IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

GENZYME CORP. and THE REGENTS OF THE UNIVERSITY OF MICHIGAN,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
CIPLA LIMITED,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Genzyme Corp. ("Genzyme") and The Regents of the University of Michigan ("U of M") (collectively, "Plaintiffs"), by way of their Complaint against Defendant Cipla Limited ("Cipla" or "Defendant"), allege as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of U.S. Patent No. 6,916,802 (the "'802 patent"), U.S. Patent No. 7,196,205 (the "'205 patent"), U.S. Patent No. 7,253,185 (the "'185 patent"), and U.S. Patent No. 7,615,573 (the "'573 patent") under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*, including § 271, and for a declaratory judgment of infringement of the '802, '205, '185, and '573 patents under 28 U.S.C. §§ 2201 and 2202. This action arises out of Cipla's submission of Abbreviated New Drug Application ("ANDA") No. 212369 seeking approval to manufacture, use and/or sell a generic version of the pharmaceutical product CERDELGA® (eliglustat) capsules (84 mg) ("Cipla's ANDA product") prior to the expiration of the '802, '205, '185, and '573 patents. Plaintiffs seek injunctive relief against infringement, attorneys' fees, and any other relief the Court deems just and proper.

PARTIES

2. Plaintiff Genzyme is a corporation organized and existing under the laws of the Commonwealth of Massachusetts, having its principal place of business at 50 Binney Street, Cambridge, Massachusetts 02142. Genzyme is engaged in the business of research, development, manufacture, and sale of pharmaceutical products.

3. The Regents of the University of Michigan is a constitutional corporation of the State of Michigan, having a principal place of business at 1600 Huron Parkway, 2nd Floor, Ann Arbor, MI 48109.

4. Upon information and belief, Defendant Cipla is a corporation organized and existing under the laws of India, having its principal place of business at Cipla House, Peninsula Business Park, Ganpatrao Kadam Marg, Lower Parel, Mumbai 400013, India.

5. Upon information and belief, Cipla caused ANDA No. 212369 to be submitted to the United States Food and Drug Administration ("FDA") and seeks FDA approval of ANDA No. 212369.

6. Upon information and belief, Cipla regularly transacts business throughout the United States and within Delaware, including but not limited to marketing, distribution, sales, and/or offers to sell generic drugs.

JURISDICTION AND VENUE

7. This action arises under the Patent Laws of the United States and the Food and Drug Laws of the United States, Titles 35 and 21, United States Code. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

8. This Court has jurisdiction over Cipla because, *inter alia*, upon information and belief, Cipla has substantial, continuous, and systematic contacts with the State

of Delaware, and directly or indirectly manufactures, imports, markets, and sells generic drugs throughout the United States, including Delaware, and Delaware would be a destination of Cipla's ANDA product. Upon information and belief, Cipla filed ANDA No. 212369. Upon information and belief, Cipla will market, distribute, and/or sell Cipla's ANDA product in the United States, including in Delaware, upon approval of ANDA No. 212369, and will derive substantial revenue from the use or consumption of Cipla's ANDA product in the State of Delaware.

9. In the alternative, this Court has jurisdiction over Cipla because the requirements of Federal Rule of Civil Procedure 4(k)(2) are met. This Court has jurisdiction over Cipla because, *inter alia*, this action arises under federal law, Cipla is a foreign defendant not subject to personal jurisdiction in the courts of any state, and Cipla has sufficient contacts with the United States as a whole, including but not limited to filing ANDAs with the FDA and manufacturing and selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Cipla satisfies due process.

10. This Court also has jurisdiction over Cipla because, *inter alia*, upon information and belief, Cipla has previously been sued in this district without objecting on the basis of lack of personal jurisdiction and has availed itself of Delaware courts through the assertions of counterclaims in suits brought in Delaware. *See, e.g.*, *Biogen Int'l GmbH and Biogen MA Inc. v. Cipla Ltd. and Cipla USA Inc.*, Civil Action No. 17-851-LPS (D. Del.); *Alcon Research, Ltd. v. Cipla Ltd. and Cipla USA, Inc.*, Civil Action No. 17-1244-GMS (D. Del.); *Viiv Healthcare Co., Shionogi & Co., Ltd. and Viiv Healthcare UK (No.3) Ltd. v. Cipla Ltd. and Cipla USA, Inc.*, Civil Action No. 17-1670-MSG-RL (D. Del.); *H. Lundbeck A/S Takeda Pharm. Co. Ltd., Takeda Pharms. U.S.A., Inc., Takeda Pharms. Int'l AG, and Takeda Pharms. America,*

