UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

PAR PHARMACEUTICAL, INC., Plaintiff, v. SUNOVION PHARMACEUTICALS, INC., and SUMITOMO DAINIPPON PHARMA CO., LTD. Defendants.	Civil Action No. _____

COMPLAINT

Plaintiff Par Pharmaceutical, Inc. ("Par"), for its Complaint against Sunovion Pharmaceuticals, Inc. ("Sunovion") and Sumitomo Dainippon Pharma Co., Ltd. ("Sumitomo") (together, "Defendants"), alleges as follows:

NATURE OF ACTION

1. Par seeks declaratory judgment of non-infringement of U.S. Patent Nos. 8,729,085, 8,883,794, and RE45,573 pursuant to the Patent Laws of the United States, 35 U.S.C. §§ 100 *et seq.*, the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 355(j)(5)(C)(i), and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 *et seq*.

PARTIES

2. Par Pharmaceutical, Inc. is a corporation organized and existing under the laws of New York, having a place of business at One Ram Ridge Road, Spring Valley, New York 10977. Par develops, manufactures, and markets safe, innovative, and cost-effective generic pharmaceutical products that help improve patient quality of life. Par also offers differentiated,

specialty dosage and sterile injectable drug products and is advancing a R&D pipeline of potential new products.

3. On information and belief, Sunovion is a corporation organized and existing under the laws of Delaware, having a principal place of business at 84 Waterford Drive, Marlborough, Massachusetts 01752. On information and belief, Sunovion is an indirect, wholly-owned subsidiary of Sumitomo.

4. On information and belief, Sumitomo is a corporation organized and existing under the laws of Japan, having a principal place of business at 6-8, Dosho-Machi 2-Chome, Chuo-Ku Osaka-Shi, Osaka, Japan 541-8524. On information and belief, Sumitomo has its U.S. base of operations via its U.S. holding company, Dainippon Sumitomo Pharma America Holdings, Inc., located at 84 Waterford Drive, Marlborough, Massachusetts 01752.

5. On information and belief, "Sunovion was formed by combining Sepracor Inc. and the U.S. operations of Sumitomo Dainippon Pharma Co., Ltd." History: Sunovion Pharmaceuticals Inc., http://www.sunovion.com/aboutSunovion/our-heritage.html (last visited December 30, 2016).

6. On information and belief, Sumitomo by itself or through its wholly-owned subsidiary and agent Sunovion, develops, manufactures, and imports pharmaceutical products for sale and use throughout the United States, including in this judicial district. On information and belief, Sumitomo, by itself or through its wholly-owned subsidiary and agent Sunovion, markets, distributes, and/or sells pharmaceutical products throughout the United States, including in Massachusetts.

7. On information and belief, Sumitomo and Sunovion have common officers and directors. For example, on information and belief, *inter alia*, Nobuhiko Tamura is Managing

Executive Officer and Senior Executive Officer at Sumitomo, and Chair and President at Sunovion; Masayo Tada is CEO of Sumitomo and a Director of Sunovion; and Hiroyuki Baba is an Executive Officer of Sumitomo and Executive Vice President of Sunovion.

8. Sumitomo and Sunovion issued a news release in this district (Marlborough, Massachusetts) stating their joint intent to enforce their patent rights for LATUDA®. *See, e.g.*, News Release (Jan. 14, 2015), http://www.ds-pharma.com/pdf_view.php?id=410 ("Sumitomo Dainippon Pharma and Sunovion believe that their patent position for LATUDA® is strong and they are prepared to vigorously protect their patent rights.") (last visited December 30, 2016).

9. On information and belief, Sumitomo has appointed attorney Kevin Marcus Colmey, Sullivan & Worcester LLP, One Post Office Square, Boston, Massachusetts 02109 as its counsel in Massachusetts authorized to accept service of process.

JURISDICTION AND VENUE

10. This Court has subject matter jurisdiction over this action under 28 U.S.C. §§ 1331, 1338(a), and 2201(a); 21 U.S.C. § 355(j)(5)(C)(i)(II); and 35 U.S.C. § 271(e)(5).

