UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

APOTEX INC.	)	
	)	
Plaintiff,	)	
	)	**Civil Action No. _____**
v.	)	
	)	
FOREST LABORATORIES, INC., FOREST LABORATORIES HOLDINGS, LTD. and H. LUNDBECK A/S	)	
	)	
Defendants.	)	
	)	

COMPLAINT FOR DECLARATORY JUDGMENT
AND DEMAND FOR JURY TRIAL

Plaintiff, Apotex Inc. ("Apotex"), for its Complaint against Defendants Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd. and H. Lundbeck A/S (collectively, "Defendants"), alleges as follows:

Nature Of The Action

1. Apotex brings—and is entitled by statute to maintain—this action for declaratory judgment of patent non-infringement under, *inter alia*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and 21 U.S.C. § 355(j)(5)(C)(i), which is part of the Hatch-Waxman Amendments to the Federal Food, Drug, and Cosmetic Act ("FFDCA"), as amended by Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA").

2. This action arises out of, *inter alia*, Apotex's submission of an Abbreviated New Drug Application ("ANDA") to the U.S. Food and Drug Administration ("FDA") seeking

approval to market a generic version of Defendants' brand-name drug Lexapro®, known generically as escitalopram oxalate.

3. Defendants purport to own U.S. Patent No. 6,916,941 ("the '941 patent") and U.S. Patent No. 7,420,069 ("the '069 patent") (collectively, "the patents-in-suit"). A true and accurate copy of the '941 patent is attached hereto as Exhibit A. A true and accurate copy of the '069 patent is attached hereto as Exhibit B.

4. Upon submission by Defendants, the '941 patent and the '069 patent were listed in FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." As a consequence of such listing, Defendants maintain, and have affirmatively represented to the world, that the '941 patent and the '069 patent claim the approved drug, Lexapro®, or a method of using that drug, and that a claim for patent infringement could reasonably be asserted against any generic ANDA applicant, including Apotex, attempting to market a generic escitalopram oxalate product before patent expiration.

5. Apotex seeks to market a non-infringing generic escitalopram oxalate product before the expiration of the '941 patent and the '069 patent. Thus, as required by statute, Apotex has certified to FDA that Apotex's ANDA product will not infringe the '941 patent and the '069 patent, and has further notified Defendants of the legal and factual bases for that certification.

6. Apotex's submission of so-called "paragraph IV" certifications to the '941 patent and the '069 patent constitute an artificial act of patent infringement putting Apotex at considerable risk of being sued by Defendants both before and after market entry. Indeed, these regulatory submissions created the necessary case or controversy and subject matter jurisdiction for Defendants to sue Apotex for patent infringement. It likewise created the necessary case or

controversy for Apotex to file and maintain an action for declaratory judgment of patent non-infringement regarding the '941 patent and the '069 patent.

7. By listing the '941 patent and the '069 patent in the Orange Book and not suing Apotex on those patents, Defendants have created patent and legal uncertainty that impairs Apotex's right to market a non-infringing generic product without the risk of catastrophic infringement damages. By virtue of Defendants' actions, Apotex is also suffering an "FDA-approval-blocking-injury," or "the harm of being unable to launch generic . . . products covered by the [Apotex] ANDA" because of another applicant's so-called 180-day exclusivity. This patent and legal uncertainty and impairment of Apotex's rights are, alone or in combination, sufficiently concrete and cognizable injuries-in-fact that are fairly traceable to the Defendants and that can be redressed only by a declaratory judgment from this Court.

8. Accordingly, there is an actual, substantial, and continuing justiciable case and controversy between Apotex and Defendants regarding infringement of the '941 patent and the '069 patent, over which this Court can and should exercise jurisdiction and declare the rights of the parties.

9. Apotex is entitled by law to bring and maintain this action for declaratory judgment of patent non-infringement under the Declaratory Judgment Act and the MMA where, as here, Defendants did not sue Apotex within 45 days of receipt of Apotex's notices of paragraph IV certification to the '941 patent and the '069 patent, and Apotex has offered Defendants an Offer of Confidential Access to Apotex's ANDA for generic escitalopram oxalate tablets.

10. Apotex is entitled to a judicial declaration that the manufacture, sale, offer for sale, use, or importation of Apotex's proposed generic escitalopram oxalate product does not and

will not infringe the '941 patent and the '069 patent. Absent the exercise of jurisdiction by this Court and such declaratory relief, Apotex faces both patent uncertainty and the indefinite delay in approval of its non-infringing generic escitalopram oxalate tablets.

