UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

CARACO PHARMACEUTICAL
LABORATORIES, LTD.,

Plaintiff,

v.

FOREST LABORATORIES, INC.,
FOREST LABORATORIES HOLDINGS,
LTD. and H. LUNDBECK A/S,

Defendants.
_____/

**COMPLAINT**

Plaintiff Caraco Pharmaceutical Laboratories, Ltd. ("Caraco"), by its attorneys, for its Complaint against Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., and H. Lundbeck A/S (collectively, "Defendants") states as follows:

**INTRODUCTION**

1. Caraco brings, and is entitled by statute to maintain, this action for declaratory judgment of patent non-infringement under, *inter alia*, the federal 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*, Caraco'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 anti-depression medication LEXAPRO®, known generically as escitalopram oxalate.

3. Defendants purport to own U.S. Patent No. 7,420,069 ("the '069 patent"). Upon submission by Defendants, the '069 patent was listed in FDA's compilation of approved drugs and their respective patents entitled "Approved Drug Products With Therapeutic Equivalence Evaluations," commonly referred to as the "Orange Book." As a consequence of such Orange Book listing, Defendants maintain, and have affirmatively represented to the world, that the '069 patent claims 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 Caraco, attempting to market a generic escitalopram product before expiration of the '069 patent.

4. There is already pending litigation between the parties for the same drug, escitalopram oxalate, for other patents already listed in the Orange Book, evidencing the preexisting dispute between the parties and the reasonable apprehension Plaintiff has for a lawsuit filed by Defendants. The '069 patent was only recently listed in the Orange Book by the Defendants, and therefore this action naturally follows from the existing litigation on the other patents listed in the Orange Book for the same escitalopram oxalate drug product at issue.

5. Caraco submitted its notice of paragraph IV certification and sent a letter to Defendants explaining its basis for certification on November 26, 2008. Defendants did not sue Caraco within 45 days of receipt of Caraco's notice of paragraph IV certification to the '069

patent, and Caraco has offered Defendants an Offer of Confidential Access to Caraco's ANDA for generic escitalopram product. Yet Defendants have not responded, leaving open the significant risks of a future lawsuit filed by the Defendants.

6. Caraco seeks to market a generic escitalopram product before the expiration of the '069 patent. Therefore, as required by the FFDCA, Caraco has certified to FDA that its ANDA products will not infringe any valid or enforceable claims of the '069 patent and has further notified Defendants of the legal and factual bases for those certifications. Caraco's submission of the so-called paragraph IV certifications to the '069 patent provides grounds for a claim of patent infringement based on the '069 patent being listed in the Orange Book, thereby putting Caraco at considerable risk of being sued by Defendants at any time, whether before or after FDA approval and market entry.

7. This regulatory submission creates the necessary case or controversy and subject matter jurisdiction for Defendants to sue Caraco—and for Caraco to obtain declaratory judgment against Defendants—regarding infringement of the '069 patent.

8. In a separate lawsuit, *Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., and H. Lundbeck A/S. v. Caraco Pharmaceutical Laboratories, Ltd. and Sun Pharmaceutical Industries, Ltd.*, Case No. 2:06-cv-13143 (BAF) (MKM), Defendants sued Caraco for infringement of another Orange Book-listed patent listed for the same escitalopram oxalate drug, specifically U.S. Patent No. 34,712 ("the '712 patent"). In another separate lawsuit, *Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., and H. Lundbeck A/S*, Case No. 2:07-cv-10737, Plaintiff Caraco filed a declaratory action regarding non-infringement of another Orange Book-listed patent listed for the same escitalopram drug, specifically U.S. Patent No. 6,916,941 ("the '941 patent").

9. Caraco has satisfied all substantive requirements for approval of its ANDA, and is prepared to begin commercial marketing of its competing generic product prior to expiration of the '712, '941, and '069 patents. But Caraco's approval has been delayed and Caraco is presently prevented from competing in the escitalopram market based upon Defendants' Orange Book listings related to the '712, '941, and '069 patents. In *Forest Laboratories, Inc., et al. v. Caraco Pharmaceutical Laboratories, Ltd., et al.*, Case No. 2:06-cv-13143, Caraco is currently litigating and will obtain a court judgment as to the invalidity, enforceability and/or infringement of the '712 patent. Similarly, Caraco is currently litigating *Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories, Inc., et al.*, Case No. 2:07-10737 and will obtain a declaratory judgment as to the invalidity and/or noninfringement of the '941 patent. A declaratory judgment from this Court as to the '069 patent can alleviate Caraco's harm and allow Caraco to obtain approval of its product and compete in the escitalopram market as soon as FDA approval is granted.

