IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

SANDOZ INC.	)	
Plaintiff,	)	
v.	)	**Case No.** 2:16-cv-81 AWA/RJK
DAIICHI SANKYO COMPANY, LIMITED,	)	
Defendant.	)	

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Sandoz Inc. ("Sandoz"), through counsel, hereby brings its Complaint for Declaratory Judgment of Non-Infringement against Daiichi Sankyo Company, Limited ("Daiichi Sankyo Co., Ltd." or "Daiichi"), and alleges as follows:

INTRODUCTION

1. This case arises under the Hatch-Waxman Act, which governs the U.S. Food and Drug Administration's ("FDA's") approval of both new and generic drugs. *See* 21 U.S.C. § 355 and 35 U.S.C. §§ 156 and 217(e). A critical feature of the Hatch-Waxman Act, relevant here, is its provision that, *inter alia*, an Abbreviated New Drug Application ("ANDA") holder can bring a declaratory judgment action seeking a declaration that a patent listed in the FDA's *Approved Drug Products with Therapeutic Equivalence Evaluations* (commonly referred to as the "Orange Book") will not be infringed by the ANDA holder's proposed drug product. *See* 21 U.S.C. § 355(j)(5)(C)(i)(I)(aa)-(cc).

2. Sandoz has submitted an ANDA with the FDA seeking approval to manufacture and sell a generic version of Daiichi's Benicar® olmesartan medoxomil tablets, 5 mg., 20 mg, 40 mg., *i.e.*, "Sandoz's ANDA products".

3. Daiichi caused two patents to be listed in the FDA's Orange Book as covering Benicar®: Daiichi's U.S. Patent No. 5,616,599 ("the '599 patent") and Daiichi's U.S. Patent No. 6,878,703 ("the '703 patent"). As a result, under the Hatch-Waxman Act, Sandoz was required to submit patent certifications to the '599 and '703 patents.

4. Sandoz's ANDA contains a paragraph III certification to Daiichi's '599 patent certifying that Sandoz will wait until the expiration of the '599 patent and any applicable pediatric exclusivity, *i.e.*, on October 25, 2016, to market Sandoz's ANDA products. Sandoz's ANDA also contains a paragraph IV certification that Sandoz's ANDA products will not infringe Daiichi's '703 patent as a matter of law because Daiichi statutorily disclaimed every claim of the '703 patent. *See Apotex, Inc. v. Daiichi Sankyo, Inc. et al.*, 781 F.3d 1356, 1359 (Fed. Cir. 2015), Case No. 15-281, *cert. denied*, 136 S. Ct. 481 (Nov. 9, 2015), and *cert. denied sub nom. Mylan Pharm. Inc. v. Apotex, Inc.*, 136 S. Ct. 485 (Nov. 9, 2015), attached as **Exhibit A,** *see also* 35 U.S.C. § 253 (statutory disclaimers).

5. In late December 2015, Sandoz notified Daiichi of the paragraph IV certification for the '703 patent that is the basis for this declaratory judgment action and provided an Offer of Confidential Access to its ANDA. Daiichi did not sue Sandoz for patent infringement within 45 days of receiving notice of Sandoz's paragraph IV certification. 21 U.S.C. § 355(j)(5)(C).

6. Accordingly, Sandoz filed this declaratory judgment action seeking a declaration that Sandoz's ANDA products will not infringe the '703 patent as a matter of law to enable Sandoz to bring its products to market at the earliest possible date allowed under applicable statutory and FDA regulatory provisions. 21 U.S.C. § 355(j)(5)(c).

7. It is undisputed that Sandoz's ANDA products do not infringe the '703 patent as a matter of law. In a recent declaratory judgment case involving the '703 patent, the Federal

Circuit held: "non-infringement of the '703 patent follows as a matter of law from the fact that Daiichi has formally disclaimed it." *Apotex, Inc. v. Daiichi Sankyo, Inc. et al.*, 781 F.3d 1356, 1359 (Fed. Cir. 2015), Ex. A.

8. Even though non-infringement is beyond dispute, there is a substantial and continuing controversy between the parties and a declaration of rights is both necessary and appropriate.

9. Daiichi's listing of the '703 patent in the Orange Book has resulted in another ANDA filer claiming that it is entitled to 180 days of marketing exclusivity for being the first paragraph IV filer for the '703 patent.

