UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF INDIANA
INDIANAPOLIS DIVISION

CIPLA LIMITED AND CIPLA USA, INC., Plaintiffs, v. ELI LILLY AND COMPANY AND ICOS CORPORATION, Defendants.	Civ. No. 1:18-cv-01671-JMS-DML

FIRST AMENDED COMPLAINT FOR DECLARATORY JUDGMENT OF INVALIDITY

Plaintiffs Cipla Limited and Cipla USA, Inc. (collectively, "Cipla" or "Plaintiffs"), by its attorneys, brings this Complaint for a declaratory judgment of patent invalidity against Eli Lilly and Company ("Lilly") and ICOS Corporation ("ICOS") (collectively, "Defendants"), and alleges as follows:

NATURE OF THE ACTION

1. Cipla seeks a declaratory judgment under the patent laws of the United States, 35 U.S.C. § 100, *et seq.* and the Declaratory Judgment Act, 28 U.S.C. § 2201 *et seq*., that United States Patent Nos. 6,821,975 ("the '975 patent") and 7,182,958 ("the '958 patent"), attached hereto as Exhibits A and B, are invalid.

THE PARTIES

2. Cipla Limited is a corporation organized and existing under the laws of India, having its corporate office at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai Maharashtra 400013, India.

3. Cipla USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, having its corporate office at 9100 S. Dadeland Blvd., Suite 1500, Miami, Florida 33156. Cipla USA, Inc. is a wholly-owned subsidiary of Invagen Pharmaceuticals, Inc. which is a wholly owned subsidiary of Cipla (EU Limited), which is a wholly owned subsidiary of Cipla Limited.

4. On information and belief, Eli Lilly and Company is an Indiana Corporation that has its principal place of business at Lilly Corporate Center, Indianapolis, Indiana 46285.

5. On information and belief, ICOS Corporation is a Delaware corporation having its corporate office at Lilly Corporate Center, Indianapolis, Indiana 46825. ICOS is a wholly owned subsidiary of Lilly.

JURISDICTION AND VENUE

6. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 1, *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. This Court has subject matter jurisdiction under 28 U.S.C. §§ 1331 and 1338.

7. Personal jurisdiction over the Defendants exists because the Defendants reside in this district.

8. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400.

9. This Court has general personal jurisdiction over Defendants because, upon information and belief, Defendants' principal place of business is in Indianapolis, Indiana.

10. This Court also has specific personal jurisdiction over Defendants because, upon information and belief, Defendants transact business in the State of Indiana and have purposefully availed themselves of the privileges of doing business in Indiana.

11. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b), (c) and 1400(b), because, upon information and belief, the Southern District of Indiana is a judicial district where Defendants have committed acts that give rise to Plaintiffs' declaratory judgment claims as alleged in this Complaint, and has a regular and established place of business, e.g., its headquarters in Indianapolis, Indiana.

FACTUAL BACKGROUND

The Patents-in-Suit

12. The '975 patent, entitled "Beta-Carboline Drug Products," issued on November 23, 2004. A copy of the '975 patent has been attached hereto as Exhibit A.

13. The '958 patent, entitled "β-Carboline Pharmaceutical Compositions," issued on February 27, 2007. A copy of the '958 patent has been attached hereto as Exhibit B.

14. On information and belief, ICOS is the assignee of the '975 and '958 patents.

15. On information and belief, Lilly is the exclusive licensee of the '975 and '958 patents.

16. On information and belief, Lilly holds approved New Drug Application ("NDA") No. 022332 for tadalafil 20 mg tablets under Section 505(b) of the Federal Food Drug and Cosmetic Act ("FFDCA").

17. The Hatch-Waxman Amendments to the FFDCA ask NDA holders to disclose the patent numbers and expiration dates of those patents that the holders believe claim the "drug" for which their NDA is submitted, or patents covering a "method of using such drug." 21 U.S.C. §§ 355(b)(1) and (c)(2).