Inc. v. Cipla Ltd. and Cipla USA Inc., Civil Action No. 18-147-LPS; *Phamacyclics LLC and Janssen Biotech, Inc. v. Cipla Ltd. and Cipla USA Inc.*, Civil Action No. 18-247-CFC (D. Del.); *Onyx Therapeutics, Inc. v. Cipla Ltd. and Cipla USA, Inc.*, Civil Action No. 18-598-LPS (D. Del.).

11. Venue is proper in this district for Cipla under 28 U.S.C. §§ 1391 and 1400(b) because, *inter alia*, Cipla is a corporation organized and existing under the laws of India, and may be sued in any judicial district. 28 U.S.C. § 1391(c).

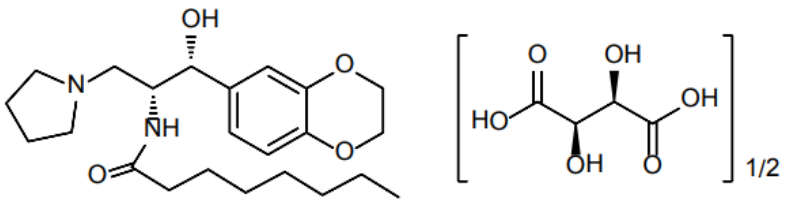
CERDELGA®

12. Genzyme is the holder of an approved New Drug Application ("NDA") No. 205494 for CERDELGA®, which the FDA approved on August 19, 2014.

13. CERDELGA® is a medication marketed and sold by Genzyme as 84 mg capsules for oral use. Genzyme received FDA approval to market CERDELGA® (eliglustat) for the long-term treatment of adult patients with Gaucher disease type 1 who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an FDA-cleared test.

14. Eliglustat is the active ingredient in CERDELGA®. Eliglustat is a novel small molecule inhibitor of glucosylceramide synthase.

15. CERDELGA® capsules contain eliglustat as a hemitartrate salt (eliglustat tartrate), which can be referred to by the chemical name N-((1*R*,2*R*)-1-(2,3-dihydrobenzo[b][1,4]dioxin-6-yl)-1-hydroxy-3-(pyrrolidin-1-yl)propan-2-yl)octanamide (2*R*,3*R*)-2,3-dihydroxysuccinate, and has the following chemical structure:



16. CERDELGA® was granted Orphan Drug Exclusivity for long-term treatment of adult patients with Gaucher disease type 1 who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an FDA-cleared test.

THE PATENTS-IN-SUIT

17. On July 12, 2005, the '802 patent, titled "Amino Ceramide-Like Compounds and Therapeutic Methods of Use," was issued by the United States Patent and Trademark Office ("PTO"). A true and correct copy of the '802 patent is attached as Exhibit A.

18. On March 27, 2007, the '205 patent, titled "Synthesis of UDP-Glucose: *N*-Acylsphingosine Glucosyltransferase Inhibitors," was issued by the PTO. A true and correct copy of the '205 patent is attached as Exhibit B.

19. On August 7, 2007, the '185 patent, titled "Amino Ceramide-Like Compounds and Therapeutic Methods of Use," was issued by the PTO. A true and correct copy of the '185 patent is attached as Exhibit C.

20. On November 10, 2009, the '573 patent, titled "Synthesis of UDP-Glucose: N-Acylsphingosine Glucosyltransferase Inhibitors," was issued by the PTO. A true and correct copy of the '573 patent is attached as Exhibit D.

21. Eliglustat and methods of treating Gaucher disease with eliglustat are covered by one or more of the claims of the '802, '205, '185, and '573 patents, which are all

listed in the *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") for NDA No. 205494.

22. The '802, '205, '185, and '573 patents are owned by Genzyme and U of M.

CIPLA'S ANDA NO. 212369

23. Plaintiffs received a letter dated October 11, 2018 from Cipla notifying Plaintiffs that Cipla had submitted ANDA No. 212369 to the FDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") seeking approval to commercially manufacture, use, sell, and/or import Cipla's ANDA product prior to the expiration of the '802, '205, '185, and '573 patents.

