IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SUMITOMO DAINIPPON PHARMA CO., LTD. and SUNOVION PHARMACEUTICALS INC.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
AMNEAL PHARMACEUTICALS, LLC,	)	
Defendant.	)	

PLAINTIFFS SUMITOMO DAINIPPON PHARMA CO., LTD AND SUNOVION PHARMACEUTICALS INC.'S COMPLAINT FOR PATENT INFRINGEMENT AGAINST AMNEAL PHARMACEUTICALS, LLC

Plaintiffs Sumitomo Dainippon Pharma Co., Ltd. ("Sumitomo") and Sunovion Pharmaceuticals Inc. ("Sunovion") (collectively, "Plaintiffs"), for their complaint against Amneal Pharmaceuticals, LLC ("Amneal" or "Defendant"), allege as follows:

NATURE OF ACTION

1. This is an action for infringement of United States Patent No. 9,815,827 ("the '827 patent") under 35 U.S.C. § 271(e)(2) and for declaratory judgment of infringement under 28 U.S.C. §§ 2201-02 and 35 U.S.C. §§ 271(b) and (c) relating to Plaintiffs' commercially successful product, Latuda®. A true and accurate copy of the '827 patent is attached hereto as Exhibit A.

THE PARTIES

2. Plaintiff Sumitomo Dainippon Pharma Co., Ltd. is a company organized and existing under the laws of Japan, with a principal place of business at 6-8, Doshomachi 2-chome, Chuo-ku, Osaka, Osaka 541-0045, Japan.

3. Plaintiff Sunovion Pharmaceuticals Inc. is a corporation organized and existing under the laws of Delaware, with a principal place of business at 84 Waterford Drive, Marlborough, Massachusetts 01752.

4. On information and belief, Defendant Amneal is a limited liability company organized under the laws of Delaware, having a principal place of business at 400 Crossing Blvd, 3rd Floor, Bridgewater, New Jersey 08807.

5. On information and belief, Amneal is in the business of manufacturing, distributing, and selling generic drugs throughout the United States, including in the District of Delaware. On further information and belief, Amneal has worked to submit to and is working to achieve final approval by the U.S. Food and Drug Administration ("FDA") of Abbreviated New Drug Application ("ANDA") No. 208002.

JURISDICTION AND VENUE

6. This action arises under the patent laws of the United States of America, United States Code, Title 35, Section 1, *et seq*., including §§ 271(e)(2), 271(b), 271(c), and 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction over the action under 28 U.S.C. §§ 1331, 1338, 2201, and 2202.

7. This Court has personal jurisdiction over Amneal by virtue of, *inter alia*, being organized under the laws of the State of Delaware and its systematic and continuous contacts with this jurisdiction, as alleged herein. On information and belief, either directly, or through its subsidiaries, agents, and/or affiliates, Amneal regularly and continuously transacts business within Delaware, including by selling pharmaceutical products in Delaware. On information and belief, Amneal derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware. Plaintiffs have been

injured in Delaware because of Amneal's filing of its ANDA and the causes of action Plaintiffs raise here, as alleged herein.

8. Further, this Court has personal jurisdiction over Amneal because Amneal has committed an act of patent infringement under 35 U.S.C. § 271(e)(2), and, on information and belief, Amneal intends a future course of conduct that includes acts of patent infringement in Delaware. On information and belief, Amneal manufactures, sells, offers for sale, markets, distributes, and/or imports versions of pharmaceutical products in the United States, including in Delaware. On information and belief, Amneal developed a generic copy of Plaintiffs' Latuda® tablets. On information and belief, Amneal prepared and filed ANDA No. 208002, seeking approval from the FDA to sell its generic lurasidone hydrochloride tablets throughout the United States, including in Delaware.

9. On information and belief, Amneal intends to market its generic lurasidone hydrochloride tablets in Delaware upon final approval of such product by the FDA.