18. On request from an NDA holder, the FDA automatically lists the NDA holder's disclosed patents pursuant to 21 U.S.C. §§ 355(b)(1) and (c)(2) in the publication *Approved Drug*

Products with Therapeutic Equivalence Evaluations, commonly called the "Orange Book." The FDA does not evaluate whether the claims of the disclosed patents actually cover the drug or method of using such drug, or whether the patent is valid; its actions are purely "ministerial." *Caraco Pharm. Labs., Ltd. v. Novo Nordisk*, 132 S. Ct. 1670, 1677 & n.2 (2012); *aaiPharma Inc. v. Thompson*, 296 F.3d 227, 243 (4th Cir. 2002).

19. Lilly, and/or ICOS caused the '975 and '958 patents to be listed in the Orange Book as patents that claim the drug and/or claim a method of using such a drug for which Lilly submitted NDA No. 022332.

20. Lilly, and/or ICOS also caused U.S. Patent No. 5,859,006 ("the '006 patent") to be listed in the Orange Book as a patent that claims the drug and/or claims a method of using such a drug for which Lilly submitted NDA No. 022332.

21. The '006 patent's pediatric exclusivity period expired on or about May 21, 2018. The '006 patent expired on November 21, 2017.

22. As of this filing, the '975 and '958 patents continue to be listed in the Orange Book and, on information and belief, Lilly and/or ICOS continue to represent to the public that the '975 and '958 patents claim the drug and/or claim a method of using such a drug approved under NDA No. 022332 and, therefore, that a claim for infringement could reasonably be brought against any unlicensed ANDA applicant who attempts to market a generic version of the approved drug prior to expiration of the '975 and/or '958 patents.

Cipla's ANDA and Prior ANDAs

23. Cipla filed Abbreviated New Drug Application ("ANDA") No. 210255 to obtain FDA approval to engage in the commercial manufacture, use, and sale of tadalafil tablets in the 20 mg dosage strength. Cipla desires to bring its generic tadalafil oral tablet 20mg to market and to

allow the public to enjoy the benefits of generic competition for this product as early as possible under the applicable statutory and FDA regulatory guidelines.

24. Cipla's ANDA No. 210255 contains a "Paragraph IV" certification under 21 U.S.C. § 505(j)(2)(A)(vii)(IV) that the '975 and '958 patents are unenforceable, invalid and/or will not be infringed by the commercial manufacture, use, or sale of the drug product described in ANDA No. 210255.

25. Pursuant to 21 U.S.C. § 355(j)(2)(B)(ii), on December 6, 2017, Cipla sent Lilly and ICOS notice of Cipla's Paragraph IV certification with ANDA No. 210255 ("Cipla's Notice Letter").

26. Cipla's Notice Letter contained an offer of confidential access to relevant portions of ANDA No. 210255 to each Defendant so that each could determine whether Cipla's generic products would infringe any valid claim of the Orange Book-listed patents, pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

27. Cipla's Notice Letter initiated a 45-day statutory period during which Defendants had the opportunity to file an action for patent infringement.

28. The Hatch-Waxman Amendments to the FFDCA authorize an ANDA filer to initiate a declaratory judgment action with respect to Orange Book-listed patents that the patent holder does not assert within 45 days of receipt of the ANDA filer's Paragraph IV notice letter. 21 U.S.C. § 355(j)(5)(C).

29. Defendants did not file an action against Cipla for infringement of the '975 or '958 patents within the 45-day statutory period, or at any time.

30. The first drug company that files an ANDA containing a Paragraph IV certification is presumptively entitled to a 180-day period of generic marketing exclusivity before the FDA may approve any later Paragraph IV ANDA based on the same NDA. 21 U.S.C. §§ 355(j)(5)(B)(iv).