24. Upon information and belief, Cipla's ANDA seeks FDA approval of Cipla's ANDA Product for long-term treatment of adult patients with Gaucher disease type 1 who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an FDA-cleared test.

25. According to applicable regulations, the purpose of Cipla's October 11, 2018 letter was to notify Plaintiffs that ANDA No. 212369 included a certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV Certification") alleging that the claims of the '802, '205, '185, and '573 patents are invalid, unenforceable, and/or would not be infringed by the commercial manufacture, use, sale, offer for sale, and/or importation of Cipla's ANDA product.

26. Included in the October 11, 2018 letter was a "Detailed Statement" of the factual and legal bases for Cipla's Paragraph IV Certification, alleging that the claims of the '802, '205, '185, and '573 patents were either invalid or would not be infringed by Cipla's ANDA product.

27. Upon information and belief, Cipla was aware of the '802, '205, '185, and '573 patents when Cipla notified Plaintiffs of its Paragraph IV Certification regarding the '802, '205, '185, and '573 patents.

28. Plaintiffs commenced this action within 45 days of receipt of Cipla's October 11, 2018 letter.

COUNT I
INFRINGEMENT OF THE '802 PATENT

29. Plaintiffs incorporate and reallege paragraphs 1-28 above, as if set forth specifically here.

30. Upon information and belief, Cipla submitted ANDA No. 212369 to the FDA under the provisions of 21 U.S.C. § 355(j).

31. Upon information and belief, Cipla's ANDA No. 212369 seeks FDA approval to engage in the commercial manufacture, use, sale, and/or importation of Cipla's ANDA product (generic eliglustat in 84 mg capsules for oral use) before the expiration of the '802 patent.

32. Plaintiffs received a letter from Cipla dated October 11, 2018, purporting to be a Notice of Certification for ANDA No. 212369 under Section 505(j)(2)(B) of the FDCA, 21 U.S.C. § 355(j)(2)(B), and 21 C.F.R. § 314.95.

33. Cipla's October 11, 2018 letter states that the active ingredient in Cipla's ANDA product for which it seeks approval is eliglustat. Upon information and belief, Cipla's ANDA seeks FDA approval of Cipla's ANDA product for the long-term treatment of adult patients with Gaucher disease type 1 who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an FDA-cleared test.

34. Upon information and belief, Cipla's ANDA product, if approved and marketed, will be accompanied by a product label that will induce physicians to treat a patient having a glycosphingolipidosis disorder, including Gaucher disease, comprising the step of administering to the patient a therapeutically effective amount of a composition comprising eliglustat, and thereby induce infringement of the methods of at least claims 6, 7, 13, and 14 of the '802 patent under 35 U.S.C. § 271(b). Plaintiffs are unaware of any substantial non-infringing uses of Cipla's ANDA product aside from treating a patient having a glycosphingolipidosis disorder, including Gaucher disease, comprising the step of administering to the patient a therapeutically effective amount of a composition comprising eliglustat, and therefore the marketing of Cipla's ANDA product will contribute to infringement of at least claims 6, 7, 13, and 14 of the '802 patent under 35 U.S.C. § 271(c).

35. Upon information and belief, Cipla made and included in its ANDA a Paragraph IV Certification stating that, in Cipla's opinion, the '802 patent is invalid, unenforceable and/or not infringed.

36. Cipla's submission of ANDA No. 212369 to obtain approval to engage in the commercial manufacture, use, sale, and/or importation of Cipla's ANDA product prior to the expiration of the '802 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

37. Cipla's commercial manufacture, use, sale, and/or importation of Cipla's ANDA product would infringe, either literally or under the doctrine of equivalents, at least claims 1, 2, 8, and 9 of the '802 patent, and the sale of such a product will induce and/or contribute to infringement of at least claims 6, 7, 13, and 14 of the '802 patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 212369, Cipla will make, use, offer to sell, or sell Cipla's ANDA product within the United States, or will import Cipla's

ANDA product into the United States, and will thereby infringe at least claims 1, 2, 6-9, 13, and 14 of the '802 patent.

38. Cipla had actual knowledge of the '802 patent prior to submission of ANDA No. 212369, and was aware that the filing of ANDA No. 212369 with the request for FDA approval prior to the expiration of the '802 patent would constitute an act of infringement of the '802 patent. Cipla had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Cipla's ANDA product will not infringe at least claims 1, 2, 6-9, 13, and 14 of the '802 patent.

