UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

FRESENIUS KABI USA, LLC, *Plaintiff*, v. BioQ Pharma Incorporated *Defendant*.	)	Civil Action No. _____

COMPLAINT

Fresenius Kabi USA, LLC ("Fresenius" or "Plaintiff") brings this action for patent infringement against Defendant BioQ Pharma Incorporated ("BioQ" or "Defendant").

1. This is an action by Fresenius against BioQ for infringement of United States Patent No. 8,476,010 ("the '010 patent"). This action arises out of BioQ's filing of a New Drug Application ("NDA") 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

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

3. Upon information and belief, Defendant BioQ is a California corporation with its principal place of business at 185 Berry Street Suit 160, San Francisco, California 94107.

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 Over BioQ

6. Upon information and belief, this Court has personal jurisdiction over BioQ because BioQ, through its affiliates and/or agents, (1) has sought approval from the FDA to market and sell its proposed generic Diprivan® product throughout the United States, including in New Jersey; (2) conducts business in this Judicial District; and (3) has engaged in continuous and systematic contacts with New Jersey and/or purposefully availed itself of this forum by, among other things, contracting and related commercial activities related to the marketing, making, shipping, using, offering to sell or selling BioQ products in this Judicial District, and deriving substantial revenue from such activities.

7. Upon information and belief, BioQ has agreements with retailers, wholesalers or distributors providing for the distribution of its products in the State of New Jersey.

8. Upon information and belief, BioQ collaborates with Sandoz Inc. to distribute BioQ's generic version of Diprivan® in the United States, including in the State of New Jersey. As of the filing of this Complaint, BioQ's website states that "BioQ Pharma will market the Propofol infusion pharmaceutical through our commercial collaborators Sandoz (for U.S.)." Upon information and belief, Sandoz Inc. has a principal place of business located at 100 College Rd. West, Princeton, New Jersey 08540.

9. Upon information and belief, BioQ 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 manufactures Diprivan®, for sale and use throughout the United States, including the State of New Jersey.

10. Upon information and belief, BioQ has applied for FDA approval to market and sell a generic version of Diprivan® throughout the United States, including in New Jersey.

11. BioQ's submission of its NDA to the FDA evinces its intent to subject itself to the jurisdiction of the courts where the drug that is the subject of the NDA will be sold, including New Jersey.

12. On January 17, 2018, BioQ sent a letter to Fresenius stating that it had filed NDA No. 209809 seeking FDA approval to market a generic Diprivan® product prior to the expiration of the '010 patent.

13. Upon information and belief, BioQ will market, sell, and offer for sale its proposed generic version of Diprivan® in the State of New Jersey following FDA approval of that product.

14. Upon information and belief, as a result of BioQ's marketing, selling, or offering for sale of its generic version of Diprivan® in the State of New Jersey, Fresenius will lose sales of Diprivan® and be injured in the State of New Jersey.

15. This Court's exercise of personal jurisdiction over BioQ is fair and reasonable. BioQ is not burdened by litigating this suit in New Jersey. New Jersey has an interest in providing a forum to resolve Hatch-Waxman litigation, including this case, because this litigation involves products that will be sold in New Jersey by a New Jersey-based company and

injury to Fresenius in New Jersey. This Court's exercise of jurisdiction serves the interests of the judicial system in efficient resolution of litigation.

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

Venue

17. Venue is proper in this district under 28 U.S.C. § 1391 and 1400(b). *See, e.g.*, *Bristol-Myers Squibb Co. v. Mylan Pharms. Inc.*, C.A. No. 17-379-LPS, 2017 WL 3980155 (D. Del. Sep. 11, 2017).

18. Upon information and belief, BioQ has a regular and establish place of business in this Judicial District and has committed and/or will commit acts of infringement in this Judicial District..

19. BioQ has a regular and establish place of business in this Judicial District at least because, upon information and belief, it: (1) has sought approval from the FDA to market and sell its proposed generic Diprivan® in this Judicial District; (2) conducts business in this Judicial District; (3) has engaged in regular and established business contacts with New Jersey by, *inter alia*, , contracting and related commercial activities related to the marketing, making, shipping, using, offering to sell or selling BioQ products in this Judicial District, and deriving substantial revenue from such activities; and (4) has made agreements with retailers, wholesalers or distributors providing for the distribution of its products in the State of New Jersey.