11. This Court also has personal jurisdiction over Defendants because, on information and belief, *inter alia*: (1) Sunovion has its principal place of business in Marlborough, Massachusetts, is registered to do business in this district, and does business in Massachusetts; (2) the causes of action arise out of and relate to Defendants' actions in this district, by acting in concert to list and enforce the patents-in-suit and other patents in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for LATUDA®; (3) Defendants have purposefully availed themselves of this forum by making and commercializing pharmaceutical products in Massachusetts, including in this judicial district, and have affiliations with Massachusetts that are pervasive, continuous, and systematic, including the direct

marketing, distribution, or sale of pharmaceutical drugs within Massachusetts and to residents of Massachusetts by Sumitomo itself or through its wholly-owned subsidiary and agent Sunovion, including engaging in the sale of LATUDA® in interstate commerce and in this judicial district, and deriving substantial revenues from such activities; (4) Sumitomo has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of Massachusetts, and is currently in active litigation in this judicial district (*see Sunovion Pharm. Inc. v. BPI Techs. Corp*., 1:14-cv-14694-GAO); (5) Sunovion has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Massachusetts, having consented to jurisdiction in this Court (*see, e.g.*, *Sunovion Pharm. Inc. v. Sullivan*, 1:16-cv-10101-JGD; *Sunovion Pharm. Inc. v. BPI Techs. Corp*., 1:14-cv-14694-GAO; and *Sunovion Pharm. Inc. v. Health Sci. Nutrition, Inc. et al*., 1:11-cv-11564-DPW).

12. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b)-(d) and 21 U.S.C. § 355(j)(5)(C)(i)(II), because Defendant Sumitomo owns the patents-in-suit and, itself and/or through its wholly-owned subsidiary and agent Defendant Sunovion, resides in and has a regular and established place of business in this district, and transacts business in this district.

13. Alternately, to the extent Sumitomo may argue that it "does not maintain offices, facilities, telephone listings, employees, or physical addresses in Massachusetts *or anywhere in the United States*," (*Sunovion Pharm. Inc. v. BPI Techs. Corp*., 1:14-cv-14694-GAO, Dkt. 59 at 7; *see also id*. at 8-10) (emphasis added), then jurisdiction is proper in this judicial district pursuant to Federal Rule of Civil Procedure 4(k)(2) and 28 U.S.C. § 1391(b)(3).

FACTUAL BACKGROUND

14. United States Patent No. 8,729,085 ("the '085 patent"), titled "Pharmaceutical Composition," issued on May 20, 2014. A true and correct copy of the '085 patent is attached hereto as Exhibit A.

15. On information and belief, the ’085 patent is currently scheduled to expire on May 26, 2026.

16. On information and belief, Sumitomo is the named assignee of the ’085 patent.

17. United States Patent No. 8,883,794 (“the ’794 patent”), titled “Pharmaceutical Composition,” issued on November 11, 2014. A true and correct copy of the ’794 patent is attached hereto as Exhibit B.

18. On information and belief, the ’794 patent is currently scheduled to expire on May 26, 2026.

19. On information and belief, Sumitomo is the named assignee of the ’794 patent.

20. United States Patent No. RE45,573 (“the RE’573 patent”), titled “Process for producing imide compound,” issued June 23, 2015 as a reissue of U.S. Patent No. 7,605,260, which originally issued on October 20, 2009. A true and correct copy of the RE’573 patent is attached hereto as Exhibit C.

21. On information and belief, the RE’573 patent is currently scheduled to expire on June 23, 2025.

22. On information and belief, Sumitomo is the named assignee of the RE’573 patent.

23. On information and belief, Sumitomo has exclusively licensed the Orange Book-listed patents for LATUDA®, including the ’085, the ’794, and the RE’573 patents, to Sunovion.

24. On information and belief, Sunovion is the holder of New Drug Application No. 200603 (“NDA 200603”) for lurasidone hydrochloride oral tablets, 20, 40, 60, 80, and 120 mg, marketed under the brand name LATUDA®. LATUDA® is an atypical antipsychotic for the treatment of schizophrenia and depressive episodes associated with Bipolar I Disorder (bipolar depression). In connection with NDA 200603, Sunovion caused the U.S. Food and Drug

Administration ("FDA") to list the '085 patent, the '794 patent, and the RE'573 patent, *inter alia,* in the Orange Book.

25. Par submitted Abbreviated New Drug Application No. 207948 ("ANDA 207948") to the FDA requesting regulatory approval to engage in the commercial manufacture, use, or sale of lurasidone hydrochloride oral tablets, 20, 40, 60, 80, and 120 mg ("Par's Lurasidone Product"), before the expiration of the '085, '794, and RE'573 patents listed for LATUDA®. ANDA 207948 contains certifications pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certifications") that the '085, '794, and RE'573 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, or sale of Par's Lurasidone Product.

26. Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), on December 12, 2014, Par provided notice to Sunovion and Sumitomo of the Paragraph IV Certifications to the '085 and '794 patents that were included in the original submission of ANDA 207948 ("Par's 2014 Notice Letter"), together with an Offer of Confidential Access to ANDA 207948 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). Par's 2014 Notice Letter included a detailed statement of the factual and legal basis why the '085 and '794 patents are invalid, unenforceable, and/or will not be infringed.

27. Par's notification through Par's 2014 Notice Letter triggered a first 45-day statutory period during which Defendants had a first opportunity to initiate patent infringement litigation. 21 U.S.C. § 355(j)(5)(B)(iii). Defendants did not assert the '085 or '794 patents against Par for Par's Lurasidone Product during the first 45-day statutory period, or at any time thereafter.

28. Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), on September 21, 2016, Par provided notice to Sunovion and Sumitomo of an amendment to ANDA 207948 to include a Paragraph IV

Certification to the RE ’573 patent (“Par’s 2016 Notice Letter”), together with another Offer of Confidential Access to ANDA 207948 pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III). Par’s 2016 Notice Letter included a detailed statement of the factual and legal basis why the RE’573 patent will not be infringed, and reserved the right to set forth factual and legal bases why the RE’573 patent is invalid and unenforceable.

29. Par’s notification through Par’s 2016 Notice Letter triggered a second 45-day statutory period during which Defendants had a second opportunity to initiate patent infringement litigation. 21 U.S.C. § 355(j)(5)(B)(iii). Defendants did not assert the RE’573 patent against Par for Par’s Lurasidone Product during the second 45-day statutory period, or at any time thereafter.

30. Where no action for patent infringement is filed within the 45-day statutory period, 21 U.S.C. § 355(j)(5)(C)(i)(II) and 35 U.S.C. § 271(e)(5) provide that the Court shall have subject matter jurisdiction under 28 U.S.C. § 2201 for a civil action to obtain patent certainty and allow ANDA filers to obtain a declaratory judgment of non-infringement and/or invalidity with respect to Orange Book-listed patents.

31. Defendants have demonstrated their intent to enforce Orange Book-listed patents for NDA 200603 and have filed suit against other parties alleging infringement of U.S. Patent No. 5,332,372, which is listed in the Orange Book for NDA 200603. *See, e.g.*, *Sumitomo Dainippon Pharma Co., Ltd. et al. v. Emcure Pharm. Ltd. et al.*, 2:15-cv-00280 (D.N.J.); *Sumitomo Dainippon Pharma Co., Ltd. et al. v. Amneal Pharm. LLC*, 2:16-cv-04596 (D.N.J.); *Sumitomo Dainippon Pharma Co., Ltd. et al. v. Teva Pharm. USA Inc., et al.*, 2:15-cv-06401 (D.N.J.).

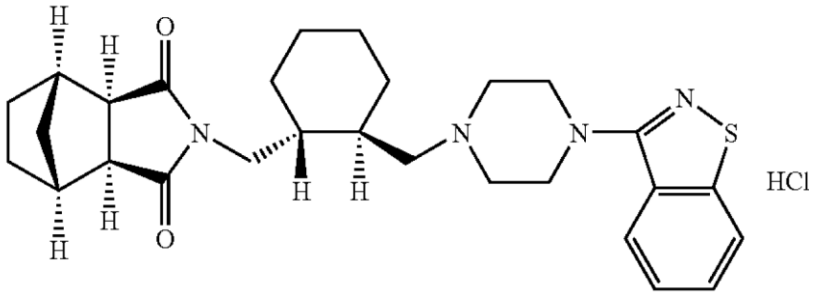
32. Par requested, but Defendants did not provide, a covenant not to sue Par on the ’085, ’794, and RE’573 patents.

33. Defendants’ actions have resulted in a substantial controversy regarding the ’085, ’794, and RE’573 patents between Par and Defendants of sufficient immediacy and reality to warrant the issuance of a declaratory judgment that the ’085, ’794, and RE’573 patents are not infringed.