10. On information and belief, Amneal's conduct has or will cause foreseeable harm and injury to Plaintiffs.

11. Further, this Court has personal jurisdiction over Amneal because Amneal has previously been sued in this district and has not challenged personal jurisdiction, and Amneal has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See, e.g., Biogen Int'l GmbH v. Amneal Pharms. LLC*, No. 17-cv-823 (D. Del.); *Purdue Pharma LP v. Amneal Pharms. LLC*, No. 17-cv-1421 (D. Del.); *Gilead Scis., Inc. v. Amneal Pharms., LLC*, No. 17-cv-943 (D. Del.).

12. In addition, Amneal has previously elected to avail itself of the benefits of litigating its patent disputes in the District of Delaware. *See, e.g.*, *Amneal Pharms., LLC et al v.*

Teva Pharms. USA, Inc., No. 17-cv-74 (D. Del.); *Amneal Pharms., LLC v. Pfizer, Inc*., No. 17-cv-454 (D. Del.); *Amneal Pharms., LLC v. GlaxoSmithKline LLC*, No. 16-cv-300 (D. Del.).

13. The Corporation Trust Company, 1209 Orange Street, Corporation Trust Center, Wilmington, Delaware 19801, serves as Amneal's registered agent in Delaware.

14. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1400(b) because Delaware is the judicial district in which Amneal resides.

15. Venue is also proper in this District under 28 U.S.C. § 1400(b) because Amneal "committed an act of infringement" in the district. Amneal submitted its ANDA No. 208002 pursuant to Section 505(j) of the Federal Food, Drug, and Cosmetics Act ("FFDCA") (codified at 21 U.S.C. § 355(j)), and, upon receiving final approval of its ANDA, will manufacture, sell, offer to sell, and/or import Amneal's proposed generic lurasidone hydrochloride tablets in the United States, including in the District of Delaware. Thus, Amneal has committed an act of infringement in this district. Amneal is also registered or licensed to do business in Delaware as a pharmacy (Reg. Nos. A4-0001536, A4-0002253) and as a distributor or manufacturer of controlled substances (Reg. No. DM-0006588).

16. The Court has jurisdiction to adjudicate this action under the Declaratory Judgment Act, 28 U.S.C. §§ 2201-02. An actual, substantial, and justiciable controversy exists between Plaintiffs and Amneal of sufficient immediacy and reality to warrant the issuance of a declaratory judgment regarding the parties' adverse legal interests with respect to the '827 patent.

FACTUAL BACKGROUND

Background of the Invention

17. Antipsychotic drug products are used in the management of psychotic symptoms associated with disorders including schizophrenia and bipolar disorder. *See, e.g.*, '827 patent col. 1 ll.47-49.

18. Conventional drug product treatments for psychotic symptoms were known to cause unwanted serious side effects. *See, e.g.*, '827 patent col.1 ll.57-63.

19. Weight gain is a well-known side effect of conventional antipsychotic drug products. *See, e.g.*, File History of U.S. Application No. 14/471,919, Notice of Allowance dated 2017-07-17 ("Notice of Allowance"), at 2 ("[C]onventional antipsychotic drug[s] cause[ ] serious side effects such as undesired metabolic changes . . . which were considered as closely linked with a weight gain."); *see also* Latuda® Prescribing Information (2/2017) at Section 5.6 ("Atypical antipsychotic drugs have been associated with metabolic changes . . . includ[ing] . . . weight gain." . . . "Weight gain has been observed with atypical antipsychotic use.").

20. On information and belief, the relationship between antipsychotic drug product use and patient weight is complex and poorly understood.

21. On information and belief, antipsychotic drug products exert different physiological effects relating to weight.

22. There is a need for drugs that are effective antipsychotics but that do not cause undesirable side effects, such as weight gain.

U.S. Patent No. 9,815,827

23. The ’827 patent, entitled “Agent for Treatment of Schizophrenia”, issued on November 14, 2017 and names Mitsutaka Nakamura, Masaaki Ogasa, and Shunsuke Sami as inventors.

24. By assignment, plaintiff Sumitomo owns all right, title, and interest in and to the ’827 patent.

25. Plaintiff Sunovion is the exclusive licensee to the ’827 patent in the United States.

26. Plaintiff Sunovion is the holder of approved New Drug Application (“NDA”) No. 200603 for lurasidone hydrochloride tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg), which are sold in the United States under the registered trademark Latuda®.

