IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ALLERGAN, INC. and ABBVIE INC. *Plaintiffs*, v. MANKIND PHARMA LTD. *Defendant*.	)	C.A. No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Allergan, Inc. ("Allergan") and AbbVie Inc. ("AbbVie") (collectively, "Plaintiffs"), by their undersigned attorneys, bring this action against Defendant Mankind Pharma Ltd. ("Mankind"), and allege as follows:

NATURE OF THE ACTION

1. This action for patent infringement, brought pursuant to the patent laws of the United States, 35 U.S.C. §§ 1 *et seq.*, arises from Mankind's submission to the United States Food and Drug Administration ("FDA") of an Abbreviated New Drug Application ("ANDA") seeking approval to market a generic version of Plaintiffs' successful pharmaceutical product LUMIGAN® 0.01% prior to the expiration of U.S. Patent No. 7,851,504 ("'504 Patent") which is listed for LUMIGAN® 0.01% in the *Approved Drug Products with Therapeutic Equivalence Evaluations* (an FDA publication commonly known as the "Orange Book").

2. Mankind has infringed one or more claims of the '504 Patent under 35 U.S.C. § 271(e)(2)(A) by filing its ANDA No. 218196 ("Mankind's ANDA") seeking FDA approval for the commercial manufacture, use, import, offer for sale, and/or sale in the United States of its

generic version of LUMIGAN® 0.01% ("Mankind's ANDA Product") prior to the expiration of the '504 Patent. Mankind will infringe one or more claims of the '504 Patent under 35 U.S.C. § 271(a), (b), and/or (c) should it engage in the commercial manufacture, use, offer for sale, sale, distribution in, or importation into the United States of Mankind's ANDA Product prior to the expiration of the '504 Patent.

LUMIGAN®

3. Open angle glaucoma is a chronic, progressive optic neuropathy that can result in blindness. Elevated intraocular pressure presents a major risk factor for glaucomatous field loss. The higher the level of intraocular pressure, the greater the likelihood of optic nerve damage and visual field loss.

4. LUMIGAN® 0.01% safely and effectively reduces intraocular pressure in patients suffering from open angle glaucoma and ocular hypertension.

5. The FDA approved LUMIGAN® 0.01% on August 31, 2010, pursuant to New Drug Application ("NDA") No. 22184.

6. Plaintiffs developed LUMIGAN® 0.01% and market and sell it in this judicial district and throughout the United States.

7. The '504 Patent, which expires June 13, 2027, is listed in the Orange Book with respect to LUMIGAN® 0.01% and NDA No. 22184.

8. In addition to the '504 Patent, the Orange Book lists eleven other patents, all expiring March 16, 2025, with respect to LUMIGAN® 0.01% and NDA No. 22184: U.S. Patent Nos. 8,278,353 ("'353 Patent"); 8,299,118 ("'118 Patent"); 8,309,605 ("'605 Patent"); 8,338,479 ("'479 Patent"); 8,524,777 ("'777 Patent"); 8,586,630 ("'630 Patent"); 8,772,338 ("'338 Patent");

8,933,120 ("'120 Patent"); 8,933,127 ("'127 Patent"); 9,155,716 ("'716 Patent"); and 9,241,918 ("'918 Patent").

9. LUMIGAN® 0.01% has been the subject of prior ANDA litigation. *See Allergan, Inc. v. Sandoz, Inc.*, C.A. No. 6:11-cv-441 (E.D. Tex.). After a bench trial, the district court found all asserted patents—the '504, '353, '118, '605, and '479 Patents—valid and infringed and entered a permanent injunction. *See* D.I. 303; *see also Allergan, Inc. v. Sandoz Inc*., No. 6:11-CV-441, 2014 WL 12622277, at *12, 37-38 (E.D. Tex. Jan. 13, 2014). The district court's decision was affirmed on appeal. *Allergan, Inc. v. Sandoz Inc*., 796 F.3d 1293 (Fed. Cir. 2015).

THE PARTIES

10. Plaintiff AbbVie is a corporation organized and existing under the laws of the State of Delaware, with its corporate headquarters at 1 North Waukegan Road, North Chicago, Illinois 60064. AbbVie is a global research and development-based biopharmaceutical company committed to developing innovative therapies for some of the world's most complex and critical conditions. AbbVie's mission is to use its expertise, dedicated people, and unique approach to innovation to markedly improve treatments across therapeutic areas, including eye diseases.

11. AbbVie holds NDA No. 22184 for LUMIGAN® 0.01%. *See* Ex. A.

12. Plaintiff Allergan is a corporation organized and existing under the laws of the State of Delaware, with a principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064. Allergan is the assignee of the '504 Patent. Allergan is an indirect wholly owned subsidiary of AbbVie.

