IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA
Richmond Division

LUPIN LIMITED,

Plaintiff,

v.

ABBOTT LABORATORIES and ASTELLAS PHARMA INC.,

Defendants.

Civil Action No. 3:06cv400

Judge Robert E. Payne

ABBOTT LABORATORIES and ASTELLAS PHARMA INC.,

Counterclaim-Plaintiffs,

v.

LUPIN LIMITED and LUPIN PHARMACEUTICALS, INC.,

Counterclaim-Defendants.

FIRST AMENDED COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Lupin Limited ("Lupin") brings this action against Defendants Abbott Laboratories and Astellas Pharma Inc. for a declaration that Lupin has not infringed, does not infringe, and will not infringe any valid and enforceable claim of U.S. Patent No. 4,935,507.

The Parties

1. Plaintiff Lupin Limited is a corporation organized and existing under the laws of the Sovereign Nation of India, having a place of business at Laxmi Towers, "B" Wing,

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5th Floor, Bandra Kurla Complex, Mumbai 400 051, India. Lupin Limited develops and manufactures prescription pharmaceutical drugs, including quality, affordable generic medicines.

2. On information and belief, Defendant Abbott Laboratories ("Abbott") is a corporation organized and existing under the laws of the State of Illinois, having a place of business at 100 Abbott Park Road, Abbott Park, Illinois 60064-3500. On information and belief, Abbott manufactures and sells pharmaceutical products throughout the United States, including within the State of Virginia and this District.

3. On information and belief, Defendant Astellas Pharma Inc. ("Astellas") is a corporation organized and existing under the laws of the Sovereign Nation of Japan, having a place of business at 2-3-11, Nihonbashi-Honcho 2-Chome, Chuo-Ku, Tokyo 103-8411, Japan. On information and belief, Astellas manufactures and sells pharmaceutical products throughout the United States, including within the State of Virginia and this District.

Jurisdiction and Venue

4. This action arises under, *inter alia*, the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

5. The Court has original jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a), because this action involves substantial claims arising under the United States Patent Act (35 U.S.C. § 1 *et seq.*), and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, because this action involves an actual controversy concerning the infringement and validity of the patent-in-suit.

6. Venue is appropriate in this District under 28 U.S.C. §§ 1391(b) and 1400(b).

7. This Court has personal jurisdiction over Defendants because they regularly conduct business in, and have regular and systematic contact with, the State of Virginia, including this District.

Background Allegations Common to All Counts

Abbott's Omnicef® (Cefdinir) Capsules

8. Abbott holds approved New Drug Application ("NDA") No. 50-739 for Omnicef® (Cefdinir) Capsules 300 mg.

9. Omnicef® (Cefdinir) is an extended-spectrum cephalosporin antibiotic indicated for the treatment of certain mild to moderate infections, including, among others, community-acquired pneumonia, chronic bronchitis, and acute maxillary sinusitis.

10. On information and belief, Abbott markets and sells Omnicef® (Cefdinir) Capsules 300 mg throughout the United States, including within the State of Virginia and this District.

11. On information and belief, Abbott markets and sells Omnicef® (Cefdinir) Capsules 300 mg throughout the United States, including within the State of Virginia and this District, under a license from Astellas.

12. On information and belief, Astellas has licensed to Abbott the right to market and sell Omnicef® (Cefdinir) Capsules 300 mg throughout the United States, including within the State of Virginia and this District.

13. Abbott's 2005 sales for Omnicef® (Cefdinir) were at least $495 million.

Patent-in-Suit

14. On or about June 19, 1990, the United States Patent and Trademark Office ("PTO") issued U.S. Patent No. 4,935,507 ("the '507 patent"), entitled "Crystalline 7-(2-(2-

aminothiazol-4-YL)-2-Hydroxyiminoacetamido)-3-Vinyl-3-Cephem-4-Carboxylic Acid (Syn Isomer)," to Takao Takaya, Fumiyuki Shirai, Hitoshi Nakamura, and Yasunobu Inaba. A true and correct copy of the '507 patent as it issued is attached to this Complaint as Exhibit A.