39. Cipla's "Detailed Statement" in its October 11, 2018 letter lacks any contention that Cipla's ANDA product will not infringe at least claims 1, 2, 6-9, 13, and 14 of the '802 patent.

40. On information and belief, Cipla's statement of the factual and legal bases for its opinions regarding invalidity of the '802 patent lacks an objective good faith basis.

41. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

42. Plaintiffs will be irreparably harmed if Cipla is not enjoined from infringing the '802 patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Cipla, injunctive relief is warranted. Further, the public interest favors entry of an injunction.

COUNT II
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '802 PATENT

43. Plaintiffs incorporate and reallege paragraphs 1-42 above, as if set forth specifically here.

44. Upon information and belief, if ANDA No. 212369 is approved, Cipla's ANDA product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Cipla and its affiliates. Cipla will therefore infringe at least claims 1, 2, 6-9, 13, and 14 of the '802 patent under 35 U.S.C. § 271.

45. Cipla's "Detailed Statement" in its October 11, 2018 letter lacks any contention that Cipla's ANDA product will not infringe at least claims 1, 2, 6-9, 13, and 14 of the '802 patent.

46. Upon information and belief, Cipla's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Cipla's ANDA product complained of herein will begin immediately after the FDA approves ANDA No. 212369. Any such conduct before the '802 patent expires will infringe at least claims 1, 2, 6-9, 13, and 14 of the '802 patent under 35 U.S.C. § 271(a)-(c).

47. There is a real, substantial, and continuing justiciable controversy between Plaintiffs and Cipla concerning liability for the infringement of the '802 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

48. Plaintiffs will be substantially and irreparably harmed by Cipla's infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

49. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT III
INFRINGEMENT OF THE '205 PATENT

50. Plaintiffs incorporate and reallege paragraphs 1-49 above, as if set forth specifically here.

51. Upon information and belief, Cipla submitted ANDA No. 212369 to the FDA under the provisions of 21 U.S.C. § 355(j).

52. Upon information and belief, Cipla's ANDA No. 212369 seeks FDA approval to engage in the commercial manufacture, use, sale, and/or importation of Cipla's ANDA product (generic eliglustat in 84 mg capsules for oral use) before the expiration of the '205 patent.

53. Plaintiffs received a letter from Cipla dated October 11, 2018, purporting to be a Notice of Certification for ANDA No. 212369 under Section 505(j)(2)(B) of the FDCA, 21 U.S.C. § 355(j)(2)(B), and 21 C.F.R. § 314.95.

54. Cipla's October 11, 2018 letter states that the active ingredient in Cipla's ANDA product for which it seeks approval is eliglustat.

55. Upon information and belief, Cipla made and included in its ANDA a Paragraph IV Certification stating that, in Cipla's opinion, the '205 patent is invalid, unenforceable and/or not infringed.

56. Cipla's submission of ANDA No. 212369 to obtain approval to engage in the commercial manufacture, use, sale, and/or importation of Cipla's ANDA product prior to the expiration of the '205 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

57. Cipla's commercial manufacture, use, sale, and/or importation of Cipla's ANDA product would infringe, either literally or under the doctrine of equivalents, at least claims 1 and 3-9 of the '205 patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 212369, Cipla will make, use, offer to sell, or sell Cipla's ANDA product within the United States, or will import Cipla's ANDA product into the United States, and will thereby infringe at least claims 1 and 3-9 of the '205 patent.

58. Cipla had actual knowledge of the '205 patent prior to submission of ANDA No. 212369, and was aware that the filing of ANDA No. 212369 with the request for FDA approval prior to the expiration of the '205 patent would constitute an act of infringement of the '205 patent. Cipla had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Cipla's ANDA product will not infringe at least claims 1 and 3-9 of the '205 patent.

59. Cipla's "Detailed Statement" in its October 11, 2018 letter lacks any contention that Cipla's ANDA product will not infringe at least claims 1 and 3-9 of the '205 patent.

60. On information and belief, Cipla's statement of the factual and legal bases for its opinions regarding invalidity of the '205 patent lacks an objective good faith basis.

61. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

62. Plaintiffs will be irreparably harmed if Cipla is not enjoined from infringing the '205 patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Cipla, injunctive relief is warranted. Further, the public interest favors entry of an injunction.

