IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

SUMITOMO PHARMA SWITZERLAND GMBH, SUMITOMO PHARMA AMERICA, INC., TAKEDA PHARMACEUTICAL COMPANY LIMITED, TAKEDA PHARMACEUTICALS INTERNATIONAL AG, and PFIZER INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
CIPLA LIMITED and CIPLA USA, INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

1. This is an action for patent infringement under the patent laws of the United States, 35 U.S.C. §§ 100 et. seq., as well as the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, against Defendants Cipla Limited and Cipla USA, Inc. (collectively, "Cipla"). This action arises out of the submission by Cipla of Abbreviated New Drug Application ("ANDA") No. 220080 (the "Cipla ANDA") to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell 120 mg tablets of relugolix, a generic version of Orgovyx® (the "ANDA Product"), prior to the expiration of U.S. Patent Nos. 11,795,178, 12,097,198, and 12,144,809 (collectively, the "Patents-in-Suit").

PARTIES

1. Plaintiff Sumitomo Pharma Switzerland GmbH ("SMPS") is a corporation organized and existing under the laws of Switzerland, with its principal place of business at Aeschengraben 27, 4051 Basel, Switzerland.

2. Plaintiff Sumitomo Pharma America, Inc. ("SMPA") is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 84 Waterford Drive, Marlborough, MA 01752.

3. Plaintiff Takeda Pharmaceutical Company Limited ("Takeda") is a corporation organized and existing under the laws of Japan, with its principal place of business at 1-1, Doshomachi 4-chome, Chuo-ku, Osaka 540-8645, Japan.

4. Plaintiff Takeda Pharmaceuticals International AG ("Takeda International") is a corporation organized and existing under the laws of Switzerland, with its principal place of business at Thurgauerstrasse 130, Glattpark-Opfikon, Zurich, 8152, Switzerland.

5. Plaintiff Pfizer Inc. is a corporation organized and existing under the laws of the State of Delaware and having a place of business at 66 Hudson Boulevard East, New York, New York 10001.

6. Plaintiffs SMPS, SMPA, Takeda, Takeda International, and Pfizer are referred to collectively herein as "Plaintiffs."

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

8. Upon information and belief, Cipla USA, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 10 Independence Boulevard, Suite 300, Warren, NJ 07059.

9. Upon information and belief, Cipla USA, Inc. is an indirect, wholly-owned subsidiary of Cipla Limited and is controlled by and/or is an alter ego of Cipla Limited.

10. Upon information and belief, Cipla Limited, itself and through its subsidiaries and agents, including Cipla USA, Inc., develops, manufactures, markets, distributes, and/or imports pharmaceutical products for sale and use throughout the United States, including in Delaware.

11. Upon information and belief, Cipla USA, Inc. is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical products for the U.S. market, including in Delaware.

12. Upon information and belief, Cipla USA, Inc. is the U.S. agent for Cipla Limited with the FDA with respect to the Cipla ANDA.

13. Upon information and belief, Cipla Limited is the holder of relugolix Drug Master File ("DMF") No. 39608.

14. Upon information and belief, Cipla Limited and Cipla USA, Inc. acted collaboratively in the preparation and submission of the Cipla ANDA.

15. Upon information and belief, following any FDA approval of the Cipla ANDA, Cipla will make, use, offer to sell, and/or sell the ANDA Product that is the subject of the Cipla ANDA throughout the United States, including in Delaware, and/or import such generic products into the United States, including into Delaware.

JURISDICTION AND VENUE

16. This case arises under the patent laws of the United States of America, 35 U.S.C. §§ 100 et. seq., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202, and this Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

17. This Court has personal jurisdiction over Cipla USA, Inc. at least because Cipla USA, Inc. is a corporation organized and existing under the laws of Delaware.

18. This Court has personal jurisdiction over Cipla Limited because, among other things, Cipla Limited has committed, contributed to, and/or participated in an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends to engage in a future course of conduct that includes acts of patent infringement under 35 U.S.C. §§ 271(a), (b) and/or (c), including in Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs. For example, upon information and belief, following approval of the Cipla ANDA, Cipla Limited either directly or indirectly through affiliated companies or agents will make, use, import, sell, and/or offer for sale the ANDA Product in the United States, including in Delaware, prior to the expiration of the Patents-in-Suit.

