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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

BRAINTREE LABORATORIES, INC.,

Plaintiff,

v.

Civil Action No. _____

HETERO LABS LIMITED, HETERO LABS LIMITED UNIT-V, ANNORA PHARMA PRIVATE LIMITED, and HETERO USA, INC.

Defendants.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Braintree Laboratories, Inc. ("Braintree" or "Plaintiff"), brings this Complaint for Patent Infringement against Defendants, Hetero Labs Limited, Hetero Labs Limited Unit-V, Annora Pharma Private Limited and Hetero USA Inc. (collectively, "Hetero" or "Defendants"), and alleges:

NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent No. 6,946,149, as reexamined ("the '149 patent"), arising under the patent laws of the United States, Title 35, United States Code, 35 U.S.C. §§ 271 and 281. This action relates to Abbreviated New Drug Application ("ANDA") No.

212903 filed or caused to be filed by Defendants with the U.S. Food and Drug Administration ("FDA") and seeking approval to market a generic version of Braintree's SUPREP® drug product.

PARTIES

2. Plaintiff Braintree is a corporation organized and existing under the laws of the Commonwealth of Massachusetts, with its principal place of business at 60 Columbian Street West, Braintree, Massachusetts 02185-0929.

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

4. Upon information and belief, Defendant Hetero Labs Unit-V ("Hetero Unit-V"), a division of Hetero Labs Limited, is a corporation organized and existing under the laws of India, having a principal place of business in Polepally, Jadcherla, Mahabubnagar - 509301, Andrha Pradesh, India.

5. Upon information and belief, Defendant Hetero USA, Inc. ("Hetero USA"), is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 1035 Centennial Avenue, Piscataway, NJ 08854. Upon information and belief, Hetero USA, Inc. is the U.S. regulatory agent of Hetero Labs Unit-V, a division of Hetero Labs, with respect to ANDA No. 212903.

6. Upon information and belief, Defendant Annora Pharma Private Limited ("Annora") is a corporation organized and existing under the laws of India, having a principal place of business at Sy. No. 261, Annaram Village, Gummadidala Mandal, Sangareddy Dist., Telangana 502313, India.

7. Upon information and belief, following any FDA approval of ANDA No. 212903, Hetero will make, use, offer to sell, and/or sell the generic products that are the subject of ANDA

No. 212903 throughout the United States, and/or import such generic products into the United States.

JURISDICTION AND VENUE

8. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq*, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a). Venue is proper in this Court under 28 U.S.C. §§ 1391 and 1400(b).

9. Based on the facts and causes alleged herein, and for additional reasons to be further developed through discovery, this Court has personal jurisdiction over Hetero.

10. This Court has personal jurisdiction over Hetero USA because the company has a principal place of business in New Jersey.

11. In addition, this Court has personal jurisdiction over Hetero USA because, upon information and belief, Hetero USA regularly does business in New Jersey and has engaged in a persistent course of conduct within New Jersey by continuously and systematically placing goods into the stream of commerce for distribution throughout the United States, including New Jersey, and/or by directly selling pharmaceutical products in New Jersey. On information and belief, Hetero USA is registered with the State of New Jersey's Division of Revenue and Enterprise Services as a business operating in New Jersey under Business ID No. 0400362826. On information and belief, Hetero USA is registered with the State of New Jersey's Department of Health as a drug wholesaler under Registration No. 5004050.

12. Upon information and belief, Hetero USA acts at the direction, and for the benefit, of Hetero Labs and Hetero Unit-V, and is controlled and/or dominated by Hetero Labs and/or Hetero Unit-V. Upon information and belief, Hetero USA, Hetero Labs, and Hetero Unit-V operate as a single integrated business.