31. The 180-day exclusivity period is triggered by the first ANDA filer's entry into the market.

32. The first ANDA filer's 180-day exclusivity period can be forfeited under certain circumstances, however.

33. For instance, if a later ANDA-filer obtains a final judgment that each of the listed drug's relevant Orange Book patents are not infringed and/or are invalid and obtains tentative approval, the first ANDA filer must market its product within 75 days of the later ANDA filer's judgment, or forfeit its period of exclusivity. 21 U.S.C. §§ 355(j)(5)(D)(i)(I).

34. Upon information and belief, Cipla was not the first generic drug manufacturer to file an ANDA directed to tadalafil tablets in the 20 mg dosage strength.

35. FDA records indicate that the first Paragraph IV certification directed to 20 mg tadalafil tablets was submitted on October 15, 2009.

36. Upon information and belief, Synthon Pharmaceuticals, Inc. ("Synthon") was the first generic ANDA applicant to have filed Paragraph IV certifications against the '975 and '958 patents with respect to tadalafil tablets in the 20 mg dosage strength (hereinafter "the Mylan/Synthon ANDA").

37. Lilly and ICOS filed suit against Synthon in the Southern District of Indiana, asserting the infringement of the '975 and '958 patents. *Eli Lilly and Company, et al. v. Synthon Pharmaceuticals, Inc.*, Civ. No. 1:10-cv-00310-SEB-TAB (S.D.Ind.), Dkt. No. 1 (complaint attached hereto as Exhibit C).

38. In its complaint, Lilly alleged that Synthon sent Lilly a "Paragraph IV Certification" with respect to the '975 and '958 patent as follows:

> Lilly received from Synthon a letter, dated January 28, 2010, and an attached memorandum (collectively, the "Synthon Notification"), stating that Synthon had included certifications in the Synthon ANDA, pursuant to 21 U.S.C. §355(j)(2)(A)(vii)(IV), that the '975 and '958 patent are invalid, unenforceable, or will not be infringed by the commercial manufacture, use, or sale of the Synthon Product ("the Paragraph IV Certification").

See Exhibit C at ¶16.

39. In addition, Synthon filed a complaint against Lilly in the Eastern District of North Carolina for declaratory judgment of non-infringement and invalidity of the '958 and '975 patents (*see Synthon Pharmaceuticals, Inc. v. Eli Lilly and Company, et al.*, 5:10-cv-150 (E.D.N.C.)) (complaint attached hereto as Exhibit D).

40. The Indiana litigation filed by Lilly was later transferred to the Eastern District of North Carolina and consolidated with the declaratory judgment action filed by Synthon (*see Eli Lilly and Company, et al. v. Synthon Pharmaceuticals, Inc.*, Civ. No. 5:10-cv-0402 (E.D.N.C.)) (complaint attached hereto as Exhibit E).

41. In its complaint for declaratory judgment, Synthon alleges that "Synthon has submitted Abbreviated New Drug Application No. 200630 to the FDA under Section 355(j) of the Federal Food, Drug and Cosmetic Act for 20 mg tadalafil tablets described in Synthon's ANDA ("Synthon's ANDA Products.") *See* Exhibit D at ¶12.

42. Synthon's complaint for declaratory judgment further alleges that "Synthon's ANDA includes a certification under 21 U.S.C. §355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") that the '975 and '958 patents are invalid, unenforceable, or will not be infringed by the commercial manufacture, use or sale of Synthon's ANDA Product." *Id*, at ¶13.

43. On or about April 16, 2012, Synthon's parent company issued a press release announcing that the Mylan/Synthon ANDA had received tentative approval from the FDA (attached hereto as Exhibit F).

44. The press release further announced that Synthon was the "Single First Filer" and, as such "will benefit from 180 days of Hatch-Waxman exclusivity upon the first commercial marketing of their generic drug product." *See* Exhibit F.