19. The Court also has personal jurisdiction over Cipla Limited because, among other things, this action arises from actions of Cipla Limited directed toward Delaware, and because Cipla Limited has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Cipla Limited regularly and continuously transacts business within Delaware, including by selling pharmaceutical products in Delaware either directly or indirectly through affiliated companies or agents. Upon information and belief, Cipla Limited derives substantial revenue from the sale of those products in Delaware and has availed itself of the privilege of conducting business within Delaware.

20. The Court also has personal jurisdiction over Cipla Limited pursuant to Federal Rule of Civil Procedure 4(k)(1) or 4(k)(2) because: (a) Cipla Limited is subject to the general jurisdiction of the laws of Delaware; and (b) to the extent that Cipla Limited is not subject to personal jurisdiction in the courts of any state, Plaintiffs' claims arise under federal law and Cipla Limited has sufficient contacts with the United States as a whole, including but not limited to

marketing and/or selling generic pharmaceutical products that are distributed and sold throughout the United States, such that this Court's exercise of jurisdiction over Cipla Limited satisfies due process.

21. Cipla Limited and Cipla USA, Inc. have previously availed themselves of this forum for the purpose of litigating its patent infringement disputes. For example, Cipla Limited and Cipla USA, Inc. have affirmatively filed claims in this forum, including in:

- *Cipla Ltd. & Cipla USA, Inc. v. AstraZeneca AB et al.*, C.A. No. 19-733-MN (D. Del.)
- *Cipla Ltd. & Cipla USA, Inc. v. AstraZeneca AB et al.*, C.A. No. 19-438-MN (D. Del.)
- *Cipla Ltd. & Cipla USA, Inc. v. Amgen Inc.*, C.A. No. 19-44-LPS (D. Del.)
- *Cipla Ltd. v. Boehringer Ingelheim Pharms. Inc. et al.*, C.A. No. 22-300-MN (D. Del)
- *Cipla Ltd. v. Sunovion Pharms. Inc.*, C.A. No. 15-424-LPS (D. Del.)
- *Meda Pharms. Inc. & Cipla Ltd. v. Perrigo UK Finco Ltd. P'ship et al.*, C.A. No. 16-794-LPS (D. Del.)
- *Meda Pharms. Inc. & Cipla Ltd. v. Teva Pharms. USA, Inc. et al.*, C.A. No. 15-785-LPS (D. Del.)
- *Meda Pharms. Inc. & Cipla Ltd. v. Apotex Inc. et al.*, C.A. No. 14-1453-LPS (D. Del.)

22. Cipla Limited and Cipla USA, Inc. have also previously availed themselves of this forum for the purpose of filing counterclaims in patent infringement disputes, including in:

- *Actelion Pharms US, Inc. et al. v. Cipla Ltd. & Cipla USA, Inc.*, C.A. No. 23-389 (D. Del.)
- *Acerta Pharma BV et al. v. Cipla Ltd. & Cipla USA, Inc.*, C.A. No. 22-162-RGA (D. Del.)
- *UCB Inc. et al. v. Cipla Ltd. & Cipla USA Inc.*, C.A. No. 21-1229-CFC (D. Del.)
- *Boehringer Ingelheim Pharms. Inc. et al. v. Cipla Ltd. & Cipla USA, Inc.*, C.A. No. 19-1494-CFC (D. Del.)