10. As a result, even though Sandoz's ANDA has received tentative approval from the FDA and Sandoz's ANDA products will not infringe the '703 patent as a matter of law, Sandoz's ANDA may not receive final FDA approval upon the expiration of the '599 patent and any applicable pediatric exclusivity on October 25, 2016, because of the first ANDA filer's claim to 180-day marketing exclusivity.

11. A first filer's 180-day marketing exclusivity is not absolute. The Medicare Modernization Act of 2003 ("MMA") sets forth certain forfeiture provisions by which a first filer can forfeit its exclusivity.

12. The forfeiture provision at issue here requires, *inter alia*, the entry of a final judgment of non-infringement or invalidity with respect to the patents against which a first ANDA filer has filed and lawfully maintained 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)(AA).

13. Sandoz's declaratory judgment action is necessary to remove the '703 patent as a barrier to Sandoz's market entry because but for Daiichi's decision to cause the now disclaimed '703 patent to be listed in the Orange Book, final FDA approval of Sandoz's ANDA products would not be independently delayed by the '703 patent. Put differently, but for Daiichi's listing of the '703 patent in the FDA's Orange Book, the FDA could grant final approval to Sandoz's ANDA upon the expiration of the '599 patent and any applicable pediatric exclusivity, on October 25, 2016.

14. Sandoz is being injured by Daiichi's listing and continued listing of the '703 patent in the FDA's Orange Book because if Sandoz's ANDA is blocked by 180-day marketing exclusivity, Sandoz 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 5 mg, 20 mg, and 40 mg tablets.

15. Subject matter jurisdiction exists in this case. The Court of Appeals for the Federal Circuit held in a declaratory judgment action filed by Apotex, Inc. ("Apotex") against Daiichi involving Apotex's olmesartan medoxomil drug product and the '703 patent: "The ['703] patent disclaimer eliminates one, but only one, potential legal barrier to Apotex's ability to make such sales sooner rather than later. The *listing* of the patent, with its current consequence of preventing FDA approval during Mylan Pharmaceuticals Inc.'s [first-filer] presumptive exclusivity period, is another, and the parties have adverse concrete interests in the truncation or preservation of that period." *Apotex, Inc. v. Daiichi Sankyo, Inc.*, 781 F.3d 1356, 1362 (Fed. Cir. 2015) (emphasis in original), Ex. A; *see also Glenmark Generics Ltd. v. Ferring B.V.*, No. 3:14CV422-HEH, 2014 WL 5162097, at *4-6 (E.D. Va. Oct. 14, 2014).

16. The Court further held: "[t]he stakes over which the parties are vigorously fighting are concrete and substantial: the amount of revenue there will be from sales of olmesartan medoxomil, and who will get what portions of it, during a period of at least six months. We conclude that the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Apotex, Inc.*, 781 F.3d at 1361-62 (citations omitted), Ex. A.

17. Relying on the Federal Circuit's decision, Judge Coleman of the Northern District of Illinois recently entered summary judgment that Apotex's proposed olmesartan medoxomil ANDA products do not infringe the '703 patent as a matter of law. *Apotex, Inc. v. Daiichi Sankyo, Inc.*, No. 12-CV-9295, 2016 WL 98572, at *1 (N.D. Ill. Jan. 8, 2016), attached as **Exhibit B**.

18. Sandoz's complaint seeks the same judgment: Sandoz's ANDA products do not infringe the '703 patent as a matter of law, thus enabling Sandoz to bring its ANDA products to market at the earliest possible date allowed under applicable statutory and FDA regulatory provisions.

THE PARTIES

19. Sandoz Inc. is a corporation organized under the laws of Colorado, having a principal place of business at 100 College Road West, Princeton, New Jersey 08540.

20. 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.

21. 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.

JURISDICTION AND VENUE

22. 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, 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 Sandoz is free, upon approval by the FDA, to manufacture, use, market, sell, offer to sell, and/or import its proposed Sandoz's ANDA products as described in its ANDA No. 90237 at the earliest possible date under applicable statutory and FDA regulatory provisions, *i.e.*, on or about October 25, 2016, upon the expiration of the '599 patent and any applicable pediatric exclusivity.

