lupin Inc.'s filing of an Abbreviated New Drug Application ("ANDA"), under Section 505(j) of the Federal Food, Drug, and Cosmetic Act ("the Act"), 21 U.S.C. § 355(j), seeking U.S. Food and Drug Administration ("FDA") approval to commercially manufacture, use, or sell a generic version of Ferring's CLENPIQ® (sodium picosulfate, magnesium oxide, and anhydrous citric acid) Oral Solution 10 mg/3.5 g/12 g ("Lupin's ANDA Product").

JURISDICTION AND VENUE

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

14. On information and belief, this Court has personal jurisdiction over Lupin Inc. On information and belief, Lupin Inc. directly or indirectly manufactures, markets, and sells generic products, including generic drug products manufactured by Lupin Ltd., throughout the United States and in this judicial district. On information and belief, Lupin Inc. purposefully has conducted and continues to conduct business in this judicial district. On information and belief, Lupin Inc. is incorporated in Delaware and has a registered agent for service of process in this judicial district. On information and belief, Lupin Inc. has previously submitted to the jurisdiction of this Court.

15. By stipulation ordered by the Court on November 12, 2019, Lupin Inc. agreed that, for purposes of this action only, it will not contest personal jurisdiction in this action and would not move to dismiss or transfer this action on grounds that the Court lacks jurisdiction over Lupin Inc. (D.I. 56 at ¶ 5.)

16. Venue is proper in this judicial district under 28 U.S.C. § 1391(c) and (d), and § 1400(b).

17. Venue is proper against Lupin Inc. because it is incorporated in Delaware.

18. By stipulation ordered by the Court on November 12, 2019, Lupin Inc. agreed that, for purposes of this action only, that it would not contest venue in this District and would not move to dismiss or change the venue of this action. (D.I. 56.)

FERRING'S CLENPIQ® NDA

19. Ferring Pharma is the holder of approved New Drug Application ("NDA") No. No. 209589 for CLENPIQ® (sodium picosulfate, magnesium oxide, and anhydrous citric acid) for Oral Solution, 10 mg/3.5 g/12 g.

20. On November 28, 2017, the United States Food and Drug Administration ("FDA") approved NDA No. 209589 for the manufacture, marketing, and sale of CLENPIQ® for cleansing of the colon as a preparation for colonoscopy in adults.

21. Ferring has sold CLENPIQ® under NDA No. 209589 since its approval.

THE PATENTS IN SUIT

22. On November 28, 2017, the United States Patent and Trademark Office ("PTO") duly and legally issued the '231 patent, which bears the title "Liquid Pharmaceutical Composition" and names Bong Gil Nam, Byeung Jun Lee, and Shunji Jin as inventors. A true and correct copy of the '231 patent is attached as Exhibit A.

23. FICSA is the owner by assignment of the '231 patent, and Ferring Pharma is an exclusive licensee of the '231 patent.

24. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, the '231 patent is listed in the FDA's APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (also known as the "Orange Book") as covering CLENPIQ®.

25. On June 6, 2017, the PTO duly and legally issued the '110 patent, which bears the title "Method for Timing a Colonoscopy" and names Raymond E. Joseph as inventor. A true and correct copy of the '110 patent is attached as Exhibit B.

26. Ferring B.V. is the owner by assignment of the '110 patent, FICSA is the exclusive licensee of the '110 patent, and Ferring Pharma is an exclusive sublicensee of the '110 patent.

27. On April 21, 2020, the PTO duly and legally issued the '879 patent, which bears the title "Liquid Pharmaceutical Composition" and names Bong Gil Nam, Byeung Jun Lee, and Shunji Jin as inventors. The '879 patent is a continuation of application No. 15/214,768, which issued as the '231 patent. A true and correct copy of the '879 patent is attached as Exhibit C.

28. FICSA is the owner by assignment of the '879 patent, and Ferring Pharma is an exclusive sublicensee of the '879 patent.

29. In accordance with 21 U.S.C. § 355(c)(2) and 21 C.F.R. § 314.53, the '879 patent is listed in the FDA's Orange Book as covering CLENPIQ.

LUPIN'S NOTICE LETTER AND THE CURRENT CONTROVERSY

30. Upon information and belief, Lupin filed or caused to be filed with the FDA ANDA No. 213029 ("Lupin's ANDA"), under Section 505(j) of the Act and 21 U.S.C. § 355(j).