15. According to the records of the PTO, Astellas is the assignee and record owner of the '507 patent.

16. On information and belief, Astellas purports and claims to own, and to have the right to enforce, the '507 patent.

17. On information and belief, Abbott is the exclusive licensee of the '507 patent.

18. On information and belief, Abbott purports and claims to have the right to enforce the '507 patent.

19. On information and belief, Abbott asserts and claims that the '507 patent covers or protects Omnicef® (Cefdinir) from generic competition.

Lupin's Generic Cefdinir Capsules

20. Lupin has filed Abbreviated New Drug Application ("ANDA") No. 65-264 seeking U.S. Food and Drug Administration ("FDA") approval for a generic version of Cefdinir Capsules 300 mg to compete with Abbott's branded Omnicef® (Cefdinir) Capsules 300 mg.

21. Lupin has filed Abbreviated New Drug Application ("ANDA") No. 65-259 seeking U.S. Food and Drug Administration ("FDA") approval for a generic version of Cefdinir Oral Suspension 125 mg/5 mL product to compete with Abbott's branded Omnicef® (Cefdinir) Oral Suspension 125 mg/5 mL products.

22. On May 19, 2006, FDA granted final marketing approval of Lupin's ANDA No. 65-264 for generic Cefdinir Capsules 300 mg. On May 31, 2006, FDA granted final marketing approval of Lupin's ANDA No. 65-259 for generic Cefdinir Oral Suspension 125 mg/5 mL products.

23. Lupin intends to manufacture, use, sell, and offer for sale in, and import into, the United States generic Cefdinir Capsules 300 mg and generic Cefdinir Oral Suspension 125 mg/5 mL before the expiration of the '507 patent.

24. Lupin's generic Cefdinir Capsules 300 mg will, and are intended to, compete directly with Abbott's Omnicef® (Cefdinir) Capsules 300 mg as a fully-substitutable generic equivalent.

25. Lupin's generic Oral Suspension 125 mg/5 mL product will, and are intended to, compete directly with Abbott's Omnicef® (Cefdinir) Oral Suspension 125 mg/5 mL product as a fully-substitutable generic equivalent.

26. Lupin has made substantial preparation to manufacture, use, sell, offer to sell in, or import into, the United States its generic Cefdinir Capsules 300 mg and Oral Suspension 125 mg/5 mL products, including within the State of Virginia and this District, prior to the expiration of the '507 patent.

27. The commercial launch of Lupin's generic Cefdinir Capsules 300 mg and Oral Suspension 125 mg/5 mL products in the United States is imminent.

28. Lupin's generic Cefdinir Capsules 300 mg, which are the subject of Lupin's approved ANDA No. 65-264, do not and will not infringe the '507 patent.

29. Lupin's generic Oral Suspension 125 mg/5 mL products, which are the subject of Lupin's approved ANDA No. 65-259, do not and will not infringe the '507 patent.

Abbott's Litigious Conduct and Lupin's Reasonable Apprehension of Suit

30. Abbott is extremely litigious, and has previously exhibited an intent and willingness to aggressively assert and enforce its purported patent rights against companies seeking to market competing generic versions of Abbott's branded products.

31. Abbott intends to, and indeed has, asserted the '507 patent against Lupin and its competing generic cefdinir product, in order to protect Abbott's Omnicef® (Cefdinir) from generic competition.

32. Lupin has attempted to amicably resolve any controversy regarding the infringement and validity of the '507 patent, but Abbott and Astellas have refused to do so.

33. On or about June 28, 2005, Lupin requested a covenant not to sue relating to the '507 patent from Abbott and Astellas based on the manufacture, sale, offer for sale, or importation of the cefdinir product that is the subject of Lupin's ANDA. With that request, Lupin offered to provide Abbott and Stellas with confidential information regarding Lupin's cefdinir product. Abbott and Astellas refused to provide the requested covenant not to sue.