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

24. This Court has personal jurisdiction over Daiichi under 35 U.S.C. § 293, which provides that in cases involving a patentee not residing in the United States, the United States District Court for the Eastern District of Virginia "shall have the same jurisdiction to take any action respecting the patent or rights thereunder that it would have if the patentee were personally within the jurisdiction of the court," assuming that "no person" has been designated to "the Patent and Trademark Office . . . on whom may be served process or notice of proceedings

affecting the patent or rights thereunder." Daiichi does not reside in the United States and has not designated an agent to accept service of process as provided by 35 U.S.C. § 293.[1]

25. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), (c), 1400 (b), 35 U.S.C. § 293 and/or 21 U.S.C. § 355.

PATENT IN SUIT

26. 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**.

27. On information and belief, at the time it issued, the '703 patent was assigned to Sankyo Company, Limited, a Japanese company.

28. On information and belief, Sankyo Company, Limited was merged with Daiichi Pharmaceutical Co., Ltd. to form Daiichi Sankyo Co., Ltd.

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

30. On July 11, 2006, every claim of the '703 patent was disclaimed. *See* Disclaimer, attached hereto as **Exhibit D;** *see also Apotex, Inc. v. Daiichi Sankyo, Inc. et al.*, 781 F.3d 1356, 1359 (Fed. Cir. 2015), Ex. A.

31. According to the status date at the United States Patent and Trademark Office Record, on or about April 12, 2009, the '703 patent expired for failure to pay maintenance fees. *See* United States Patent and Trademark Record, attached hereto as **Exhibit E**.

[1] Sandoz has filed a declaratory judgment suit in District of New Jersey seeking the same relief that it seeks here. This action is being filed as a protective action because personal jurisdiction over Daiichi Sankyo Co., Ltd. is undisputable in this District under 35 U.S.C. § 293.

LEGAL FRAMEWORK AND FACTUAL BACKGROUND

A. The Hatch-Waxman Act and the MMA

32. In 1984, Congress passed the Drug Price Competition and Patent Term Restoration Act, commonly referred to as the Hatch-Waxman Act. *See* 21 U.S.C. § 355 and 35 U.S.C. §§ 156 and 271(e). The Hatch-Waxman Act was intended to encourage generic-drug competition while leaving intact incentives for research and development of new drugs by pioneering, *i.e.*, "branded," drug companies. *See* H.R. Rep. No. 98-857, pt. 1, at 14-15 (1984), reprinted in 1984 U.S.C.C.A.N. 2647, 2648.

33. Pursuant to the Hatch-Waxman Act, a brand-name drug sponsor seeking FDA approval of a new drug must submit a New Drug Application ("NDA"). *See* 21 U.S.C. § 355. The NDA holder must inform the FDA of every patent that claims the "drug" or "method of using [the] drug" for which a claim of patent infringement could reasonably be asserted against unlicensed manufacture, use, or sale of that drug product. *See* 21 U.S.C. § 355(b)(1); *see also* 21 U.S.C. § 355(c)(2); 21 C.F.R. §§ 314.53(b) and 314.53(c)(2). Upon approval of the NDA, the FDA publishes a listing of patent information for the approved drug in the FDA's Orange Book. *See* 21 U.S.C. § 355(b)(1)(G). The new FDA-approved drug is known as the "reference-listed drug" or "RLD."

34. The Hatch-Waxman Act provides a streamlined process for approving generic drugs. Before marketing a generic version of an FDA-approved drug, a generic-drug manufacturer must submit an ANDA to the FDA seeking approval to market a generic version of the RLD. *See* 21 U.S.C. § 355(j)(4)(F).

35. An ANDA must contain one of four certifications for each patent listed in the Orange Book for the RLD: (i) that there are no patents listed in the Orange Book; (ii) that any listed patent has expired; (iii) that the patent will expire before the generic manufacturer is

seeking to market its generic product; or (iv) that the patent is invalid, unenforceable or will not be infringed by the manufacture, use or sale of the generic drug for which the ANDA is submitted. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(I-IV); 21 C.F.R. § 314.94(a)(12). The last of these is commonly referred to as a "paragraph IV certification."

36. An ANDA applicant who files a paragraph IV certification must notify both the patent holder and NDA holder of its paragraph IV certification. *See* 21 U.S.C. § 355(j)(2)(B)(i).

37. The first company to file and lawfully maintain an ANDA with a paragraph IV certification to an Orange Book listed patent is eligible for a 180-day period of generic marketing exclusivity from the date of its "first commercial marketing" of the drug product before other generic companies will be approved by the FDA to enter the market. 21 U.S.C. § 355(j)(5)(B)(iv).

