Michael E. Patunas
PATUNAS LAW LLC
24 Commerce Street, Suite 606
Newark, NJ 07102
973-396-8740

OF COUNSEL:

James F. Hurst
Marcus E. Sernel, P.C.
KIRKLAND & ELLIS LLP
300 North LaSalle
Chicago, IL 60654
(312) 862-2000

Jeanna M. Wacker
Mira A. Mulvaney
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
(212) 446-4800

Attorneys for Plaintiff

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

IMPAX LABORATORIES, INC., Plaintiff, v. SANDOZ INC., Defendants.	)	Civil Action No. _____

COMPLAINT

Plaintiff, Impax Laboratories, Inc. ("Impax"), by its undersigned attorneys, for its Complaint against Defendant Sandoz Inc. ("Sandoz") hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the Food and Drug Laws and Patent Laws of the United States, Titles 21 and 35 of the United States Code, respectively, arising from Defendants' submissions of Abbreviated New Drug Application ("ANDA") to the Food and Drug Administration ("FDA") seeking approval to manufacture and sell generic versions of Plaintiff's RYTARY® (Levodopa/Carbidopa) capsules prior to the expiration of United States Patent Nos. 7,094,427, 8,377,474, 8,454,998, 8,557,283, 9,089,607, 9,089,608, 9,463,246, and 9,533,046.

THE PARTIES

2. Plaintiff Impax Laboratories, Inc. ("Impax") is a corporation organized and existing under the laws of the State of Delaware, having a principal place of business at 30831 Huntwood Avenue, Hayward, CA 94544.

3. On information and belief, Defendant Sandoz Inc. ("Sandoz") is a corporation organized and existing under the laws of the State of Colorado, having a principal place of business at 100 College Road West, Princeton, New Jersey, 08540.

4. On information and belief, Sandoz is in the business of preparing, manufacturing, and distributing pharmaceutical products throughout the United States, including the State of New Jersey.

JURISDICTION AND VENUE

5. This action arises under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*., generally, and 35 U.S.C. § 271(e)(2), specifically, and this Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

6. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b).

PERSONAL JURISDICTION OVER SANDOZ

7. Plaintiff realleges all preceding paragraphs as if fully set forth herein.

8. On information and belief, Sandoz develops, manufactures, and/or distributes generic drugs for sale and use throughout the United States, including in this judicial district.

9. This Court has personal jurisdiction over Sandoz because, *inter alia*, Sandoz, on information and belief: (1) has substantial, continuous, and systematic contacts with this State; (2) is registered to do business in the State of New Jersey under entity ID 0100097265; (3) intends to market, sell, and/or distribute Sandoz's infringing ANDA products to residents of this State; (4) maintains a principal place of business in this State; (5) maintains a broad distributorship network within this State; and (6) enjoys substantial income from sales of its generic pharmaceutical products in this State.

10. Additionally, on information and belief, Sandoz has previously been sued in this judicial district without objecting on the basis of lack of personal jurisdiction and has availed itself of this judicial district through the assertion of counterclaims.

BACKGROUND

U.S. Patent No. 7,094,427

11. On August 22, 2006, the U.S. Patent and Trademark Office ("PTO") duly and legally issued United States Patent No. 7,094,427 ("the '427 patent") entitled "Combination Immediate Release Controlled Release Levodopa/Carbidopa Dosage Forms" to inventors Chien-Hsuan Han, Larry Hsu and Ann F. Hsu. A true and correct copy of the '427 patent is attached as Exhibit 1.

U.S. Patent No. 8,377,474

12. On February 19, 2013, the PTO duly and legally issued United States Patent No. 8,377,474 ("the '474 patent") entitled "Controlled Release Formulations of Levodopa and Uses Thereof" to inventors Ann Hsu, Jim H. Kou and Laman Alani. A true and correct copy of the '474 patent is attached as Exhibit 2.

U.S. Patent No. 8,454,998

13. On June 4, 2013, the PTO duly and legally issued United States Patent No. 8,454,998 ("the '998 patent") entitled "Controlled Release Formulations of Levodopa and Uses Thereof" to inventors Ann Hsu, Jim H. Kou and Laman Alani. A true and correct copy of the '998 patent is attached as Exhibit 3.