45. More particularly, the press release states as follows:

> Synthon today announced that its subsidiary Synthon Pharmaceuticals, Inc. has received tentative approval from the U.S. Food and Drug Administration for its abbreviated new drug application for tadalafil tablets, 20 mg on April 13, 2012. Synthon's product is a generic and bioequivalent version of Eli Lilly & Co and United Therapeutics' Adcirca® tablets, which are indicated for the treatment of pulmonary arterial hypertension to improve exercise ability.
>
> Consistent with its business model, Synthon intends to commercialize the product by partnering with a leading generic company in the United States. Synthon is the 'Single First Filer' and will benefit from 180 days of Hatch-Waxman exclusivity upon the first commercial marketing of their generic drug product. The period of 180 days exclusivity will be beneficial to the company, as well as to the U.S. health care system.

See Exhibit F.

46. Upon information and belief, Synthon received tentative approval for the Mylan/Synthon ANDA on or about April 13, 2012.

47. The FDA website reports that the Mylan/Synthon ANDA was tentatively approved on April 13, 2012. *See* https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=overview.process&ApplNo=200630 (attached hereto as Exhibit G).

48. Upon information and belief, Mylan Pharmaceuticals, Inc. ("Mylan") has acquired the rights to the Mylan/Synthon ANDA and has been substituted for Synthon in the litigations

between Synthon, Lilly and ICOS. *See Synthon Pharmaceuticals, Inc. v. Eli Lilly and Company, et al.*, 5:10-cv-150 (E.D.N.C.), Dkt. No. 57 (attached hereto as Exhibit H).

49. On May 17, 2018, Mylan, Lilly, and ICOS stipulated to a dismissal of the ongoing litigation between the parties regarding the '975 and '958 patents without any findings as to the validity or invalidity of the patents. *See Synthon Pharmaceuticals, Inc. v. Eli Lilly and Company, et al.*, 5:10-cv-150 (E.D.N.C.), Dkt. No. 59 (attached hereto as Exhibit I).

50. No district court judgment of invalidity or non-infringement has been entered with respect to the '975 and '958 patents.

51. Despite receiving tentative approval in 2012, Mylan has not received final approval from the FDA to market the product proposed in the Mylan/Synthon ANDA. *See* Exhibit G.

52. In order to be eligible for 180-day first applicant exclusivity, an applicant must be the first to submit "a substantially complete application that contains and lawfully maintains a [Paragraph IV certification] for the drug." 21 U.S.C. §§ 355(j)(5)(B)(iv)(II)(bb).

53. Further, the first applicant must not forfeit its exclusivity under any of the forfeiture events enumerated under 21 U.S.C. §§ 355(j)(5)(D), namely "failure to market" (21 U.S.C. §§ 355(j)(5)(D)(i)(I)), "withdrawal of application" ((21 U.S.C. §§ 355(j)(5)(D)(i)(II)), "amendment of certification" ((21 U.S.C. §§ 355(j)(5)(D)(i)(III)), "failure to obtain tentative approval" ((21 U.S.C. §§ 355(j)(5)(D)(i)(IV)), "agreement with another applicant, the listed drug application holder, or the patent owner" ((21 U.S.C. §§ 355(j)(5)(D)(i)(V)), and "expiration of all patents" ((21 U.S.C. §§ 355(j)(5)(D)(i)(VI)).

54. Upon information and belief, the Mylan/Synthon ANDA was the first substantially complete ANDA for a generic tadalafil 20 mg tablet, containing a Paragraph IV certification as to any patent listed on the Orange Book for that drug product.

55. Upon information and belief, Synthon and later Mylan has lawfully and continuously maintained Paragraph IV certifications against the '975 and '958 patents with respect to the Mylan/Synthon ANDA.

56. Upon information and belief, no forfeiture event has occurred that would divest first applicant exclusivity for the Mylan/Synthon ANDA under 21 U.S.C. §§ 355(j)(5)(D), nor has the FDA determined that any such forfeiture has occurred.