27. In conjunction with NDA No. 200603, Sunovion has listed with the FDA nine patents for Latuda®. The listed patents are U.S. Patent Nos. 5,532,372, 8,729,085, 8,883,794, 9,174,975, 9,259,423, 9,555,027, 9,815,827, 9,827,242, and RE45573. The FDA has published these nine patents in the Approved Drug Products with Therapeutic Equivalence Evaluations, commonly referred to as the “Orange Book.” The Orange Book identifies drug products approved on the basis of safety and effectiveness by the FDA under the FFDCA.

28. Latuda®, or approved methods of using Latuda®, are covered by at least one claim of the ’827 patent listed in the Orange Book.

29. The ’827 patent is directed to methods of treating patients, including those with schizophrenia or manic depressive psychosis, with an antipsychotic without a clinically significant weight gain. The methods of treatment disclosed in the ’827 patent accomplish this through the oral administration of a particular dose, 20 mg to 120 mg, of lurasidone or a pharmaceutically acceptable salt of lurasidone (e.g., lurasidone hydrochloride) such that the

patient does not experience clinically significant weight gain for specific periods of time, including after six weeks of administration. Administration of such specific doses, and for such specific periods of treatment, result in a patient not experiencing clinically significant weight gain, which was not well understood, routine, or a conventional technique in the art.

30. Claims 40 and 43 of the ’827 patent are illustrative and recite:

> 40. A method of treating a patient with an antipsychotic without a clinically significant weight gain, comprising:
>
> orally administering once daily to the patient a pharmaceutical composition comprising 20 to 120 mg of (1R, 2S, 3R, 4S)-N-[(1R, 2R)-2-[4-(1,2-benzoisothiazol-3-ly)-1-piperazinylmethyl]-1-cyclohexylmethyl]-2,3-bicyclo[2.2.1]heptanedicarboximide or a pharmaceutically acceptable salt thereof as the sole active ingredient such that the patient does not experience a clinically significant weight gain.
>
> 43. The method of claim 41, wherein the administering is conducted such that the patient does not experience a clinically significant weight gain after six weeks of administration.

(’827 patent, Cls. 40, 43.)

31. The claimed elements of exemplary claims 40 and 43 are found in the Latuda® Prescribing Information.

32. The Latuda® Prescribing Information describes Latuda® as “an atypical antipsychotic belong to the chemical class of benzisothiazol derivatives.” (Latuda® Prescribing Information (2/2017) at Section 11.)

33. The Latuda® Prescribing Information states “LATUDA tablets are intended for oral administration only. Each tablet contains 20 mg, 40 mg, 60 mg, 80 mg, or 120 mg of lurasidone hydrochloride.” (Latuda® Prescribing Information (2/2017) at Section 11; *see also id.* at Section 3.)

34. The Latuda® Prescribing Information describes Latuda is indicated for treatment of adult and adolescent patients age 13 to 17 years with schizophrenia, monotherapy treatment of adult patients with major depressive episodes associated with bipolar I disorder (bipolar depression), and adjunctive treatment with lithium or valproate in adult patients with major depressive episodes associated with bipolar I disorder (bipolar depression). (Latuda® Prescribing Information (2/2017) at Section 1.)

35. It further describes the dosage and administration for Latuda®. With respect to adult patients with schizophrenia, the Latuda® Prescribing Information states "[t]he recommended starting dose of LATUDA is 40 mg once daily. Initial dose titration is not required. LATUDA has been shown to be effective in a dose range of 40 mg per day to 160 mg per day. . . The maximum recommended dose is 160 mg per day." (Latuda Prescribing Information (2/2017) at Section 2.1.) With respect to adolescent patients with schizophrenia, the Latuda® Prescribing Information states "[t]he recommended starting dose of LATUDA is 40 mg once daily. Initial dose titration is not required. LATUDA has been shown to be effective in a dose range of 40 mg per day to 80 mg per day . . . The maximum recommended dose is 80 mg per day." (*Id*.)

