IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FERRING PHARMACEUTICALS INC. and FERRING INTERNATIONAL CENTER S.A.,	)	
Plaintiffs,	)	
v.	)	C.A. No.
HETERO USA INC, HETERO LABS LIMITED UNIT-V, and HETERO LABS LIMITED,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Ferring Pharmaceuticals Inc. ("Ferring Pharma") and Ferring International Center S.A. ("FICSA") (collectively, "Ferring") bring this action against Defendants Hetero USA Inc. ("Hetero USA"), Hetero Labs Limited Unit-V ("Hetero Unit-V"), and Hetero Labs Limited ("Hetero Labs") (collectively, "Defendants") and allege as follows:

PARTIES

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

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

3. On information and belief, Defendant Hetero Labs is a corporation organized and existing under the laws of India, having its principal place of business at 7-2-A2, Hetero Corporate Industrial Estates, Sanath Nagar, Hyderabad – 500018, Telangana, INDIA.

4. On information and belief, Hetero Unit-V is a division of Hetero Labs, having its principal place of business at Polepally Village, Jadcherla, Mahaboob Nagar, 509301, Telengana, INDIA.

5. On information and belief, Defendant Hetero USA is a domestic Delaware corporation having a principal place of business at 1031 Centennial Avenue, Piscataway, New Jersey 08854.

6. On information and belief, Hetero Labs is the parent corporation of Hetero USA.

JURISDICTION AND VENUE

7. 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.

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

9. This Court has personal jurisdiction over Hetero USA under the laws of the State of Delaware, 10 *Del. C.* § 3104(c).

10. This Court has personal jurisdiction over Hetero Labs and Hetero Unit-V under Federal Rule of Civil Procedure 4(k)(2).

11. On information and belief, Defendants, directly or through their affiliates, are 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. On information and belief, Defendants derive substantial revenue from products sold or consumed in Delaware.

12. On information and belief, Defendants have extensive contacts with the State of Delaware. For example, Hetero USA is a domestic Delaware corporation. Hetero USA is

registered to do business in the State of Delaware (File Number 4837317) and has appointed an agent in Delaware to receive service of process—W/K Incorporating Services, Inc., 3500 S. DuPont Highway, Dover, Delaware 19901.

13. On information and belief, Defendants have previously submitted to jurisdiction in this District, *see, e.g., Takeda Pharmaceuticals U.S.A., Inc. v. Hetero Labs Ltd. et al.*, No. 17-cv-01929-RGA, and have affirmatively availed themselves of the jurisdiction of this Court by filing counterclaims in this District, *see, e.g., Novartis Pharmaceuticals Corporation v. Accord Healthcare Inc., et al.*, No. 18-cv-1043-LPS (D. Del.); *Bristol-Myers Squibb Company et al., v. Hetero USA Inc. et al*, No. 17-cv-376-LPS (D. Del.); and *Amgen Inc. v. Hetero USA Inc., et al.*, No. 16-cv-928-GMS (D. Del.).

14. On information and belief, Hetero Unit-V and/or Hetero Labs have designated Hetero USA as its/their U.S. Regulatory Agent for any Abbreviated New Drug Application ("ANDA") filed with the United States Food and Drug Administration ("FDA"), including ANDA No. 212789 for Citric acid; Magnesium oxide; Sodium picosulfate for solution 12gm/packet; 3.5gm/packet; 10mg/packet" ("the Hetero ANDA")

15. Defendants have filed an ANDA with the FDA for a generic drug product, which indicates their intention to sell that product throughout the United States, including in the State of Delaware. If the Hetero ANDA is approved, the drug product which is the subject of the Hetero ANDA ("Hetero's ANDA product") will, *inter alia*, be marketed and distributed in the State of Delaware, and/or prescribed by physicians practicing in the State of Delaware, and/or dispensed by pharmacies located within the State of Delaware, all of which will have a substantial effect on the State of Delaware. Defendants know and intend that Hetero's ANDA product will be distributed and sold in the United States, including in the State of Delaware. If Defendants are

permitted to market Hetero's ANDA product, Ferring will be specifically harmed by Defendants' sales of Hetero's ANDA product, including their sales in the State of Delaware.

16. Venue is proper in this District under 28 U.S.C. § 1400(b) and/or 28 U.S.C. § 1391(b) and/or (c).

NATURE OF THE ACTION

17. This is an action for infringement of United States Patent Numbers 8,450,338 ("the '338 patent") and 8,481,083 ("the '083 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

18. 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.

19. 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.

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

THE PATENTS IN SUIT

21. 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.

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

23. 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.

24. Plaintiff FICSA is the owner by assignment of the ’083 patent, and Plaintiff Ferring Pharma is an exclusive licensee of the ’083 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®.