57. Upon information and belief, Mylan is eligible for and has retained a 180-day first generic applicant exclusivity by virtue of its lawfully maintained Paragraph IV certifications against the '975 and '958 patents in the Mylan/Synthon ANDA.

58. The FDA will be prohibited from granting final approval to Cipla to market its 20 mg tadalafil tablets until 180 days after Mylan chooses to market its own 20 mg tadalafil tablets, unless Mylan otherwise forfeits its exclusivity.

59. The '975 and '958 patents are a barrier to Cipla's entry into the market.

60. The FDA cannot approve Cipla's ANDA for 20 mg tadalafil tablets until Mylan's 180-day exclusivity period is either forfeited or runs out.

61. Cipla has not yet received tentative approval for its ANDA, but it expects to do so soon.

62. Tentative approval is "not a precondition to the existence of a case or controversy concerning patents listed in the Orange Book." *Apotex Inc. v. Daiichi Sankyo, Inc.*, 781 F.3d 1356, 1366 (Fed. Cir. 2015).

63. One of the ways that forfeiture of the first ANDA filer's exclusivity period may be triggered so as to precipitate Cipla's entry into the market is by obtaining a final favorable

judgment that the relevant Orange Book-listed patents in connection with NDA No. 210255 are invalid and/or not infringed.

64. On information and belief, no court has entered a "final decision" as described in 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA) with respect to the '975 or '958 patents.

65. Upon information and belief, no court has entered a final decision from which an appeal has been or can be taken that either the '975 or '958 patents are invalid or not infringed.

66. On information and belief, no court has signed a "settlement order or consent decree" as described in 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(BB) that enters final judgment which includes a finding that the '975 or '958 patents are invalid or not infringed.

67. As of the date of this Complaint, the '975 and '958 patents are the only two remaining unexpired patents listed on the Orange Book for NDA No. 022332.

68. There are no patents listed on the Orange Book barring a first ANDA filer from entering the market for tadalafil 20 mg tablets.

69. Mylan may not market the product described in the Mylan/Synthon ANDA until it receives final approval from the FDA.

70. On information and belief, despite the expiration of pediatric exclusivity of the '006 patent, Mylan has been unable to secure final approval for the Mylan/Synthon ANDA from the FDA and is therefore unable to enter the market.

71. On information and belief, no first ANDA filer has entered the market.

72. On information and belief, Mylan remains eligible for 180-day first applicant exclusivity. Therefore, unless the Court declares the '975 and '958 patents invalid, unenforceable or not infringed by Cipla's ANDA Product, Cipla will be prohibited from marketing the product described in Cipla's ANDA until 180 days after Mylan begins commercial marketing of the

product described in the Mylan/Synthon ANDA, thereby injuring Cipla by depriving it of sales revenue from that period of time and injury the public by depriving the public of the benefit of the generic competition that would otherwise be provided by the product described in Cipla's ANDA.

73. Mylan has not received final approval, and is unable to launch its product. Cipla's ANDA is therefore "parked" behind the Mylan/Synthon ANDA.

74. Cipla will be delayed entry into the market unless and until it can trigger the forfeiture of Mylan's exclusivity by receiving a judgment of invalidity of the '975 and '958 patents.

75. "[T]he dispute as to infringement or invalidity of the relevant Orange-Book-listed patents constitutes 'a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment.'" *Caraco Pharm. Labs., Ltd. v. Forest Labs.,* 527 F.3d 1278, 1296-97 (Fed. Cir. 2008) (citation omitted).

The '975 and '958 Patents Have Already Been Held Unpatentable Through *Inter Partes* Review

76. On January 13, 2015, Actelion Pharmaceuticals Ltd. filed petitions for *inter partes* review ("IPR") with the United States Patent and Trademark Office ("USPTO") Patent Trial and Appeal Board ("PTAB") seeking to invalidate the '975 and '958 patents.