The Parties

11. Plaintiff Apotex Inc. is a corporation organized and existing under the laws of Canada and having a place of business at 150 Signet Drive, Weston, Ontario, Canada M9L 1T9.

12. On information and belief, Defendant Forest Laboratories, Inc. is a Delaware corporation having a principal place of business at 909 Third Avenue, New York, New York 10022.

13. On information and belief, Defendant Forest Laboratories Holdings, Ltd. is an Irish corporation having offices at Milner House, 18 Parliament Street, Hamilton JM11, Bermuda.

14. On information and belief, Defendant H. Lundbeck A/S is a Danish corporation having a principal place of business at Ottiliavej 9, DK-2500 Valby, Copenhagen, Denmark.

15. On information and belief, Defendants, through their various agents, affiliates, representatives, subsidiaries and/or alter egos, develop, manufacture, and sell pharmaceutical products throughout the world, including in the United States and in this District.

16. On information and belief, this Court has personal jurisdiction over Defendants because Defendants conduct substantial business in, and have regular and systematic contact with, this District.

17. On information and belief, Defendants maintain such a continuous and systematic contact with the State of Michigan and this District by conducting substantial, regular and systematic business therein through the marketing and sales of their pharmaceutical products,

including Lexapro® – the purported commercial embodiment of the '941 patent and the '069 patent – to allow this Court to reasonably exercise personal jurisdiction over Defendants.

18. On information and belief, Defendants purposefully avail themselves of the privilege of doing business in the State of Michigan and in this District.

19. On information and belief, Defendants also allegedly own United States patents that purport to cover pharmaceutical products sold in the United States and in this District, and from which Defendants derive substantial revenue. On information and belief, Defendants facilitate the sale of its pharmaceutical products in the United States and in this District through various agents, affiliates, representatives, subsidiaries and/or alter egos.

20. On information and belief, Defendants' prescription medicines – including Lexapro® – are regularly prescribed by physicians and dispensed by pharmacists in the United States and in this District.

Jurisdiction And Venue

21. This action arises under, *inter alia*, the Patent Laws of the United States, 35 U.S.C. §§ 1 *et seq.*; the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and the MMA (21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5)).

22. This Court has original jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a), because it involves substantial claims arising under the United States Patent Act, 35 U.S.C. §§ 1 *et seq.*; under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, because it is an actual controversy concerning the infringement of the '941 patent and the '069 patent; and under the MMA (21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5)), because Congress has directed that district courts maintain and exercise jurisdiction in such cases.

23. There exists a substantial and continuing actual, justiciable case or controversy between Apotex and Defendants regarding non-infringement of the '941 patent and the '069 patent.

24. This Court can and should declare the rights and legal relations of the parties regarding non-infringement of the '941 patent and the '069 patent pursuant to, *inter alia*, the Declaratory Judgment Act, 28 U.S.C. §§ 2201, 2202, and the MMA (21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5)).

25. Apotex has the statutory right to bring and maintain this declaratory judgment action under 21 U.S.C. § 355(j)(5)(C)(i). This Court can and should exercise its declaratory judgment jurisdiction over Apotex's claims pursuant to 35 U.S.C. § 271(e)(5).

26. This Court has personal jurisdiction over Defendants because, on information and belief, Defendants conduct substantial business in, and have regular and systematic contact with, this District. On information and belief, Defendants, *inter alia*:

a. market, promote and sell in this District, on a continuous and systematic basis, their pharmaceutical products, including purported commercial embodiments of the '941 patent and the '069 patent, through various agents, affiliates, representatives, subsidiaries and/or alter egos;

b. derive substantial revenues, on a continuous and systematic basis, from their pharmaceutical products, including purported commercial embodiments of the '941 patent and the '069 patent, that are marketed, promoted and sold in the United States and within this District;

c. promote physicians in the State of Michigan to prescribe their medicines, including purported commercial embodiments of the '941 patent and the '069 patent, through its agents, affiliates, representatives, subsidiaries and/or alter egos;

d. have created various agents, affiliates, representatives, subsidiaries and/or alter egos in the United States and in this District that serve no other business purpose or goal except to act solely for, in concert with and/or at the direction of Defendants;

e. through their various agents, affiliates, representatives, subsidiaries and/or alter egos, have previously submitted to and/or benefited from the jurisdiction of this District;

f. have availed themselves of the rights and privileges of this forum by suing other ANDA applicants in this District relating to patents purportedly covering the drug Lexapro®, including in *Forest Laboratories, Inc. v. Caraco Pharmaceutical Laboratories, Ltd.*, Case No. 2:06-cv-13143 (BAF) (MKM);

g. have submitted and consented to the jurisdiction of this Court in actions involving the '941 patent and the '069 patent, including in *Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories, Inc.*, Case No. 2:07-cv-10737 (BAF) (MKM); and *Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories, Inc.*, Case No. 2:09-cv-10274 (BAF) (MKM); and

h. have otherwise purposefully availed themselves of the privileges of conducting activities within this District.