31. Upon information and belief, ANDA No. 213029 seeks FDA approval to engage in the commercial manufacture, use, or sale in the United States of Lupin's ANDA Product before the expiration of the '231 patent.

32. On April 5, 2019 and April 8, 2019, Ferring Pharma and FICSA, respectively, received a letter from Lupin Inc. dated April 4, 2019, purporting to be a Notice of Certification for Lupin's ANDA ("Lupin's Notice Letter") under Section 505(j)(2)(B)(ii)-(iv) of the Act and 21 C.F.R. § 314.95(c). Lupin's Notice Letter was addressed to Ferring Pharma and FICSA.

33. Lupin's Notice Letter alleges that Lupin Inc. submitted ANDA No. 213029 to the FDA seeking approval to engage in the commercial manufacture, use, and sale in the United States of Lupin's ANDA Product.

34. Lupin's Notice Letter does not set forth any non-infringement defense related to claims 1-13, or 16-20 of the '231 patent.

35. Upon information and belief, Lupin Inc.'s actions related to ANDA No. 213029 were directed, authorized, assisted, or were in cooperation or participation with one or more of Lupin Ltd., Lupin Atlantis, and Lupin Pharma, and Novel.

36. Ferring commenced this action within forty-five (45) days of receiving Lupin's Notice Letter.

37. On information and belief, Lupin intends to seek permission from the FDA to market its ANDA Product prior to expiration of the '879 patent.

38. There is an actual, real, immediate, and justiciable controversy between Ferring and Lupin regarding whether Lupin's ANDA Product will infringe the patents in suit.

COUNT I

Infringement of the ’231 Patent

39. Ferring realleges paragraphs 1 to 39 and incorporates them by reference.

40. Lupin’s submission of ANDA No. 213029 to engage in the commercial manufacture, use, offer for sale, or sale within the United States or importation into the United States of Lupin’s ANDA Product before the expiration of the ’231 patent constitutes infringement of one of more claims of the ’231 patent under 35 U.S.C. § 271(e)(2)(A).

41. A justiciable controversy exists between the parties hereto as to infringement of the ’231 patent.

42. Unless enjoined by this Court, upon FDA approval of Lupin’s ANDA No. 213029, Lupin will infringe, either literally or under the doctrine of equivalents, one or more of claims 1-13, 16, 19-20 of the ’231 patent under 35 U.S.C. § 271(a).

43. Unless enjoined by this Court, upon FDA approval of Lupin’s ANDA No. 213029, Lupin will infringe, either literally or under the doctrine of equivalents, claim 14 and/or 15 of the ’231 patent by actively inducing infringement by others under 35 U.S.C. § 271(b). On information and belief, after the FDA has approved Lupin’s ANDA No. 213029, Lupin intends to manufacture, market, sell, and offer to sell Lupin’s ANDA Product with an FDA-approved product insert that will direct physicians and patients in the use of Lupin’s ANDA Product. On information and belief, Lupin will actively and intentionally aid, abet, encourage, participate, and induce others to perform acts that Lupin knows will directly infringe, either literally or under the doctrine of equivalents, claims 14 and/or 15 of the ’231 patent by marketing Lupin’s ANDA Product with the FDA-approved product insert. On information and belief, Lupin has knowledge of the ’231 patent and knows that the use of Lupin’s ANDA Product in accordance with the

FDA-approved product insert will directly infringe, either literally or under the doctrine of equivalents, claims 14 and/or 15 of the '231 patent.

44. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA No. 213029, Lupin's importation into the United States, and/or use, offer to sell, and/or sale within the United States, of Lupin's ANDA Product will constitute infringement, either literally or under the doctrine of equivalents, of one or more of claims 17 and/or 18 of the '231 patent under 35 U.S.C. § 271(g).

45. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA No. 213029, Lupin will contributorily infringe claims 14 and/or 15 of the '231 patent under 35 U.S.C. § 271(c), by offering to sell and/or selling within the United States, and/or importing into the United States, Lupin's ANDA Product. On information and belief, Lupin knew and knows that Lupin's ANDA Product is designed for a use that infringes claims 14 and/or 15 of the '231 patent, and Lupin's ANDA Product lacks a substantial non-infringing use.

46. Ferring will be irreparably harmed by Lupin's infringing activities unless those activities are enjoined by this Court.