77. Case number IPR2015-00562 was directed to invalidating all claims of the '975 patent.

78. Case number IPR2015-00561 was directed to invalidating all claims of the '958 patent.

79. Both cases were instituted on August 4, 2015.

80. On August 3, 2016, the PTAB held unpatentable all claims of both the '975 and '958 patents.

81. Specifically, the PTAB found that the '975 patent was unpatentably obvious because all elements of the claims were taught by the combination of four references: Daugan et al., WO 97/03675, published Feb. 6, 1997 ("Daugan"); Butler et al., WO 96/38131, published Dec. 5, 1996 ("Butler"); Seth et al., U.S. Patent No. 4,721,709, issued Jan. 26, 1988 ("Seth"); and Deodatt A. Wadke, Abu T. M. Serajuddin, and Harold Jacobson, Preformulation Testing in PHARMACEUTICAL DOSAGE FORMS: TABLETS, VOL. 1, Chpt. 1, pp. 1-73, Marcel Decker (Herbert A. Lieberman, Leon Lachman and Joseph B. Schwartz, Eds., 2nd ed., rev. and expanded 1989) ("Wadke"). *See* Final Written Decision attached as Exhibit J.

82. The PTAB further found that the '958 patent was unpatentably obvious over the combination of Daugan, Seth, and Butler in view of the common pharmaceutical knowledge evidenced in Wadke, Edward M. Rudnic & Mary Kathryn Kottke, Tablet Dosage Forms, MODERN PHARMACEUTICS 333–94 (Gilbert S. Banker & Christopher T. Rhodes eds., 3d ed., Marcel Decker 1996) ("Rudnic"), and Gilbert S. Banker & Neil R. Anderson, Tablets, in THE THEORY AND PRACTICE OF INDUSTRIAL PHARMACY, 293, 324–29 (Leon Lachman et al. eds., 3d ed., Lea & Febiger 1986) ("Banker"). *See* Final Written Decision attached as Exhibit K.

83. ICOS appealed the PTAB's IPR decisions regarding the '975 and '958 patents to the Federal Circuit on October 5, 2016. The appeals were captioned *ICOS Corporation v. Actelion Pharmaceuticals Ltd.*, Case Nos. 17-1017 and 17-1018. Both cases were subsequently consolidated on October 19, 2016, with 17-1017 designated as the "Lead Appeal."

84. On April 18, 2018, a Federal Circuit panel affirmed the PTAB judgment that the '975 and '958 patents were unpatentable. A copy of the Federal Circuit's opinion is attached as Exhibit L. Specifically, the Federal Circuit found that the PTAB's factual findings regarding the

motivation to micronize tadalafil and the teachings of the asserted prior art were supported by substantial evidence. Exhibit K at 5.

85. As of the date of this Complaint, Defendants have not sought a rehearing *en banc* or otherwise any other additional appellate relief.

86. On May 25, 2018, the Federal Circuit issued a mandate, closing the appeal.

87. The text of the Hatch-Waxman Act expressly provides a triggering event when a court enters a final decision in "an infringement action" or "a declaratory judgment action" pertaining to Orange Book patents. *See* 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA).

88. The FDA has not determined that IPR proceedings before the PTAB may qualify as either an infringement action or a declaratory judgment action under 21 U.S.C. § 355(j)(5)(D)(i)(I)(bb)(AA).

89. On information and belief, the FDA has not determined that the invalidation of the '975 and '958 patents by the PTAB provided a triggering event that may result in the forfeiture of Mylan's exclusivity.

COUNT I
(Invalidity of U.S. Patent No. 6,821,975)

90. Plaintiffs repeat and reallege Paragraphs 1-47 as though fully set forth herein.

91. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

92. There is a real, immediate, substantial, and justiciable controversy between the Plaintiffs and Defendants concerning whether the claims of the '975 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and 116.

93. The claims of the '975 patent are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including but not limited to §§ 101, 102, 103, 112, and 116.