13. On information and belief, Defendant Mankind is a corporation organized and existing under the laws of India, with a principal place of business at 208 Okhla Industrial Estate, Phase III, New Delhi, India 110020.

14. On information and belief, Mankind is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through its own actions and through the actions of various operating subsidiaries, including through its wholly-owned U.S. subsidiary, Lifestar Pharma LLC ("Lifestar"), a Delaware limited liability company with a principal place of business at 1200 MacArthur Boulevard, Mahwah, New Jersey 07430. On information and belief, Lifestar operates at the direction, under the control, and for the direct benefit of Mankind.

JURISDICTION AND VENUE

15. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

16. This is an action for patent infringement arising under the patent laws of the United States, 35 U.S.C. §§ 100 *et seq*., generally, and 35 U.S.C. § 271(e)(2), specifically. Therefore, subject matter jurisdiction is proper under 28 U.S.C. §§ 1331 and 1338(a).

17. Venue is proper under 28 U.S.C. §§ 1391(c)(3), because Mankind is a foreign corporation organized and existing under the laws of India, not residing in any United States district, and is subject to personal jurisdiction in this district.

18. This Court has personal jurisdiction over Mankind because, *inter alia*, Mankind, on information and belief: (1) has substantial, continuous, and systematic contacts with this State either directly or through at least one of its wholly-owned subsidiaries or agents; (2) intends to market, sell, and/or distribute the infringing Mankind ANDA Product to residents of this State upon approval of ANDA No. 218196, either directly or through at least one of its wholly-owned subsidiaries or agents; (3) enjoys substantial income from sales of its generic pharmaceutical

products in this State; and (4) controls and directs its wholly-owned subsidiary, Lifestar, which is a Delaware company.

19. On information and belief, Mankind, through its actions and through the actions of its agents and subsidiaries, has engaged in research and development of Mankind's ANDA Product, and has been and continues to be responsible for the preparation, filing, request for approval, and maintenance of ANDA No. 218196, including its certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("Paragraph IV certification") regarding the '504 Patent.

20. On information and belief, if the FDA approves ANDA No. 218196, Mankind intends to market, offer for sale, sell, and/or distribute Mankind's ANDA Product in Delaware and to residents of Delaware, and Mankind will derive substantial revenue from the use or consumption of Mankind's ANDA Product in Delaware. Through at least these activities, Mankind has purposely availed itself of the rights and benefits of Delaware law such that it should reasonably anticipate being hauled into court in this judicial district.

21. If ANDA No. 218196 is approved, Plaintiffs will be harmed by the marketing, distribution, offer for sale, and/or sale of Mankind's ANDA Product, including in Delaware.

22. This Court also has personal jurisdiction over Mankind because, *inter alia*, it has availed itself of this forum previously for the purpose of litigating a patent dispute. Mankind has been sued multiple times in this District without challenging personal jurisdiction and has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this district. *See Boehringer Ingelheim Pharma. Inc. v. Mankind Pharma Ltd*., C.A. No. 1:19-cv-1498-CFC (D. Del. Sept. 4, 2019) (D.I. 10); *Boehringer Ingelheim Pharma. Inc. et al v. Mankind Pharma Ltd*., C.A. No. 1:21-cv-1766-CFC (D. Del. Mar. 4, 2022) (D.I. 12); *Boehringer Ingelheim Pharma. Inc. v. Lupin Ltd*., C.A. No. 1:18-cv-1689-CFC (D. Del. Jan. 11, 2019) (D.I. 13).

23. Additionally, this Court may exercise personal jurisdiction over Mankind pursuant to Fed. R. Civ. P. 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Mankind is a foreign defendant not subject to general personal jurisdiction in the courts of any State; and (c) Mankind has sufficient contacts with the United States as a whole, including, but not limited to, preparing and filing ANDAs with the FDA and manufacturing, importing, offering to sell, and/or selling generic pharmaceutical products that are distributed throughout the United States, such that this Court's exercise of jurisdiction over Mankind satisfies due process.

THE '504 PATENT

24. The '504 Patent, entitled "Enhanced bimatoprost ophthalmic solution," was duly and legally issued on December 14, 2010. A true and correct copy of the '504 Patent is attached as Exhibit B.

25. The United States Patent & Trademark Office awarded 819 days of patent term adjustment to the '504 Patent.

26. The '504 Patent expires June 13, 2027.

27. Allergan is the assignee of the '504 Patent.

MANKIND'S ANDA

28. On information and belief, Mankind through its actions and/or through the actions of its agents and subsidiaries, prepared and submitted Mankind's ANDA to the FDA. Mankind's ANDA seeks approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation into the United States, including Delaware, of Mankind's ANDA Product, a generic version of LUMIGAN® 0.01%, before the expiration of the '504 Patent.