Par’s Lurasidone Product Does Not Infringe the ’085 Patent

34. The ’085 patent contains 27 claims, of which claims 1, 20, 26, and 27 are independent. Claim 1 reads as follows:

> An oral preparation which comprises N-[4-[4-(1,2-benzisothiazol-3-yl)-1-piperazinyl]-(2R,3R)-2,3-tetramethylene-butyl]-(1'R,2'S,3'R,4'S)-2,3-bicyclo[2,2,1]heptanedicarboxylmide hydrochloride (lurasidone) of the formula (1):

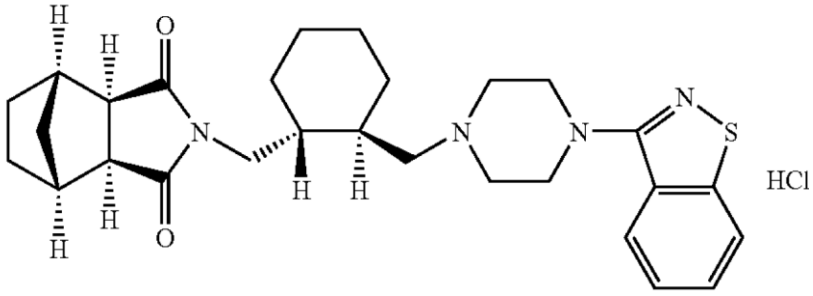


> a pregelatinized starch, a water-soluble excipient and a water-soluble polymer binder; wherein a content of lurasidone in the preparation is 20 to 45% (wt/wt), and the pregelatinized starch is incorporated in an amount of 20 to 50% (wt/wt) based on the weight of the preparation.

35. Claims 2-19, and 21-25 are dependent on claim 1 and, therefore, incorporate all of the limitations of claim 1.

36. Claim 20 reads as follows:

An oral preparation which comprises N-[4-[4-(1,2-benzisothiazol-3-yl)-1-piperazinyl]-(2R,3R)-2,3-tetramethylene-butyl]-(1'R,2'S,3'R,4'S)-2,3-bicyclo[2,2,1]heptanedicarboxylmide hydrochloride (lurasidone) of the formula (1):



a pregelatinized starch, a water-soluble excipient and a water-soluble polymer binder, wherein the oral preparation contains 20 to 45% (wt/wt) of lurasidone, the oral preparation contains 20 mg to 120 mg of lurasidone, the pregelatinized starch is incorporated in an amount of 20 to 50% (wt/wt) based on the weight of the oral preparation, and the oral preparation exhibits an equivalent dissolution profile across the range of lurasidone per oral preparation.

37. Claim 26 reads as follows:

An oral preparation which comprises N-[4-[4-(1,2-benzisothiazol-3-yl)-1-piperazinyl]-(2R,3R)-2,3-tetramethylene-butyl]-(1'R,2'S,3'R,4'S)-2,3-bicyclo[2,2,1]heptanedicarboxylmide hydrochloride (lurasidone), a pregelatinized starch, a water-soluble excipient and a water-soluble polymer binder, wherein a content of lurasidone in the preparation is 20 to 45% (wt/wt),

the pregelatinized starch is incorporated in an amount of 20 to 30% (wt/wt) based on the weight of the preparation,

the water-soluble excipient is mannitol or lactose, and

the water-soluble polymer binder is one or more agents selected from the group of hydroxypropylcellulose, hydroxypropylmethylcellulose, polyvinylpyrrolidone and polyvinyl alcohol.

38. Claim 27 reads as follows:

An oral preparation which comprises N-[4-[4-(1,2-benzisothiazol-3-yl)-1-piperazinyl]-(2R,3R)-2,3-tetramethylene-butyl]-(1'R,2'S,3'R,4S)-2,3-bicyclo[2,2,1]heptanedicarboxylmide hydrochloride (lurasidone), a pregelatinized starch, a water-soluble excipient and a water-soluble polymer binder, and further comprises a disintegrant and a lubricant, wherein a content of lurasidone in the preparation is 20 to 45% (wt/wt),

the pregelatinized starch is incorporated in an amount of 20 to 30% (wt/wt) based on the weight of the preparation,

the water-soluble excipient is mannitol,

the water-soluble polymer binder is hydroxypropylmethylcellulose, and

the oral preparation is a tablet.

39. Claims 1-27 of the ’085 patent all require oral preparations of lurasidone that contain pregelatinized starch in an amount of 20 to 50% (wt/wt) (claims 1, 2, 4-16, 18-25) or 20 to 30% (wt/wt) (claims 3, 17, 26, 27) based on the weight of the preparation.

