IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FRESENIUS KABI USA, LLC, *Plaintiff*, v. MEITHEAL PHARMACEUTICALS, INC., *Defendant*.	)	Civil Action No. _____

COMPLAINT

Fresenius Kabi USA, LLC ("Fresenius" or "Plaintiff") brings this action for patent infringement against Defendant Meitheal Pharmaceuticals, Inc. ("Meitheal" or "Defendant").

1. This is an action by Fresenius against Defendant for infringement of United States Patent No. 8,476,010 ("the '010 patent"). This action arises out of Defendant's filing of an Abbreviated New Drug Application ("ANDA") seeking approval by the United States Food and Drug Administration ("FDA") to sell a generic version of Diprivan®, an innovative intravenously administered sedative and anesthetic, prior to the expiration of the '010 patent.

THE PARTIES

Plaintiff

2. Fresenius is a Delaware limited liability company with its principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047. Fresenius was formerly known as APP Pharmaceuticals, LLC.

Defendant

3. Upon information and belief, Defendant Meitheal is a corporation organized and existing under the laws of Delaware, having a principal place of business at 8700 W. Bryn Mawr Avenue, Suite 600S, Chicago, IL 60631.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

4. This action for patent infringement arises under 35 U.S.C. § 271.

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

Personal Jurisdiction

6. Upon information and belief, this Court has personal jurisdiction over Defendant because, *inter alia,* it has maintained continuous and systematic contacts with the State of Delaware.

7. Upon information and belief, this Court also has personal jurisdiction over Defendant because, *inter alia*, it has committed, or aided, abetted, contributed to, or participated in the commission of, tortious conduct, which will lead to foreseeable harm and injury to Fresenius in the State of Delaware, and by doing so, Defendant has purposefully directed its activities at the residents of this forum.

8. Upon information and belief, this Court has personal jurisdiction over Defendant because it is incorporated in Delaware.

9. Upon information and belief, Defendant has previously availed itself of this Judicial District by not contesting personal jurisdiction in at least the following action: *Astellas US LLC et al. v. Meitheal Pharms., Inc.*, Civil Action No. 1:20-cv-01182-CFC (D. Del. filed Sept. 25, 2020).

10. Upon information and belief, Defendant has engaged in continuous and systematic contacts with the State of Delaware and/or purposefully has availed itself of this forum by, *inter alia*, making, marketing, shipping, using, offering to sell or selling Defendant's pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities.

11. Upon information and belief, Defendant has engaged in and maintained systematic and continuous business contacts within the State of Delaware, and has purposefully availed itself of the benefits and protections of the laws of the State of Delaware, rendering it at home in the State of Delaware.

12. Upon information and belief, Defendant operates as a single vertically-integrated business with respect to the regulatory approval, manufacturing, marketing, sale and distribution of pharmaceutical products throughout the United States, including in this Judicial District.

13. Upon information and belief, Defendant has committed, or aided, abetted, contributed to and/or participated in the commission of the tortious action of patent infringement that has led to foreseeable harm and injury to Fresenius, which sells Diprivan® for use throughout the United States, including the State of Delaware.

14. Upon information and belief, Defendant has applied for FDA approval to market and sell a generic version of Diprivan® throughout the United States, including the State of Delaware.

15. Defendant's submission of its ANDA to FDA evinces its intent to subject itself to the jurisdiction of the courts where the drug that is the subject of the ANDA will be sold, including in the State of Delaware.

16. Defendant sent a letter, dated August 11, 2023 ("First Notice Letter"), to Fresenius, a Delaware company, stating that Defendant had filed ANDA No. 217945 seeking FDA approval

to market generic Diprivan® products ("Defendant's generic Diprivan® products") prior to the expiration of the '010 patent.

17. Defendant sent a second letter, dated August 29, 2023 ("Second Notice Letter"), to Fresenius, a Delaware company, stating that Defendant had filed ANDA No. 217945 seeking FDA approval to market generic Diprivan® products ("Defendant's generic Diprivan® products") prior to the expiration of the '010 patent.

18. Upon information and belief, Defendant will market, sell and offer for sale Defendant's generic Diprivan® products in the State of Delaware following FDA approval of those products.

19. Upon information and belief, as a result of Defendant's marketing, selling, or offering for sale of Defendant's generic Diprivan® products in the State of Delaware, Fresenius will lose sales of Diprivan® and be injured in the State of Delaware.

20. This Court's exercise of jurisdiction over Defendant is fair and reasonable. Defendant is not burdened by litigating this suit in the State of Delaware. The State of Delaware has an interest in providing a forum to resolve Hatch-Waxman litigation, including in this case, because this case involves products that will be sold in the State of Delaware by Delaware-based companies and injury to Fresenius in the State of Delaware. This Court's exercise of jurisdiction serves the interests of the judicial system in efficient resolution of Hatch-Waxman litigation.