27. Venue is proper in this District under 28 U.S.C. § 1400(b). Venue is also proper in this District under 28 U.S.C. §§ 1391 because, *inter alia*, Defendants are subject to personal jurisdiction in this District.

Background

I. Statutory Scheme For Approval Of New And Generic Drugs.

28. The approval of new and generic drugs is governed by the applicable provisions of the FFDCA, 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) (commonly known as the "Hatch-Waxman Amendments" or "Hatch-Waxman"), and as further amended by the MMA (codified as amended in relevant part at 21 U.S.C. § 355 and 35 U.S.C. § 271).

A. New/previously-unapproved drugs and patent listing requirements.

29. Before marketing a previously-unapproved drug (*i.e.*, not a generic drug) in the United States, the FFDCA, as amended by Hatch-Waxman and the MMA, requires that an applicant submit, and that FDA approve, a new drug application ("NDA") under 21 U.S.C.

§ 355(b). The NDA must include, *inter alia*, technical data on the composition of the drug, the means for manufacturing it, clinical trial results to establish the safety and efficacy of the drug, and labeling relating to the use of the drug for which approval is requested.

30. An NDA applicant is required, within its NDA, to submit information (*e.g.*, the patent number and purported expiration date) regarding each patent that claims the "drug" or a "method of using [the] drug" that is the subject of the NDA and for which a claim of patent infringement could reasonably be asserted if a person not licensed by the patent owner engaged in the manufacture, use, or sale of the drug product. 21 U.S.C. § 355(b)(1); *see also id.* § 355(c)(2).

31. Upon approval of the NDA, FDA publishes patent information submitted by an NDA-holder in *Approved Drug Products with Therapeutic Equivalence Evaluations*, commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

32. By filing an NDA and submitting a patent for listing in the Orange Book, the NDA-holder/patent owner, by law, necessarily maintains that the listed patent claims the approved NDA drug, or a method of using that drug, and that an infringement suit could reasonably be asserted against anyone who engages in the manufacture, use, or sale of the drug, and, in particular, against any company that is seeking to make a generic bioequivalent version of the NDA drug before patent expiration.

33. Thus, the NDA-holder/patent owner necessarily puts all prospective generic ANDA applicants on notice that a suit for infringement can and will be asserted against any ANDA applicant that attempts to seek approval for and market a generic version of the NDA drug before patent expiration.

34. Such conduct by the NDA-holder/patent owner gives rise to a reasonable apprehension on the generic applicant's part that it will face an infringement suit, or the threat of one, if it attempts to seek approval for or to market a generic version of the NDA drug before patent expiration.

B. Generic drugs and patent certification requirements.

35. The FFDCA, as amended by Hatch-Waxman and the MMA, provides for an ANDA approval process that enables generic pharmaceutical manufacturers to obtain regulatory approval of lower-priced generic versions of previously approved brand-name or NDA drugs on an expedited basis, thereby benefiting the U.S. health-care system and American consumers. The ANDA process is a streamlined version of the full NDA procedure and results in a generic drug product that is normally marketed under the chemical name of the active drug ingredient.

36. An applicant may invoke this procedure for expedited FDA approval of a generic version of an already-approved NDA drug by submitting an ANDA to FDA under 21 U.S.C. § 355(j).

37. Instead of repeating the clinical studies of safety and efficacy conducted for the previously-approved NDA drug, a generic applicant submitting an ANDA is required to establish, among other details, that its proposed generic product is bioequivalent to the already-approved NDA drug (*i.e.*, has no significant difference in rate and extent of absorption) and that it has the same active ingredient, dosage form, dosage strength, route of administration, and labeling (with certain exceptions) as the approved NDA drug. 21 U.S.C. § 355(j)(2)(A).