U.S. Patent No. 8,557,283

14. On October 15, 2013, the PTO duly and legally issued United States Patent No. 8,557,283 ("the '283 patent") entitled "Controlled Release Formulations of Levodopa and Uses Thereof" to inventors Ann Hsu, Jim H. Kou and Laman Lynn Alani. A true and correct copy of the '283 patent is attached as Exhibit 4.

U.S. Patent No. 9,089,607

15. On July 28, 2015, the PTO duly and legally issued United States Patent No. 9,089,607 ("the '607 patent") entitled "Controlled Release Formulations of Levodopa and Uses Thereof" to inventors Ann Hsu, Jim H. Kou and Laman Lynn Alani. A true and correct copy of the '607 patent is attached as Exhibit 5.

U.S. Patent No. 9,089,608

16. On July 28, 2015, the PTO duly and legally issued United States Patent No. 9,089,608 ("the '608 patent") entitled "Controlled Release Formulations of Levodopa and Uses Thereof" to inventors Ann Hsu, Jim H. Kou and Laman Lynn Alani. A true and correct copy of the '607 patent is attached as Exhibit 6.

U.S. Patent No. 9,463,246

17. On October 11, 2016, the PTO duly and legally issued United States Patent No. 9,463,246 ("the '246 patent") entitled "Controlled Release Formulations of Levodopa and Uses Thereof" to inventors Ann Hsu, Jim H. Kou and Laman Lynn Alani. A true and correct copy of the '246 patent is attached as Exhibit 7.

U.S. Patent No. 9,533,046

18. On January 3, 2017, the PTO duly and legally issued United States Patent No. 9,533,046 ("the '046 patent") entitled "Controlled Release Formulations of Levodopa and Uses Thereof" to inventors Ann Hsu, Jim H. Kou and Laman Alani. A true and correct copy of the '046 patent is attached as Exhibit 8.

RYTARY®

19. Impax is the holder of New Drug Application ("NDA") No. 203312 ("the NDA") for carbidopa and levodopa capsules, for oral use, in 23.75 mg/95 mg, 36.25 mg/145 mg, 48.75 mg/195 mg, 61.25 mg/245 mg dosages, which is sold under the trade name RYTARY®.

20. RYTARY® is listed in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations database ("Orange Book") as having New Dosage Form Exclusivity until January 7, 2018.

21. Pursuant to 21 U.S.C. § 355(b)(1), and attendant FDA regulations, the ’427, ’474, ’998, ’283, ’607, ’608, ‘246, and ‘046 patents are listed in the “Orange Book” with respect to RYTARY®.

SANDOZ’S PARAGRAPH IV CERTIFICATION

22. On information and belief, Sandoz submitted ANDA No. 208895 (the “Sandoz ANDA”) to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market carbidopa/levodopa extended release capsules, for oral use, in 23.75 mg/95 mg, 36.25 mg/145 mg, 48.75 mg/195 mg, 61.25 mg/245 mg dosages (the “Sandoz ANDA Product”).

23. Sandoz ANDA No. 208895 refers to and relies upon the RYTARY® NDA and contains data that, according to Sandoz, demonstrate the bioequivalence of the Sandoz ANDA Product and RYTARY®.

24. Plaintiff received a letter from Sandoz on or about February 14, 2017, stating that Sandoz had included certifications in the Sandoz ANDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), that, *inter alia*, certain claims of the ’427, ’474, ’998, ’283, ’607, ’608, 246, and ‘046 patents are either invalid or will not be infringed by the commercial manufacture, use, or sale of the Sandoz ANDA Products (the “Sandoz Paragraph IV Certification”) Sandoz’s Paragraph IV Certification included only legal arguments regarding non-infringement of many of the claims of the ’427, ’474, ’998, ’283, ’607, ’608, ‘246, and ‘046 patents and did not factually challenge infringement with respect to most of the ’427, ’474, ’998, ’283, ’607, ’608, ‘246, and ‘046 patent claims.

