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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

BAUSCH HEALTH IRELAND LIMITED, Plaintiff, v. APOTEX INC., Defendant.	Civil Action No. 19-14474 *Document Electronically Filed*

COMPLAINT

This is a patent infringement action brought by Plaintiff Bausch Health Ireland Limited ("Bausch Ireland") for infringement of U.S. Patent Nos. 7,780,987 (the "'987 Patent") and 8,323,692 (the "'692 Patent") (collectively "Patents-in-Suit") by Defendant Apotex Inc. ("Apotex" or "Defendant"), through the filing of Abbreviated New Drug Application ("ANDA") No. 213356 for the approval of Defendant's generic version of Plaintiff's Glumetza® products described therein. Plaintiff hereby alleges as follows:

THE PARTIES

1. Plaintiff Bausch Ireland is a private company incorporated in Ireland with its office located at 3013 Lake Drive, Citywest Business Campus, Dublin 24, Ireland.

2. On information and belief, defendant Apotex, is a corporation organized and existing under the laws of Canada, having a principal place of business at 150 Signet Drive, Toronto, Ontario, Canada M9L 1T9.

NATURE OF THE ACTION

3. This is a civil action for infringement of the Patents-in-Suit. This action arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq.

4. This action arises out of Apotex filing ANDA No. 213356 ("Apotex ANDA") including its "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging, *inter alia*, that the Patents-in-Suit are invalid, unenforceable, and or will not be infringed by the commercial manufacture, use, sale, or importations of the Apotex ANDA Products.

JURISDICTION AND VENUE

5. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over Apotex because, *inter alia*, the fact that it has committed, or aided, abetted, contributed to, and/or participated in the commission of, the tortious act of patent infringement that has led to foreseeable harm and injury to Plaintiff in this District.

7. This Court has personal jurisdiction over Apotex for the further reasons that, *inter alia*, Apotex (1) has substantial, continuous, and systematic contacts with this State, (2) markets, sells, and/or distributes generic pharmaceutical drug products to residents of this State, (3) intentionally markets and sells generic pharmaceutical drug products to residents of this State, (4) maintains a broad distributorship network within this State, and (5) enjoys substantial income from sales of its generic pharmaceutical products in this State.

8. Apotex has a past practice of consenting to personal jurisdiction in this Court for other litigation matters. For example, Apotex has consented to personal jurisdiction in this Court in *Novartis Pharm. Corp. v. Apotex Inc., et al.*, Civil Action No. 15-3634, *Dexcel Pharma Technologies Ltd*. v. *Apotex Corp., et al*., Civil Action No. 17-2423, and *Celgene Corporation v. Hetero Labs Limited, et al.*, Civil Action No. 17-3387.

9. On information and belief, Apotex Corp. is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 2400 North Commerce Parkway, Weston, Florida 33326.

10. Upon information and belief Apotex Corp. is the North American division of Apotex and is registered with the State of New Jersey as a drug wholesaler, under Registration No. 5003192.

11. Apotex through its subsidiraries and various agents (for example Apotex Corp.) offers generic pharmaceutical products for sale in New Jersey and elsewhere in the United States and earns revenue from the distribution and sale in New Jersey of its generic pharmaceutical products.

12. Upon information and belief, this Court has personal jurisdiction over Apotex because, on information and belief, Apotex will collaborate with Apotex Corp. for the purposes of marketing and selling the Apotex ANDA Products once approved by the FDA. Apotex directly or through its affiliates and agents, such as Apotex Corp., develops, formulates, synthesizes, manufactures, markets, imports, offers to sell, and/or sells pharmaceutical drug products including the Apotex ANDA Products in New Jersey.

13. In the alternative, Plaintiff is further informed and believes, and on that basis alleges, that this Court has personal jurisdiction over Apotex pursuant to Federal Rule of Civil

Procedure 4(k)(2) because Apotex has extensive contacts with the United States, including but not limited to the above-described contact, is not subject to jurisdiction in any particular state, and exercising jurisdiction over Apotex is consistent with the laws of the United States and the United States Constitution.

14. Venue is proper as to Apotex because it is a foreign defendant and can be sued in any district.

THE PATENTS-IN-SUIT

15. On August 4, 2010, the ’987 Patent entitled “Controlled Release Dosage Forms” was duly and legally issued. The named inventors of the ’987 Patent are Fang Zhou and Paul Maes. According to the Orange Book, the ’987 Patent expires on March 23, 2025. (A copy of the ’987 Patent is attached as Exhibit 1.)

16. On December 4, 2012, the ’692 Patent entitled “Controlled Release Dosage Forms” was duly and legally issued. The inventor of the ’692 Patent is Steven Frisbee. According to the Orange Book, the ’692 Patent expires on March 30, 2023. (A copy of the ’692 Patent is attached as Exhibit 2.)

17. Bausch Ireland is the assignee of the ’987 Patent and the ’692 Patent.

ACTS GIVING RISE TO THIS ACTION

18. Santarus Inc. holds the approved New Drug Application No. 21748 for Glumetza® 1 gm dosage strength.

19. Pursuant to 21 U.S.C. § 355(b)(1), the ’987 Patent and the ’692 Patent are listed in the Orange Book for Glumetza® 1 gm.