COUNT IV
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '205 PATENT

63. Plaintiffs incorporate and reallege paragraphs 1-62 above, as if set forth specifically here.

64. Upon information and belief, if ANDA No. 212369 is approved, Cipla's ANDA product will be made, offered for sale, sold, or otherwise distributed in the United States,

including in the State of Delaware, by or through Cipla and its affiliates. Cipla will therefore infringe at least claims 1 and 3-9 of the '205 patent under 35 U.S.C. § 271.

65. Cipla's "Detailed Statement" in its October 11, 2018 letter lacks any contention that Cipla's ANDA product will not infringe at least claims 1 and 3-9 of the '205 patent.

66. Upon information and belief, Cipla's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Cipla's ANDA product complained of herein will begin immediately after the FDA approves ANDA No. 212369. Any such conduct before the '205 patent expires will infringe at least claims 1 and 3-9 of the '205 patent under 35 U.S.C. § 271.

67. There is a real, substantial, and continuing justiciable controversy between Plaintiffs and Cipla concerning liability for the infringement of the '205 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

68. Plaintiffs will be substantially and irreparably harmed by Cipla's infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

69. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT V
INFRINGEMENT OF THE '185 PATENT

70. Plaintiffs incorporate and reallege paragraphs 1-69 above, as if set forth specifically here.

71. Upon information and belief, Cipla submitted ANDA No. 212369 to the FDA under the provisions of 21 U.S.C. § 355(j).

72. Upon information and belief, Cipla's ANDA No. 212369 seeks FDA approval to engage in the commercial manufacture, use, sale, and/or importation of Cipla's ANDA product (generic eliglustat in 84 mg capsules for oral use) before the expiration of the '185 patent.

73. Plaintiffs received a letter from Cipla dated October 11, 2018, purporting to be a Notice of Certification for ANDA No. 212369 under Section 505(j)(2)(B) of the FDCA, 21 U.S.C. § 355(j)(2)(B), and 21 C.F.R. § 314.95.

74. Cipla's October 11, 2018 letter states that the active ingredient in Cipla's ANDA product for which it seeks approval is eliglustat.

75. Upon information and belief, Cipla made and included in its ANDA a Paragraph IV Certification stating that, in Cipla's opinion, the '185 patent is invalid, unenforceable and/or not infringed.

76. Cipla's submission of ANDA No. 212369 to obtain approval to engage in the commercial manufacture, use, sale, and/or importation of Cipla's ANDA product prior to the expiration of the '185 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

77. Cipla's commercial manufacture, use, sale, and/or importation of Cipla's ANDA product would infringe, either literally or under the doctrine of equivalents, claims 1-4 of the '185 patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 212369, Cipla will make, use, offer to sell, or sell Cipla's ANDA product within the United States, or will import Cipla's ANDA product into the United States, and will thereby infringe claims 1-4 of the '185 patent.

78. Cipla had actual knowledge of the '185 patent prior to submission of ANDA No. 212369, and was aware that the filing of ANDA No. 212369 with the request for

FDA approval prior to the expiration of the '185 patent would constitute an act of infringement of the '185 patent. Cipla had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Cipla's ANDA product will not infringe claims 1-4 of the '185 patent.

79. Cipla's "Detailed Statement" in its October 11, 2018 letter lacks any contention that Cipla's ANDA product will not infringe claims 1-4 of the '185 patent.

80. On information and belief, Cipla's statement of the factual and legal bases for its opinions regarding invalidity of the '185 patent lacks an objective good faith basis.

81. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

82. Plaintiffs will be irreparably harmed if Cipla is not enjoined from infringing the '185 patent. Plaintiffs do not have an adequate remedy at law, and considering the balance of hardships between Plaintiffs and Cipla, injunctive relief is warranted. Further, the public interest favors entry of an injunction.

COUNT VI
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '185 PATENT

83. Plaintiffs incorporate and reallege paragraphs 1-82 above, as if set forth specifically here.

84. Upon information and belief, if ANDA No. 212369 is approved, Cipla's ANDA product will be made, offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Cipla and its affiliates. Cipla will therefore infringe claims 1-4 of the '185 patent under 35 U.S.C. § 271.