36. For depressive episodes associated with bipolar I disorder, the Latuda® Prescribing Information states "the recommended starting dose of LATUDA in adults is 20 mg given once daily as monotherapy or as adjunctive therapy with lithium or valproate. Initial dose titration is not required. LATUDA has been shown to be effective in a dose range of 20 mg per day to 120 mg per day as monotherapy or as adjunctive therapy with lithium or valproate . . . The maximum recommended dose, as monotherapy or as adjunctive therapy with lithium or valproate, is 120 mg per day." (Latuda® Prescribing Information (2/2017) at Section 2.2.)

37. When 20 mg to 120 mg of Latuda® is orally administered to patients, they do not experience a clinically significant weight gain. For example, the Latuda® Prescribing Information describes the following:

Weight Gain

Weight gain has been observed with atypical antipsychotic use. Clinical monitoring of weight is recommended.

Schizophrenia

Adults

Pooled data from short-term, placebo-controlled schizophrenia studies are presented in Table 9. The mean weight gain was +0.43 kg for LATUDA-treated patients compared to -0.02 kg for placebo-treated patients. Change in weight from baseline for olanzapine was +4.15 kg and for quetiapine extended-release was +2.09 kg in Studies 3 and 5 *[see Clinical Studies (14.1)]*, respectively. The proportion of patients with a ≥7% increase in body weight (at Endpoint) was 4.8% for LATUDA-treated patients versus 3.3% for placebo-treated patients.

Table 9: Mean Change in Weight (kg) from Baseline in Adult Schizophrenia Studies

	Placebo (n=696)	LATUDA 20 mg/day (n=71)	40 mg/day (n=484)	80 mg/day (n=526)	120 mg/day (n=291)	160 mg/day (n=114)
All Patients	-0.02	-0.15	+0.22	+0.54	+0.68	+0.60

In the uncontrolled, longer-term schizophrenia studies (primarily open-label extension studies), LATUDA was associated with a mean change in weight of -0.69 kg at week 24 (n=755), -0.59 kg at week 36 (n=443) and -0.73 kg at week 52 (n=377).

Adolescents

Data from the short-term, placebo-controlled adolescent schizophrenia study are presented in Table 10. The mean weight gain was +0.5 kg for LATUDA-treated patients compared to +0.2 kg for placebo-treated patients. The proportion of patients with a ≥7% increase in body weight (at Endpoint) was 3.3% for LATUDA-treated patients versus 4.5% for placebo-treated patients.

Table 10: Mean Change in Weight (kg) from Baseline in the Adolescent Schizophrenia Study

	Placebo (n=111)	LATUDA 40 mg/day (n=109)	80 mg/day (n=104)
All Patients	+0.2	+0.3	+0.7

Bipolar Depression

Monotherapy

Data from the adult short-term, flexible-dosed, placebo-controlled monotherapy bipolar depression study are presented in Table 11. The mean weight gain was +0.29 kg for LATUDA-treated patients compared to -0.04 kg for placebo-treated patients. The proportion of patients with a ≥7% increase in body weight (at Endpoint) was 2.4% for LATUDA-treated patients versus 0.7% for placebo-treated patients.

Table 11: Mean Change in Weight (kg) from Baseline in the Adult Monotherapy Bipolar Depression Study

	Placebo (n=151)	LATUDA 20 to 60 mg/day (n=143)	80 to 120 mg/day (n=147)
All Patients	-0.04	+0.56	+0.02

Patients were randomized to flexibly dosed LATUDA 20 to 60 mg/day, LATUDA 80 to 120 mg/day, or placebo

In the uncontrolled, open-label, longer-term bipolar depression study, patients who received LATUDA as monotherapy in the short-term and continued in the longer-term study had a mean change in weight of -0.02 kg at week 24 (n=130).

