IN UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

APOTEX INC.	)	
	)	
Plaintiff,	)	
	)	
v.	)	Civil Action No.
	)	
DAIICHI SANKYO, INC.,	)	
	)	
and	)	
	)	
DAIICHI SANKYO CO., LTD.	)	
	)	
Defendants.	)	

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Apotex Inc. ("Apotex"), through counsel, hereby brings its Complaint for Declaratory Judgment against Daiichi Sankyo, Inc. and Daiichi Sankyo Co., Ltd. (collectively "Daiichi"), and alleges as follows:

INTRODUCTION

1. This is a declaratory judgment action seeking a declaration of non-infringement of United States Patent No. 6,878,703 ("the '703 patent") to enable Apotex to bring its generic 20/12.5 mg, 40/12.5 mg, or 40/25 mg olmesartan medoxomil/hydrochlorothiazide product ("Apotex's Proposed ANDA HCT Product") to market at the earliest possible date under the applicable statutory and FDA regulatory provisions and to allow the public to enjoy the benefits of generic competition for these products. *Apotex, Inc. v. Daiichi Sankyo Inc.*, N.D. Ill., Case No. 12-CV-09295 (SJC), is a similar pending case involving Apotex's generic 5mg, 20mg, or 40mg olmesartan medoxomil product. The Court of Appeals for the Federal Circuit recently held that Apotex's complaint in that case presents a justiciable case or controversy because "[u]nder the

statute that governs marketing approval of generic, Apotex has a concrete, potentially high-value stake in obtaining the judgment it seeks." *Apotex, Inc. v. Daiichi Sankyo Inc.*, 781 F.3d 1356 (Fed. Cir. 2015).

THE PARTIES

2. Apotex Inc. is a Canadian corporation having its principal place of business at 150 Signet Drive, Toronto, Ontario M9L 1T9, Canada.

3. On information and belief, Daiichi Sankyo, Inc. is a Delaware corporation with its principal place of business at Two Hilton Court, Parsippany, New Jersey 07054 and has a registered agent for service of process in Illinois, National Registered Agents Inc., located at 208 So. LaSalle St., Ste. 814, Chicago, Illinois 60604.

4. On information and belief, Daiichi Sankyo Co., Ltd. was formed as the result of a merger between Daiichi Pharmaceutical Co., Ltd. and Sankyo Co., Ltd.

5. On information and belief, Daiichi Sankyo Co., Ltd., is a Japanese corporation having its principal place of business at 3-5-1, Nihonbashi-honcho, Chuo-ku, Tokyo 103-8426, Japan.

6. On information and belief, Daiichi Sankyo Co., Ltd is the parent company of Daiichi Sankyo, Inc. and Daiichi Sankyo, Inc. operates as the U.S. headquarters of Daiichi Sankyo, Co., Ltd.

JURISDICTION AND VENUE

7. This Complaint arises under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq., as amended by the Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, 98 Stat. 1585 (1984 (codified as amended at 21 U.S.C. § 355)) (hereinafter "Hatch-Waxman Amendments"), and the Medicare Prescription Drug,

Improvement and Modernization Act of 2003, Pub. L. No. 108-173, 17 Stat. 2066 (2003) ("hereinafter "MMA"), based upon an actual controversy between the parties to declare that Apotex is free, upon approval by the FDA, to manufacture, use, market, sell, offer to sell, and/or import Apotex's Proposed ANDA HCT Product as described in ANDA 204261 upon the expiration of United States Patent No. 5,616,599 ("the '599 patent") and any applicable pediatric exclusivity.

8. This Court has original jurisdiction over the subject matter of these claims pursuant to 28 U.S.C. §§ 1331 and 1338(a).

9. Upon information and belief, Daiichi Sankyo Inc. is the U.S. subsidiary of Daiichi Sankyo Co. Ltd. that sells pharmaceutical products manufactured by Daiichi Sankyo Co. Ltd. in the U.S. and in this judicial district, and "forms the nucleus" of Daiichi Sankyo Co. Ltd.'s U.S. Operations. See website of Daiichi Sankyo Co., Ltd. attached hereto as **Exhibit A**.

10. This Court has personal jurisdiction over Daiichi Sankyo Inc. because it has designated an agent in this district for service of process. On information and belief, Daiichi Sankyo also has a regular and established regional sales office in the Chicago area and employs sales agents in Chicago to sell its pharmaceutical products in the Northern District of Illinois. See website of Daiichi Sankyo, Inc., attached as **Exhibit B**.