20. On information and belief, Apotex submitted the Apotex ANDA to the FDA seeking approval to engage in the commercial manufacture, use or sale of the Apotex 1000 mg Product, herein collectively referred to as the "Apotex ANDA Products."

21. Plaintiff received from Apotex a letter, dated May 14, 2019, (the "Apotex Notice Letter"), stating that Apotex had certified in the Apotex ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that the '987 and '692 Patents are invalid, or will not be infringed by the commercial manufacture, use, or sale of the Apotex ANDA Products (the "Paragraph IV Certification").

22. The Apotex ANDA refers to and relies upon the Glumetza® NDA and contains data that, according to Apotex, demonstrate the bioequivalence of the Apotex ANDA Products and Glumetza®.

23. This action was commenced by Plaintiff within 45 days of the date of receipt of the Apotex Notice Letter.

CLAIMS FOR RELIEF

COUNT I
(Infringement the '987 Patent)

24. Plaintiff realleges and incorporates by reference the allegations contained in the preceding paragraphs.

25. On information and belief, Apotex has infringed at least one claim of the '987 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Apotex ANDA, by which Apotex seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale within the United States, or importation into the United States of the Apotex ANDA Products prior to the expiration of the '987 Patent.

26. Moreover, if Apotex manufactures, uses, sells, offers for sale, or imports into the United States, the Apotex ANDA Products, or induces or contributes to any such conduct, prior to the expiration of the '987 Patent, including any applicable exclusivities or extensions, Apotex would further infringe (either literally or under the doctrine of equivalents) at least one claim of the '987 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

27. Plaintiff 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 the Apotex ANDA be a date that is not earlier than the expiration of the term of the '987 Patent, including any extension(s) granted by the United States Patent and Trademark Office ("PTO") pursuant to 35 U.S.C. §§ 154 or 156, or any late expiration of exclusivity for the '987 Patent to which Plaintiff is or becomes entitled.

28. Plaintiff will be substantially and irreparably harmed if Apotex is not enjoined from infringing the '987 Patent.

29. Plaintiff has no adequate remedy at law.

30. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT II
(Infringement of the '692 Patent)

31. Plaintiff realleges and incorporates by reference the allegations contained in the preceding paragraphs.

32. On information and belief, Apotex has infringed at least one claim of the '692 Patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting the Apotex ANDA, by which Apotex seeks approval from the FDA to engage in the commercial manufacture, use, offer to sell, sale within the United States, or importation into the United States of the Apotex ANDA Products prior to the expiration of the '692 Patent.

33. Moreover, if Apotex manufactures, uses, sells, offers for sale, or imports into the United States, the Apotex ANDA Products, or induces or contributes to any such conduct, prior to the expiration of the '692 Patent, including any applicable exclusivities or extensions, Apotex would further infringe (either literally or under the doctrine of equivalents) at least one claim of the '692 Patent under 35 U.S.C. § 271(a), (b), and/or (c).

34. Plaintiff 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 the Apotex ANDA be a date that is not earlier than the expiration of the term of the '692 Patent, including any extension(s) granted by the PTO pursuant to 35 U.S.C. §§ 154 or 156, or any late expiration of exclusivity for the '692 Patent to which Plaintiff is or becomes entitled.

35. Plaintiff will be substantially and irreparably harmed if Apotex is not enjoined from infringing the '692 Patent.

36. Plaintiff has no adequate remedy at law.

37. This case is exceptional, and Plaintiff is entitled to an award of attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff seeks relief as follows:

1. A judgment that Apotex has infringed one or more valid claims of the '987 and '692 Patents by submitting or causing to be submitted the Apotex ANDA to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of the Apotex ANDA Products before the expiration of the Patents-in-Suit;

2. A judgment pursuant to 35 U.S.C. § 271(e)(4)(B) for a preliminary and permanent injunction enjoining Apotex, its officers, agents, servants, employees, and those persons acting in

active concert or participation with all or any of them from manufacturing, using, offering to sell, or selling the Apotex ANDA Products within the United States, or importing the Apotex ANDA Products into the United States, prior to the expiration of the Patents-in-Suit;

3. A judgment ordering, that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of the Apotex ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '987 and/or '692 Patents, including any extensions;

4. A judgment declaring and enjoining Apotex, its officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from manufacturing, using, offering to sell, or selling the Apotex ANDA Products and any other product that infringes or induces or contributes to the infringement of one or more claims of the Patents-in-Suit prior to their expiration, including any exclusivities or extensions to which Plaintiff is or becomes entitled;

5. That Plaintiff be awarded damages for its costs, disbursements, expert witness fees, and attorneys' fees and costs incurred in prosecuting this action, for an exceptional case pursuant to 35 U.S.C. § 285 and as otherwise provided by law; and

6. Such other and further relief as the Court deems just and appropriate.

Dated: June 28, 2019
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.
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CERTIFICATION OF NON-ARBITRABILITY PURSUANT TO LOCAL CIVIL RULE 201.1(d)

Pursuant to Local Civil Rule 201.1(d), the undersigned counsel hereby certifies that this action seeks declaratory and injunctive relief and, therefore, is not subject to mandatory arbitration.

I certify under penalty of perjury that the foregoing is true and correct.

Dated: June 28, 2019
Newark, New Jersey

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