34. Lupin subsequently and repeatedly offered to provide Abbott and Astellas with samples of Lupin's cefdinir product for testing, so that Abbott and Astellas could confirm that Lupin's cefdinir product does not infringe. Once again, Abbott and Astellas refused Lupin's offer, and refused to provide the requested covenant not to sue.

35. On or about January 3, 2006, Lupin provided Abbott and Astellas with a sample of Lupin's cefdinir product for testing and evaluation. Lupin reiterated its request for a covenant not to sue relating to the '507 patent. Once again, to date, Abbbott and Astellas have refused Lupin's request for a covenant not to sue.

36. Rather, in response to the approval of Lupin's cefdinir ANDA, Abbott publicly stated that it "will enforce its patents on Omnicef as appropriate."

37. At or around that same time, Abbott also inquired whether Lupin is planning to launch its cefdinir product, and whether Lupin would provide Abbott with advance notice of any launch, presumably so that Abbott can file suit against Lupin for infringement of the '507 patent prior to the commercial launch of Lupin's cefdinir product.

38. Abbott has sued numerous companies seeking to market generic versions of Abbott's brand drugs, including, but not limited to, Biaxin®, Depakote®, Tricor®, and Hytrin. Abbott also has publicly threatened to enforce its patents on Omnicef® as appropriate. In fact, Abbott has actually attempted to enforce the '507 patent against other generic companies in infringement actions filed in the U.S. district Court for the Northern District of Illinois.

39. On information and belief, Abbott's public threats to enforce its patents on Onmicef® as appropriate were made with the knowledge, cooperation, consent, and/or authorization of Astellas.

40. Since the filing of Lupin's original Complaint, Abbott and Astellas have, in fact, asserted claims for patent infringement against Lupin Ltd. and Lupin Pharmaceuticals, Inc. with regard to the '507 patent.

41. Based on the totality of circumstances, Lupin is under a reasonable apprehension that it will face suit for infringement of the '507 patent by manufacturing, using, selling, offering for sale, or importing its competing generic cefdinir capsules, which will compete directly with Abbott's Omnicef® product.

42. There is an actual, substantial, and continuing justiciable case or controversy between Defendants and Lupin regarding the infringement and validity of the '507 patent.

COUNT I
(Declaratory Judgment of Non-Infringement of the '507 Patent)

43. Lupin repeats each of the foregoing paragraphs as if fully set forth herein.

44. There is an actual, substantial, and continuing justiciable case or controversy between Defendants and Lupin regarding the infringement of the '507 patent.

45. The manufacture, use, sale, offer for sale, or importation of Lupin's generic Cefdinir Capsules 300 mg, which are the subject of ANDA No. 65-264, have not infringed, do not infringe, and will not infringe any valid and/or enforceable claim of the '507 patent.

46. The manufacture, use, sale, offer for sale, or importation of Lupin's generic Oral Suspension 125 mg/5 mL products, which are the subject of Lupin's approved ANDA No. 65-259, have not infringed, do not infringe, and will not infringe any valid and/or enforceable claim of the '507 patent.

47. Lupin is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of Lupin's generic Cefdinir Capsules 300 mg, which are the subject of ANDA No. 65-264, have not infringed, do not infringe, and will not infringe any valid and/or enforceable claim of the '507 patent.

48. Lupin is entitled to a judicial declaration that the manufacture, use, sale, offer for sale, or importation of Lupin's generic Oral Suspension 125 mg/5 mL products, which

are the subject of Lupin's approved ANDA No. 65-259, have not infringed, do not infringe, and will not infringe any valid and/or enforceable claim of the '507 patent.

COUNT II
(Declaratory Judgment of Invalidity of the '507 Patent)

49. Lupin repeats each of the foregoing paragraphs as if fully set forth herein.

50. There is an actual, substantial, and continuing justiciable case or controversy between Defendants and Lupin regarding the validity of the '507 patent.