10. In addition to a court order finding the '712 and '941 patents invalid and/or not infringed, unless Caraco obtains a similar court order on the '069 patent, Caraco faces potentially enormous infringement liability if it markets its generic product prior to expiration of the '069 patent. Only a declaratory judgment from this Court can alleviate and prevent this harm and allow Caraco to obtain approval of its product so that it can provide generic versions of escitalopram drugs to the public.

11. Accordingly, there is an actual, substantial, and continuing justiciable case and controversy between Caraco and Defendants regarding the '069 patent, over which this Court can and should exercise jurisdiction and declare the rights of the parties. Caraco 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, the parties dispute whether the '069 patent applies to Plaintiff's products.

12. Caraco is entitled to a judicial declaration that the manufacture, sale, offer for sale, use, or importation of Caraco's proposed generic escitalopram product does not and will not infringe the '069 patent. Absent the exercise of jurisdiction by this Court and such declaratory relief, Caraco and the American public will be irreparably harmed by the substantial delay in the market entry and availability of lower-priced generic escitalopram.

**THE PARTIES**

13. Plaintiff Caraco Pharmaceutical Laboratories, Ltd. is a Michigan corporation having a principal place of business at 1150 Elijah McCoy Drive, Detroit, Michigan 48202.

14. Defendant Forest Laboratories, Inc. is a Delaware corporation having a principal place of business at 909 Third Avenue, New York, New York 10022.

15. Defendant Forest Laboratories Holdings, Ltd. is an Irish corporation having offices at Milner House, 18 Parliament Street, Hamilton JM11, Bermuda.

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

**U.S. PATENT NO. 7,420,069**

17. According to the face of the '069 patent, the patent issued on September 2, 2008 naming H. Lundbeck A/S as assignee, titled "Crystalline Composition Containing Escitalopram," a copy of which is attached hereto as Exhibit A.

18. Upon information and belief, the '069 patent is scheduled to expire on August 12, 2022, with pediatric exclusivity extending protection until February 12, 2023.

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

20. Upon information and belief, Forest Laboratories Holdings, Ltd. is the exclusive licensee of the '069 patent and Forest Laboratories, Inc. holds New Drug Application ("NDA") No. 21323 on LEXAPRO® brand escitalopram oxalate tablet products.

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

22. Upon information and belief, Defendants have the right to sue for any infringement of the '069 patent.

**JURISDICTION AND VENUE**

23. Substantial, present, genuine and justiciable controversies exist between Defendants and Caraco regarding the '069 patent.

24. 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)).

25. 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 '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.

26. This Court can and should declare the rights and legal relations of the parties regarding 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)).

27. Caraco 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 Caraco's claims pursuant to 35 U.S.C. § 271(e)(5).

28. Upon 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.

29. Upon 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 '069 patent—to allow this Court to reasonably exercise personal jurisdiction over Defendants.

30. This Court also has personal jurisdiction over Defendants because Defendants have submitted to the jurisdiction of this Court in two prior related matters, *Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., and H. Lundbeck A/S. v. Caraco Pharmaceutical Laboratories, Ltd. and Sun Pharmaceutical Industries, Ltd.*, Case No. 2:06-cv-13143 (BAF) (MKM) and *Caraco Pharmaceutical Laboratories, Ltd. v. Forest Laboratories, Inc., Forest Laboratories Holdings, Ltd., and H. Lundbeck A/S*, Case No. 2:07-cv-10737, both of which are currently pending in this Court.

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

32. 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 and because Defendants are alien corporations.

## BACKGROUND

### I. Regulatory Framework

#### A. FDA Approval Of New Drug Applications (NDAs)

33. The Federal Food, Drug, and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301 *et seq.*, as amended by the Hatch-Waxman Amendments and Title XI of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 ("MMA"), sets forth the rules that the Food and Drug Administration ("FDA") follows when considering whether to approve the marketing of both brand-name and generic drugs.