25. Sandoz's Paragraph IV Certification contained an Offer of Confidential Access, offering to provide Impax's outside counsel with certain portions of ANDA No. 208895, subject to certain limitations, for the purpose of evaluation whether suit should be brought.

26. Since receiving Sandoz's Paragraph IV Certification and the accompanying Offer of Confidential Access, Impax has negotiated with Sandoz to procure a copy of the ANDA under restrictions "as would apply had a protective order been issued." The parties reached agreement on March 28, 2017 and Impax returned the executed Offer of Confidential Access that same day. Nevertheless, to date, Sandoz has not provided any portions of its ANDA to Impax. With the 45-day statutory window to institute litigation about to expire, Impax is left with no choice but to file the instant action prior to receipt of Sandoz's ANDA.

ACTS GIVING RISE TO THIS ACTION

COUNT I - INFRINGEMENT OF THE '427 PATENT BY SANDOZ

27. Plaintiff realleges all preceding paragraphs as if fully set forth herein.

28. Sandoz has infringed at least one claim of the '427 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Sandoz ANDA, by which Sandoz seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Sandoz ANDA Products prior to the expiration of the '427 patent.

29. Sandoz has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Sandoz ANDA Products in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Sandoz's infringement of the '427 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

30. Sandoz's manufacture, use, offer to sell, or sale of the Sandoz ANDA Products in the United States or importation of the Sandoz ANDA Products into the United States during the term of the '427 patent would further infringe at least one claim of the '427 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

31. On information and belief, the Sandoz ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '427 patent either literally or under the doctrine of equivalents.

32. On information and belief, the use of the Sandoz ANDA Products constitute a material part of at least one of the claims of the '427 patent; Sandoz knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the '427 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

33. On information and belief, the offering to sell, sale, and/or importation of the Sandoz ANDA Products would contributorily infringe at least one of the claims of the '427 patent, either literally or under the doctrine of equivalents.

34. On information and belief, Sandoz had knowledge of the '427 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another's direct infringement of at least one of the claims of the '427 patent, either literally or under the doctrine of equivalents.

35. On information and belief, the offering to sell, sale, and/or importation of the Sandoz ANDA Products would actively induce infringement of at least one of the claims of the ’427 patent, either literally or under the doctrine of equivalents.

36. Plaintiff will be substantially and irreparably harmed if Sandoz is not enjoined from infringing the ’427 patent.

37. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Impax’s reasonable attorney fees.

COUNT II - INFRINGEMENT OF THE ’474 PATENT BY SANDOZ

38. Plaintiff realleges all preceding paragraphs as if fully set forth herein.

39. Sandoz has infringed at least one claim of the ’474 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Sandoz ANDA, by which Sandoz seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Sandoz ANDA Products prior to the expiration of the ’474 patent.

40. Sandoz has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Sandoz ANDA Products in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Sandoz’s infringement of the ’474 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

41. Sandoz’s manufacture, use, offer to sell, or sale of the Sandoz ANDA Products in the United States or importation of the Sandoz ANDA Products into the United States during the term of the ’474 patent would further infringe at least one claim of the ’474 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

42. On information and belief, the Sandoz ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the ’474 patent either literally or under the doctrine of equivalents.

43. On information and belief, the use of the Sandoz ANDA Products constitute a material part of at least one of the claims of the ’474 patent; Sandoz knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the ’474 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

44. On information and belief, the offering to sell, sale, and/or importation of the Sandoz ANDA Products would contributorily infringe at least one of the claims of the ’474 patent, either literally or under the doctrine of equivalents.

45. On information and belief, Sandoz had knowledge of the ’474 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another’s direct infringement of at least one of the claims of the ’474 patent, either literally or under the doctrine of equivalents.

46. On information and belief, the offering to sell, sale, and/or importation of the Sandoz ANDA Products would actively induce infringement of at least one of the claims of the ’474 patent, either literally or under the doctrine of equivalents.