94. The PTAB has already found all the claims of the '975 patent to be unpatentable at least as being obvious under 35 U.S.C. § 103 over the prior art, and the Federal Circuit has affirmed this decision.

95. Specifically, the claims of the '975 patent are at least unpatentable as obvious over the combination of Daugan, Seth, Butler and Wadke references, as determined by the PTAB in IPR Case No. IPR2015-00562 and affirmed by the Federal Circuit in *ICOS Corporation v. Actelion Pharmaceuticals Ltd.*, Case No. 17-1018.

96. The final decision of an *inter parties* review is binding on civil actions.

97. For these reasons, Cipla is entitled to a judicial district court declaration that the claims of the '975 patent are invalid.

COUNT II
(Invalidity of U.S. Patent No. 7,182,958)

98. Plaintiffs repeat and reallege Paragraphs 1-54 as though fully set forth herein.

99. This claim arises under the Patent Laws of the United States, 35 U.S.C. § 100, *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202.

100. There is a real, immediate, substantial, and justiciable controversy between the Plaintiffs and Defendants concerning whether the claims of the '958 patent are invalid for failure to comply with the statutory prerequisites of Title 35 of the United States Code, including, without limitation, one or more of §§ 101, 102, 103, 112, and 116.

101. The claims of the '958 patent are invalid for failing to comply with one or more provisions of Title 35 of the United States Code, including but not limited to §§ 101, 102, 103, 112, and 116.

102. The PTAB has already found all the claims of the '958 patent to be unpatenable at least as being obvious under 35 U.S.C. § 103 over the prior art, and the Federal Circuit has affirmed this decision.

103. Specifically, the claims of the '958 patent are at least invalid as obvious over the combination of Daugan, Seth, and Butler references in view of the common pharmaceutical knowledge reflected in the Wadke, Rudnic, and Baker references, as determined by the PTAB in IPR Case No. IPR2015-00561 and affirmed by the Federal Circuit in *ICOS Corporation v. Actelion Pharmaceuticals Ltd.*, Case No. 17-1017.

104. The final decision of an *inter parties* review is binding on civil actions.

105. Cipla is entitled to a judicial district court declaration that the claims of the '958 patent are invalid.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully ask this Court to enter judgment in its favor and against Defendants and against Defendants' respective subsidiaries, successors, parents, affiliates, officers, directors, agents, servants and employees, and all persons in active concert or participation with Defendants, granting the following relief:

A. The entry of judgment in favor of Plaintiffs and against Defendants on all Counts, declaring that the '975 and '958 patents are invalid;

B. The entry of judgment in favor of Plaintiffs and against Defendants on all Counts, declaring that the finding of unpatentability of the '975 and '958 patents by the

PTAB in IPR Case No. IPR2015-00562 and IPR Case No. IPR2015-00561 and affirmed by the Federal Circuit in *ICOS Corporation v. Actelion Pharmaceuticals Ltd.*, Case Nos. 17-1017 and 17-1018 are binding on this Court, and that therefore the '975 and '958 patents are invalid;

C. For a judgment declaring that this case is exceptional and awarding Cipla its expenses, costs, and attorneys' fees in accordance with 35 U.S.C. § 285 and Rule 54(d) of the Federal Rules of Civil Procedure; and

D. For such other relief to which Cipla is entitled under law, and any other and further relief that this Court or a jury may deem just and proper.

Dated: July 27, 2018

Respectfully submitted,

/s/ Steven M. Coyle

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CERTIFICATE OF SERVICE

The undersigned hereby certifies that on July 27, 2018, a copy of the foregoing document was filed electronically using the Court's CM/ECF system. Notice of this filing will be sent by operation of the CM/ECF system to all parties indicated on the electronic filing receipt. All other parties will be served by regular U.S. mail.

By: /s/ Steven M. Coyle

Steven M. Coyle (*pro hac vice*)

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