40. Par’s Lurasidone Product does not contain 20 to 50% or 20 to 30% (wt/wt) pregelatinized starch based on the total weight of the preparation, as required by each claim of the ’085 patent.

41. Par's Lurasidone Product therefore does not literally infringe any claim of the '085 patent because it does not meet the limitation of claims 1, 2, 4-16, 18-25, requiring 20 to 50% (wt/wt) pregelatinized starch, or the limitation of claims 3, 17, 26, 27, requiring 20 to 30% (wt/wt) pregelatinized starch based on the total weight of the preparation.

42. Par's Lurasidone Product also does not infringe any claim of the '085 patent under the doctrine of equivalents because it does not contain any equivalent to the claim limitation requiring 20 to 50% or 20 to 30% (wt/wt) pregelatinized starch based on the total weight of the preparation.

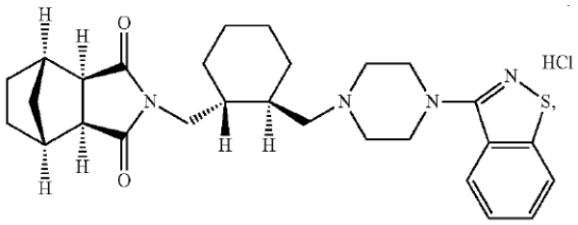
43. During prosecution of the '085 patent, the Applicant surrendered the range of 10 to 20% (wt/wt) pregelatinized starch. Specifically, the Applicant presented claims reciting 10 to 50% (wt/wt) pregelatinized starch, and subsequently amended the claims to narrow that range to 20 to 50% to avoid prior art. This amendment was made for reasons related to patentability.

44. The Applicant also disclaimed the range of 10-20% (wt/wt) pregelatinized starch by disclosing this range in the '085 patent specification, but choosing not to claim it. *See* Exhibit A at, *e.g.*, 3:22-25 ("the pregelatinized starch is incorporated in an amount of 10 to 50% (wt/wt) based on the weight of the preparation").

Par's Lurasidone Product Does Not Infringe the '794 Patent

45. The '794 patent contains 14 claims, of which claim 1 is independent. Claim 1 reads as follows:

> An oral preparation comprising 20 to 120 mg of N-[4-[4-(1,2-benzisothiazol-3-yl)-1-piperazinyl]-(2R,3R)-2,3-tetramethylene-butyl]-(1′R,2′S,3′R,4′S)-2,3-bicyclo[2,2,1]heptanedicarboxylmide hydrochloride (lurasidone) of formula (1):



a pregelatinized starch, a water-soluble excipient, a water-soluble polymer binder, a disintegrant, and a lubricant, wherein the content of lurasidone in the preparation is 20 to 45% (wt/wt), and the content of the pregelatinized starch in the preparation is 20 to 30% (wt/wt).

46. Claims 2-14 are dependent on claim 1 and, therefore, incorporate all of the limitations of claim 1.

47. Claims 1-14 of the ’794 patent all require oral preparations of lurasidone that contain pregelatinized starch in an amount of 20 to 30% (wt/wt) based on the weight of the preparation.

48. Par’s Lurasidone Product does not contain 20 to 30% (wt/wt) pregelatinized starch in the preparation, as required by each claim of the ’794 patent.

49. Par’s Lurasidone Product therefore does not literally infringe any claim of the ’794 patent because it does not meet the limitation of claims 1-14 requiring 20 to 30% (wt/wt) pregelatinized starch in the preparation.

50. Par’s Lurasidone Product also does not infringe any claim of the ’794 patent under the doctrine of equivalents because it does not contain any equivalent to the claim limitation requiring 20 to 30% (wt/wt) pregelatinized starch in the preparation.

51. The ’794 patent issued from U.S. Application No. 14/183,283, which is a continuation of U.S. Application No. 11/919,678, which issued as the ’085 patent. Exhibit B at

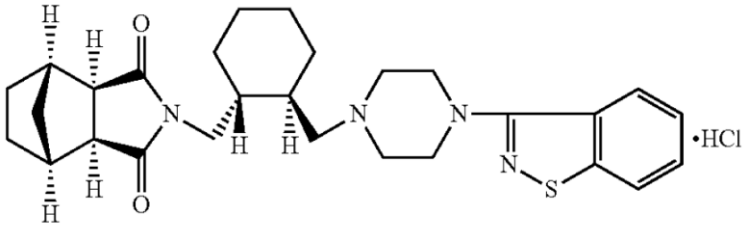
cover page. The ’794 patent incorporates the content of U.S. Application No. 11/919,678. *Id*. at 1:3-8.