38. An ANDA applicant also is required to address each patent properly listed in the Orange Book in connection with the approved NDA drug. In particular, Hatch-Waxman requires an ANDA applicant to submit one of four types of patent certifications for each properly listed

patent: (I) that the NDA-holder/patent owner has not submitted any patent information to FDA; (II) that the listed patent has expired; (III) that the patent will expire on a future date, and that the generic applicant will not market its product until after the expiration date (commonly referred to as a "paragraph III certification"); or, (IV) that the listed patent is invalid, unenforceable and/or will not be infringed by the manufacture, use, or sale of the generic drug for which the ANDA is submitted (commonly referred to as a "paragraph IV certification"). 21 U.S.C. §§ 355(j)(2)(A)(vii)(I)-(IV). This last type of certification, a paragraph IV certification, signifies that the generic ANDA applicant intends to market its generic product prior to expiration of the subject patent. Such a paragraph IV certification constitutes an artificial act of patent infringement under 35 U.S.C. § 271(e)(2)(A).

39. When an ANDA applicant submits a paragraph IV certification for a listed patent, the generic applicant must notify the NDA-holder/patent owner that it has filed an ANDA to obtain regulatory approval of a generic version of the NDA drug, and that the ANDA contains a paragraph IV certification for a listed patent (indicating that the ANDA applicant intends to market its generic product before expiration of the listed patent). 21 U.S.C. § 355(j)(2)(B). This notice must contain a detailed statement of the factual and legal bases for the ANDA applicant's certification that the listed patent is invalid and/or will not be infringed by the manufacture, use, or sale of the generic applicant's generic drug product. 21 U.S.C. § 355(j)(2)(B)(iv).

40. The submission of a paragraph IV certification has two important consequences.

41. First, an applicant that is first to submit an ANDA containing a paragraph IV certification for a listed patent is entitled to 180 days of generic market exclusivity during which time no other ANDA for that drug product will be approved. 21 U.S.C. § 355(j)(5)(B)(iv).

42. Second, the submission of a paragraph IV certification for a listed patent constitutes an act of patent infringement that creates the necessary case or controversy and subject matter jurisdiction to enable an NDA-holder/patent owner to file, and a district court to resolve, an action for patent infringement—before the generic drug is actually made, used, or sold—to determine whether the generic drug, if marketed and sold in accordance with the ANDA, would infringe the relevant patent.

43. The submission of a paragraph IV certification likewise creates the necessary case or controversy and subject matter jurisdiction for an ANDA applicant to file a declaratory judgment action against the NDA-holder/patent owner if the ANDA applicant is not sued within the applicable 45-day period, as set forth below.

44. Upon receiving notice of a paragraph IV certification for a listed patent submitted by an ANDA applicant, the NDA-holder/patent owner may file suit for alleged infringement of the listed patent under 35 U.S.C. § 271(e)(2)(A) within 45 days of receiving such notification. Such a suit automatically delays FDA from issuing final approval of the ANDA for up to thirty (30) months. 21 U.S.C. § 355(j)(5)(B)(iii). An ANDA applicant is statutorily prohibited from seeking a declaratory judgment during the 45-day period in which the NDA-holder/patent owner may bring suit after receiving notification of the ANDA and paragraph IV certification. *Id.*

45. If the NDA-holder/patent owner does not file such a suit, the ANDA applicant can file and maintain a suit for declaratory judgment against the NDA-holder/patent owner to obtain patent certainty. Indeed, as explained below, Congress explicitly mandated that an ANDA-filer is entitled to maintain a declaratory judgment action when it is not sued. 21 U.S.C. § 355(j)(5)(C).

46. Congress enacted Hatch-Waxman and the ANDA approval process in order to expedite the marketing of lower-priced generic drug products. Congress intended that the generic manufacturing and marketing of a drug should be allowed as soon as it is determined that the particular generic drug does not violate patent rights. Congress also determined that full generic competition would not be delayed indefinitely by the 180-day exclusivity period.

II. Congress Explicitly Mandated That An ANDA-Filer May Bring And Maintain A Declaratory Judgment Action When The Brand Company Does Not Bring An Infringement Action.

47. On December 8, 2003, the MMA was signed into law. Title XI of the MMA, labeled "Access to Affordable Pharmaceuticals," amended provisions of the FFDCA and, in particular, Hatch-Waxman.

48. Under the MMA, an ANDA applicant who has filed a paragraph IV certification is statutorily entitled to institute and maintain an action for declaratory judgment against an NDA-holder/patent owner if: (1) the 45-day period has passed since notice of the paragraph IV certification was received; (2) neither the patent owner nor the NDA-holder/patent owner brought an action for infringement of the patent within the 45-day period; and, (3) the notice of paragraph IV certification contains an Offer of Confidential Access to the ANDA. 21 U.S.C. §§ 355(j)(5)(C)(i)(I)(aa)-(cc).