34. Under the FFDCA, an applicant seeking to market a new brand-name drug must prepare an NDA for consideration by FDA. *See* 21 U.S.C. § 355.

35. The NDA must include, among other things, the number of any patent that claims the "drug" or a "method of using [the] drug" for which the NDA was submitted and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. *See* 21 U.S.C. § 355(b)(1), -(c)(2); 21 C.F.R. § 314.53(b), -(c)(2).

36. Upon approval of the NDA, FDA publishes patent information for the approved drug in the "Approved Drug Products with Therapeutic Equivalence Evaluations," commonly known as the "Orange Book." *See* 21 U.S.C. § 355(j)(7)(A)(iii).

37. 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 of the NDA drug before patent expiration.

38. 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.

39. Such conduct by the NDA-holder/patent owner gives rise to a real and concrete belief 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. Defendants have not provided any consent judgment for the '069 patent stating that Caraco does not infringe or that the '069 patent is invalid.

**B. Generic Competition: Abbreviated New Drug Applications (ANDA)**

40. Generic drugs are versions of brand-name prescription drugs that typically contain the same active ingredients, but not necessarily the same inactive ingredients or form of ingredients or manufacturing process, as the brand-name original.

41. In 1984, Congress enacted the Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Amendments to the FFDCA. *See* Pub. L. No. 98-417, 98 Stat. 1585 (1984) (codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271(e)).

42. Congress passed the Hatch-Waxman Amendments, which simplified the procedure for obtaining approval of generic drugs, for the purpose of decreasing the cost of pharmaceuticals through increased competition and to expedite the marketing of lower-priced generic drug products. Under the Hatch-Waxman Amendments, a generic manufacturer submits what is called an Abbreviated New Drug Application ("ANDA").

43. To receive approval of its ANDA, an applicant must show, *inter alia*, that its generic drug is "bioequivalent" to the listed reference drug. *See* 21 U.S.C. § 355(j)(4)(F).

44. An ANDA also must contain a "certification" to each patent that the NDA holder has submitted to FDA for listing in the Orange Book in connection with the listed reference drug. *See* 21 U.S.C. § 355(j)(2)(A)(vii); 21 C.F.R. § 314.94(a)(12).

45. A so-called "paragraph IV" certification asserts that the listed patent is invalid, unenforceable, and/or will not be infringed and, on that basis, seeks FDA approval of the generic product prior to patent expiration. *See* 21 U.S.C. § 355(j)(2)(A)(vii)(IV); 21 C.F.R. § 314.94(a)(12).

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

47. First, a generic 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 no other competing generic drug products may be marketed. 21 U.S.C. § 355(j)(5)(B)(iv). This statutory benefit to the first filer is commonly known as "180-day exclusivity."

48. In particular, the statutory provision of the FFDCA applicable here provides that "[i]f the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) and is for a drug for which a previous application has been submitted under this section [containing] such a certification, the application shall be made effective not earlier than one hundred and eighty days after" the earlier of: (a) the first commercial marketing of that ANDA applicant's proposed drug; or, (b) a court decision—whether it involves the first applicant or not—that the particular patent that is the subject of the paragraph IV certification is invalid or not infringed. 21 U.S.C. § 355(j)(5)(B)(iv). Thus, unless a subsequent generic applicant can obtain a court decision of noninfringement and/or invalidity as Congress intended, the approval of its ANDA can be delayed indefinitely by the purported exclusivity of the first-filer.

49. Second, the submission of a paragraph IV certification for a listed patent provides grounds for a claim of an artificial act of 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.

50. 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 on the listed patent within the applicable 45-day period.

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

52. Upon receiving notice of the paragraph IV certification, the NDA holder/patent owner has 45 days in which to file an infringement suit against the generic manufacturer. *See* 21 U.S.C. § 355(j)(5)(B)(iii); 35 U.S.C. § 271(e)(2)(A).

53. The NDA holder/patent owner's filing of a lawsuit prior to the expiration of 45 days prevents FDA from issuing final approval of the generic maker's ANDA for a period of 30 months, absent certain exceptions. *See* 21 U.S.C. § 355(j)(5)(B)(iii). The NDA holder/patent owner not filing a lawsuit does not prohibit it from filing a lawsuit at some point in the future.