85. Cipla's "Detailed Statement" in its October 11, 2018 letter lacks any contention that Cipla's ANDA product will not infringe claims 1-4 of the '185 patent.

86. Upon information and belief, Cipla's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Cipla's ANDA product complained of herein will begin immediately after the FDA approves ANDA No. 212369. Any such conduct before the '185 patent expires will infringe claims 1-4 of the '185 patent under 35 U.S.C. § 271.

87. There is a real, substantial, and continuing justiciable controversy between Plaintiffs and Cipla concerning liability for the infringement of the '185 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

88. Plaintiffs will be substantially and irreparably harmed by Cipla's infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

89. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

COUNT VII
INFRINGEMENT OF THE '573 PATENT

90. Plaintiffs incorporate and reallege paragraphs 1-89 above, as if set forth specifically here.

91. Upon information and belief, Cipla submitted ANDA No. 212369 to the FDA under the provisions of 21 U.S.C. § 355(j).

92. Upon information and belief, Cipla's ANDA No. 212369 seeks FDA approval to engage in the commercial manufacture, use, sale, and/or importation of Cipla's ANDA product (generic eliglustat in 84 mg capsules for oral use) before the expiration of the '573 patent.

93. Plaintiffs received a letter from Cipla dated October 11, 2018, purporting to be a Notice of Certification for ANDA No. 212369 under Section 505(j)(2)(B) of the FDCA, 21 U.S.C. § 355(j)(2)(B), and 21 C.F.R. § 314.95.

94. Cipla's October 11, 2018 letter states that the active ingredient in Cipla's ANDA product for which it seeks approval is eliglustat. Upon information and belief, Cipla's ANDA seeks FDA approval of Cipla's ANDA product for the long-term treatment of adult patients with Gaucher disease type 1 who are CYP2D6 extensive metabolizers (EMs), intermediate metabolizers (IMs), or poor metabolizers (PMs) as detected by an FDA-cleared test.

95. Upon information and belief, Cipla's ANDA product, if approved and marketed, will be accompanied by a product label that will induce physicians to inhibit glucosylceramide synthase or lower glycosphingolipid concentrations in a subject in need thereof, or treat Gaucher disease, comprising administering to the subject an effective amount of eliglustat, and thereby induce infringement of the methods of at least claims 1-5 and 21-25 of the '573 patent under 35 U.S.C. § 271(b). Plaintiffs are unaware of any substantial non-infringing uses of Cipla's ANDA product aside from inhibiting glucosylceramide synthase or lowering glycosphingolipid concentrations in a subject in need thereof, or treating Gaucher disease, comprising administering to the subject an effective amount of eliglustat, and therefore the marketing of Cipla's ANDA product will contribute to infringement of at least claims 1-5 and 21-25 of the '573 patent under 35 U.S.C. § 271(c).

96. Upon information and belief, Cipla made and included in its ANDA a Paragraph IV Certification stating that, in Cipla's opinion, the '573 patent is invalid, unenforceable and/or not infringed.

97. Cipla's submission of ANDA No. 212369 to obtain approval to engage in the commercial manufacture, use, sale, and/or importation of Cipla's ANDA product prior to the expiration of the '573 patent constituted an act of infringement under 35 U.S.C. § 271(e)(2)(A).

98. Cipla's commercial offer for sale and/or sale of Cipla's ANDA product would induce and/or contribute to infringement of at least claims 1-5 and 21-25 of the '573 patent. Accordingly, unless enjoined by this Court, upon FDA approval of ANDA No. 212369, Cipla will offer to sell and/or sell Cipla's ANDA product within the United States, and will thereby infringe at least claims 1-5 and 21-25 of the '573 patent.

99. Cipla had actual knowledge of the '573 patent prior to submission of ANDA No. 212369, and was aware that the filing of ANDA No. 212369 with the request for FDA approval prior to the expiration of the '573 patent would constitute an act of infringement of the '573 patent. Cipla had no reasonable basis for asserting that the commercial manufacture, use, offer for sale, or sale of Cipla's ANDA product will not infringe at least claims 1-5 and 21-25 of the '573 patent.

100. Cipla's "Detailed Statement" in its October 11, 2018 letter lacks any contention that Cipla's ANDA product will not infringe at least claims 1-5 and 21-25 of the '573 patent.

101. On information and belief, Cipla's statement of the factual and legal bases for its opinions regarding invalidity of the '573 patent lacks an objective good faith basis.

102. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

103. Plaintiffs will be irreparably harmed if Cipla is not enjoined from infringing the '573 patent. Plaintiffs do not have an adequate remedy at law, and considering the

balance of hardships between Plaintiffs and Cipla, injunctive relief is warranted. Further, the public interest favors entry of an injunction.

COUNT VIII
DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '573 PATENT

104. Plaintiffs incorporate and reallege paragraphs 1-103 above, as if set forth specifically here.

105. Upon information and belief, if ANDA No. 212369 is approved, Cipla's ANDA product will be offered for sale, sold, or otherwise distributed in the United States, including in the State of Delaware, by or through Cipla and its affiliates. Cipla will therefore infringe at least claims 1-5 and 21-25 of the '573 patent under 35 U.S.C. § 271(b)-(c).

106. Cipla's "Detailed Statement" in its October 11, 2018 letter lacks any contention that Cipla's ANDA product will not infringe at least claims 1-5 and 21-25 of the '573 patent.

107. Upon information and belief, Cipla's infringing activity, including the commercial manufacture, use, offer to sell, sale, or importation of Cipla's ANDA product complained of herein will begin immediately after the FDA approves ANDA No. 212369. Any such conduct before the '573 patent expires will infringe at least claims 1-5 and 21-25 of the '573 patent under 35 U.S.C. § 271.

108. There is a real, substantial, and continuing justiciable controversy between Plaintiffs and Cipla concerning liability for the infringement of the '573 patent for which this Court may grant declaratory relief consistent with Article III of the United States Constitution.

109. Plaintiffs will be substantially and irreparably harmed by Cipla's infringing activities unless those activities are enjoined by this Court. Plaintiffs have no adequate remedy at law.

110. This case is exceptional, and Plaintiffs are entitled to an award of attorneys' fees under 35 U.S.C. § 285.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

A. A judgment that the claims of the '802, '205, '185, and '573 patents were infringed by Cipla's submission of ANDA No. 212369 under 35 U.S.C. § 271 (e)(2)(A), and that the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla's ANDA product prior to the expiration of the '802, '205, '185, and '573 patents will constitute an act of infringement of at least 1, 2, 6-9, 13, and 14 of the '802 patent, claims 1 and 3-9 of the '205 patent, claims 1-4 of the '185 patent, and claims 1-5 and 21-25 of the '573 patent;

B. A declaratory judgment that under 35 U.S.C. § 271, Cipla's commercial manufacture, use, offer for sale, or sale in, or importation into, the United States of Cipla's ANDA product would constitute infringement of at least 1, 2, 6-9, 13, and 14 of the '802 patent, claims 1 and 3-9 of the '205 patent, claims 1-4 of the '185 patent, and claims 1-5 and 21-25 of the '573 patent;

C. An order permanently enjoining Cipla, its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with it, from making, using, offering to sell, or selling in the United States, or importing into the United States, Cipla's ANDA product until after the expiration of the '802, '205, '185, and '573 patents, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

D. An order under 35 U.S.C. § 271 (e)(4)(A) that the effective date of any FDA approval of ANDA No. 212369 shall be a date that is not earlier than the expiration date of

the ’802, ’205, ’185, and ’573 patents, inclusive of any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

E. A declaration under 28 U.S.C. § 2201 that if Cipla, its officers, agents, servants, employees, licensees, representatives, and attorneys, and any other persons acting or attempting to act in active concert or participation with it or acting on its behalf, engages in the commercial manufacture, use, offer for sale, sale, and/or importation of the product described in ANDA No. 212369, it will constitute an act of infringement of the ’802, ’205, ’185, and ’573 patents;

F. A judgment that the claims of the ’802, ’205, ’185, and ’573 patents are valid and enforceable;

G. An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Cipla engages in the commercial manufacture, use, offer for sale, sale, and/or importation of Cipla’s ANDA product, or any product that infringes the ’802, ’205, ’185, and ’573 patents, prior to the expiration of the ’802, ’205, ’185, and ’573 patents, inclusive of any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

H. A declaration that this is an exceptional case under 35 U.S.C. §§ 285 and 271(e)(4) and awarding Plaintiffs’ costs, expenses, and disbursements in this action, including reasonable attorney fees; and

I. An award of such other and further relief as this Court deems just and proper.

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