38. Pursuant to the MMA amendments, the 180-day exclusivity period can be forfeited. The forfeiture provision at issue here requires, *inter alia*, the entry of a final judgment of non-infringement or invalidity with respect to the patent against which a first ANDA filer submitted and lawfully maintained a paragraph IV certification qualifying it for 180-day marketing exclusivity. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb).

39. Pursuant to the MMA amendments, an ANDA applicant may bring a declaratory judgment action for invalidity or non-infringement of an Orange Book listed patent if the NDA holder does not sue the ANDA holder within 45 days of receiving notice of the ANDA holder's paragraph IV certification. 21 U.S.C. § 355(j)(5)(C).

B. Daiichi lists the '703 patent in the FDA's Orange Book for Benicar®

40. On information and belief, Daiichi Sankyo, Inc. is the current holder of approved NDA No. 21-286 for Benicar® tablets containing olmesartan medoxomil 5 mg, 20 mg, and 40

mg tablets. Daiichi and Daiichi Sankyo, Inc. market olmesartan medoxomil products, including Benicar®, for treating hypertension.

41. On information and belief, in connection with the Benicar® NDA, Daiichi caused or authorized Daiichi's '599 and '703 patents to be listed in the FDA's 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 olmesartan medoxomil 5 mg, 20 mg, and 40 mg tablets ("olmesartan medoxomil products"). 21 U.S.C. § 355(b)(1). The '599 and '703 patents remain listed in the Orange Book for Benicar®.

42. Daiichi's '599 patent covers the active ingredient of the drug, olmesartan medoxomil, in Benicar®. It expires on April 25, 2016. The FDA Orange Book lists a six-month pediatric exclusivity for the '599 patent, which on information and belief will prevent ANDA filers from obtaining final FDA approval until six months after the expiration of the '599 patent, *i.e.*, on or about October 25, 2016. Daiichi's '703 patent covers methods of treatment with Benicar®.

C. Mylan files the first paragraph IV certification for Benicar®

43. On information and belief, in April 2006, Matrix Laboratories Limited, which is now Mylan Pharmaceuticals Inc. ("Mylan"), was the first generic ANDA applicant to file a paragraph IV certification against both the '599 and '703 patents for Benicar® challenging, *inter alia*, the validity of both patents.

44. In July 2006, after receiving notice of Mylan's paragraph IV certification, Daiichi disclaimed all claims of the '703 patent. *See* 35 U.S.C. § 253. Daiichi Sankyo, Inc. subsequently requested that the FDA delist the '703 patent from the Orange Book. The '703 patent remains listed in the Orange Book for Benicar®.

45. On information and belief, the FDA continues to list the '703 patent in the Orange Book because it cannot delist a patent at the request of the NDA holder or patentee if the patent is the basis for an ANDA holder's claim to 180-day marketing exclusivity. *Apotex, Inc. v. Daiichi Sankyo, Inc.*, 781 F.3d at 1359, 1362, Ex. A.

46. On July 31, 2006, Daiichi sued Mylan in the District of New Jersey for patent infringement of the '599 patent; it did not assert infringement of the '703 patent. 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), attached as **Exhibit F**.

47. Because Mylan failed to invalidate the '599 patent, Mylan's paragraph IV certification with respect to that patent 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 products. On information and belief, the earliest date that the FDA can grant final approval to Mylan's ANDA is October 25, 2016.

48. On information and belief, despite Mylan's failure to invalidate the '599 patent, Mylan is eligible for 180-day marketing exclusivity by virtue of being the first to file and maintain a paragraph IV certification against the '703 patent. As such, the FDA currently cannot give final approval to any other ANDA holder unless Mylan forfeits its exclusivity.

49. Mylan may forfeit its exclusivity if more than 75 days before October 25, 2016, an ANDA holder has tentative FDA approval, and in a declaratory judgment action 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).

50. Mylan also may forfeit its exclusivity if more than 75 days before October 25, 2016, an ANDA holder has tentative FDA approval, and in a declaratory judgment action a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the '703 patent is invalid or not infringed. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(BB).

D. Sandoz applies for FDA approval to market its olmesartan medoxomil tablets

51. Sandoz has submitted ANDA No. 90237 for a proposed drug product containing 5 mg, 20 mg, or 40 mg olmesartan medoxomil, *i.e.*, Sandoz's ANDA Product. Sandoz's ANDA seeks FDA approval for the commercial manufacture, use, importation, offer for sale and sale of generic olmesartan medoxomil 5 mg, 20 mg, and 40 mg tablets.