47. Ferring has no adequate remedy at law.

48. This case is an exceptional one, and Ferring is entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT II

Infringement of the '110 Patent

49. Ferring realleges paragraphs 1 to 39 and incorporates them by reference.

50. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

51. There is an actual case or controversy such that the Court may entertain Ferring's request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

52. Lupin has made, and will continue to make, substantial preparation to manufacture, use, offer to sell, and/or sell within the United States, and/or to import into the United States, Lupin's ANDA Product prior to the expiration of the '110 patent.

53. Unless enjoined by the Court, upon FDA approval of Lupin's ANDA No. 213029, Lupin will infringe, either literally or under the doctrine of equivalents, one or more claims of the '110 patent by actively inducing infringement by others under 35 U.S.C. § 271(b).

54. On information and belief, after the FDA has approved Lupin's ANDA No. 213029, Lupin intends to manufacture, market, sell, and offer to sell Lupin's ANDA Product with an FDA-approved product insert that will direct physicians and patients in the use of Lupin's ANDA Product.

55. On information and belief, Lupin will actively and intentionally aid, abet, encourage, participate, and induce others to perform acts that Lupin knows will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '110 patent by marketing Lupin's ANDA Product with the FDA-approved product insert.

56. On information and belief, Lupin has knowledge of the '110 patent and knows that the use of Lupin's ANDA Product in accordance with the FDA-approved product insert will directly infringe, either literally or under the doctrine of equivalents, one or more claims of the '110 patent.

57. Ferring will be irreparably harmed by Lupin's infringing activities unless those activities are enjoined by this Court.

58. Ferring has no adequate remedy at law.

59. This case is an exceptional one, and Ferring is entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT III

Infringement of the '879 Patent

60. Ferring realleges paragraphs 1 to 39 and incorporates them by reference.

61. Lupin's submission of ANDA No. 213029 to engage in the commercial manufacture, use, offer for sale, or sale within the United States or importation into the United States of Lupin's ANDA Product before the expiration of the '879 patent constitutes infringement of one of more claims of the '879 patent under 35 U.S.C. § 271(e)(2)(A).

62. The '879 patent is listed in the Orange Book for NDA No. 209589.

63. Pursuant to 21 CFR §§ 314.107(b)(2) & 314.94(a)(12)(viii)(C)(1)(ii), Lupin must submit a certification for the '879 patent in connection with ANDA No. 213029 before obtaining FDA approval of the ANDA. Ferring received a Notice Letter dated June 4, 2020 from Lupin indicating that it had submitted an amendment to its ANDA to add a paragraph IV certification against the '879 patent.

64. These claims also arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

65. There is an actual case or controversy such that the Court may entertain Ferring's request for declaratory relief consistent with Article III of the United States Constitution, and this actual case or controversy requires a declaration of rights by this Court.

66. Lupin has made, and will continue to make, substantial preparation to manufacture, use, offer to sell, and/or sell within the United States, and/or to import into the United States, Lupin's ANDA Product prior to the expiration of the '879 patent.

67. On information and belief, Lupin intends to seek permission from the FDA to market its ANDA Product prior to expiration of the '879 patent. Accordingly, a justiciable controversy exists between the parties hereto as to infringement of the '879 patent.

68. Unless enjoined by this Court, upon FDA approval of Lupin's ANDA No. 213029, Lupin will infringe, either literally or under the doctrine of equivalents, one or more of claims of the '879 patent under 35 U.S.C. § 271(a).

69. Ferring will be irreparably harmed by Lupin's infringing activities unless those activities are enjoined by this Court.

70. Ferring has no adequate remedy at law.

71. This case is an exceptional one, and Ferring is entitled to an award of their reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Ferring respectfully requests the following judgment and relief:

a. A declaration that the claims of United States Patent Number 9,827,231 are valid and enforceable;

b. A declaration that the claims of United States Patent Number 9,669,110 are valid and enforceable;

c. A declaration that the claims of United States Patent Number 10,624,879 are valid and enforceable;

d. A declaration that Lupin's submission to the FDA of Lupin's ANDA No. 213029 to obtain approval for the commercial manufacture, use, offer for sale, sale within, or importation into, the United States of Lupin's ANDA Product before the expiration of United States Patent Number 9,827,231 was an act of infringement under 35 U.S.C. § 271(e)(2)(A);