51. The claims of the '507 patent are invalid for failure to satisfy one or more of the conditions for patentability in 35 U.S.C. § 1 *et seq.* and/or for obviousness-type double patenting.

52. Lupin is entitled to a judicial declaration that the claims of the '507 patent are invalid.

COUNT III
(Declaratory Judgment of Invalidity of PTE for the '507 Patent)

53. Lupin repeats each of the foregoing paragraphs as if fully set forth herein.

54. There is an actual, substantial, and continuing justiciable case or controversy between Defendants and Lupin regarding the validity of the patent term extension ("PTE") for the '507 patent.

55. The natural term of the '507 patent expires on August 8, 2008.

56. Pursuant to 35 U.S.C. § 156, Astellas, through its prior licensee, applied for and received a PTE for the '507 patent, purportedly extending the term of the '507 patent to on or about December 4, 2011.

57. The PTE for the '507 patent is invalid because Astellas already received a PTE on an earlier patent for cefdinir. Section 156 does not permit the additional PTE for the '507 patent.

58. Lupin is entitled to a judicial declaration that the PTE for the '507 patent is invalid and that the term of such patent expires no later than August 8, 2008.

COUNT IV
(Declaratory Judgment of Unenforceability of the '507 Patent)

59. Lupin asserts and re-alleges each of the foregoing paragraphs as if fully set forth herein.

60. The '507 patent is unenforceable because one or more of the originally-named inventors of the '507 patent; their agents; and/or their attorneys engaged in inequitable conduct during the prosecution of the patent.

Events that led to naming four individuals as inventors on the '507 patent when it issued

61. When the '507 patent issued on June 19, 1990, it listed four individuals as inventors: Takayo Takaya; Fumiyuki Shirai; Hitoshi Nakamura; and Yasunobu Inaba ("Original Inventors").

62. When the '507 patent issued on June 19, 1990, Fujisawa Pharmaceutical Co., Ltd. ("Fujisawa") was identified as the assignee of the '507 patent. Astellas Pharma Inc. is the successor in interest to Fujisawa.

63. Upon information and belief, individuals within Fujisawa and Astellas have served as the agents of one or more of the Original Inventors for the purposes of securing the '507 patent.

64. Dr. Takaya had the idea to prepare cefdinir as crystals before Astellas filed the Japanese patent application that eventually served as the priority document to the '507 patent.

65. On or prior to August of 1985, Dr. Takaya had the idea to prepare cefdinir as crystals.

66. After Dr. Takaya had the idea to prepare cefdinir as crystals, he communicated his idea to prepare crystals to Dr. Shirai.

67. Dr. Takaya communicated his idea to prepare crystals to Dr. Shirai.

68. On Dr. Takaya's order, Dr. Shirai set about preparing cefdinir as crystals.

69. Prior to Dr. Takaya's order, Dr. Shirai had not prepared cefdinir as crystals.

70. Dr. Shirai would never have prepared cefdinir as crystals without Dr. Takaya's prior instruction to do so.

71. Dr. Shirai did, at some point, prepare cefdinir as crystals as Dr. Takaya had instructed.

72. Upon information and belief, Mr. Nakamura and Mr. Inaba were named as inventors of the '507 patent because Fujisawa believed that each had contributed to the conception and/or reduction to practice of the preparation of cefdinir as crystals on a commercial scale.

73. The words "[c]rystalline cefdinir" are found in each and every claim in the '507 patent.

74. Astellas contends that crystalline cefdinir was not disclosed in the art prior to August of 1987.

75. On or prior to August of 1987, Dr. Takao Takaya submitted an order to the Intellectual Property department at Fujisawa.

76. At that time, Dr. Takaya sought to use the Intellectual Property department's services to seek patent protection for crystalline cefdinir.

