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. 17-cv-435-RGA
v.	)	
TEVA PHARMACEUTICALS USA, INC.	)	
Defendant.	)	

FIRST 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 Teva Pharmaceuticals USA, Inc. ("Teva") 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 Teva is a Delaware corporation having a principal place of business at 425 Privet Road, Horsham, Pennsylvania, 19044.

JURISDICTION AND VENUE

5. This action arises under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively.

6. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

7. This Court has personal jurisdiction over Teva.

8. On information and belief, Teva is in the business of, *inter alia*, developing, manufacturing, packaging, and obtaining regulatory approval for numerous generic versions of branded pharmaceutical products for sale and use throughout the United States, including this District.

9. On information and belief, Teva has extensive contacts with the State of Delaware. Teva is a Delaware corporation, has appointed an agent in Delaware to receive service of process, and previously has submitted to jurisdiction in this District.

10. On information and belief, Teva has continuous and systematic contacts with this District, at least because Teva is registered with the Delaware Board of Pharmacy as a Pharmacy-Wholesale and Distributor/Manufacturer CSR to distribute drugs in Delaware, has substantial marketing and sales activities in this District, including but not limited to the substantial, continuous, and systematic distribution, marketing, and/or sales of generic pharmaceutical products in this District.

11. On information and belief, Teva conducts substantial business in this District, regularly solicits business from, does business with, and derives value from goods and services provided to customers in this District.

12. On information and belief, Teva has derived substantial revenue from sales of pharmaceutical products in this District.

13. Venue is proper in this District under 28 U.S.C. §§ 1391 and 1400.

14. On information and belief, Teva is subject to personal jurisdiction in this District and thus resides in this District under 28 U.S.C. § 1391(b)(1).

NATURE OF THE ACTION

15. This is an action for infringement of United States Patent Numbers 8,450,338 ("the '338 patent"), 8,481,083 ("the '083 patent"), and 9,669,110 ("the '110 patent") (collectively, the "patents in suit") under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively. This action involves Ferring's drug product Prepopik®, indicated for cleansing of the colon as a preparation for colonoscopy in adults.

FERRING'S PREPOPIK® NDA

16. Ferring Pharma is the holder of approved New Drug Application ("NDA") No. 202535 for Prepopik® (sodium picosulfate, magnesium oxide and citric acid) for Oral Solution.

17. On July 16, 2012, the United States Food and Drug Administration ("FDA") approved NDA No. 202535 for the manufacture, marketing, and sale of Prepopik® for cleansing of the colon as a preparation for colonoscopy in adults.

18. Ferring has sold Prepopik® under NDA No. 202535 since its approval.

THE PATENTS IN SUIT

19. On May 28, 2013, the United States Patent and Trademark Office ("USPTO") duly and legally issued the '338 patent, which bears the title "Granular Compositions of Sodium

Picosulfate and Potassium Bicarbonate and Uses Thereof" naming Haijun Xu and Tiejun Diao as inventors. A true and correct copy of the '338 patent is attached as Exhibit A.

20. Plaintiff FICSA is the owner by assignment of the '338 patent, and Plaintiff Ferring Pharma is an exclusive licensee of the '338 patent.

21. On July 9, 2013, the USPTO duly and legally issued the '083 patent, which bears the title "Granular Compositions of Magnesium Oxide and Citric Acid and Uses Thereof" naming Haijun Xu and Tiejun Diao as inventors. A true and correct copy of the '083 patent is attached as Exhibit B.

22. Plaintiff FICSA is the owner by assignment of the '083 patent, and Plaintiff Ferring Pharma is an exclusive licensee of the '083 patent.

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

24. Plaintiff Ferring B.V. is the owner by assignment of the '110 patent, and Plaintiff Ferring Pharma is an exclusive licensee of the '110 patent.

25. In accordance with 21 U.S.C. § 355(b)(1) and 21 C.F.R. § 314.53, the '338 patent and the '083 patent are listed in the FDA's APPROVED DRUG PRODUCTS WITH THERAPEUTIC EQUIVALENCE EVALUATIONS (also known as the "Orange Book") as covering Prepopik®.