BACKGROUND

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

20. 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 on June 1, 2025. A true and accurate copy of the ’010 patent is attached hereto as Exhibit A.

21. The ’010 patent is listed in the FDA publication “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly referred to as “The Orange Book” (“Orange Book”) with respect to Diprivan®.

The Diprivan® Drug Product

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

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

24. 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) in connection with the Diprivan® 1% (propofol) injectable emulsion product containing 10 mg propofol per 1 mL of emulsion.

The BioQ NDA

25. BioQ filed with the FDA an NDA under 21 U.S.C. § 355(b)(2) ("BioQ NDA") seeking approval to manufacture, use, offer for sale, sell in and import into the United States a propofol injectable emulsion containing 10 mg propofol per 1 mL of emulsion formulation in a 50 mL single-use dispenser ("BioQ's generic Diprivan® product") prior to the expiration of the '010 patent.

26. The FDA assigned the BioQ NDA the number 209809.

27. BioQ filed with the FDA, pursuant to 21 U.S.C. § 355(b)(2)(A)(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 BioQ's generic Diprivan® products ("BioQ's Paragraph IV Certification"). BioQ notified Fresenius of this certification, in a letter dated January 17, 2018 sent by U.S. Mail ("BioQ Notice Letter").

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

28. The allegations of paragraphs 1-27 are realleged and incorporated herein by reference.

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

30. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of BioQ's generic Diprivan® products would infringe one or more claims of the '010 patent.

31. BioQ has infringed the '010 patent by submitting and maintaining the BioQ NDA before the FDA seeking approval to market BioQ's generic Diprivan® products containing propofol before the expiration of the '010 patent.

32. BioQ was aware of the ’010 patent when engaging in these knowing and purposeful activities and was aware that filing BioQ’s NDA with the Paragraph IV Certification with respect to the ’010 patent constituted an act of infringement of the ’010 patent.

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

34. The foregoing actions by BioQ constitute and/or would constitute direct, induced and/or contributory infringement of the ’010 patent.

35. Upon information and belief, BioQ acted without a reasonable basis for believing that it would not be liable for infringing the ’010 patent, actively inducing infringement of the ’010 patent, and/or contributing to the infringement by others of the ’010 patent.

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

37. BioQ’s activities render this case an exceptional one, and Fresenius is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

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

38. The allegations of paragraphs 1-37 are realleged and incorporated herein by reference.

39. Upon information and belief, BioQ’s, in conjunction with one or more New Jersey based entities, plans to begin manufacturing, marketing, selling, offering to sell and/or

importing its generic Diprivan® products soon after FDA approval of BioQ's NDA.

40. Such conduct will constitute direct or indirect infringement of one or more claims of the '010 patent under 35 U.S.C. § 271.

41. BioQ's infringing patent activity complained of herein is imminent and will begin following FDA approval of BioQ's NDA.

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

43. Upon information and belief, BioQ will knowingly and willfully infringe the '010 patent.

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

PRAYER FOR RELIEF

WHEREFORE, Fresenius respectfully requests the following relief:

a. A judgment that BioQ's submission of BioQ's NDA No. 209809 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 BioQ's generic Diprivan® product prior to the expiration of the '010 patent will infringe of one or more claims of the patent;

b. An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of BioQ's NDA No. 209809 seeking approval to manufacture, use, offer for sale, sell in and import into the United States BioQ's generic Diprivan® product 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 patent;

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 BioQ'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 patent;

d. An Order enjoining Defendant and all persons acting in concert with Defendant from seeking, obtaining, or maintaining approval of the BioQ's NDA No. 209809 before the expiration of the '010 patent;

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

f. A judgment that this is an exceptional case and awarding Plaintiff its attorneys' fees under 35 U.S.C. § 285;

g. An award of Plaintiff's reasonable costs and expenses in this action; and

h. An award of any further and additional relief to Plaintiff as this Court deems just and proper.

Dated: March 1, 2018

Respectfully submitted,

/s/ Michael E. Patunas
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