- *Genentech, Inc. et al. v. Cipla Ltd., Cipla USA, Inc. et al.*, C.A. No. 19-219-RGA (D. Del)
- *H. Lundbeck A/S et al. v. Cipla Ltd. & Cipla USA Inc.*, C.A. No. 18-753-LPS (D. Del)
- *Pharmacyclics LLC et al. v. Cipla Ltd. & Cipla USA Inc.*, C.A. No. 18-247-GMS (D. Del)
- *Alcon Research, Ltd. v. Cipla Ltd & Cipla USA, Inc.*, C.A. No. 17-1244-GMS (D. Del)
- *Onyx Therapeutics, Inc. v. Cipla Ltd. & Cipla USA, Inc.*, C.A. No. 16-988-LPS (D. Del.)
- *Amgen Inc. v. Cipla Ltd & Cipla USA, Inc.*, C.A. No. 16-880-GMS (D. Del.)
- *Bristol-Myers Squibb Co. v. Cipla USA, Inc. & Cipla Ltd.*, C.A. No. 16-74-LPS (D. Del.)

23. Venue is proper in this Court as to Cipla Limited under 28 U.S.C. § 1391(c)(3) because, upon information and belief, Cipla Limited is a foreign corporation and may thus be sued in any judicial district.

24. Venue is proper in this Court as to Cipla USA, Inc. under 28 U.S.C. § 1400(b) because, *inter alia*, Cipla USA, Inc. is incorporated in Delaware.

BACKGROUND

25. Orgovyx® (relugolix) is a nonpeptide GnRH receptor antagonist, for oral administration, approved by the FDA for the treatment of adult patients with advanced prostate cancer. Orgovyx® is marketed in the United States pursuant to New Drug Application (NDA) No. 214621, which was approved by the FDA on December 18, 2020. SMPS holds the NDA for Orgovyx®.

26. The Patents-in-Suit cover Orgovyx® and/or its FDA-approved methods of use, and have been properly listed in connection with Orgovyx® in the FDA's publication, *Approved Drug Products with Therapeutic Equivalence Evaluations*, referred to as the "Orange Book."

27. U.S. Patent No. 11,795,178 (the "'178 Patent"), titled "Compositions of Thienopyrimidine Derivatives" (Ex. A), was duly and legally issued on October 24, 2023 and will

expire on September 27, 2033. Takeda owns the '178 Patent.

28. U.S. Patent No. 12,097,198 (the "'198 Patent"), titled "Treatment of Prostate Cancer," (Ex. B), was duly and legally issued on September 24, 2024, and will expire on September 29, 2037. SMPS and Takeda jointly own the '198 Patent.

29. U.S. Patent No. 12,144,809 (the "'809 Patent"), titled "Treatment of Prostate Cancer," (Ex. C), was duly and legally issued on November 19, 2024, and will expire on September 29, 2037. SMPS and Takeda jointly own the '809 Patent.

30. Takeda International, SMPS, and Pfizer are exclusive licensees of the Patents-in-Suit.

31. Orgovyx® is marketed and sold by SMPA and Pfizer throughout the United States, including in Delaware.

32. By letter dated January 31, 2025, Cipla notified SMPS, SMPA, Takeda, and Pfizer, that Cipla had submitted the Cipla ANDA to the FDA for approval of relugolix tablets, 120 mg, a generic version of Orgovyx®.

33. By submitting the Cipla ANDA, Cipla has represented to the FDA that the ANDA Product has the same active ingredient as Orgovyx®, has the same dosage form and strength as Orgovyx®, and is bioequivalent to Orgovyx®.

34. In Cipla's Paragraph IV Notice Letter, dated January 31, 2025 ("Notice Letter"), Cipla stated that its ANDA included a paragraph IV certification pursuant to 21 U.S.C. § 355(j) with respect to the Patents-in-Suit, and alleged that the Patents-in-Suit are invalid or will not be infringed by the commercial manufacture, use, or sale of the ANDA Product. The Notice Letter further stated that Cipla is seeking approval to engage in the commercial manufacture, use, offer for sale, sale, or importation of the ANDA Product before the Patents-in-Suit expire.

35. Upon information and belief, Cipla had knowledge of the Patents-in-Suit no later than when the Cipla ANDA was submitted to the FDA.

36. In the Notice Letter, Cipla provided an Offer of Confidential Access ("OCA") to the Cipla ANDA pursuant to 21 U.S.C. § 355(j)(5)(C) and 21 C.F.R. § 314.95(c)(8). Plaintiffs engaged in good faith negotiations with Cipla regarding the terms of its OCA. Cipla, however, refused to provide its ANDA under reasonable terms as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information, for example, terms governing the scope of applicable patent prosecution and FDA regulatory bars, in accordance with terms previously and widely accepted by courts.