47. Plaintiff will be substantially and irreparably harmed if Sandoz is not enjoined from infringing the ’474 patent.

48. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Impax’s reasonable attorney fees.

COUNT III - INFRINGEMENT OF THE ’998 PATENT BY SANDOZ

49. Plaintiff realleges all preceding paragraphs as if fully set forth herein.

50. Sandoz has infringed at least one claim of the ’998 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Sandoz ANDA, by which Sandoz seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Sandoz ANDA Products prior to the expiration of the ’998 patent.

51. Sandoz has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Sandoz ANDA Products in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Sandoz’s infringement of the ’998 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

52. Sandoz’s manufacture, use, offer to sell, or sale of the Sandoz ANDA Products in the United States or importation of the Sandoz ANDA Products into the United States during the term of the ’998 patent would further infringe at least one claim of the ’998 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

53. On information and belief, the Sandoz ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly

infringe at least one of the claims of the ’998 patent either literally or under the doctrine of equivalents.

54. On information and belief, the use of the Sandoz ANDA Products constitute a material part of at least one of the claims of the ’998 patent; Sandoz knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the ’998 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

55. On information and belief, the offering to sell, sale, and/or importation of the Sandoz ANDA Products would contributorily infringe at least one of the claims of the ’998 patent, either literally or under the doctrine of equivalents.

56. On information and belief, Sandoz had knowledge of the ’998 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another’s direct infringement of at least one of the claims of the ’998 patent, either literally or under the doctrine of equivalents.

57. On information and belief, the offering to sell, sale, and/or importation of the Sandoz ANDA Products would actively induce infringement of at least one of the claims of the ’998 patent, either literally or under the doctrine of equivalents.

58. Plaintiff will be substantially and irreparably harmed if Sandoz is not enjoined from infringing the ’998 patent.

59. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Impax's reasonable attorney fees.

COUNT IV - INFRINGEMENT OF THE '283 PATENT BY SANDOZ

60. Plaintiff realleges all preceding paragraphs as if fully set forth herein.

61. Sandoz has infringed at least one claim of the '283 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Sandoz ANDA, by which Sandoz seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Sandoz ANDA Products prior to the expiration of the '283 patent.

62. Sandoz has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Sandoz ANDA Products in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Sandoz's infringement of the '283 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

63. Sandoz's manufacture, use, offer to sell, or sale of the Sandoz ANDA Products in the United States or importation of the Sandoz ANDA Products into the United States during the term of the '283 patent would further infringe at least one claim of the '283 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

64. On information and belief, the Sandoz ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '283 patent either literally or under the doctrine of equivalents.

65. On information and belief, the use of the Sandoz ANDA Products constitute a material part of at least one of the claims of the ’283 patent; Sandoz knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the ’283 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

66. On information and belief, the offering to sell, sale, and/or importation of the Sandoz ANDA Products would contributorily infringe at least one of the claims of the ’283 patent, either literally or under the doctrine of equivalents.

67. On information and belief, Sandoz had knowledge of the ’283 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another’s direct infringement of at least one of the claims of the ’283 patent, either literally or under the doctrine of equivalents.

68. On information and belief, the offering to sell, sale, and/or importation of the Sandoz ANDA Products would actively induce infringement of at least one of the claims of the ’283 patent, either literally or under the doctrine of equivalents.

69. Plaintiff will be substantially and irreparably harmed if Sandoz is not enjoined from infringing the ’283 patent.

70. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Impax’s reasonable attorney fees.

COUNT V - INFRINGEMENT OF THE ’607 PATENT BY SANDOZ

71. Plaintiff realleges all preceding paragraphs as if fully set forth herein.

72. Sandoz has infringed at least one claim of the ’607 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Sandoz ANDA, by which Sandoz seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Sandoz ANDA Products prior to the expiration of the ’607 patent.

73. Sandoz has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Sandoz ANDA Products in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Sandoz’s infringement of the ’607 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

74. Sandoz’s manufacture, use, offer to sell, or sale of the Sandoz ANDA Products in the United States or importation of the Sandoz ANDA Products into the United States during the term of the ’607 patent would further infringe at least one claim of the ’607 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

75. On information and belief, the Sandoz ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the ’607 patent either literally or under the doctrine of equivalents.