**C. ANDA-Filer May Bring A Declaratory Judgment Action**

54. 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, the Hatch-Waxman Amendments.

55. 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. §§ 3550(j)(5)(C)(i)(I)(aa)-(cc).

56. 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).

57. The FFDCA provides that the first applicant to file a substantially complete ANDA containing a paragraph IV certification to a listed patent will be eligible for a 180-day period of exclusivity beginning either from the date it begins commercial marketing of the generic drug product, or from the date of a court decision finding the listed patent invalid, unenforceable or not infringed, whichever is first.

58. These events—first commercial marketing and a court decision—are often called triggering events, because under the statute they can trigger the beginning of the 180-day exclusivity period.

59. The 180-day exclusivity can begin to run, with a court decision by any applicant, even before the first applicant has received approval for its ANDA or before the first applicant has begun commercial marketing of the ANDA product. In that case, some, or all, of the 180-day exclusivity period could expire without the first ANDA applicant marketing its generic drug.

60. Conversely, if there is no court decision on a listed patent and the first applicant does not begin commercial marketing of the generic drug, there may be prolonged or indefinite delays in the beginning of the first applicant's 180-day exclusivity period.

61. Until an eligible ANDA applicant's 180-day exclusivity period has been triggered (and expires), the FDA cannot approve subsequently submitted ANDAs for the same drug, even if the later ANDAs are otherwise ready for approval and the applicants are willing to immediately begin marketing.

62. By specifically allowing declaratory actions under these circumstances, Congress intended that full generic competition would not be delayed indefinitely by the first filer's 180-day exclusivity period. A declaratory action by a subsequent ANDA filer can result in a court decision that would trigger the first filer's 180-day exclusivity period, thereby clearing the way for approval of the subsequent ANDA filer.

63. Congress also intended to allow generic applicants to obtain patent certainty before marketing their generic products in order to avoid potentially catastrophic infringement damages.

## II. Caraco's ANDA No. 78-219

### A. Caraco Has The Right To Bring Declaratory Lawsuit On The '069 Patent

64. In March 2006, Caraco filed an ANDA (No. 78-219) with the FDA seeking generic approval for 5, 10, and 20 mg tablets of escitalopram oxalate (the "ANDA Products").

65. Defendants listed the '712 and '941 patents, and much later the '069 patent in the Orange Book in connection with NDA No. 21323 and the brand name drug LEXAPRO®, which comprises the active ingredient escitalopram oxalate.

66. By listing the ‘712, ‘941, and ‘069 patents in the Orange Book, Defendants maintain, and have affirmatively represented to the world, that the ‘712, ‘941, and ‘069 patents claim LEXAPRO®, or a method of using that drug, and that an infringement suit could reasonably be asserted against any generic ANDA applicant, including Caraco, that attempts to seek approval for, and market, a generic version of LEXAPRO® before the expiration of the ‘712, ‘941, and ‘069 patents. The listing of the ‘712, ‘941, and ‘069 patents in the Orange Book alone objectively creates the necessary case or controversy and subject matter jurisdiction for an ANDA-filer who makes a paragraph IV certification as to the ‘712, ‘941, and ‘069 patents.

67. Because Caraco seeks FDA approval to market its ANDA Products before expiration of the ‘712, ‘941, and ‘069 patents, Caraco’s ANDA includes paragraph IV certifications to all of the ‘712, ‘941, and ‘069 patents.

68. On May 24, 2006, before the issuance and Orange Book-listing of the ‘069 patent, Caraco sent to Defendants a statutorily-required notice letter of its paragraph IV certifications, which contains a detailed factual and legal statement as to why the ‘712 and ‘941 patents are invalid, unenforceable, and/or not infringed by Caraco’s ANDA Products.

69. On July 10, 2006, Defendants filed a patent infringement lawsuit against Caraco, alleging that Caraco's ANDA Products would infringe the '712 patent. That lawsuit is currently pending in this Court. On February 20, 2007, Caraco filed a declaratory judgment action against Defendants, seeking a declaration that Caraco's ANDA Products will not infringe the '941 patent. In 2008, the Federal Circuit held that Caraco, as an ANDA applicant, alleged a judicially cognizable injury-in-fact sufficient to bring a declaratory action for infringement despite a covenant not to sue given by Defendants, and that lawsuit was returned to this court and is also currently pending. *Caraco Pharma. Labs., Ltd. v. Forest Labs., Inc.*, 527 F.3d 1278, 1294 (Fed. Cir. 2008) ("Caraco has alleged precisely the type of injury that the Declaratory Judgment Act is designed to remedy.")