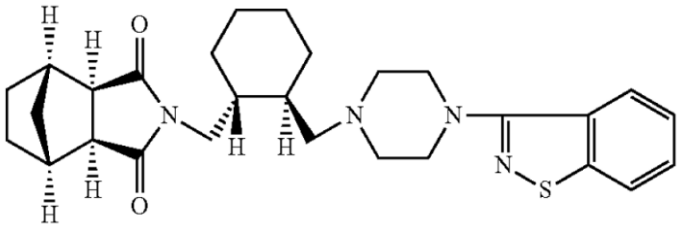
52. As stated above, during prosecution of the ’085 patent, which is a parent of the ’794 patent, the Applicant surrendered the range of 10 to 20% (wt/wt) pregelatinized starch. Specifically, during prosecution of the parent ’085 patent, the Applicant presented claims reciting 10 to 50% (wt/wt) pregelatinized starch, and subsequently amended the claims to narrow that range to 20 to 50% to avoid prior art. This amendment was made for reasons related to patentability.

53. The Applicant also disclaimed the range of 10-20% (wt/wt) pregelatinized starch by disclosing this range in the ’794 patent specification, but choosing not to claim it. *See* Exhibit B at, *e.g*., 3:37-39 (“the pregelatinized starch is incorporated in an amount of 10 to 50% (wt/wt) based on the weight of the preparation”).

Par’s Lurasidone Product Does Not Infringe the RE’573 Patent

54. The RE’573 patent contains 12 claims, of which claims 1 and 7 are independent. Claim 1 reads as follows:

> A process for producing an imide compound hydrochloride of the formula (2):
>
> 
>
>
> or an enantiomer thereof,
>
> which comprises treating a compound of the formula (1):



or an enantiomer thereof with 1.8 to 5.0% aqueous hydrochloric acid solution in acetone, crystallizing the resultant hydrochloride of the formula (2), and isolating the crystallized hydrochloride of the formula (2).

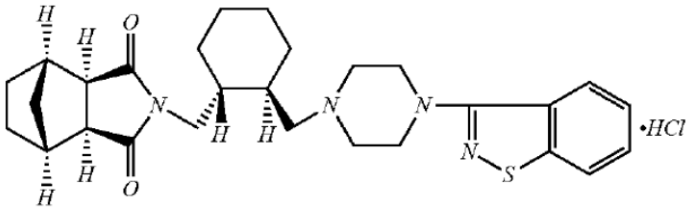
55. Claim 2 is dependent on claim 1 and, therefore, incorporates all of the limitations of claim 1. Further, claim 2 recites:

The process for producing the imide compound hydrochloride according to claim 1, wherein the aqueous hydrochloric acid solution is a 3.0-5.0% aqueous hydrochloric acid solution.

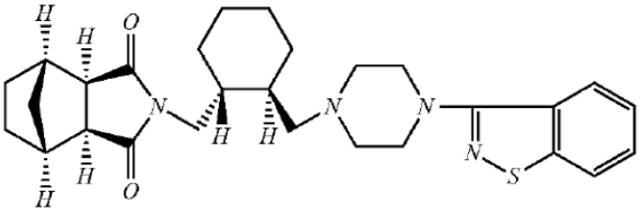
56. Claims 3-6 of the RE'573 patent require a lurasidone hydrochloride product obtained by the process of claim 1 or 2.

57. Claim 7 of the RE'573 patent reads as follows:

A process for producing an imide compound hydrochloride of the formula (2):



which comprises treating a compound of the formula (1):



> with 1.8 to 5.0% aqueous hydrochloric acid solution in acetone, crystallizing the resultant hydrochloride of the formula (2), and isolating the crystallized hydrochloride of the formula (2).

58. Claim 8 is dependent on claim 7 and, therefore, incorporates all of the limitations of claim 7. Further, claim 8 recites:

> The process for producing the imide compound hydrochloride according to claim 7, wherein the aqueous hydrochloric acid solution is a 3.0-5.0% aqueous hydrochloric acid solution.