DEFENDANTS’ NOTICE LETTER AND THE CURRENT CONTROVERSY

26. On information and belief, Defendants submitted ANDA No. 212789 seeking approval to engage in the commercial use, manufacture, sale, offer for sale, or importation of a generic version of Ferring’s Prepopik® drug product (i.e., Hetero’s ANDA product) prior to the expiration of the patents in suit.

27. In February 2019, Ferring received a letter on Hetero USA’s letterhead from John Thallemer, Esq. dated February 15, 2019 (the “Notice Letter”) notifying Ferring that Defendants had filed the Hetero ANDA under 21 U.S.C. § 355(j)(1) and (2)(A) and that the Hetero ANDA contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) seeking approval to commercially manufacture, use, or sell a generic version of Ferring’s Prepopik® prior to the expiration of the patents in suit. The Notice Letter stated that Defendants were providing information to Ferring pursuant to subsection 505(j)(2)(B) of the Federal Food, Drug, and

Cosmetic Act. Ferring Pharma received the Notice Letter on February 19, 2019, and FICSA received the Notice Letter on February 21, 2019.

28. As stated in the Notice Letter, the Hetero ANDA purports to contain certifications under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) indicating that Defendants allege that the patents in suit are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use or sale of the drug product described in the Hetero ANDA.

29. The Notice Letter included an allegedly detailed statement of the factual and legal bases for Defendants' opinion that the claims of the patents in suit are invalid, unenforceable and/or will not be infringed, which was titled "Detailed Statement for ANDA 212789" to the Notice Letter (the "Detailed Statement"). The Detailed Statement alleges that Hetero's ANDA product will not infringe the claims of the patents in suit. The Detailed Statement does not allege that the patents in suit are invalid or unenforceable.

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

31. There is an actual, real, immediate, and justiciable controversy between Ferring and Defendants regarding whether Hetero's ANDA product, or the use of Hetero's ANDA product, will infringe the patents in suit.

COUNT I
Infringement of the '338 patent

32. Ferring realleges paragraphs 1 to 32 and incorporates them by reference.

33. Defendants' submission of the Hetero ANDA to the FDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Hetero's ANDA product prior to the expiration of the '338 patent was an act of infringement of the '338 patent under 35 U.S.C. § 271(e)(2).

34. Defendants' manufacture, use, sale, offer for sale in, or importation into the United States of Hetero'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).

35. 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 Defendants' ANDA No. 212789 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 under 35 U.S.C. §§ 154 or 156, or any later expiration of exclusivity for the '338 patent to which Ferring is or becomes entitled.

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

37. Defendants have 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 Hetero'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.

38. Defendants' importation into the United States, and/or use, offer to sell, and/or sale of Hetero'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 is entitled to a declaratory judgment that Defendants' importation into the United States, and/or use, offer to sell, and/or sale of Hetero'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).

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

COUNT II
Infringement of the ’083 patent

41. Ferring realleges paragraphs 1 to 32 and incorporates them by reference.

42. Defendants’ submission of the Hetero ANDA to the FDA under 21 U.S.C. § 355(j) for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Hetero’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).

43. Defendants’ manufacture, use, sale, offer for sale, or importation into the United States of Hetero’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).

44. 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 Defendants’ ANDA No. 212789 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.

45. Ferring will be irreparably harmed by Defendants’ 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 and United States Patent Number 8,481,083 are valid and enforceable;

b. A declaration that Defendants' submission to the FDA of ANDA No. 212789 to obtain approval for the commercial manufacture, use, offer for sale, sale in, or importation into the United States of Hetero'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 Defendants' manufacture, use, offer to sell, sale in, and/or importation into the United States of Hetero's ANDA product prior to the expiration of United States Patent Number 8,450,338 and United States Patent Number 8,481,083 will infringe one or more claims of United States Patent Number 8,450,338 and United States Patent Number 8,481,083 under 35 U.S.C. § 271;

d. An order that the effective date of the approval of ANDA No. 212789 be a date that is not earlier than the expiration of the term of United States Patent Number 8,450,338 and United States Patent Number 8,481,083, 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;

e. A permanent injunction under 35 U.S.C. §§ 271(e)(4)(B) and/or 283, enjoining Defendants 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 and United States Patent Number 8,481,083 prior to 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 permanent injunction enjoining Defendants 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. 212789 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;

g. A judgment granting Ferring compensatory damages in an amount to be determined at trial and including both pre-judgment and post-judgment interest, if Defendants engage in the commercial manufacture, use, importation into the United States, sale, or offer for sale of Hetero's ANDA product before the expiration of United States Patent Number 8,450,338 and United States Patent Number 8,481,083, and any additional dates of exclusivity;

h. 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

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

Dated: April 4, 2019

/s/ Mary W. Bourke
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