49. Once these three conditions are met, the MMA specifically and unequivocally provides that an ANDA applicant "may, in accordance with section 2201 of Title 28 [of the United States Code] bring a civil action under such section against the owner or holder referred to in such subclause . . . for a declaratory judgment that the patent is invalid or will not be infringed by the drug for which the applicant seeks approval . . . ." 21 U.S.C. § 355(j)(5)(C)(i)(II).

50. An ANDA applicant may exercise its right to file and maintain a declaratory judgment action under the MMA regardless of whether or not the Offer of Confidential Access to Application is accepted.

51. The new declaratory judgment provision contained in the MMA, Section 1101 of the MMA, 117 Stat. 2066, 2454-2456, applies to all ANDAs pending on or after December 8, 2003, which includes these proceedings.

52. Congress' intent in amending 21 U.S.C. § 355(j)(5)(C)(i) and 35 U.S.C. § 271(e)(5) was to extend to ANDA applicants, like Apotex here, the right to file and maintain a declaratory judgment action for patent non-infringement and/or invalidity against an NDA-holder/patent owner, and grant the court subject matter jurisdiction in such an action.

53. The purpose of this provision was two-fold. The first purpose was to allow generic applicants to obtain patent certainty before marketing their generic products.

54. The second purpose was to allow generic applicants to obtain court decisions that would expedite the introduction of generic drugs by triggering any 180-day exclusivity that would block or delay the timely approval of a subsequent applicant's ANDA.

55. As to this second purpose, the United States Court of Appeals for the Federal Circuit ("Federal Circuit") has squarely held that there is subject matter jurisdiction for a declaratory judgment action to trigger another generic ANDA applicant's 180-day exclusivity in order to clear the path to earlier FDA approval. *See Teva Pharms. USA, Inc. v. Eisai Co.*, 620 F.3d 1341 (Fed. Cir. 2010) ("*Eisai*").

56. In particular, the Federal Circuit has held that an "FDA-approval-blocking-injury"—or "the harm of being unable to launch generic . . . products covered by the . . . ANDA" because of another applicant's 180-day exclusivity—is a sufficiently concrete and cognizable

injury-in-fact, that is fairly traceable to the brand company's actions, and that "can be redressed by . . . a declaratory judgment of noninfringement [that] would trigger the first-filer's exclusivity period, which currently blocks FDA approval of the . . . ANDA." *Eisai*, 620 F.3d at 1343. As the Federal Circuit has explained:

> [*Caraco Pharm. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278 (Fed. Cir. 2008)] holds that the exclusion of non-infringing generic drugs from the market can be a judicially cognizable injury-in-fact. Because a company is not free to manufacture or market drugs until it receives FDA approval, under the Hatch-Waxman framework such an injury occurs when the holder of an approved NDA takes action that delays FDA approval of subsequent ANDAs. . . . As we explained in *Caraco*, the generic drug company's injury (i.e., exclusion from the market) is fairly traceable to the defendant's actions because "but-for" the defendant's decision to list a patent in the Orange Book, FDA approval of the generic drug company's ANDA would not have been independently delayed by that patent. When an Orange Book listing creates an "independent barrier" to entering the marketplace that cannot be overcome without a court judgment that the listed patent is invalid or not infringed-as for Paragraph IV filers-the company manufacturing the generic drug has been deprived of an economic opportunity to compete. A declaratory judgment redresses this alleged injury because it eliminates the potential for the corresponding listed patent to exclude the generic drug from the market.

Id. at 1346-47 (internal citations omitted).

57. The Federal Circuit has also squarely rejected any notion that statutory disclaimers and/or covenants-not-to-sue could eliminate or otherwise impact jurisdiction. *Eisai*, 620 F.3d at 1348 n.3 ("Neither the statutory disclaimers nor Eisai's covenant-not-to-sue render this declaratory judgment action moot because the DJ patents remain listed in the Orange Book. Thus, regardless of whether Eisai could bring an infringement action with respect to the DJ patents, under the Hatch-Waxman Act Teva still needs a court judgment of noninfringement or invalidity to obtain FDA approval and enter the market." (internal citations omitted)).

III. The Patents-In-Suit.

58. According to the face of the '941 patent, the patent purportedly issued on July 12, 2005, naming H. Lundbeck A/S as the purported assignee, and is entitled "Crystalline

Composition Containing Escitalopram." The '941 patent lists Troels Volsgaard Christensen, Ken Liljegren, Michiel Onne Elema, Lene Andresen, Shashank Mahashabde and Sebastian P. Assenza as purported named inventors. A copy of the '941 patent is attached as Exhibit A.