11. This Court has personal jurisdiction over Daiichi Sankyo Inc. and Daiichi Sankyo Co., Ltd. at least because of their continuous and systematic contacts with the state of Illinois, including conducting of substantial and regular business therein through marketing and sales of pharmaceutical products in Illinois, including but not limited to olmesartan medoxomil/hydrochlorothiazide products.

12. This Court has personal jurisdiction over Daiichi Sankyo Inc. because Daiichi Sankyo Inc., upon information and belief, directly or indirectly markets and sells pharmaceutical products throughout the United States and in this judicial district. Upon information and belief, Daiichi Sankyo Inc. purposefully has conducted and continues to conduct business in this judicial district, and this judicial district is a destination of Daiichi Sankyo Inc.'s pharmaceutical products. Upon information and belief Daiichi Sankyo Inc. has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by filing suit in this jurisdiction.

13. This court has personal jurisdiction over Daiichi Sankyo Co., Ltd. because, upon information and belief, Daiichi Sankyo Co., Ltd. is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products and directly, or through its wholly-owned subsidiaries, manufactures, markets and sells pharmaceutical drug products throughout the United States and in this judicial district. Upon information and belief, Daiichi Sankyo Co., Ltd has previously submitted to the jurisdiction of this Court and has further availed itself of this Court by filing suit in this jurisdiction.

14. Venue is proper in this District under 28 U.S.C. §§ 1391 (b), (c), 1400 (b) and/or 21 U.S.C. §355.

PATENT IN SUIT

15. On its face the '703 patent entitled "Pharmaceutical Composition" indicates it was issued by the United States Patent and Trademark Office on April 12, 2005. A copy of the '703 patent is attached as **Exhibit C**.

16. According to the records at the United States Patent and Trademark Office, Sankyo Company, Limited is the assignee of the '703 patent.

17. On information and belief, Daiichi Sankyo Co., Ltd. is the successor in interest to the '703 patent after the merger between Daiichi Pharmaceutical Co., Ltd. and Sankyo Co., Ltd.

18. On July 11, 2006, the term of every claim of the '703 patent was disclaimed. See Disclaimer, dated July 11, 2006, attached hereto as **Exhibit D**.

19. On April 13, 2009, the '703 patent expired for failure to pay maintenance fees. See United States Patent and Trademark Record, attached hereto as **Exhibit E**.

BACKGROUND

20. In December 2003, Congress passed the Medicare Modernization Act of 2003 ("MMA"). Title XI of that Act entitled "Access to Affordable Pharmaceuticals," which included a provision allowing an ANDA applicant to bring a declaratory judgment action for invalidity or non-infringement of an Orange Book listed patent if the NDA holder does not sue within 45 days of receiving notice of a Paragraph IV certification. 21 U.S.C. §355(j)(5)(C).

21. The MMA also added forfeiture provisions for the 180-day exclusivity to which a first generic ANDA filer might otherwise be entitled pursuant to the Hatch Waxman Act. 21 U.S.C. §355 (j)(5)(D). The forfeiture provision at issue here requires, *inter alia*, the entry of a judgment of non-infringement, unenforceability or invalidity with respect to the patents against which a first ANDA filer has filed a Paragraph IV certification, regardless of whether those patents are asserted against subsequent ANDA filers. 21 U.S.C. §355(j)(5)(D)(i)(I)(bb).

22. Upon information and belief, Daiichi Sankyo Inc. is the current holder of approved New Drug Application ("NDA") No. 21-532 for Benicar® HCT tablets containing 20 mg or 40 mg olmesartan medoxomil combined with 12.5 mg hydrochlorothiazide, or 40 mg of olmesartan medoxomil combined with 25 mg of hydrochlorothiazide.

23. Daiichi identified the '703 patent along with the '599 patent to the Food and Drug Administration ("FDA") for listing in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly referred to as the "Orange Book"), as patents to which "a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the

manufacture, use, or sale of the drug" products containing 20 mg or 40 mg olmesartan medoxomil combined with 12.5 mg hydrochlorothiazide, or 40 mg of olmesartan medoxomil combined with 25 mg of hydrochlorothiazide ("olmesartan medoxomil/hydrochlorothiazide products").

24. The '599 and '703 patents remain listed in the Orange Book with respect to NDA No. 21-532 and Daiichi maintains and continues to represent to the public that the '703 patent claims the drug approved in NDA 21-532 or a method of using that drug, and that a claim of patent infringement could reasonably be asserted against any unlicensed ANDA applicant who attempts to market a generic version of the drug prior to the delisting of the '703 patent. The FDA Orange Book also lists a six month pediatric exclusivity for the '599 patent, which upon information and belief will prevent ANDA filers from obtaining final FDA marketing approval for their generic olmesartan medoxomil/hydrochlorothiazide products until six months after the expiration of the '599 patent.