52. Sandoz's ANDA contains a paragraph III certification for the '599 patent certifying that Sandoz will wait until the expiration of the '599 patent and any applicable pediatric exclusivity to market its ANDA products, and a paragraph IV certification certifying that the '703 patent will not be infringed by the manufacture, use, or sale of Sandoz's ANDA Products.

53. Sandoz filed its first paragraph IV certification for the '703 patent on May 27, 2008. In accordance with 35 U.S.C. §§ 355(j)(2)(B)(i) and 21 C.F.R. § 314.95, Sandoz notified Daiichi and Daiichi Sankyo, Inc. of Sandoz's ANDA and paragraph IV certification seeking approval to engage in the commercial manufacture, use, importation, offer for sale, or sale of Sandoz's ANDA products before the expiration of the '703 patent.

54. Sandoz's notice letter contained a detailed statement informing Daiichi and Daiichi Sankyo, Inc. that Sandoz's ANDA products did not infringe the '703 patent because its products did not contain one of the '703 patent's claim limitations that was in all of the patent's

claims. Sandoz reserved its right to allege the same, similar, different or new theories of non-infringement and/or invalidity. Daiichi did not sue Sandoz for infringement of the '703 patent.

55. On December 29, 2015, in view of the Federal Circuit's decision and Supreme Court's denial of certiorari of that decision in *Apotex v. Daiichi*, Sandoz amended its ANDA and filed the paragraph IV certification that is the basis for this declaratory judgment action. *Apotex, Inc. v. Daiichi Sankyo, Inc. et al.*, 781 F.3d 1356, 1359 (Fed. Cir. 2015), Case No. 15-281, *cert. denied*, 136 S. Ct. 481 (Nov. 9, 2015), and *cert. denied sub nom. Mylan Pharm. Inc. v. Apotex, Inc.*, 136 S. Ct. 485 (Nov. 9, 2015), Ex. A.

56. Pursuant to 21 U.S.C. § 355(j)(2)(B)(i), Sandoz notified Daiichi and Daiichi Sankyo, Inc. of its paragraph IV certification by sending a notice letter to Daiichi and Daiichi Sankyo, Inc. and its counsel via certified mail/return receipt requested and to Daiichi Sankyo Co., Ltd., via Federal Express, with a detailed statement of the legal and factual basis for Sandoz's paragraph IV certification. Sandoz's notice letter informed Daiichi and Daiichi Sankyo, Inc. that the manufacture, use, or sale of Sandoz's ANDA Products will not infringe the '703 patent as a matter of law because the '703 patent had been disclaimed in its entirety and the patent expired for failure to pay maintenance fees. *See Apotex, Inc. v. Daiichi Sankyo, Inc. et al.*, 781 F.3d 1356, 1359 (Fed. Cir. 2015), Ex. A.

57. Sandoz's notice letter included an Offer of Confidential Access ("OCA") to its ANDA.

58. Daiichi Sankyo, Inc., received Sandoz's notice letter on January 4, 2016. Daiichi Sankyo Co., Ltd., received Sandoz's notice letter on January 5, 2016.

E. Daiichi did not sue Sandoz for infringement of the '703 patent

59. Under the MMA, *inter alia*, an ANDA applicant who notifies the patent owner and the NDA holder that it has filed a paragraph IV certification for an Orange Book listed patent and includes an OCA to its ANDA may bring a declaratory judgment action against the patent owner or NDA holder that the patent is invalid or will not be infringed if the NDA holder and/or patent owner do not sue for infringement within 45 days of receiving notice of the ANDA holder's paragraph IV certification. 21 U.S.C. § 355(j)(5)(C).

60. Neither Daiichi nor Daiichi Sankyo, Inc. requested access to Sandoz's ANDA and neither filed suit against Sandoz for infringement of the '703 patent within the statutory 45-day period as set forth in 21 U.S.C. § 355(c)(3)(C).

61. Accordingly, Sandoz filed this declaratory judgment action for non-infringement of the '703 patent pursuant to 21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5) to enable Sandoz to remove the '703 patent as a barrier to market entry so that Sandoz may get final FDA approval to market and sell its noninfringing olmesartan medoxomil tablets at the earliest possible date allowed under applicable statutory and FDA regulatory provisions, *i.e.,* October 25, 2016.