21. Upon information and belief, this Court has personal jurisdiction over Defendant for the reasons stated herein, including, *inter alia,* Defendant's activities in the forum, activities directed at the forum, and significant contacts with the forum, all of which render Defendant at home in the forum. Personal jurisdiction is proper at least under *Acorda Therapeutics Inc. v. Mylan Pharms. Inc.*, 817 F.3d 755 (Fed. Cir. 2016).

Venue

22. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391 and 1400(b).

23. Upon information and belief, Defendant has not contested venue in this Judicial District in at least the following action: *Astellas US LLC et al. v. Meitheal Pharms., Inc.*, Civil Action No. 1:20-cv-01182-CFC (D. Del. filed Sept. 25, 2020).

BACKGROUND

The Patent-in-Suit: United States Patent No. 8,476,010

24. The '010 patent, entitled "Propofol Formulations with Non-Reactive Container Closures," was duly and lawfully issued on July 2, 2013, to inventors Neil P. Desai, Andrew Yang, and Sherry Xiaopei Ci. The named inventors assigned the '010 patent to APP Pharmaceuticals, LLC, which later changed its name to Fresenius Kabi USA, LLC. Accordingly, Fresenius is the owner of all rights, title and interest in the '010 patent. The '010 patent will expire, with a period of pediatric exclusivity, on June 1, 2025. A true and accurate copy of the '010 patent is attached hereto as Exhibit A.

25. The '010 patent is listed in FDA's publication entitled, "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly referred to as "The Orange Book," with respect to Diprivan®.

26. On or about January 16, 2020, after the conclusion of *inter partes* review (and the appeal therefrom), the United States Patent and Trademark Office cancelled claims 1, 13-15, 17, 18, 20 and 24-28 of the '010 patent. Fresenius is not asserting any of claims 1, 13-15, 17, 18, 20 and 24-28 of the '010 patent in this action. The remaining claims of the '010 patent are, and remain, valid and enforceable.

The Diprivan® Drug Product

27. Fresenius currently sells, promotes, distributes and markets Diprivan® (propofol) injectable emulsion in the United States.

28. Diprivan® is indicated, generally speaking, for the induction and maintenance of general anesthesia and sedation in certain patient populations.

29. Fresenius holds an approved New Drug Application ("NDA") No. 19627, under Section 505(b) of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(a), for and in connection with the Diprivan® (propofol) injectable emulsion product containing 10 mg propofol per 1 mL of emulsion.

Defendant's ANDA

30. Defendant filed with the FDA an ANDA, under 21 U.S.C. § 355(j) ("Defendant's ANDA"), seeking approval to manufacture, use, offer for sale, sell in and import into the United States Defendant's generic Diprivan® products (Propofol Injectable Emulsion USP, 500 mg/50mL and 1000 mg/100 mL (each 10 mg/mL)), prior to the expiration of the '010 patent.

31. The FDA assigned Defendant's ANDA the number 217945.

32. Defendant filed with FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the claims of the '010 patent are invalid, unenforceable and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of Defendant's generic Diprivan® products ("Defendant's Paragraph IV Certification"). Defendant notified Fresenius of Defendant's Paragraph IV Certification in its First Notice Letter sent by Federal Express.

33. This action is being commenced within forty-five (45) days of Fresenius' receipt of Defendant's First Notice Letter and Defendant's Second Notice Letter.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 8,476,010 BY DEFENDANT

34. The allegations of paragraphs 1-33 are realleged and incorporated herein by reference.

35. Defendant has infringed the '010 patent by submitting and maintaining Defendant's ANDA to and before FDA seeking approval to market Defendant's generic Diprivan® products before the expiration of the '010 patent.

36. The use of Defendant's generic Diprivan® products is covered by one or more claims of the '010 patent literally and/or under the doctrine of equivalents.

37. Upon information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Defendant's generic Diprivan® products would infringe one or more claims of the '010 patent, for example, at least claim 21 of the '010 patent.

38. Claim 21, which depends directly from claim 1, claims and is directed to: a sterile pharmaceutical composition of propofol in a container, comprising: a container which includes a closure and a composition in the container, and the composition in the container comprising from 0.5% to 10% by weight propofol and from about 0 to about 10% by weight solvent for propofol, where when the composition in the container sealed with the closure is agitated at a frequency of 300-400 cycles/minute for 16 hours at room temperature, the composition maintains a propofol concentration (w/v) measured by HPLC that is at least 93% of the starting concentration (w/v) of the propofol; where the closure is selected from the group consisting of siliconized bromobutyl rubber, metal, and siliconized chlorobutyl rubber; and wherein the closure also comprises metal.