13. This Court has personal jurisdiction over Hetero Labs, Hetero Unit-V, and Annora because, for example, they regularly do business in New Jersey and have engaged in a persistent course of conduct within New Jersey directly and/or indirectly through their affiliate, Hetero USA. Upon information and belief, Hetero USA, Hetero Labs, Hetero Unit-V, and Annora work in concert either directly or indirectly through one or more of their wholly owned subsidiaries with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in New Jersey. For example, on the website www.heteroworld.com, Hetero notes that it "has a strong established global presence," including manufacturing facilities and branch offices/subsidiaries located in the United States.

14. Upon information and belief, Annora and Hetero USA acted collaboratively in the submission and preparation of ANDA No. 212903. For example, Braintree received two, essentially identical Paragraph IV Certification letters related to ANDA No. 212903: one from Hetero USA and one from Annora. The letter from Hetero USA states that ANDA No. 212903 was submitted by Hetero USA (and/or Hetero Labs and/or Hetero Unit-V) and describes the proposed product as "the Hetero Product." The letter from Annora states that ANDA No. 212903 was submitted by Annora and describes the product as "the Annora Product." Upon information and belief, Hetero USA is also the listed U.S. Agent for Annora on at least one other ANDA filed with the FDA in March 2018.

15. Upon information and belief, Hetero Labs, Hetero Unit-V, Hetero USA, and Annora will manufacture, market, and/or sell within the United States the generic version of Braintree's SUPREP® drug product described in ANDA No. 212903 if approved by the FDA. If ANDA No. 212903 is approved, the generic version of Braintree's SUPREP® drug product charged with infringing Braintree's '149 patent, would, upon information and belief, among other things, be marketed and distributed in New Jersey, prescribed by physicians practicing in New

Jersey, dispensed by pharmacies located in New Jersey, and/or used by persons in New Jersey, all of which would have a substantial effect on New Jersey.

16. Furthermore, this Court has personal jurisdiction over Hetero because it has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and has sent notice of that infringement to Braintree from Hetero USA in the State of New Jersey. On information and belief, Hetero intends a future course of conduct that includes acts of patent infringement in New Jersey, including infringement of Braintree's '149 patent. These acts have led and will continue to lead to foreseeable harm and injury to Braintree in New Jersey.

17. In addition, Hetero has previously submitted to the jurisdiction of this Court and has previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction. For example, Hetero Labs, Hetero Unit-V, and Hetero USA sought declaratory judgment of non-infringement and/or invalidity in *Celgene Corp. v. Hetero Labs Ltd. et al*, No. 2:19-cv-05797, D.I. 13 (D.N.J.); *Celgene Corp. v. Hetero Labs Ltd. et al.*, No. 2:18-cv-14111-ES-MAH, D.I. 12 (D.N.J.); and *Celgene Corp. v. Hetero Labs Ltd et al.*, No. 2:17-cv-03387-ES-JAD, D.I. 26 (D.N.J.). Additionally, Hetero USA and Annora sought declaratory judgments of invalidity in *Celgene Corp. v. Annora Pharma Private Limited, et al.*, No. 3:18-cv-11220-MAS-DEA, D.I. 32 (D.N.J.).

18. In the alternative, this Court may exercise personal jurisdiction over Hetero Labs, Hetero Unit-V, and Annora pursuant to Federal Rule of Civil Procedure 4(k)(2) because Braintree's claims arise under Federal law, and Hetero Labs, Hetero Unit-V, and Annora each have 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 any or all of them would satisfy due process.

BACKGROUND

19. Braintree holds approved New Drug Application ("NDA") No. 22372 for SUPREP® Bowel Prep Kit ("SUPREP"). SUPREP is a sodium sulfate, potassium sulfate and magnesium sulfate osmotic laxative and was approved by the FDA on August 5, 2010. SUPREP is indicated for bowel cleansing prior to an adult patient having a colonoscopy procedure.

20. Pursuant to 21 U.S.C. § 355 (b)(1) and attendant FDA regulations, the '149 patent has been listed in connection with SUPREP in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, which is referred to as the "Orange Book." SUPREP, or its use or formulation, is covered by one or more claims of the '149 patent.