59. Claims 9-12 of the RE'573 patent require a lurasidone hydrochloride product obtained by the process of claim 7 or 8.

60. Thus, claims 1, 2, 7, and 8 of the RE'573 patent all require a process for producing lurasidone hydrochloride (a compound of formula (2)) which comprises treating lurasidone free base (a compound of formula (1)), with an aqueous hydrochloric acid solution in acetone, crystallizing the resultant lurasidone hydrochloride, and isolating the crystallized lurasidone hydrochloride.

61. Par will not literally infringe claims 1, 2, 7, or 8 of the RE'573 patent, because Par's Lurasidone Product will not be manufactured using a process that includes treating lurasidone free base with 1.8 to 5.0% aqueous hydrochloric acid solution in acetone, as required by the claims.

62. Par also will not infringe claims 1, 2, 7, or 8 of the RE'573 patent, under the doctrine of equivalents because Par's Lurasidone Product will not be manufactured using a process that includes treating lurasidone free base with 1.8 to 5.0% aqueous hydrochloric acid solution in acetone, or any equivalent thereof.

63. The Patentee disclaimed the use of solvents other than acetone. During prosecution of the RE'573 patent, the Applicant amended the claims of the parent application (U.S. Application No. 10/565,105) to narrow the claimed "hydrophilic solvent" to the specific hydrophilic solvent "acetone" to avoid prior art. This amendment was made for reasons related to patentability.

64. Dependent claims 3-6 and 9-12 of the RE'573 patent require a lurasidone hydrochloride product obtained by the process of claim 1, 2, 7, or 8. Par's Proposed Lurasidone Product will not be manufactured using a process that meets the limitations of process claims 1, 2, 7, or 8, either literally or under the doctrine of equivalents. Par's Proposed Lurasidone Product, therefore, cannot and does not infringe any of dependent claims 3-6 or 9-12, either literally or under the doctrine of equivalents.

COUNT ONE
Declaratory Judgment Regarding Non-Infringement of U.S. Patent No. 8,729,085

65. Par reasserts and realleges paragraphs 1-64 above as if fully set forth herein.

66. The submission of ANDA 207948 does not infringe any claim of the '085 patent.

67. The commercial manufacture, use, offer for sale, sale, or importation of Par's Lurasidone Product will not infringe any claim of the '085 patent.

68. An actual and justiciable controversy exists between the parties with respect to the '085 patent. Par is entitled to a declaratory judgment that the '085 patent is not infringed.

COUNT TWO
Declaratory Judgment Regarding Non-Infringement of U.S. Patent No. 8,883,794

69. Par reasserts and realleges paragraphs 1-64 above as if fully set forth herein.

70. The submission of ANDA 207948 does not infringe any claim of the '794 patent.

71. The commercial manufacture, use, offer for sale, sale, or importation of Par's Lurasidone Product will not infringe any claim of the '794 patent.

72. An actual and justiciable controversy exists between the parties with respect to the ’794 patent. Par is entitled to a declaratory judgment that the ’794 patent is not infringed.

COUNT THREE
Declaratory Judgment Regarding Non-Infringement of U.S. Patent No. RE 45,573

73. Par reasserts and realleges paragraphs 1-64 above as if fully set forth herein.

74. The submission of ANDA 207948 does not infringe any claim of the RE’573 patent.

75. The commercial manufacture, use, offer for sale, sale, or importation of Par’s Lurasidone Product will not infringe any claim of the RE’573 patent.

76. An actual and justiciable controversy exists between the parties with respect to the RE’573 patent. Par is entitled to a declaratory judgment that the RE’573 patent is not infringed.

PRAYER FOR RELIEF

WHEREFORE, Par respectfully requests that this Court enter judgment in its favor and against Defendants and grant the following relief:

A. Declare that the filing of Par’s ANDA 207948 does not infringe any claim of the ’085 patent;

B. Declare that the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Par’s Lurasidone Product will not infringe any claim of the ’085 patent;

C. Declare that the filing of Par’s ANDA 207948 does not infringe any claim of the ’794 patent;

D. Declare that the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Par’s Lurasidone Product will not infringe any claim of the ’794 patent;

E. Declare that the filing of Par's ANDA 207948 does not infringe any claim of the RE'573 patent;

F. Declare that the manufacture, use, offer for sale, sale, marketing, distribution, or importation of Par's Lurasidone Product will not infringe any claim of the RE'573 patent;

G. Award Par its costs and reasonable attorneys' fees; and

H. Award Par such other and further relief as the Court deems just and proper.

Respectfully Submitted,

Dated: January 4, 2017

/s/ Charles H. Sanders

Charles H. Sanders
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