77. In particular, Dr. Takaya sought at that time to use the Intellectual Property department's services to seek patent protection for forms of crystalline cefdinir.

78. When Dr. Takaya submitted the order prior to August of 1987 seeking to use the Intellectual Property department's services to seek patent protection for cefdinir, he included Crystal A cefdinir within that order.

79. When Dr. Takaya submitted the order prior to August of 1987 seeking to use the Intellectual Property department's services to seek patent protection for cefdinir, he included Crystal B cefdinir within that order.

80. Prior to submitting the U.S. patent application that eventually led to the issuance of the '507 patent, individual(s) within the Fujisawa Intellectual Property department interviewed Dr. Takaya to evaluate his involvement with the development of cefdinir in the form of crystals.

81. Prior to submitting the U.S. patent application that eventually led to the issuance of the '507 patent, individual(s) within the Fujisawa Intellectual Property department interviewed Dr. Shirai to evaluate his involvement with the development of cefdinir in the form of crystals.

82. Prior to submitting the U.S. patent application that eventually led to the issuance of the '507 patent, individual(s) within the Fujisawa Intellectual Property department

interviewed Mr. Inaba to evaluate his involvement with the development of cefdinir in the form of crystals.

83. Prior to submitting the U.S. patent application that eventually led to the issuance of the '507 patent, individual(s) within the Fujisawa Intellectual Property department interviewed Mr. Nakamura to evaluate his involvement with the development of cefdinir in the form of crystals.

84. Fujisawa acted as Dr. Takaya's agent in securing patent protection for the subject matter presently claimed by the '507 patent.

85. The law firm presently known as "Oblon Spivak" (then called Oblon, Spivak, McClelland, Maier & Neustadt) served as the Attorney, Agent or Firm of record during the prosecution of the '507 patent before the U.S. Patent and Trademark Office ("PTO").

86. The Oblon Spivak law firm served as the Attorney, Agent or Firm of record during the prosecution of U.S. Patent No. 4,559,334 ("the '334 patent") before the PTO.

87. The Oblon Spivak law firm has, for the past twenty-five years, marketed itself as having specialized expertise in patent prosecution issues.

88. The Oblon Spivak law firm is nationally recognized as having expertise in matters of patent prosecution.

89. The Oblon Spivak law firm has, since at least 1983, represented Fujisawa Pharmaceutical Co. (now part of Astellas) on patent prosecution matters.

90. Mr. Richard D. Kelly of the Oblon Spivak law firm was an attorney of record before the PTO during the prosecution of the '334 patent.

91. Mr. Richard D. Kelly of the Oblon Spivak law firm was an attorney of record before the PTO during the prosecution of the '507 patent.

92. Mr. Richard D. Kelly of the Oblon Spivak law firm is today an attorney of record on behalf of Astellas in Civil Action No. 3:06cv400, pending in the Eastern District of Virginia before the Honorable Judge Robert E. Payne.

93. Upon information and belief, prior to submitting the U.S. patent application that led to the issuance of the '507 patent, one or more individuals at the Oblon Spivak law firm analyzed the correctness of the inventorship of the '507 patent.

94. Upon information and belief, prior to submitting the Declaration and Power of Attorney naming Dr. Takaya, Dr. Shirai, Mr. Nakamura, and Mr. Inaba as inventors on the U.S. patent application that led to the issuance of the '507 patent, one or more individuals at the Oblon Spivak law firm analyzed the correctness of the inventorship of the '507 patent.

95. Upon information and belief, prior to submitting the October 20, 1989 Declaration of Dr. Takayo Takaya to the PTO during the prosecution of the U.S. patent application that led to the issuance of the '507 patent, one or more individuals at the Oblon Spivak law firm independently evaluated whether Dr. Takaya was correctly named as an inventor on the '507 patent.

96. By statute, a patent shall not issue unless the correct inventors are identified on the face of the patent. *See* 35 U.S.C. § 102(f).