THE '149 PATENT

21. Braintree is the lawful owner by assignment of the '149 patent, entitled "Salt Solution for Colon Cleansing," which was duly and legally issued by the U.S. Patent and Trademark Office on September 20, 2005. The '149 patent was the subject of an *ex parte* reexamination procedure that Braintree requested on October 15, 2008. A reexamination certificate was issued by the U.S. Patent and Trademark Office on June 30, 2009. As a result of the reexamination, it was determined that claims 1, 6, 8-9, 13-14, 17 and 21 were cancelled, claims 2-4, 7, 10, 15 and 18 were patentable as amended, and claims 5, 11-12, 16, 19-20 and 22-23, each dependent on an amended claim, were patentable. A true and correct copy of the '149 patent and its reexamination certificate are attached hereto as Exhibit A. The claims of the '149 patent are valid and enforceable.

22. The '149 patent, *inter alia*, claims compositions and methods for use of the compositions for inducing purgation of the colon.

23. The '149 patent will expire no earlier than March 7, 2023.

24. Braintree, as the owner of the entire right, title and interest in the '149 patent, possesses the right to sue for infringement of the '149 patent. The Federal Circuit has affirmed the validity of the '149 patent. *See Braintree Labs., Inc. v. Novel Labs., Inc.*, 749 F.3d 1349, 1358-60 (Fed. Cir. 2014).

INFRINGEMENT BY HETERO

25. By letter dated June 12, 2019 ("Hetero USA Notice Letter"), Hetero USA notified Braintree that Hetero USA, the U.S. Regulatory Agent for Hetero Unit-V, a division of Hetero Labs, had submitted ANDA No. 212903 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval, prior to the expiration of the '149 patent, to engage in the commercial manufacture, use, or sale and/or importation of the sodium sulfate, potassium sulfate and magnesium sulfate oral lavage solution currently listed in the Orange Book for SUPREP.

26. By letter dated June 13, 2019 ("Annora Notice Letter"), Annora notified Braintree that Annora had submitted ANDA No. 212903 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval, prior to the expiration of the '149 patent, to engage in the commercial manufacture, use, or sale and/or importation of the sodium sulfate, potassium sulfate and magnesium sulfate oral lavage solution currently listed in the Orange Book for SUPREP.

27. By filing ANDA No. 212903, Hetero has represented to the FDA that the components of its proposed generic magnesium sulfate anhydrous, potassium sulfate, and sodium sulfate for oral solution, respectively 1.6g/3.13g/17.5g per bottle, have the same active ingredients, the same route of administration, dosage form, and the same strengths as the corresponding components of SUPREP. Upon information and belief, Hetero has represented that its proposed

generic magnesium sulfate anhydrous, potassium sulfate, and sodium sulfate for oral solution is bioequivalent to SUPREP.

28. Hetero has committed an act of infringement, pursuant to 35 U.S.C. § 271(e)(2), by filing ANDA No. 212903 under 21 U.S.C. § 355(j) seeking approval to engage in the commercial manufacture, use and/or sale of such generic magnesium sulfate anhydrous, potassium sulfate, and sodium sulfate for oral solution before the expiration of the '149 patent.

29. Braintree is entitled under 35 U.S.C. § 271(e)(4) to full relief from Hetero's acts of infringement, including an Order by this Court ensuring that the effective date of any approval from the FDA of ANDA No. 212903, relating to Hetero's proposed generic oral solution, shall not be earlier than the expiration of the exclusivity afforded the '149 patent.

30. This Complaint is being filed before the expiration of the forty-five day period from the day after Braintree received the Hetero USA Notice Letter and the Annora Notice Letter. Braintree received the Hetero Notice Letter, which was dated June 12, 2019, on June 13, 2019. Braintree received the Annora Notice Letter, which was dated June 13, 2019, on June 13, 2019.