e. A declaration that Lupin's manufacture, use, offer to sell, sale within, and/or importation into, the United States of Lupin's ANDA Product prior to the expiration of United States Patent Number 9,827,231 will infringe one or more claims of United States Patent Number 9,827,231 under 35 U.S.C. § 271;

f. A declaration that Lupin's manufacture, use, offer to sell, sale within, and/or importation into, the United States of Lupin's ANDA Product prior to the expiration of United States Patent Number 9,669,110 will infringe one or more claims of United States Patent Number 9,669,110 under 35 U.S.C. § 271;

g. A declaration that Lupin's continuance to seek approval of Lupin's ANDA No. 213029 for the commercial manufacture, use, offer for sale, sale within, or importation into, the United States of Lupin's ANDA Product before the expiration of United States Patent Number 10,624,879 was an act of infringement under 35 U.S.C. § 271(e)(2)(A);

h. A declaration that Lupin's manufacture, use, offer to sell, sale within, and/or importation into, the United States of Lupin's ANDA Product prior to the expiration of United States Patent Number 10,624,879 will infringe one or more claims of United States Patent Number 10,624,879 under 35 U.S.C. § 271;

i. An order that the effective date of the approval of Lupin's ANDA No. 213029 be a date that is not earlier than the expiration of the term of United States Patent Number

9,827,231, including any extension(s) granted by the USPTO under 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity to which Ferring is or becomes entitled;

j. An order that the effective date of the approval of Lupin's ANDA No. 213029 be a date that is not earlier than the expiration of the term of United States Patent Number 10,624,879, including any extension(s) granted by the USPTO under 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity to which Ferring is or becomes entitled;

k. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283, enjoining Lupin and all officers, agents, servants, employees, privies, and others acting for, or on behalf of, or in concert with any of them, from infringing any claims of United States Patent Number 9,827,231 prior to the expiration date of United States Patent Number 9,827,231 and any additional dates of exclusivity;

l. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283, enjoining Lupin and all officers, agents, servants, employees, privies, and others acting for, or on behalf of, or in concert with any of them, from infringing any claims of United States Patent Number 10,624,879 prior to the expiration date of United States Patent Number 10,624,879 and any additional dates of exclusivity;

m. A permanent injunction under 35 U.S.C. § 283, enjoining Lupin and all officers, agents, servants, employees, privies, and others acting for, or on behalf of, or in concert with any of them, from infringing any claims of United States Patent Number 9,669,110 prior to the expiration date of United States Patent Number 9,669,110 and any additional dates of exclusivity;

n. A permanent injunction enjoining Lupin and all officers, agents, servants, employees, privies, and others acting for, or on behalf of, or in concert with any of them, from

seeking, obtaining, or maintaining approval of ANDA No. 213029 until the expiration date of United States Patent Number 9,827,231 and any additional dates of exclusivity;

o. A permanent injunction enjoining Lupin and all officers, agents, servants, employees, privies, and others acting for, or on behalf of, or in concert with any of them, from seeking, obtaining, or maintaining approval of ANDA No. 213029 until the expiration date of United States Patent Number 10,624,879 and any additional dates of exclusivity;

p. A judgment granting Ferring compensatory damages in an amount to be determined at trial and including both pre-judgment and post-judgment interested, if Lupin engages in the manufacture, use, offer to sell, sale within, and/or importation into, the United States of Lupin's ANDA Product before the expiration of United States Patent Number 9,827,231 and any additional dates of exclusivity;

q. A judgment granting Ferring compensatory damages in an amount to be determined at trial and including both pre-judgment and post-judgment interested, if Lupin engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale in the United States of Lupin's ANDA Product before the expiration of United States Patent Number 9,669,110 and any additional dates of exclusivity;

r. A judgment granting Ferring compensatory damages in an amount to be determined at trial and including both pre-judgment and post-judgment interested, if Lupin engages in the manufacture, use, offer to sell, sale within, and/or importation into, the United States of Lupin's ANDA Product before the expiration of United States Patent Number 10,624,879 and any additional dates of exclusivity;

s. A judgment and order that this is an exceptional case under 35 U.S.C. § 285 and awarding Ferring its reasonable attorneys' fees, costs, and expenses; and

t. Any and all other and further relief as this Court deems just and proper.

Dated: June 12, 2020

/s/ Mary W. Bourke
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