76. On information and belief, the use of the Sandoz ANDA Products constitute a material part of at least one of the claims of the ’607 patent; Sandoz knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the ’607 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not

staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

77. On information and belief, the offering to sell, sale, and/or importation of the Sandoz ANDA Products would contributorily infringe at least one of the claims of the ’607 patent, either literally or under the doctrine of equivalents.

78. On information and belief, Sandoz had knowledge of the ’607 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another’s direct infringement of at least one of the claims of the ’607 patent, either literally or under the doctrine of equivalents.

79. On information and belief, the offering to sell, sale, and/or importation of the Sandoz ANDA Products would actively induce infringement of at least one of the claims of the ’607 patent, either literally or under the doctrine of equivalents.

80. Plaintiff will be substantially and irreparably harmed if Sandoz is not enjoined from infringing the ’607 patent.

81. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Impax’s reasonable attorney fees.

COUNT VI - INFRINGEMENT OF THE ’608 PATENT BY SANDOZ

82. Plaintiff realleges all preceding paragraphs as if fully set forth herein.

83. Sandoz has infringed at least one claim of the ’608 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Sandoz ANDA, by which Sandoz

seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Sandoz ANDA Products prior to the expiration of the ’608 patent.

84. Sandoz has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Sandoz ANDA Products in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Sandoz’s infringement of the ’608 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

85. Sandoz’s manufacture, use, offer to sell, or sale of the Sandoz ANDA Products in the United States or importation of the Sandoz ANDA Products into the United States during the term of the ’608 patent would further infringe at least one claim of the ’608 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

86. On information and belief, the Sandoz ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the ’608 patent either literally or under the doctrine of equivalents.

87. On information and belief, the use of the Sandoz ANDA Products constitute a material part of at least one of the claims of the ’608 patent; Sandoz knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the ’608 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

88. On information and belief, the offering to sell, sale, and/or importation of the Sandoz ANDA Products would contributorily infringe at least one of the claims of the ’608 patent, either literally or under the doctrine of equivalents.

89. On information and belief, Sandoz had knowledge of the ’608 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another’s direct infringement of at least one of the claims of the ’608 patent, either literally or under the doctrine of equivalents.

90. On information and belief, the offering to sell, sale, and/or importation of the Sandoz ANDA Products would actively induce infringement of at least one of the claims of the ’608 patent, either literally or under the doctrine of equivalents.

91. Plaintiff will be substantially and irreparably harmed if Sandoz is not enjoined from infringing the ’608 patent.

92. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Impax’s reasonable attorney fees.

COUNT VII - INFRINGEMENT OF THE ’246 PATENT BY SANDOZ

93. Plaintiff realleges all preceding paragraphs as if fully set forth herein.

94. On information and belief, Sandoz submitted ANDA No. 208895 (the “Sandoz ANDA”) to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market carbidopa/levodopa extended release capsules, for oral use, in 23.75 mg/95 mg, 36.25 mg/145 mg, 48.75 mg/195 mg, 61.25 mg/245 mg dosages (the “Sandoz ADNA Product”).

95. Sandoz ANDA No. 208895 refers to and relies upon the RYTARY® NDA and contains data that, according to Sandoz, demonstrate the bioequivalence of the Sandoz ANDA Product and RYTARY®.

96. Sandoz has infringed at least one claim of the '246 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Sandoz ANDA, by which Sandoz seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Sandoz ANDA Products prior to the expiration of the '246 patent.

97. Sandoz has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Sandoz ANDA Products in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Sandoz's infringement of the '246 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

98. Sandoz's manufacture, use, offer to sell, or sale of the Sandoz ANDA Products in the United States or importation of the Sandoz ANDA Products into the United States during the term of the '246 patent would further infringe at least one claim of the '246 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

99. On information and belief, the Sandoz ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly infringe at least one of the claims of the '246 patent either literally or under the doctrine of equivalents.