Adjunctive Therapy with Lithium or Valproate

Data from the adult short-term, flexible-dosed, placebo-controlled adjunctive therapy bipolar depression studies are presented in Table 12. The mean weight gain was +0.11 kg for LATUDA-treated patients compared to +0.16 kg for placebo-treated patients. The proportion of patients with a ≥7% increase in body weight (at Endpoint) was 3.1% for LATUDA-treated patients versus 0.3% for placebo-treated patients.

Table 12: Mean Change in Weight (kg) from Baseline in the Adult Adjunctive Therapy Bipolar Depression Studies

	Placebo (n=307)	LATUDA 20 to 120 mg/day (n=327)
All Patients	+0.16	+0.11

Patients were randomized to flexibly dosed LATUDA 20 to 120 mg/day or placebo as adjunctive therapy with lithium or valproate.

In the uncontrolled, open-label, longer-term bipolar depression study, patients who were treated with LATUDA, as adjunctive therapy with either lithium or valproate in the short-term and continued in the longer-term study, had a mean change in weight of +1.28 kg at week 24 (n=86).

(Latuda® Prescribing Information (2/2017) at Section 5.6.) The change in weight results shown in Tables 9 and 11 reflect the change in weight after six weeks of administration of Latuda® as described in the short-term, placebo-controlled schizophrenia and short-term, flexible-dosed, placebo-controlled monotherapy bipolar depression studies, respectively, described in the Latuda® Prescribing Information. (Latuda® Prescribing Information (2/2017) at Section 14.) The label also describes the weight gain seen in patients from longer term, open-label studies. (Latuda® Prescribing Information (2/2017) at Section 10.)

38. The therapeutic use of Latuda® represents an improvement over prior art methods of treating patients with an antipsychotic drug product, including those patients with schizophrenia and bipolar disorder.

Acts Giving Rise to This Action

39. On information and belief, Amneal submitted to the FDA ANDA No. 208002 pursuant to Section 505(j) of the FFDCA, seeking the FDA's approval to engage in the commercial manufacture, use, and/or sale of lurasidone hydrochloride tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) (Amneal's "Proposed ANDA Product") prior to the expiration of the '827 patent. On information and belief, Amneal's ANDA No. 208002 contains data from bioavailability or bioequivalence studies for such tablets.

40. On information and belief, Amneal sent a "Notice of Paragraph IV Certification of U.S. Patents 9,815,827 and 9,827,242" to Plaintiffs ("Notice Letter"), purporting to be a notice pursuant to 21 U.S.C. § 355(j)(2)(B)(ii)(I), (B)(iv)(I). Amneal's Notice Letter bears the date January 8, 2018.

41. Plaintiff Sunovion received Amneal's Notice Letter on January 9, 2018.

42. Plaintiff Sumitomo received Amneal's Notice Letter on January 11, 2018.

43. Plaintiffs commenced this action within 45 days after receiving Amneal's Notice Letter.

44. On information and belief, Amneal's proposed label for its Proposed ANDA Product ("Proposed Label") will refer to the product as, *inter alia*, an atypical antipsychotic for the treatment of schizophrenia in adults and adolescents (13 to 17) and depressive episodes associated with Bipolar I Disorder (bipolar depression) in adults, and will describe the strength of the generic lurasidone hydrochloride tablets as 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg. On

information and belief, Amneal's Proposed Label will instruct physicians and healthcare providers to administer Amneal's Proposed ANDA Product for, *inter alia*, the treatment of schizophrenia and depressive episodes associated with bipolar I disorder (bipolar depression).

45. On information and belief, Amneal's Proposed Label will contain data relating to patient weight gain, obtained from clinical studies involving, *inter alia*, Latuda® (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg). On information and belief, the weight gain data in Amneal's Proposed Label demonstrate that patients receiving Latuda® and/or Amneal's Proposed ANDA Product will not experience clinically significant weight gain.

46. On information and belief, Amneal's Proposed Label will encourage physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

47. On information and belief, Amneal's Proposed Label will induce and contribute to the direct infringement of the '827 patent by encouraging physicians and healthcare providers to administer generic lurasidone hydrochloride in order to treat, *inter alia*, schizophrenia and manic depressive psychosis, without the patient experiencing clinically significant weight gain.