59. According to the electronic records of the FDA, the '941 patent is purportedly scheduled to expire on or about August 12, 2022, with pediatric exclusivity extending until February 12, 2023.

60. According to the face of the '069 patent, the patent purportedly issued on September 2, 2008, naming H. Lundbeck A/S as the purported assignee, and is entitled "Crystalline Composition Containing Escitalopram." The '069 patent lists Troels Volsgaard Christensen, Ken Liljegren, Michiel Onne Elema, Lene Andresen, Shashank Mahashabde and Sebastian P. Assenza as purported named inventors. A copy of the '069 patent is attached as Exhibit B.

61. According to the electronic records of the FDA, the '069 patent is purportedly scheduled to expire on or about August 12, 2022, with pediatric exclusivity extending until February 12, 2023.

62. Upon information and belief, H. Lundbeck A/S is the purported owner of the '941 patent and the '069 patent.

63. Upon information and belief, Forest Laboratories Holdings, Ltd. is the purported exclusive licensee of the '941 patent and the '069 patent.

64. Upon information and belief, Defendants purport and claim to own and have the right to enforce the '941 patent and the '069 patent.

IV. Lexapro® (escitalopram oxalate).

65. Forest Laboratories, Inc. is the purported holder of approved NDA No. 21-323 for escitalopram oxalate tablets, which are sold under the brand-name Lexapro®.

66. Lexapro® (escitalopram oxalate) is indicated for, among other things, the acute and maintenance treatment of major depressive disorder (MDD) in adults and in adolescents 12 to 17 years of age, and the acute treatment of generalized anxiety disorder (GAD) in adults.

67. FDA approved Lexapro® in 2002. Today, Lexapro® remains the only escitalopram oxalate tablet product on the market.

68. Upon information and belief, Forest Laboratories Holdings, Ltd. has appointed Forest Laboratories, Inc. as its exclusive distributor of Lexapro® brand escitalopram oxalate products in the United States.

69. On information and belief, Defendants submitted information on the '941 patent and the '069 patent to FDA for listing in the Orange Book. By virtue of that submission, FDA listed the '941 patent and the '069 patent in the Orange Book in connection with Defendant Forest Laboratories, Inc.'s approved NDA for Lexapro® (escitalopram oxalate) tablets. The '941 and '069 patents remain listed in the Orange Book today.

70. By listing the '941 patent and the '069 patent in the Orange Book, Defendants maintain, and have affirmatively represented to the world, that the '941 patent and the '069 patent claim Lexapro® (escitalopram oxalate) tablets, or a method of using that drug, and that an infringement suit could reasonably be asserted against any generic ANDA applicant, including Apotex, that attempts to seek approval for, and market, a generic version of Lexapro® before patent expiration.

71. The listing of the '941 patent and the '069 patent in the Orange Book alone objectively creates the necessary case or controversy and subject matter jurisdiction for an ANDA-filer to file and maintain a declaratory judgment action if it is not sued by Defendants within the requisite 45-day period.

V. Apotex's ANDA For Escitalopram Oxalate Tablets.

72. Apotex has submitted an ANDA (No. 78-777) to FDA seeking approval to market a generic version of Lexapro® (escitalopram oxalate) tablets in 5, 10 and 20 mg strengths ("Apotex's ANDA Product").

73. Apotex devoted considerable resources researching, developing and testing its generic escitalopram oxalate product, all toward compiling the information necessary to submit its ANDA No. 78-777 for generic escitalopram oxalate tablets.

74. Apotex's ANDA included a paragraph IV certification to the '941 patent, stating that the '941 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of Apotex's generic escitalopram oxalate tablets and/or that the '941 patent is invalid. This certification signified that Apotex intends to market and commercialize its generic escitalopram oxalate product prior to expiration of the '941 patent.

75. Defendants submitted the '069 patent to FDA for listing in the Orange Book after Apotex submitted its ANDA. By law, Apotex was required to amend its ANDA No. 78-777 to contain a certification to the '069 patent.

76. Apotex amended its ANDA to include a paragraph IV certification to the '069 patent, stating that the '069 patent will not be infringed by the manufacture, use, offer for sale, sale, or importation of Apotex's generic escitalopram oxalate tablets and/or that the '069 patent

is invalid. This certification signified that Apotex intends to market and commercialize its generic escitalopram oxalate product prior to expiration of the '069 patent.

77. Apotex's ANDA No. 78-777 is substantially complete and was accepted for filing by FDA.

78. Apotex intends, and is prepared, to market its generic escitalopram oxalate product before expiration of the '941 patent and the '069 patent.