39. Upon information and belief, Defendant's generic Diprivan® products comprise: a sterile pharmaceutical composition of propofol in a container; a container which includes a closure and a composition in the container; a composition in the container comprising from 0.5% to 10%

by weight propofol and from about 0 to about 10% by weight solvent for propofol, where when the composition in the container sealed with the closure is agitated at a frequency of 300-400 cycles/minute for 16 hours at room temperature, the composition maintains a propofol concentration (w/v) measured by HPLC that is at least 93% of the starting concentration (w/v) of the propofol; a closure selected from the group consisting of siliconized bromobutyl rubber, metal, and siliconized chlorobutyl rubber; and wherein the closure also comprises metal.

40. Defendant's First Notice Letter does not contest, or otherwise assert any grounds challenging, the validity or enforceability of claim 21 of the '010 patent.

41. Defendant was aware of the '010 patent prior to the submission of Defendant's ANDA and was further aware that filing Defendant's ANDA with Defendant's Paragraph IV Certification constituted an act of infringement of the '010 patent.

42. Upon information and belief, Defendant intends to engage, or direct or induce others to engage, in the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Defendant's generic Diprivan® products immediately and imminently upon approval of Defendant's ANDA.

43. The foregoing actions by Defendant constitute and/or would constitute direct, induced and/or contributory infringement of the '010 patent.

44. Fresenius will be substantially and irreparably harmed by Defendant's infringing activities unless the Court enjoins those activities. Fresenius will have no adequate remedy at law if Defendant is not enjoined from the commercial manufacture, use, offer to sell, sale in and importation into the United States of Defendant's generic Diprivan® products.

COUNT II FOR DECLARATORY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 8,476,010 BY DEFENDANT

45. The allegations of paragraphs 1-44 are realleged and incorporated herein by reference.

46. Upon information and belief, Defendant plans to begin manufacturing, marketing, selling, offering to sell and/or importing Defendant's generic Diprivan® products soon after FDA approval of Defendant's ANDA.

47. Upon information and belief, such conduct will constitute direct or indirect infringement of one or more claims of the '010 patent under 35 U.S.C. § 271.

48. Defendant's infringing activity complained of herein is imminent and will begin following FDA approval of Defendant's ANDA.

49. As a result of the foregoing facts, there is a real, substantial and continuing justiciable controversy between Fresenius and Defendant as to liability for infringement of the '010 patent. Defendant's actions have created in Fresenius a reasonable apprehension of irreparable harm and loss resulting from Defendant's threatened imminent actions.

50. Fresenius will be irreparably harmed if Defendant is not enjoined from infringing the '010 patent.

PRAYER FOR RELIEF

WHEREFORE, Fresenius respectfully requests the following relief:

a. A judgment that Defendant's submission of Defendant's ANDA No. 217945 infringes one or more claims of the '010 patent and that the making, using, offering to sell or selling in the United States, or importing into the United States of Defendant's generic Diprivan® products prior to the expiration of the '010 patent will infringe one or more claims of the '010 patent;

b. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of Defendant's ANDA No. 217945 seeking approval to manufacture, use, offer for sale, sell in and import into the United States Defendant's generic Diprivan® products or any product or compound the use of which infringes the '010 patent, shall be a date that is not earlier than the expiration of the '010 patent, including any period of pediatric exclusivity;

c. An Order permanently enjoining Defendant and all persons acting in concert with Defendant from commercially manufacturing, using, offering for sale, selling, marketing, distributing or importing Defendant's generic Diprivan® products, or any other product or compound the use of which infringes the '010 patent, or inducing or contributing to the infringement of the '010 patent, until after the expiration of the '010 patent;

d. An Order enjoining Defendant and all persons acting in concert with Defendant from seeking, obtaining or maintaining approval of Defendant's ANDA No. 217945 before the expiration of the '010 patent;

e. An award of Fresenius' damages or other monetary relief to compensate Fresenius if Defendant engages in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into, the United States of Defendant's generic Diprivan® products, or any product or compound the use of which infringes the '010 patent, prior to the expiration of the '010 patent in accordance with 35 U.S.C. § 271(e)(4)(C);

f. An award of Fresenius' reasonable costs and expenses in this action; and

g. An award of any further and additional relief to Fresenius as this Court deems just and proper, including attorneys' fees under 35 U.S.C. § 285 if supported by the totality of the circumstances.

Dated: September 26, 2023

Respectfully submitted,

FARNAN LLP

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