COUNT I (INFRINGEMENT OF THE '149 PATENT BY HETERO)

31. Each of the preceding paragraphs 1 through 30 is incorporated as if fully set forth.

32. Hetero's submission of ANDA No. 212903 to obtain approval to engage in the commercial manufacture, use, and/or sale of such magnesium sulfate anhydrous, potassium sulfate, and sodium sulfate for oral solution prior to the expiration of the '149 patent constitutes infringement of one or more of the claims of the '149 patent under 35 U.S.C. § 271(e)(2)(A).

33. Hetero offers no basis for noninfringement of the '149 patent in the Hetero USA Notice Letter or the Annora Notice Letter.

34. Upon information and belief, Hetero had actual and constructive knowledge of the '149 patent prior to filing ANDA No. 212903, and was aware that the filing of its ANDA with the FDA constituted an act of infringement of the '149 patent.

35. Upon information and belief, use of such generic magnesium sulfate anhydrous, potassium sulfate, sodium sulfate for oral solution would infringe one or more claims of the '149 patent.

36. Upon information and belief, Hetero knows that its generic magnesium sulfate anhydrous, potassium sulfate, sodium sulfate for oral solution, and the proposed labeling for that product, are especially made or adapted for use in infringing the '149 patent, and that the generic magnesium sulfate anhydrous, potassium sulfate, sodium sulfate for oral solution and the proposed labeling are not suitable for any substantial noninfringing use. Upon information and belief, Hetero plans and intends to infringe, and will induce and/or contribute to the infringement of, the '149 patent, immediately and imminently upon FDA approval of ANDA No. 212903.

37. Upon FDA approval of ANDA No. 212903, Hetero will infringe the '149 patent by making, using, offering to sell, and selling such generic magnesium sulfate anhydrous, potassium sulfate, sodium sulfate for oral solution in the United States and/or importing such solution into the United States, and by actively inducing and contributing to infringement by others, in violation of 35 U.S.C. § 271 (a)-(c), unless enjoined by the Court.

38. If infringement of the '149 patent by Hetero is not enjoined, Braintree will suffer substantial and irreparable harm for which there is no adequate remedy at law.

REQUEST FOR RELIEF

WHEREFORE, Braintree requests that this Court grant the following relief:

1. A judgment that one or more claims of the '149 patent are infringed by Hetero's submission of ANDA No. 212903, and that the making, using, offering to sell, or selling in the

United States, or importing into the United States, of the proposed generic magnesium sulfate anhydrous, potassium sulfate, sodium sulfate for oral solution by Hetero will infringe, actively induce infringement, and/or contribute to the infringement of the '149 patent;

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 212903 shall be a date which is not earlier than the expiration date of the '149 patent, including any extensions and/or additional periods of exclusivity to which Braintree is or becomes entitled;

3. An order permanently enjoining Hetero, its affiliates, subsidiaries, and each of its officers, agents, servants and employees, and those acting in privity or concert with it, from making, using, offering to sell, or selling in the United States, or importing into the United States, such generic magnesium sulfate anhydrous, potassium sulfate, sodium sulfate for oral solution until after the expiration date of the '149 patent, including any extensions and/or additional periods of exclusivity to which Braintree is or becomes entitled;

4. That Braintree be awarded its attorneys' and experts' fees and costs of this litigation; and

5. Such further relief as this Court deems proper and just, including but not limited to any appropriate relief under Title 35.

Dated: July 22, 2019

s/ Keith J. Miller
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LOCAL CIVIL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy in this case is not the subject of any action pending in any court, or of any pending arbitration or administrative proceeding, except for the prior matter *Braintree Laboratories, Inc. v. Lupin Atlantis Holdings SA*, Civil Action No. 2:11-cv-1341 (PS/LHG), which involves the same plaintiff and the same patent for the same drug product.

Dated: July 22, 2019

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