79. In accordance with 21 U.S.C. §§ 355(j)(2)(B), Apotex provided Defendants with the requisite notice that it submitted ANDA No. 78-777 and paragraph IV certifications to the '941 patent and the '069 patent.

80. Upon receipt of Apotex's notice of paragraph IV certification to the '941 patent, Defendants did not sue Apotex within the 45-day period for instituting an infringement suit under 21 U.S.C. § 271(e).

81. Upon receipt of Apotex's notice of paragraph IV certification to the '069 patent, Defendants did not sue Apotex within the 45-day period for instituting an infringement suit under 21 U.S.C. § 271(e).

VI. Apotex's Offers Of Confidential Access To Application.

82. Apotex—by letter and as required under 21 U.S.C. § 355(j)(5)(C)—extended to Defendants an Offer of Confidential Access to Application to access certain information in Apotex's ANDA for escitalopram oxalate tablets in its notice of paragraph IV certification to the '941 patent dated May 22, 2007.

83. Apotex—by letter and as required under 21 U.S.C. § 355(j)(5)(C)—again extended to Defendants an Offer of Confidential Access to Application to access certain information in Apotex's ANDA for escitalopram oxalate tablets in its notice of paragraph IV certification to the '069 patent dated September 24, 2008.

84. By providing an Offer of Confidential Access to Application, and because Defendants did not sue Apotex within 45 days of receipt of Apotex's notices of paragraph IV certification, Apotex is statutorily entitled to file and maintain a declaratory judgment action against Defendants under 28 U.S.C. §§ 2201 and 2202, pursuant to 21 U.S.C. § 355(j)(5)(C).

VII. Defendants' Litigious Conduct And Vigorous Enforcement Of Its Intellectual Property Rights Regarding Lexapro®.

85. Defendants have a long history and orchestrated program of vigorously enforcing their intellectual property for Lexapro® against generic ANDA applicants.

86. For example, Defendants have sued multiple ANDA-filers for alleged infringement of patents purportedly covering its drug Lexapro®, including in the Eastern District of Michigan. *See Forest Labs., Inc. et al. v. Caraco Pharm. Labs., Ltd. et al.*, No. 2:06-cv-13143 (BAF) (MKM) (E.D. Mich.); *Forest Labs, Inc. et al. v. Ivax Pharms., Inc. et al.*, No. 1:03-cv-891 (JJF) (D. Del.); *Forest Labs., Inc. et al. v. Alphapharm Pty. Ltd.*, No. 1:04-cv-1244 (JJF) (D. Del.).

VIII. There Is A Substantial And Continuing Justiciable Controversy Between Apotex And Defendants Regarding Infringement Of The Patents-In-Suit.

87. By submitting the '941 patent and the '069 patent to FDA for listing in the Orange Book, Defendants have affirmatively represented to the world, and in particular Apotex, that "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." *See* 21 U.S.C. § 355(b)(1); *see also id.* § 355(c)(2). In other words, Defendants necessarily maintain that an infringement claim on the '941 patent and the '069 patent could be reasonably asserted against Apotex.

88. Defendants have not consented to a judgment of non-infringement on the '941 and '069 patents, and nor have they covenanted or otherwise promised not to sue or otherwise hold Apotex liable for infringement of such patents.

89. By preparing and filing Apotex's ANDA No. 78-777, Apotex has substantially prepared to make, use, import, offer to sell, and sell generic escitalopram oxalate tablets in the United States.

90. By submitting its ANDA No. 78-777 to engage in the commercial manufacture, use, offer for sale, sale, or importation of generic escitalopram oxalate tablets before the expiration of the '941 patent and the '069 patent, as well as filing paragraph IV certifications to the '941 patent and the '069 patent, Apotex has committed an artificial act of infringement sufficient to create case or controversy jurisdiction under 35 U.S.C. § 271(e)(2) and Article III of the Constitution.

91. Defendants' listing of the '941 patent and the '069 patent and Apotex's paragraph IV certifications to those patents satisfy Article III of the Constitution by creating the necessary case or controversy between Defendants and Apotex regarding infringement of the '941 patent and the '069 patent.

92. By listing the '941 patent and the '069 patent in the Orange Book and not suing Apotex on those patents, Defendants have created patent and legal uncertainty that impairs Apotex's right to market a non-infringing generic product without the risk of catastrophic infringement damages. This patent and legal uncertainty and impairment of Apotex's rights is a sufficiently concrete and cognizable injury-in-fact that is fairly traceable to the Defendants and that can be redressed only by a declaratory judgment from this Court. Apotex has a legally cognizable interest in obtaining patent certainty via a declaratory judgment action. These facts

alone give rise to a substantial and continuing case or controversy under Article III of the Constitution over which this Court has subject matter jurisdiction.