70. On November 26, 2008, after the '069 patent issued in September 2008 and after Defendants listed the '069 patent in the Orange Book, Caraco sent to Defendants a notice letter of its paragraph IV certifications, which contains a detailed factual and legal statement as to why the '069 patent is invalid, unenforceable, and/or not infringed by Caraco's ANDA Products and contains an offer for confidential access.

71. Upon information and belief, Defendants received Caraco's notice letter of its paragraph IV certifications on December 3, 2008.

72. Although a case or controversy exists between the parties on the '069 patent, Defendants did not yet bring a lawsuit that Caraco's ANDA Products would infringe the '069 patent. Defendants may still bring a lawsuit in the future, and the real and significant risk of a lawsuit, and the significance to Caraco of having its rights resolved, warrants this declaratory judgment action.

73. Caraco, on its notice letter and as required under 21 U.S.C. § 355(i)(5)(C), extended to Defendants an Offer of Confidential Access to Application to access certain information in Caraco's ANDA for escitalopram product.

74. By providing this Offer of Confidential Access to Application, and because Defendants did not sue Caraco on the '069 patent within 45 days of receipt of Caraco's notice of paragraph IV certification, Caraco 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).

**B. Caraco's Need To Obtain Court Judgment On The '069 Patent**

75. Caraco is not only entitled to bring this lawsuit but requires the decision of this lawsuit to avoid indefinite delays in its approval of ANDA No. 78-219.

76. Upon information and belief, Caraco is not the first ANDA filer on the '069 patent.

77. If another filer is a first filer for the '069 patent, and this filer is given precedence despite Caraco's earlier filings and lawsuits, then generic competition for escitalopram products may be delayed until 180 days after expiration of the '069 patent in 2023, unless the first filer begins commercial marketing of its generic escitalopram product prior to the '069 patent's expiration date. Defendants' refusal to litigate the validity and/or noninfringement of the '069 patent is preventing a court decision of invalidity, unenforceability and/or noninfringement on the '069 patent, which would trigger the first filer on the '069 patent's 180-day exclusivity period for the '069 patent, thereby allowing generic competition to the benefit of both Caraco and the American public.

78. Moreover, until and unless Caraco obtains a court decision of noninfringement and/or invalidity on the '069 patent, it faces a risk of potentially enormous infringement damages if it commences marketing before the '069 patent expires. Caraco can alleviate this harm and obtain patent certainty only through a declaratory judgment from this Court on the '069 patent.

**COUNT I**
**Declaration of Noninfringement of the '069 Patent**

79. Caraco realleges and incorporates by reference the allegations of Paragraphs 1-78.

80. This Declaratory Action arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, pursuant to 21 U.S.C. § 355(j)(5)(C), and seeks a declaration that one or more claims of the '069 patent will not be infringed by the manufacture, use, or sale of Caraco's ANDA Products.

81. A present, genuine, and justiciable controversy exists between Defendants and Caraco regarding, *inter alia*, the issue of whether the manufacture, use, or sale of Caraco's ANDA Products would infringe one or more claims of the '069 patent.

82. The manufacture, use, or sale of Caraco's ANDA Products would not infringe the claims of the '069 patent.

83. Caraco is entitled to a declaration that the manufacture, use, or sale of its ANDA Products would not infringe the claims of the '069 patent.

**Prayer for Relief**

WHEREFORE, Defendant Caraco Pharmaceutical Laboratories, Ltd. respectfully requests that this Court enter a Judgment and Order in its favor and against Defendants as follows:

(a) declaring that Caraco has not infringed and that Caraco's manufacture, use, or sale of products covered by ANDA No. 78-219 would not infringe the claims of U.S. Patent No. 7,420,069;

(b) declaring that this is an exceptional case under 35 U.S.C. § 285 and awarding Caraco its attorneys' fees, costs, and expenses in this action; and

(c) awarding Caraco any further and additional relief as the Court deems just and proper.

Dated: January 26, 2009

By: /s/ Moheeb H. Murray

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