TEVA'S PARAGRAPH IV NOTICE LETTER AND THE CURRENT CONTROVERSY

26. Teva sent a letter dated March 9, 2017 to Ferring Pharma, FICSA, and Ferring Pharmaceuticals S.A. (the "Notice Letter") notifying Ferring that Teva had filed ANDA No. 209960 ("Teva's ANDA") seeking approval to commercially manufacture, use, or sell a generic version of Ferring's Prepopik® ("Teva's ANDA Product") prior to the expiration of the '338

patent and the ’083 patent (*i.e.*, the patents in suit). The Notice Letter stated that Teva was providing information to Ferring pursuant to § 505(j)(2)(B) of the Federal Food, Drug, and Cosmetic Act (“the FDCA”), 21 U.S.C. § 355(j)(2)(B), and 21 C.F.R. § 314.95. Ferring Pharma received the Notice Letter on March 10, 2017. FICSA received the Notice Letter on March 13, 2017.

27. As stated in the Notice Letter, Teva’s ANDA contains certifications under 21 U.S.C. § 355(j)(2) indicating that, in Teva’s opinion, the patents in suit are invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of Teva’s ANDA Product (“Paragraph IV Certifications”).

28. Teva attached its “Detailed Factual and Legal Bases for Teva USA’s Paragraph IV Certification that the Claims of U.S. Patent Nos. 8,450,338 and 8,481,083 Are Invalid, Unenforceable and/or Not Infringed” to the Notice Letter (the “Detailed Statement”). The Detailed Statement alleges that patents in suit are invalid and Teva’s ANDA Product will not infringe the claims of the patents in suit.

29. Ferring commenced this action within forty-five (45) days of receiving the Notice Letter.

30. There is an actual, real, immediate, and justiciable controversy between Ferring and Teva regarding the validity and enforceability of the patents in suit and whether Teva’s ANDA Product will infringe the patents in suit.

COUNT I

Infringement of the ’338 patent

31. Ferring realleges paragraphs 1 to 30 and incorporates them by reference.

32. Teva's submission of Teva's ANDA to the FDA under § 505(j) of the FDCA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Teva's ANDA Product before the expiration of the '338 patent was an act of infringement of the '338 patent under 35 U.S.C. § 271(e)(2).

33. Teva's manufacture, use, sale, offer for sale in, or importation into the United States of Teva's ANDA Product prior to the expiration of the '338 patent, including any applicable exclusivities or extensions, will infringe, either literally or under the doctrine of equivalents, one or more claims of the '338 patent under 35 U.S.C. § 271(a).

34. Ferring is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Teva's ANDA No. 209960 be a date that is not earlier than the expiration of the term of the '338 patent, including any extension(s) granted by the USPTO pursuant to 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity for the '338 patent to which Ferring is or becomes entitled.

35. There is an actual case or controversy between Ferring and Teva regarding whether the process used to make Teva's ANDA Product infringes, either literally or under the doctrine of equivalents, claims 8 to 19 of the '338 patent.

36. Teva has made, and will continue to make, substantial preparation to import into the United States, and/or to use, offer to sell, and/or sell within the United States Teva's ANDA Product, which is made by a process claimed in one more of claims 8 to 19 of the '338 patent, prior to the expiration of the '338 patent.

37. Teva's importation into the United States, and/or use, offer to sell, and/or sale of Teva's ANDA Product within the United States will constitute infringement, either literally or

under the doctrine of equivalents, of one or more of claims 8 to 19 of the ’338 patent under 35 U.S.C. § 271(g).

38. Ferring is entitled to a declaratory judgment that Teva’s importation into the United States, and/or use, offer to sell, and/or sale of Teva’s ANDA Product within the United States will constitute infringement, either literally or under the doctrine of equivalents, of one or more of claims 8 to 19 of the ’338 patent under 35 U.S.C. § 271(g).

39. Ferring will be irreparably harmed by Teva’s infringing activities unless those activities are enjoined by this Court. Ferring has no adequate remedy at law.