48. On information and belief, such administration will directly infringe the '827 patent's claims.

49. On information and belief, the FDA has tentatively approved ANDA No. 208002.

50. On information and belief, following approval of ANDA No. 208002, Amneal will sell its approved generic version of Plaintiffs' Latuda® tablets (20 mg, 40 mg, 60 mg, 80 mg, and 120 mg) throughout the United States, including in Delaware.

COUNT I

Infringement of the '827 Patent Under 35 U.S.C. § 271(e)(2) by Amneal's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

51. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

52. Amneal submitted ANDA No. 208002 to the FDA under section 505(j) of the FFDCA to obtain approval to engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product throughout the United States. By submitting this application, Amneal has committed an act of infringement of the '827 patent under 35 U.S.C. § 271(e)(2)(A).

53. The commercial manufacture, importation, use, sale, or offer for sale of Amneal's Proposed ANDA Product will constitute an act of infringement of the '827 patent.

54. On information and belief, Amneal became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

55. On information and belief, Amneal will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, Amneal will engage in such activities upon the FDA's approval of Amneal's ANDA.

56. On information and belief, Amneal knows or should know that its commercial manufacture, use, offer for sale, sale, and/or importation of its Proposed ANDA Product will actively induce and contribute to the actual infringement of the '827 patent.

57. The commercial manufacture, importation, use, sale, or offer for sale of Amneal's Proposed ANDA Product in violation of Plaintiffs' patent rights will cause harm to Plaintiffs for which damages are inadequate.

58. Unless and until Amneal is enjoined from infringing the '827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

59. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including, *inter alia*, an order of this Court stating that the effective date of approval for Amneal's ANDA be a date that is not earlier than the expiration date of the '827 patent, as well as any extensions thereof.

COUNT II

Declaratory Judgment of Infringement of the '827 Patent Under 35 U.S.C. §§ 271 (b) and/or (c) by Amneal's Proposed Generic Lurasidone Hydrochloride Tablets, 20 mg, 40 mg, 60 mg, 80 mg, and 120 mg

60. Plaintiffs incorporate each of the preceding paragraphs as if fully set forth herein.

61. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

62. There is an actual case or controversy such that the Court may entertain Plaintiffs' request for declaratory relief consistent with Article III of the United States Constitution, and that actual case or controversy requires a declaration of rights by this Court.

63. On information and belief, Amneal's Proposed ANDA Product is covered by the claims of the '827 patent.

64. Amneal has actual knowledge of the '827 patent.

65. On information and belief, Amneal became aware of the '827 patent no later than when it was issued by the Patent Office and/or listed in the Orange Book as covering the approved formulation of Latuda®.

66. On information and belief, Amneal has acted with full knowledge of the '827 patent and without a reasonable basis for believing that it would not be liable for actively inducing or contributing to the infringement of the '827 patent.

67. On information and belief, Amneal will engage in the commercial manufacture, importation, use, sale, or offer for sale of its Proposed ANDA Product. On information and belief, Amneal will engage in such activities upon the FDA's approval of Amneal's ANDA.

68. The commercial manufacture, use, sale, offer for sale, and/or importation of Amneal's Proposed ANDA Product will induce the actual infringement of the '827 patent.

69. On information and belief, Amneal knows or should know that its commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product, will actively induce the actual infringement of the '827 patent.

70. On information and belief, Amneal will include within the packaging of its Proposed ANDA Product, or will otherwise make available to prospective patients upon FDA approval, a label and/or instructions for use that instruct physicians and patients on the methods of treatment claimed in the '827 patent.

71. On information and belief, Amneal will encourage another's infringement of the '827 patent by and through the commercial manufacture, use, sale, offer for sale, and/or importation of its Proposed ANDA Product, which is covered by the claims of the '827 patent.

72. Amneal's act of infringement will be done with the knowledge of the '827 patent and with the intent to encourage infringement.

73. The foregoing actions by Amneal will constitute active inducement of the infringement of the '827 patent.

74. On information and belief, Amneal knows or should know that its Proposed ANDA Product will be especially made or especially adapted for use in an infringement of the '827 patent, and is not a staple article or commodity of commerce suitable for substantial non-infringing use.