100. On information and belief, the use of the Sandoz ANDA Products constitute a material part of at least one of the claims of the '246 patent; Sandoz knows that its ANDA

Products are especially made or adapted for use in infringing at least one of the claims of the ’246 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

101. On information and belief, the offering to sell, sale, and/or importation of the Sandoz ANDA Products would contributorily infringe at least one of the claims of the ’246 patent, either literally or under the doctrine of equivalents.

102. On information and belief, Sandoz had knowledge of the ’246 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another’s direct infringement of at least one of the claims of the ’246 patent, either literally or under the doctrine of equivalents.

103. On information and belief, the offering to sell, sale, and/or importation of the Sandoz ANDA Products would actively induce infringement of at least one of the claims of the ’246 patent, either literally or under the doctrine of equivalents.

104. Plaintiff will be substantially and irreparably harmed if Sandoz is not enjoined from infringing the ’246 patent.

105. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Impax’s reasonable attorney fees.

COUNT VIII - INFRINGEMENT OF THE ’046 PATENT BY SANDOZ

106. Plaintiff realleges all preceding paragraphs as if fully set forth herein.

107. On information and belief, Sandoz submitted ANDA No. 208895 (the "Sandoz ANDA") to the FDA, pursuant to 21 U.S.C. § 355(j), seeking approval to market carbidopa/levodopa extended release capsules, for oral use, in 23.75 mg/95 mg, 36.25 mg/145 mg, 48.75 mg/195 mg, 61.25 mg/245 mg dosages (the "Sandoz ADNA Product").

108. Sandoz ANDA No. 208895 refers to and relies upon the RYTARY® NDA and contains data that, according to Sandoz, demonstrate the bioequivalence of the Sandoz ANDA Product and RYTARY®.

109. Sandoz has infringed at least one claim of the '046 patent, pursuant to 35 U.S.C. § 271(e)(2)(A), by submitting, or causing to be submitted the Sandoz ANDA, by which Sandoz seeks approval from the FDA to engage in the manufacture, use, offer to sell, sale, or importation of the Sandoz ANDA Products prior to the expiration of the '046 patent.

110. Sandoz has declared its intent to manufacture, use, offer to sell, or sell in the United States or to import into the United States, the Sandoz ANDA Products in the event that the FDA approves the Sandoz ANDA. Accordingly, an actual and immediate controversy exists regarding Sandoz's infringement of the '046 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

111. Sandoz's manufacture, use, offer to sell, or sale of the Sandoz ANDA Products in the United States or importation of the Sandoz ANDA Products into the United States during the term of the '046 patent would further infringe at least one claim of the '046 patent under 35 U.S.C. §§ 271 (a), (b), and/or (c).

112. On information and belief, the Sandoz ANDA Products, when offered for sale, sold, and/or imported, and when used as directed, would be used in a manner that would directly

infringe at least one of the claims of the ’046 patent either literally or under the doctrine of equivalents.

113. On information and belief, the use of the Sandoz ANDA Products constitute a material part of at least one of the claims of the ’046 patent; Sandoz knows that its ANDA Products are especially made or adapted for use in infringing at least one of the claims of the ’046 patent, either literally or under the doctrine of equivalents; and its ANDA Products are not staple articles of commerce or commodities of commerce suitable for substantial noninfringing use.

114. On information and belief, the offering to sell, sale, and/or importation of the Sandoz ANDA Products would contributorily infringe at least one of the claims of the ’046 patent, either literally or under the doctrine of equivalents.

115. On information and belief, Sandoz had knowledge of the ’046 patent and, by its promotional activities and package inserts for its ANDA Products, knows or should know that it will aid and abet another’s direct infringement of at least one of the claims of the ’046 patent, either literally or under the doctrine of equivalents.

116. On information and belief, the offering to sell, sale, and/or importation of the Sandoz ANDA Products would actively induce infringement of at least one of the claims of the ’046 patent, either literally or under the doctrine of equivalents.