37. Upon information and belief, Cipla intends to engage in the manufacture, use, offer for sale, sale, and/or importation of the ANDA Product immediately and imminently upon approval of the Cipla ANDA.

38. This action is being commenced before the expiration of 45 days from the date of Plaintiffs' receipt of the Notice Letter.

CLAIMS FOR RELIEF

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 11,795,178

39. Plaintiffs incorporate each of the preceding paragraphs 1-38 as if fully set forth herein.

40. Cipla's submission of the Cipla ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product before the expiration of the '178 Patent constituted an act of infringement of at least claim 1 of the '178 Patent, under 35 U.S.C. § 271(e)(2)(A).

41. Cipla's commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product and/or its active ingredient prior to expiration of the '178 Patent, and Cipla's inducement of and/or contribution to such conduct, would further infringe at least claim 1 of the '178 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c).

42. Upon FDA approval of the Cipla ANDA, Cipla will infringe at least claim 1 of the '178 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the ANDA Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of at least claim 1 of the '178 Patent by others, including but not limited to healthcare providers and patients, under 35 U.S.C. § 271(a), unless enjoined by the Court. Such infringement is imminent because, among other things, Cipla has notified Plaintiffs of the submission of Cipla's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product before the expiration of the '178 Patent.

43. Upon information and belief, Cipla will actively induce infringement of at least claim 1 of the '178 Patent under 35 U.S.C. § 271(b) by encouraging others, including but not limited to healthcare providers and patients, to make, use, offer for sale, sell, or import the ANDA Product in the United States. Upon information and belief, immediately and imminently upon FDA approval of the Cipla ANDA, Cipla will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '178 Patent and with knowledge that its acts are encouraging infringement.

44. Unless enjoined by this Court, upon FDA approval of the Cipla ANDA, Cipla will contributorily infringe at least claim 1 of the '178 Patent under 35 U.S.C. § 271(c) by offering to

sell, selling, and/or importing the ANDA Product and/or its active ingredient in the United States. The ANDA Product and/or its active ingredient constitute a material part of the inventions of the claims of the '178 Patent. Upon information and belief, Cipla knows that the ANDA Product and/or its active ingredient are especially made or adapted for use in infringing the '178 Patent, and that the ANDA Product and/or its active ingredient are not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Cipla plans and intends to, and will, contribute to the infringement of the '178 Patent immediately and imminently upon approval of the Cipla ANDA.

45. A substantial and justiciable controversy exists between the parties as to the infringement of the '178 Patent.

46. Pursuant to 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Cipla's making, using, offering to sell, selling, and/or importing the ANDA Product will infringe the '178 Patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

47. Upon information and belief, Cipla acted, and upon FDA approval of the Cipla ANDA, will act, without a reasonable basis for believing that it would not be liable for directly and/or indirectly infringing the '178 Patent. This is an exceptional case.

48. Unless Cipla is enjoined from directly or indirectly infringing the '178 Patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT II: INFRINGEMENT OF U.S. PATENT NO. 12,097,198

49. Plaintiffs incorporate each of the preceding paragraphs 1-48 as if fully set forth herein.

50. Cipla's submission of the Cipla ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product before

the expiration of the '198 Patent constituted an act of infringement of at least claims 1-2, 4-6, and 10-12 of the '198 Patent, under 35 U.S.C. § 271(e)(2)(A). In the Notice Letter, Cipla did not present any allegations that it will not indirectly infringe claims 1-2, 4-6, and 10-12 of the '198 Patent.

51. Cipla's commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product and/or its active ingredient prior to expiration of the '198 Patent, and Cipla's inducement of and/or contribution to such conduct, would further infringe at least claims 1-2, 4-6, and 10-12 of the '198 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c).