COUNT II

Infringement of the ’083 patent

40. Ferring realleges paragraphs 1 to 30 and incorporates them by reference.

41. Teva’s submission of Teva’s ANDA to the FDA under § 505(j) of the FDCA for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Teva’s ANDA Product before the expiration of the ’083 patent was an act of infringement of the ’083 patent under 35 U.S.C. § 271(e)(2).

42. Teva’s manufacture, use, sale, offer for sale, or importation into the United States of Teva’s ANDA Product, prior to the expiration of the ’083 patent, including any applicable exclusivities or extensions, will infringe, either literally or under the doctrine of equivalents, one or more claims of the ’083 patent under 35 U.S.C. § 271(a).

43. Ferring is entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of Teva’s ANDA No. 209960 be a date that is not earlier than the expiration of the term of the ’083 patent, including any extension(s)

granted by the USPTO pursuant to 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity for the ’083 patent to which Ferring is or becomes entitled.

44. Ferring will be irreparably harmed by Teva’s infringing activities unless those activities are enjoined by this Court. Ferring has no adequate remedy at law.

COUNT III

Declaratory Judgment of Infringement of the ’110 patent

45. Ferring realleges paragraphs 1 to 30 and incorporates them by reference.

46. Teva has made, and will continue to make, substantial preparation to import into the United States, and/or to use, offer to sell, and/or sell within the United States Teva’s ANDA Product.

47. Upon FDA approval of Teva’s ANDA Product, Teva 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).

48. On information and belief, after the FDA has approved Teva’s ANDA No. 209960, Teva intends to manufacture, market, sell, and offer to sell Teva’s ANDA Product with an FDA-approved product insert that will direct physicians and patients in the use of Teva’s ANDA Product.

49. There is an actual case or controversy between Ferring and Teva regarding whether the use of Teva’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 and whether Teva will induce others to infringe one or more claims of the ’110 patent.

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

51. On information and belief, Teva has knowledge of the ’110 patent and knows that the use of Teva’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.

52. Ferring will be irreparably harmed by Teva’s infringing activities unless those activities are enjoined by this Court. Ferring has no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Ferring respectfully requests the following judgment and relief:

a. A declaration that the claims of United States Patent Number 8,450,338, United States Patent Number 8,481,083, and United States Patent Number 9,669,110 are valid and enforceable;

b. A declaration that Teva’s submission to the FDA of Teva’s ANDA No. 209960 to obtain approval for the commercial manufacture, use, offer for sale, sale in, or importation into the United States of Teva’s ANDA Product before the expiration of United States Patent Number 8,450,338 and United States Patent Number 8,481,083 was an act of infringement under 35 U.S.C. § 271(e)(2)(A);

c. A declaration that Teva’s manufacture, use, offer to sell, sale in, and/or importation into the United States of Teva’s ANDA Product prior to the expiration of United States Patent Number 8,450,338, United States Patent Number 8,481,083, and United States

Patent No. 9,669,110 will infringe one or more claims of United States Patent Number 8,450,338, United States Patent Number 8,481,083, and United States Patent Number 9,669,110 under 35 U.S.C. § 271;

d. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283, enjoining Teva 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 8,450,338, United States Patent Number 8,481,083, and United States Patent Number 9,669,110 prior to the expiration date of United States Patent Number 8,450,338, United States Patent Number 8,481,083, and United States Patent Number 9,669,110, and any additional dates of exclusivity; and

e. A permanent injunction enjoining Teva 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. 209960 until the expiration date of United States Patent Number 8,450,338 and United States Patent Number 8,481,083 and any additional dates of exclusivity;

f. A judgment granting Ferring compensatory damages in an amount to be determined at trial and including both pre-judgment and post-judgment interested, if Teva engages in the commercial manufacture, use, importation into the United States, sale, or offer for sale of its ANDA Product before the expiration of United States Patent Number 8,450,338, United States Patent Number 8,481,083, and United States Patent Number 9,669,110, and any additional dates of exclusivity;

g. 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

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

Dated: July 19, 2017

/s/ Mary W. Bourke
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