97. The PTO obligates applicants for patent to correctly name the inventors of the subject matter claimed by the invention.

98. Attorneys who represent prospective patentees have an affirmative, independent obligation to assess whether applicants for patent are correctly named as the inventors of the subject matter claimed by the invention.

99. When the '507 patent issued, it identified as inventors individuals who did not invent subject matter claimed by the '507 patent.

100. When Lupin's original Complaint in the present action was filed, the '507 patent identified as inventors individuals who did not invent subject matter claimed by the '507 patent.

101. The decision by Dr. Takaya to identify himself as a co-inventor of subject matter claimed in the application that led to the issuance of the '507 patent was intentional.

102. The decision by Dr. Takaya to identify himself as a co-inventor of subject matter claimed in the application that led to the issuance of the '507 patent was deliberate.

103. The decision by Fujisawa to identify Dr. Takaya as a co-inventor of subject matter claimed in the application that led to the issuance of the '507 patent was intentional.

104. The decision by Fujisawa to identify Dr. Takaya as a co-inventor of subject matter claimed in the application that led to the issuance of the '507 patent was deliberate.

105. The decision by Fujisawa to identify Dr. Takaya as a co-inventor of subject matter claimed in the application that led to the issuance of the '507 patent occurred after an interview with Dr. Takaya.

The October 20, 1989 Takaya Declaration

106. In an Office Action dated May 11, 1989, the PTO Examiner rejected the pending claims of the patent application that led to the issuance of the '507 patent.

107. In the May 11, 1989 Office Action, the PTO Examiner rejected pending claims 1-9 under 35 U.S.C. § 103 "as being unpatentable over Takaya 4,559,334".

108. In response to the PTO's obviousness rejection, the Oblon Spivak law firm submitted to the PTO a Declaration from Dr. Takaya dated October 20, 1989.

109. In the October 20, 1989 Takaya Declaration, Dr. Takaya stated as follows:

> I am a co-inventor of the above-identified U.S. patent application;
>
> I prepared the following test samples of the above-identified U.S. patent application and of U.S.P. 4,559,334 according to the methods disclosed therein.
>
> Test Sample
>
> Sample 1 --- the compound of Example 14 of U.S.P. 4,559,334
>
> Sample 2 --- the compound of Example 16 of U.S.P. 4,559,334
>
> Sample A --- Crystal A of the present application
>
> The samples 1, 2 and A were delivered to Mr. Yoshihiko Okamoto for use in comparative tests on stability.

Dr. Takaya's signature appears on the Declaration.

110. Dr. Takaya voluntarily signed his Declaration dated October 20, 1989.

111. Dr. Takaya signed his Declaration dated October 20, 1989 under penalty of perjury.

112. At the time he signed his Declaration, Dr. Takaya owed the PTO an obligation of candor.

113. At the time he signed his Declaration, Dr. Takaya owed the PTO an obligation of good faith.

114. At the time he signed his Declaration, Dr. Takaya owed the PTO an obligation of fair dealing.

115. Dr. Takaya expected the PTO to rely on his Declaration when it was submitted to the PTO.

116. Dr. Takaya intended for the PTO to rely on his Declaration when it was submitted to the PTO.

117. Fujisawa intended for the PTO to rely on Dr. Takaya's Declaration when it was submitted to the PTO.

118. Dr. Takaya's patent attorney(s) at the Oblon Spivak law firm expected the PTO to rely on Dr. Takaya's October 20, 1989 Declaration.

119. Dr. Takaya's patent attorney(s) at the Oblon Spivak law firm independently confirmed whether the representations Dr. Takaya made to the PTO in his October 20, 1989 Declaration were accurate.

120. After Dr. Takaya's October 20, 1989 Declaration was submitted to the PTO, the PTO relied on it to withdraw its obviousness rejection over the '334 patent.

121. The PTO withdrew its objection because the Declarations and attorney argument from the Oblon Spivak law firm convinced him that the '334 patent disclosed only amorphous cefdinir.