52. Upon FDA approval of the Cipla ANDA, Cipla will infringe at least claims 1-2, 4-6, and 10-12 of the '198 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the ANDA Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of the '198 Patent by others, including but not limited to healthcare providers and patients, under 35 U.S.C. § 271(a), unless enjoined by the Court. Such infringement is imminent because, among other things, Cipla has notified Plaintiffs of the submission of Cipla's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product before the expiration of the '198 Patent.

53. Upon information and belief, Cipla will actively induce infringement of at least claims 1-2, 4-6, and 10-12 of the '198 Patent under 35 U.S.C. § 271(b) by encouraging others, including but not limited to healthcare providers and patients, to make, use, offer for sale, sell, or import the ANDA Product in the United States. Upon information and belief, immediately and imminently upon FDA approval of the Cipla ANDA, Cipla will intentionally encourage acts of

direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '198 Patent and with knowledge that its acts are encouraging infringement. For example, marketing the ANDA Product with its proposed labeling will induce healthcare providers and patients to practice the claimed methods of the '198 Patent.

54. Unless enjoined by this Court, upon FDA approval of the Cipla ANDA, Cipla will contributorily infringe at least claims 1-2, 4-6, and 10-12 of the '198 Patent under 35 U.S.C. § 271(c) by offering to sell, selling, and/or importing the ANDA Product and its proposed labeling in the United States. The ANDA Product and its proposed labeling are materials for use in practicing methods claimed in the '198 Patent and constitute a material part of those claims' inventions. Upon information and belief, Cipla knows that the ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '198 Patent, and that the ANDA Product and its proposed labeling are not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Cipla plans and intends to, and will, contribute to the infringement of the '198 Patent immediately and imminently upon approval of the Cipla ANDA.

55. A substantial and justiciable controversy exists between the parties as to the infringement of the '198 Patent.

56. Pursuant to 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Cipla's making, using, offering to sell, selling, and/or importing the ANDA Product, inducement thereof or contribution thereto, will infringe the '198 Patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

57. Upon information and belief, Cipla acted, and upon FDA approval of the Cipla ANDA, will act, without a reasonable basis for believing that it would not be liable for directly

and/or indirectly infringing the '198 Patent. This is an exceptional case.

58. Unless Cipla is enjoined from directly or indirectly infringing the '198 Patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

COUNT III: INFRINGEMENT OF U.S. PATENT NO. 12,144,809

59. Plaintiffs incorporate each of the preceding paragraphs 1-58 as if fully set forth herein.

60. Cipla's submission of the Cipla ANDA to obtain approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product before the expiration of the '809 Patent constituted an act of infringement of at least claims 1, 3, 5, 9, 12, 19, and 23-29 of the '809 Patent, under 35 U.S.C. § 271(e)(2)(A). In the Notice Letter, Cipla did not present any allegations that it will not indirectly infringe claims 1, 3, 5, 9, 12, 19, and 23-29 of the '809 Patent.

61. Cipla's commercial manufacture, use, offer for sale, sale and/or importation of the ANDA Product and/or its active ingredient prior to expiration of the '809 Patent, and Cipla's inducement of and/or contribution to such conduct, would further infringe at least claims 1, 3, 5, 9, 12, 19, and 23-29 of the '809 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c).

62. Upon FDA approval of the Cipla ANDA, Cipla will infringe at least claims 1, 3, 5, 9, 12, 19, and 23-29 of the '809 Patent, either literally or under the doctrine of equivalents, by making, using, offering to sell, selling, and/or importing the ANDA Product and/or its active ingredient, and/or by actively inducing and contributing to infringement of the '809 Patent by others, including but not limited to healthcare providers and patients, under 35 U.S.C. § 271(a), unless enjoined by the Court. Such infringement is imminent because, among other things, Cipla

has notified Plaintiffs of the submission of Cipla's ANDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the ANDA Product before the expiration of the '809 Patent.