F. Final FDA approval of Sandoz's ANDA is blocked by Daiichi's listing of the '703 patent in the Orange Book

62. Sandoz's ANDA has received tentative FDA approval. *See* **Exhibit G.**

63. Sandoz desires to bring Sandoz's ANDA products to market at the earliest possible date allowed under the applicable statutory and FDA regulatory provisions.

64. On information and belief, currently the earliest possible date that Sandoz can obtain final FDA approval is upon the expiration of the '599 patent and any applicable pediatric exclusivity.

65. Sandoz may not be able to receive final FDA approval upon the expiration of the '599 patent and any applicable exclusivity, however, unless Mylan forfeits its 180-day marketing exclusivity.

66. Mylan can forfeit its exclusivity if more than 75 days before the expiration of the '599 patent and any applicable pediatric exclusivity, a court enters a final court 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).

67. Alternatively, Mylan can forfeit its exclusivity if more than 75 days before the expiration of the '599 patent and any applicable pediatric exclusivity, a court signs a settlement order or consent decree that enters a final judgment that includes a finding that the patent is invalid or not infringed. 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(BB)

68. As such, absent a court declaration that the '703 patent is not infringed, Sandoz may be unable to sell its non-infringing olmesartan medoxomil products until 180 days after Mylan chooses to market its olmesartan medoxomil products, thereby injuring Sandoz by depriving it of sales revenue that it could earn for that period of time.

69. 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).

70. 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).

71. As alleged *supra*, Judge Coleman of the Northern District of Illinois has entered summary judgment that Apotex's ANDA products do not infringe the '703 patent, but that

judgment is not yet a "final decision" as set forth in 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA). Moreover, on information and belief, Apotex does not have tentative approval.

COUNT I

DECLARATORY JUDGMENT OF NON-INFRINGEMENT OF THE '703 PATENT

72. Sandoz repeats and realleges each of the allegations in paragraphs 1-71 as if fully set forth herein.

73. Because Daiichi statutorily disclaimed each and every claim of the '703 patent and because the '703 patent has expired for failure to pay maintenance fees, the manufacture, marketing, use, offer for sale, sale, and/or importation of the product that is the subject of Sandoz's ANDA No. 90237 will not as a matter of law 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 Sandoz's ANDA 90237.

74. There is a substantial and continuing controversy between Daiichi and Sandoz and a declaration of rights is both necessary and appropriate to establish that Sandoz does not infringe any valid or enforceable claim of the '703 patent and to allow Sandoz to bring its ANDA products to market upon the expiration of the '599 patent and any applicable pediatric exclusivity.

75. But for Daiichi's decision to list the '703 patent in the Orange Book, final FDA approval of Sandoz's ANDA would not have been independently delayed by that patent. Sandoz is being injured by Daiichi's actions of requesting the FDA to list the '703 patent in the FDA Orange Book and the continued listing of the '703 patent in the FDA Orange Book.

76. Sandoz's injury can be redressed by the requested relief: a declaratory judgment of non-infringement would trigger first applicant Mylan's 180-day exclusivity period, which otherwise may block final FDA marketing approval of Sandoz's ANDA even after the expiration

of the '599 patent and any applicable pediatric exclusivity. If Sandoz is blocked by Mylan's 180-day exclusivity, Sandoz will be monetarily harmed as it will lose sales of Sandoz's ANDA products by virtue of not being able to enter the market and sell its noninfringing products 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 5 mg, 20 mg, and 40 mg tablets.

PRAYER FOR RELIEF

WHEREFORE, Sandoz 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 Sandoz's ANDA 90237;

B. Declaring that the manufacture, marketing, use, offer for sale, sale, and/or importation of the products that are the subject of Sandoz's ANDA 90237 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. Awarding Sandoz its costs, expenses and reasonable attorneys' fees pursuant to 35 U.S.C. § 285;

D. Awarding Sandoz such other relief that the Court deems just and proper under the circumstances.

WINSTON & STRAWN LLP
Attorneys for Plaintiff
Sandoz Inc.

By: _____
Andrew R. Sommer (VSB # 70304)
asommer@winston.com
Winston & Strawn LLP
1700 K Street, N.W.

Washington, D.C. 20006-3817
1 (202) 282-5000

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OF COUNSEL:

Maureen Rurka
Lynn M. Ulrich
Joanna Cornwell
WINSTON & STRAWN LLP
35 West Wacker Drive
Chicago, Illinois 60601
(312) 558-5600