Material misrepresentations to the PTO and intent to deceive

122. In 2006, Dr. Takaya represented to the PTO in another Declaration ("2006 Declaration") that he was not an inventor of subject matter claimed by the '507 patent.

123. Dr. Takaya prepared the 2006 Declaration at the request of Astellas.

124. Dr. Takaya prepared the 2006 Declaration upon the recommendation of attorneys at the Oblon Spivak law firm.

125. Dr. Takaya has materially misrepresented his knowledge of and involvement with the development of crystalline cefdinir that is the subject matter of the claimed invention to the PTO.

126. For example, upon information and belief, Astellas presently believes that Dr. Takaya's sole involvement with the development of cefdinir as crystals was providing Dr. Shirai with the order to make them.

127. Astellas' current beliefs are contradictory to Dr. Takaya's representations to the PTO that he actually prepared the product of Examples 14 and 16 of the '334 patent, as well as "Crystal A of the present invention."

128. It cannot be simultaneously true that Dr. Takaya played little to no substantive role in the conception of crystalline cefdinir products and processes claimed by the '507 patent (the factual basis for his 2006 Declaration), and that Dr. Takaya personally prepared the products of Examples 14, 16, and "Crystal A of the present invention" (the facts as represented in his 1989 Declaration). Such contradictions do not arise as a consequence of bona fide errors or innocent mistakes. One or more assertions of fact made in the Takaya Declarations are materially false. Such false representations were intentionally made to the PTO. Dr. Takaya knew at the time he submitted his Declarations to the PTO that the PTO would reasonably expect to rely on the accuracy of the information Dr. Takaya provided in his Declarations. Dr. Takaya knew at the time he submitted his Declarations to the PTO that he was preparing them under penalty of perjury.

129. A reasonable PTO Examiner would have given considerable weight, when considering whether the teachings of the '334 patent rendered the subject matter of the '507 patent obvious, to the fact that Dr. Takaya, a named inventor on the '334 patent, declared under oath that the '334 patent did not teach the preparation of crystalline cefdinir.

130. Had the PTO Examiner known that Dr. Takaya did not actually prepare the product of Examples 14 and 16 in the '334 patent, that information would have been highly material to patentability.

131. Had the PTO Examiner known that Dr. Takaya did not personally prepare the product of Examples 14 and 16 in the '334 patent that Dr. Takaya references in his 1989 Declaration, that information would have been highly material to patentability.

132. Dr. Takaya's 1989 Declaration to the PTO Examiner was necessary to establish a chain of custody and lay a foundation for the samples he identified, as such samples were subjected to further testing in a second Declartion submitted to the PTO that was relied upon to allege the subject matter of the pending claims in the application that led to the issuance of the '507 patent was patentable.

133. Had the PTO Examiner known that Dr. Takaya did not personally prepare the sample in his Declaration that he identified as corresponding to "Crystal A of the present application", that information would have been highly material to patentability.

134. If the PTO Examiner knew that Dr. Takaya's role in the development of crystalline cefdinir was limited to merely passing on the idea of making cefdinir, and that Dr. Takaya actually performed nor conducted experimental work himself on the project, the PTO Examiner would have considered that fact highly material to patentability.

135. If, at the time the PTO considered Dr. Takaya's October 20, 1989 Declaration, the PTO would have known that Dr. Takaya was not an actual inventor of subject matter claimed by the '507 patent, that fact would have been highly material to patentability.

136. Subsequent to the issuance of the '507 patent, and after Lupin Ltd. had filed the original Complaint in this action, attorneys from the Oblon Spivak law firm recommended that Astellas change the named inventors on the '507 patent.

137. Upon information and belief, Astellas now believes that Dr. Takaya played no role in the development of any kind of crystalline cefdinir, besides suggesting to Dr. Shirai that it be made.