75. On information and belief, Amneal knows or should know that there are no substantial non-infringing uses for its Proposed ANDA Product.

76. The commercial manufacture, use, sale, offer for sale, and/or importation of Amneal's Proposed ANDA Product will contribute to the actual infringement of the '827 patent.

77. On information and belief, Amneal knows or should know that its offer for sale, sale and/or importation of its Proposed ANDA Product will contribute to the actual infringement of the '827 patent.

78. The foregoing actions by Amneal will constitute contributory infringement of the '827 patent.

79. On information and belief, Amneal intends to, and will, actively induce and contribute to the infringement of the '827 patent when ANDA No. 208002 is approved, and plan and intend to, and will, do so immediately and imminently upon final approval.

80. Plaintiffs are entitled to a declaratory judgment that future commercial manufacture, use, offer for sale, sale, and /or importation of Amneal's Proposed ANDA Product by Amneal will induce and/or contribute to infringement of the '827 patent.

81. The commercial manufacture, use, offer for sale, sale, and/or importation of Amneal's Proposed ANDA Product, which will actively induce and/or contribute to the infringement of the '827 patent, in violation of Plaintiffs' patent rights, will cause harm to Plaintiffs for which damages are inadequate.

82. Unless Amneal is enjoined from actively inducing and contributing to the infringement of the '827 patent, Plaintiffs will suffer irreparable injury for which damages are an inadequate remedy.

83. On information and belief, despite having actual notice of the ’827 patent, Amneal continues to prepare to actively induce and/or contribute to infringement of the ’827 patent in disregard of Plaintiffs’ rights, making this case exceptional and entitling Plaintiffs to reasonable attorneys’ fees pursuant to 35 U.S.C. § 285.

RELIEF SOUGHT

WHEREFORE, Plaintiffs request:

A) That a judgment be entered that Amneal has infringed the ’827 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 208002 under section 505(j) of the FFDCA, and that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of Amneal’s Proposed ANDA Product will constitute an act of infringement of the ’827 patent;

B) That a judgment be entered declaring that the ’827 patent remains valid and enforceable;

C) That an Order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of Amneal’s ANDA No. 208002 shall be a date which is not earlier than the expiration date of the ’827 patent as extended by any applicable period of exclusivity;

D) That an injunction be granted pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Amneal, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, from engaging in the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product covered by the ’827 patent;

E) That a judgment be entered declaring that if Amneal engages in the commercial manufacture, use, offer to sell, sale, or importation of Amneal's generic product disclosed in its ANDA No. 208002 prior to the expiration of the '827 patent, as extended by any applicable period of exclusivity, a preliminary injunction and/or permanent injunction will be entered enjoining such conduct pursuant to 35 U.S.C. § 283;

F) That a judgment be entered declaring that if Amneal engages in the commercial manufacture, use, offer to sell, sale, or importation of the Proposed ANDA Product disclosed in its ANDA No. 208002 prior to the expiration of the '827 patent, as extended by any applicable period of exclusivity, Plaintiffs are entitled to damages or other monetary relief resulting from such infringement under 35 U.S.C. § 271(e)(4)(C), increased to treble the amount found or assessed together with interest pursuant to 35 U.S.C. § 284;

G) That a judgment be entered pursuant to 28 U.S.C. § 2201 declaring that if Amneal, its officers, agents, servants, employees, licensees, representatives, and attorneys, and all other persons acting or attempting to act in active concert or participation with it or acting on its behalf, engage in the commercial manufacture, use, offer for sale, sale, and/or importation of Amneal's Proposed ANDA Product prior to the expiration of the '827 patent, it will constitute an act of infringement of the '827 patent under 35 U.S.C. §§ 271(b) and/or (c);

H) That a judgment be entered that this is an exceptional case under 35 U.S.C. § 285, and that Plaintiffs be awarded reasonable attorneys' fees and costs;

I) An accounting for infringing sales not presented at trial and an award by the Court of additional damages for any such infringing sales; and

J) Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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