63. Upon information and belief, Cipla will actively induce infringement of at least claims 1, 3, 5, 9, 12, 19, and 23-29 of the '809 Patent under 35 U.S.C. § 271(b) by encouraging others, including but not limited to healthcare providers and patients, to make, use, offer for sale, sell, or import the ANDA Product in the United States. Upon information and belief, immediately and imminently upon FDA approval of the Cipla ANDA, Cipla will intentionally encourage acts of direct infringement by others, including but not limited to healthcare providers and patients, with knowledge of the '809 Patent and with knowledge that its acts are encouraging infringement. For example, marketing the ANDA Product with its proposed labeling will induce healthcare providers and patients to practice the claimed methods of the '809 Patent.

64. Unless enjoined by this Court, upon FDA approval of the Cipla ANDA, Cipla will contributorily infringe at least claims 1, 3, 5, 9, 12, 19, and 23-29 of the '809 Patent under 35 U.S.C. § 271(c) by offering to sell, selling, and/or importing the ANDA Product and its proposed labeling in the United States. The ANDA Product and its proposed labeling are materials for use in practicing methods claimed in the '809 Patent and constitute a material part of those claims' inventions. Upon information and belief, Cipla knows that the ANDA Product and its proposed labeling are especially made or adapted for use in infringing the '809 Patent, and that the ANDA Product and its proposed labeling are not a staple article or commodity of commerce suitable for substantial noninfringing use. Upon information and belief, Cipla plans and intends to, and will, contribute to the infringement of the '809 Patent immediately and imminently upon approval of the Cipla ANDA.

65. A substantial and justiciable controversy exists between the parties as to the infringement of the '809 Patent.

66. Pursuant to 28 U.S.C. § 2201, Plaintiffs are entitled to a declaratory judgment that Cipla's making, using, offering to sell, selling, and/or importing the ANDA Product, inducement thereof or contribution thereto, will infringe the '809 Patent pursuant to 35 U.S.C. §§ 271(a), (b), and/or (c).

67. Upon information and belief, Cipla acted, and upon FDA approval of the Cipla ANDA, will act, without a reasonable basis for believing that it would not be liable for directly and/or indirectly infringing the '809 Patent. This is an exceptional case.

68. Unless Cipla is enjoined from directly or indirectly infringing the '809 Patent, Plaintiffs will suffer irreparable injury. Plaintiffs have no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs ask that this Court grant the following relief:

(a) A judgment that the claims of the '178 Patent, the '198 Patent, and the '809 Patent were infringed by Cipla's submission of the Cipla ANDA under 35 U.S.C. § 271(e)(2)(A), and that Cipla's manufacture, use, offer to sell, sale, or importation of the ANDA Product, inducement thereof or contribution thereto, prior to the expiration of the '178 Patent, the '198 Patent, and the '809 Patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled, will infringe the '178 Patent, the '198 Patent, and the '809 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c);

(b) A judgment that the claims of the '178 Patent, the '198 Patent, and the '809 Patent are not invalid;

(c) An Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of the Cipla ANDA shall not be earlier than the expiration of the '178 Patent, the '198 Patent, and the '809 Patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

(d) A declaratory judgment that Cipla's manufacture, use, offer to sell, sale, or importation, including inducement thereof and contribution thereto, of the ANDA Product and/or its active ingredient prior to the expiration of the '178 Patent, the '198 Patent, and the '809 Patent, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled, would infringe the '178 Patent, the '198 Patent, and the '809 Patent, either literally or under the doctrine of equivalents, under 35 U.S.C. §§ 271(a), (b), and/or (c);

(e) An Order permanently enjoining Cipla and its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with Cipla, from making, using, offering to sell, selling, or importing the ANDA Product and/or its active ingredient until after the expiration of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

(f) Damages or other monetary relief, including costs, attorneys' fees, pre-judgement interest and post-judgment interest to Plaintiffs if Cipla engages in commercial manufacture, use, offers to sell, sale, or importation into the United States of the ANDA Product prior to the expiration of the Patents-in-Suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

(g) Declaring this to be an exceptional case pursuant to 35 U.S.C. § 285 entitling Plaintiffs to their attorneys' fees and enhanced damages; and

(h) Such further and other relief as this Court deems proper and just.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

/s/ Karen Jacobs

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March 12, 2025