93. Furthermore, upon information and belief, Apotex is not the first ANDA-filer to submit a paragraph IV certification to the '941 and/or '069 patents. Upon information and belief, another ANDA-filer (Teva/Ivax) submitted the first paragraph IV certification to the '941 and/or '069 patents and secured a period of 180-day exclusivity that will delay the approval of Apotex's non-infringing ANDA products absent a declaratory judgment from this Court. This "FDA-approval-blocking-injury"—or "the harm of being unable to launch generic . . . products covered by the [Apotex] ANDA" because of another applicant's 180-day exclusivity—is a sufficiently concrete and cognizable injury-in-fact, that is fairly traceable to Defendants' actions, and that "can be redressed by . . . a declaratory judgment of noninfringement [that] would trigger the first-filer's exclusivity period, which currently blocks FDA approval of the [Apotex] ANDA." Apotex has a legally cognizable interest in beginning or triggering the first-filer's exclusivity period via a declaratory judgment action. These facts also give rise to a substantial and continuing case or controversy under Article III of the Constitution over which this Court has subject matter jurisdiction.

94. Defendants did not sue Apotex for infringement of the '941 or '069 patents within 45 days of receipt of Apotex's notices of paragraph IV certification. In compliance with 21 U.S.C. § 355(j)(5)(C), Apotex granted Defendants an Offer of Confidential Access to Apotex's ANDA for generic escitalopram oxalate tablets. As such, Apotex is statutorily entitled to institute—and this Court has constitutional authority to adjudicate—a declaratory judgment action against Defendants. 35 U.S.C. § 271(e)(5).

95. To avoid legal uncertainty, to protect its substantial investment, to protect its anticipated future investments in its manufacturing process for Apotex's generic escitalopram oxalate tablets, and to obtain earlier approval of its generic escitalopram oxalate products, Apotex has instituted this action and is entitled to a declaration of the rights of the parties with respect to the '941 patent and the '069 patent.

CLAIMS FOR RELIEF

COUNT I
Declaratory Judgment Of Non-Infringement Of U.S. Patent No. 6,916,941

96. Apotex asserts and realleges paragraphs 1 through 95 above as if fully set forth herein.

97. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Defendants regarding infringement of the '941 patent.

98. The manufacture, sale, offer for sale, use, or importation of Apotex's proposed escitalopram oxalate drug product, that is the subject of ANDA No. 78-777, does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '941 patent.

99. Apotex is entitled to a judicial declaration that the manufacture, sale, offer for sale, use, or importation of Apotex's proposed generic escitalopram oxalate drug product, that is the subject of ANDA No. 78-777, does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '941 patent.

COUNT II
Declaratory Judgment Of Non-Infringement Of U.S. Patent No. 7,420,069

100. Apotex asserts and realleges paragraphs 1 through 99 above as if fully set forth herein.

101. There is an actual, substantial, and continuing justiciable case or controversy between Apotex and Defendants regarding infringement of the '069 patent.

102. The manufacture, sale, offer for sale, use, or importation of Apotex's proposed escitalopram oxalate drug product, that is the subject of ANDA No. 78-777, does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '069 patent.

103. Apotex is entitled to a judicial declaration that the manufacture, sale, offer for sale, use, or importation of Apotex's proposed generic escitalopram oxalate drug product, that is the subject of ANDA No. 78-777, does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '069 patent.

Prayer For Relief

WHEREFORE, Apotex Inc. respectfully prays for judgment in its favor and against Defendants:

(a) Declaring that the manufacture, sale, offer for sale, use, or importation of Apotex's proposed generic escitalopram oxalate drug product, that is the subject of ANDA No. 78-777, does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '941 patent; and,

(b) Declaring that the manufacture, sale, offer for sale, use, or importation of Apotex's proposed generic escitalopram oxalate drug product, that is the subject of ANDA No. 78-777, does not and will not infringe (either literally or under the doctrine of equivalents), directly or indirectly (either by inducement or contributorily), any valid or enforceable claim of the '069 patent; and,

(c) Awarding Apotex its reasonable attorneys' fees and costs of this action; and

(d) Awarding Apotex such other and further relief as the Court may deem just and proper.

Jury Demand

Plaintiff, Apotex Inc., hereby demands a trial by jury on all issues so triable.

s/Catherine T. Dobrowitsky
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