117. Plaintiff will be substantially and irreparably harmed if Sandoz is not enjoined from infringing the ’046 patent.

118. This is an exceptional case within the meaning of 35 U.S.C. § 285, which warrants reimbursement of Impax's reasonable attorney fees.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully request that the Court enter judgment against Defendants and for the following relief:

a. A Judgment be entered that Sandoz has infringed at least one claim of the '427, '474, '998, '283, '607, '608, '246 and '046 patents by submitting the Sandoz ANDA;

b. That Defendants, their officers, agents, servants, employees, and those persons acting in active concert or participation with all or any of them from be preliminarily and permanently enjoined from: (i) engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of drugs or methods of administering drugs claimed in the '427, '474, '998, '283, '607, '608, '246 and/or '046 patents, and (ii) seeking, obtaining or maintaining approval of ANDA until the expiration of the '427, '474, '998, '283, '607, '608, '246 and/or '046 patents or such other later time as the Court may determine;

c. A judgment ordering that pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Defendants' ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) shall not be earlier than the latest of the expiration dates of the '427, '474, '998, '283, '607, '608, '246 and/or '046 patents, including any extensions;

d. That Impax be awarded monetary relief if Defendants commercially use, offer to sell, or sell their respective proposed generic versions of RYTARY® or any other product that infringes or induces or contributes to the infringement of the '427, '474, '998, '283, '607, '608, '246

and/or '046 patents, within the United States, prior to the expiration of those patents, including any extensions, and that any such monetary relief be awarded to Impax with prejudgment interest;

e. Costs and expenses in this action; and

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

Dated: March 31, 2017

Respectfully submitted,

s/ Michael E. Patunas

Michael E. Patunas
PATUNAS LAW LLC
24 Commerce Street, Suite 606
Newark, NJ 07102
(973)-396-8740
mpatunas@patunaslaw.com

Attorney for Plaintiff

OF COUNSEL:

James F. Hurst
Marcus E. Sernel, P.C.
KIRKLAND & ELLIS LLP
300 North LaSalle
Chicago, IL 60654
(312) 862-2000

Jeanna M. Wacker
Mira A. Mulvaney
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
(212) 446-4800

RULE 11.2 CERTIFICATION

I hereby certify that, to the best of my knowledge, the matter in controversy is related to the following matter: *Impax Labs, Inc. v. Actavis Labs FL, Inc. et al.*, No. 15-cv-6934-SRC-CLW, pending in the United States District Court for the District of New Jersey.

I further certify that, to the best of my knowledge, the matter in controversy is not the subject of any other pending or anticipated litigation in any court or arbitration proceeding other than the above referenced matter, nor are there any non-parties known to Plaintiff that should be joined to this action. In addition, I recognize a continuing obligation during the course of this litigation to file and to serve on all other parties and with the Court an amended certification if there is a change in the facts stated in this original certification.

Dated: March 31, 2017

PATUNAS LAW LLC

s/ Michael E. Patunas

Michael E. Patunas
24 Commerce Street, Suite 606
Newark, NJ 07102
973-396-8740

Attorney for Plaintiff

OF COUNSEL:

James F. Hurst
Marcus E. Sernel P.C.
KIRKLAND & ELLIS LLP
300 North LaSalle
Chicago, IL 60654
(312) 862-2000

Jeanna M. Wacker
Mira A. Mulvaney
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
(212) 446-4800

RULE 201.1 CERTIFICATION

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that the Plaintiff seeks, *inter alia*, injunctive relief.

Dated: March 31, 2017

PATUNAS LAW LLC

s/ Michael E. Patunas

Michael E. Patunas
24 Commerce Street, Suite 606
Newark, NJ 07102
973-396-8740

Attorney for Plaintiff

OF COUNSEL:

James F. Hurst
Marcus E. Sernel, P.C.
KIRKLAND & ELLIS LLP
300 North LaSalle
Chicago, IL 60654
(312) 862-2000

Jeanna M. Wacker
Mira A. Mulvaney
KIRKLAND & ELLIS LLP
601 Lexington Avenue
New York, NY 10022
(212) 446-4800