138. Upon the advice of attorneys at Oblon Spivak, in 2006 Astellas secured Declarations from Dr. Takaya and Dr. Shirai in which each represented to the PTO that Dr. Shirai was the sole inventor of subject matter claimed by the '507 patent.

139. In 2006, the PTO changed the inventorship of the '507 patent to remove Dr. Takaya, Mr. Nakamura, and Mr. Inaba, in reliance on the representations made to the PTO by such individuals in their 2006 Declarations.

140. If, in fact, Dr. Takaya's representations to the PTO in his 1989 Declaration were true, no matter what his present-day recollection is, Dr. Takaya's representation to the PTO that he was not a co-inventor of subject matter claimed in the application that led to the issuance of the '507 patent was materially false.

141. During prosecution of the '507 patent, Dr. Takaya made a knowingly false statement in a Declaration submitted to the PTO.

142. During prosecution of the '507 patent, Dr. Shirai made a knowingly false statement in a Declaration submitted to the PTO.

143. During prosecution of the '507 patent, and/or during the efforts to change the inventorship of the '507 patent, Dr. Takaya knowingly made a false statement in a Declaration submitted to the PTO.

144. During prosecution of the '507 patent, and/or during the efforts to change the inventorship of the '507 patent, Dr. Shirai knowingly made a false statement in a Declaration submitted to the PTO.

145. During prosecution of the '507 patent, and/or during the efforts to change the inventorship of the '507 patent, Dr. Takaya, his agents and/or attorneys made such material misrepresntations to the PTO with the intent to deceive the PTO.

146. During prosecution of the '507 patent, and/or during the efforts to change the inventorship of the '507 patent, Dr. Shirai, his agents and/or attorneys made such material misrepresntations to the PTO with the intent to deceive the PTO.

147. Dr. Shirai, Dr. Takaya, their agents, Declarants, and or attorneys acting on their behalf failed to comply with their duty of good faith and candor before the PTO. Dr. Shirai, Dr. Takaya, their agents, Declarants, and or attorneys acting on their behalf engaged in inequitable conduct before the PTO during the prosecution of the '507 patent.

148. Further evidence of intent to deceive may be inferred by the pattern of activity that Fujisawa and later Astellas have engaged in with regard to the '507 patent. So-called mistakes of this nature do not occur, for example, when a party is represented by attorneys such as those of the caliber of the Oblon Spivak law firm, unless there is an intent or motivation to misrepresent and/or conceal information from the PTO.

The '507 patent is unenforceable for inequitable conduct

149. Prosecuting a patent application, and the correction of inventorship under 35 U.S.C. § 256, is an *ex parte* process, and therefore, the law imposes a duty of good faith, candor, and disclosure on everyone associated with prosecuting the application. *See* 37 C.F.R. § 1.56; *Manual of Patent Examining Procedure* § 2000. The duty of candor/disclosure requires,

inter alia, the applicant, his or her agents and/or attorneys, and anyone else substantively involved in prosecuting the application to disclose all information that a reasonable Examiner reviewing the application would consider important in determining whether to allow the proposed claims to issue.

150. In connection with the application leading to the '507 patent, Dr. Shirai, Dr. Takaya, Mr. Inaba and Mr. Nakamura, their declarants and/or attorneys affirmatively misrepresented material facts to the PTO and/or withheld material information from the PTO, with an intent to deceive the PTO. This included the submission of materially false and misleading declarations.

151. Dr. Takaya has intentionally submitted false and misleading statements in his Declarations, knowing they were materially false and misleading, in order to induce the PTO to issue the '507 patent and/or to ensure that the '507 patent was not struck down as invalid.

152. The intentional submission of materially false and misleading information with an intent to deceive the PTO constitutes inequitable conduct and renders the '507 patent unenforceable.

153. There is an actual, substantial, and continuing justiciable case or controversy between Lupin and Astellas and Abbott regarding the unenforceability of the '507 patent.

154. Lupin is entitled to a judicial declaration that the '507 patent is unenforceable for inequitable conduct.

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