29. On information and belief, following FDA approval of the ANDA, Mankind will commercially manufacture, use, sell, offer for sale, and/or import Mankind's ANDA Product throughout the United States, including within the State of Delaware.

30. On information and belief, pursuant to 21 U.S.C. § 355(j)(2)(B)(iv), Mankind prepared and sent to Plaintiffs letters dated January 27, 2023 (the "Notice Letter") and March 7, 2023, purporting to inform Plaintiffs that Mankind had filed a certification to the FDA with respect to the '504 Patent.

31. On information and belief, Mankind has filed certifications to the FDA pursuant to 21 U.S.C. § 355(j)(2)(B)(iii) with respect to the '353, '118, '605, '479, '777, '630, '338, '120, '127, '716, and '918 Patents.

CLAIM FOR RELIEF
COUNT I: INFRINGEMENT OF THE '504 PATENT BY MANKIND

32. Plaintiffs incorporate by reference the prior paragraphs of this Complaint as if fully set forth herein.

33. On information and belief, Mankind submitted Mankind's ANDA to the FDA, and thereby seeks FDA approval of Mankind's ANDA Product.

34. On information and belief, Mankind's ANDA Product infringes one or more claims of the '504 Patent, either literally or under the doctrine of equivalents.

35. Mankind has infringed one or more claims of the '504 Patent under 35 U.S.C. § 271(e)(2)(A) by submitting Mankind's ANDA with Paragraph IV certification thereby seeking FDA approval of a generic version of LUMIGAN® 0.01% prior to the expiration of the '504 Patent.

36. On information and belief, the importation, manufacture, sale, offer for sale, or use of Mankind's ANDA Product prior to the expiration of the '504 Patent would infringe one or more claims of the '504 Patent under 35 U.S.C. § 271(a), and/or Mankind would induce or contribute to

the inducement of the infringement of one or more claims of the '504 Patent under 35 U.S.C. § 271(b) and/or (c).

37. Mankind had actual and constructive notice of the '504 Patent prior to filing Mankind's ANDA and was aware that the filing of Mankind's ANDA with the request for FDA approval prior to the expiration of the '504 Patent would constitute an act of infringement of the '504 Patent.

38. Plaintiffs will be irreparably harmed if Mankind is not enjoined from infringing and from actively inducing or contributing to the infringement of the '504 Patent. Plaintiffs do not have an adequate remedy at law and, considering the balance of hardships between Plaintiffs and Defendant, a remedy in equity is warranted. Further, the public interest would not be disserved by the entry of a permanent injunction.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request the following relief:

(a) A Judgment that Mankind has infringed the '504 Patent under 35 U.S.C. § 271(e)(2)(A);

(b) A Judgment and Order, pursuant to 35 U.S.C. § 271(e)(4)(A), that the effective date of any FDA approval for Mankind's ANDA shall be no earlier than the expiration date of the '504 Patent;

(c) A Judgment and Order, pursuant to 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283, that Mankind, its directors, officers, agents, attorneys, affiliates, divisions, subsidiaries, successors and employees, and those acting in privity or concert with them, are restrained and enjoined from seeking, obtaining, and/or maintaining approval of the Mankind ANDA prior to the expiration of the '504 Patent;

(d) A Judgment and Order that Mankind, its directors, officers, agents, attorneys, affiliates, divisions, subsidiaries, successors and employees, and those acting in privity or concert with them, are permanently enjoined from commercially manufacturing, using, offering to sell, selling, marketing, distribution, or importing the Mankind ANDA Product and any other product that infringes or induces or contributes to the infringement of the '504 Patent, prior to the expiration of the '504 Patent;

(e) A Judgment declaring that making, using, selling, offering for sale, or importing of Mankind's ANDA Product, or inducing or contributing to such conduct, prior to the expiration of the '504 Patent would constitute infringement of the '504 Patent under 35 U.S.C. § 271 (a), (b), and/or (c);

(f) A declaration pursuant to 28 U.S.C. § 2201 *et seq*. that if Mankind, its directors, officers, agents, attorneys, affiliates, divisions, subsidiaries, successors and employees, and all persons and entities acting in concert with it or on its behalf, engage in commercial manufacture, use, offer for sale, sale, or importation of Mankind's ANDA Product, it will constitute an act of infringement of the '504 Patent under 35 U.S.C. § 271 (a), (b), and/or (c);

(g) An award of damages or other relief, pursuant to 35 U.S.C. § 271(e)(4)(C), if Mankind engages in the commercial manufacture, use, offer to sell, sale, and/or importation of Mankind's ANDA Product, or any product that infringes the '504 Patent, or induces or contributes to such conduct, prior to the expiration of the '504 Patent;

(h) A finding that this case is an exceptional case and an award of attorneys' fees in this action under 35 U.S.C. § 285;

(i) Costs and expenses in this action; and

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

Dated: March 13, 2023

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