25. According to Orange Book listings, Benicar® HCT or treatments using Benicar® HCT are claimed in the '703 patent.

26. Apotex has submitted an Abbreviated New Drug Application ("ANDA") 204261 for Apotex's Proposed ANDA HCT Product. Apotex's ANDA seeks FDA approval for the commercial manufacture, use, importation, offer for sale and sale of its generic Apotex's Proposed ANDA HCT Product.

27. Apotex filed a certification under 21 U.S.C. §355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") certifying that the '703 patent will not be infringed by the manufacture, use, or sale of the Apotex's Proposed ANDA HCT Product.

28. In accordance with 35 U.S.C. §§355(j)(2)(B) and 21 C.F.R. §314.95, Apotex, on or about August 17, 2012, served Daiichi with a Notice Letter informing Daiichi of Apotex's ANDA

seeking approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of Apotex's Proposed ANDA HCT Product before the expiration of the '703 patent. Apotex's Notice Letter included a Paragraph IV certification, that the '703 patent would not be infringed by the manufacture, use, or sale of Apotex's Proposed ANDA HCT Product because the '703 patent expired in 2009 and the term of every claim had been disclaimed in 2007.

29. Apotex desires to bring its generic Apotex's Proposed ANDA HCT Product to market and to allow the public to enjoy the benefits of generic competition for these products at the earliest possible date under the applicable statutory and FDA regulatory provisions.

30. On information and belief, the earliest possible date that Apotex can obtain final FDA marketing approval for Apotex's Proposed ANDA HCT Product is upon the expiration of the '599 patent and any applicable pediatric exclusivity. However, unless more than 75 days before the expiration of the '599 patent and any applicable pediatric exclusivity, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the '703 patent is invalid or not infringed, Apotex will not be able begin marketing its ANDA Product upon the expiration of the '599 patent and any applicable pediatric exclusivity.

31. Upon information and belief, Matrix Laboratories Limited ("Matrix"), now Mylan Laboratories Limited ("Mylan"), and hereinafter referred to as Mylan, was the first generic ANDA applicant to have filed a Paragraph IV certification against both the '599 and '703 patents with respect to 20 mg or 40 mg olmesartan medoxomil combined with 12.5 mg hydrochlorothiazide, or 40 mg of olmesartan medoxomil combined with 25 mg of hydrochlorothiazide, challenging, *inter alia*, the validity of both patents. Daiichi filed suit against Mylan in the District of New Jersey for patent infringement, alleging that Mylan infringed the '599 patent, but on information and belief

did not assert the ’703 patent against Mylan in that lawsuit. Mylan initially filed counterclaims requesting a Declaratory Judgment that both the ’599 and ’703 patents were not infringed and invalid, but later amended its counterclaims and dropped the counterclaim relating to the ’703 patent because Mylan wanted to try to avoid obtaining a judgment of noninfringement or invalidity of that patent and thereby avoid a forfeiture event under 21 U.S.C. §355(j)(5)(D). Mylan failed in its Paragraph IV challenge to the validity of the ’599 patent, and in 2010, the Federal Circuit affirmed the validity of the ’599 patent in *Daiichi Sankyo Co. v. Matrix Labs.*, 619 F.3d 1346 (Fed. Cir. 2010).

32. After Mylan failed in its attempt to have the ’599 patent held invalid, Mylan’s Paragraph IV certification with respect to that patent in its ANDA for olmesartan medoxomil/hydrochlorothiazide products converted to a Paragraph III certification, which requires Mylan to wait until the expiration of the ’599 patent and any applicable pediatric exclusivity before it can market its generic olmesartan hct products.

33. On information and belief, despite Mylan’s failure to invalidate the ’599 patent, Mylan remains eligible for a 180-day first generic applicant exclusivity by virtue of Mylan’s Paragraph IV certification against the ’703 patent. As such, the FDA will be prohibited from granting final approval to Apotex to market Apotex’s Proposed ANDA HCT Product upon the expiration of the ’599 patent and any applicable pediatric exclusivity, unless more than 75 days before the expiration of the ’599 patent and any applicable pediatric exclusivity, a court enters a final decision from which no appeal (other than a petition to the Supreme Court for a writ of certiorari) has been or can be taken that the ’703 patent is invalid or not infringed. 21 U.S.C. §355(j)(5)(D)(i)(I)(bb)(AA). As such, unless the Court first declares the ’703 patent invalid, unenforceable or not infringed by Apotex’s Proposed ANDA HCT Product, Apotex will be

prohibited from selling that product until 180 days after Mylan chooses to market its generic product, thereby injuring Apotex by depriving it of sales revenue for that period of time and injuring the public by depriving the public of the benefit of the generic competition that would otherwise be provided by Apotex's Proposed ANDA HCT product.

34. On information and belief, no court has entered the "final decision" identified in 21 U.S.C. §355(j)(5)(D)(i)(I)(bb)(AA) with respect to the '703 patent. Upon information and belief, no court has entered a final decision from which an appeal has been or can be taken that the '703 patent is invalid or not infringed.

35. On information and belief, no court has signed a "settlement order or consent decree" identified in 21 U.S.C. §355(j)(5)(D)(i)(I)(bb)(BB) that enters final judgment which includes a finding that the '703 patent is invalid or not infringed.

COUNT I

DECLARATORY JUDGMENT OF NONINFRINGEMENT OF THE '703 PATENT

36. Apotex repeats and realleges each of the allegations in paragraphs 1-35 as if fully set forth herein.

37. Because the '703 patent has expired for failure to pay maintenance fees and every claim was disclaimed, the manufacture, marketing, use, offer for sale, sale and/or importation of the product that is the subject of Apotex's ANDA No. 204261 will not directly infringe, induce or contribute to the infringement by others of the claims of the '703 patent, nor are the claims of the '703 patent being infringed by the filing of Apotex's ANDA 204261.

38. There is a substantial and continuing controversy between Daiichi and Apotex and a declaration of rights is both necessary and appropriate to establish that Apotex does not infringe any valid or enforceable claim of the '703 patent and allow it to bring Apotex's Proposed ANDA

HCT Product to market upon the expiration of the ’599 patent and any applicable pediatric exclusivity.

39. But for Daiichi’s decision to list the ’703 patent in the Orange Book, FDA approval of Apotex’s Proposed ANDA HCT Product would not have been independently delayed by that patent. Apotex is being injured by Daiichi’s actions of requesting the FDA to list the ’703 patent in the FDA Orange Book and continuing said listing in the FDA Orange Book.

40. Apotex’s injury can be redressed by the requested relief: a declaratory judgment of noninfringement is necessary to cause forfeiture of first applicant Mylan’s exclusivity period, which otherwise will block final FDA marketing approval of Apotex’s ANDA even after the expiration of the ’599 patent and any applicable pediatric exclusivity. If Apotex is blocked by Mylan’s first applicant exclusivity, Apotex will be monetarily harmed, as it will lose sales of its ANDA product by virtue of not being able to enter the market at the earliest possible date under the applicable statutory and FDA regulatory provisions, and be deprived of an economic opportunity to compete in the market for olmesartan medoxomil/hydrochlorothiazide products

PRAYER FOR RELIEF

WHEREFORE, Apotex respectfully requests the Court to enter judgment as follows:

(A) Declaring that the claims of the ’703 patent have not been infringed by the filing of Apotex’s ANDA 204261;

(B) Declaring that the manufacture, marketing, use, offer for sale, sale and/or importation of the products that are the subject of Apotex’s ANDA 204261 have not infringed, do not infringe, and would not, if marketed, infringe or induce or contribute to the infringement by others of any claims of the ’703 patent;

(C) Declaring that the Food & Drug Administration may approve Apotex’s Abbreviated New Drug Application (No. 204261) concerning 20 mg or 40 mg olmesartan

medoxomil combined with 12.5 mg hydrochlorothiazide, or 40 mg of olmesartan medoxomil combined with 25 mg of hydrochlorothiazide tablets whenever that application is otherwise in condition for approval, without awaiting any further order, judgment, or decree of this Court; that the judgment entered in this case is a judgment reflecting a decision that the patent in suit is not infringed pursuant to 21 U.S.C. §355(j)(5)(B)(iii)(I)(aa); and that the thirty-month period referred to in 21 U.S.C. §355(j)(5)(B)(iii) and any other marketing exclusivity periods to which Defendants might otherwise be entitled (including any pediatric exclusivity) with respect to the ’703 patent are shortened to expire upon the date of entry of judgment in this case;

(D) Awarding Apotex its costs, expenses and reasonable attorneys’ fees pursuant to 35 U.S.C. §285;

(E) Awarding Apotex such other relief that the Court deems just and proper under the circumstances.

Respectfully submitted,

HUSCH BLACKWELL LLP

Date: April 27, 2015 By: s/Sherry L. Rollo

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