IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ABBVIE INC., ALLERGAN, INC., ALLERGAN SALES, LLC, and JOHNSON & JOHNSON VISION CARE INC.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
ALEMBIC PHARMACEUTICALS LIMITED and ALEMBIC PHARMACEUTICALS, INC.,	)	
Defendants.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs AbbVie Inc. ("AbbVie"), Allergan, Inc. ("Allergan"), Allergan Sales, LLC ("ASLLC"), and Johnson & Johnson Vision Care Inc. ("JJVCI") (collectively, "Plaintiffs") bring this action against Defendants Alembic Pharmaceuticals Limited and Alembic Pharmaceuticals, Inc. (collectively "Alembic"), and allege as follows:

THE PARTIES

1. Plaintiff AbbVie is a corporation organized under the laws of the state of Delaware with a principal place of business at 1 N. Waukegan Road, North Chicago, IL 60064.

2. Plaintiff Allergan is a corporation organized and existing under the laws of the State of Delaware and having a principal place of business at 1 N. Waukegan Road, North Chicago, IL 60064.

3. Plaintiff ASLLC is a limited liability company organized and existing under the laws of the State of Delaware and having a principal place of business at 1 N. Waukegan Road, North Chicago, IL 60064.

4. Plaintiff JJVCI is a corporation organized and existing under the laws of the State of Florida and having a principal place of business at 7500 Centurion Parkway, Suite 100, Jacksonville, Florida 32259.

5. On information and belief, defendant Alembic Pharmaceuticals Limited is a company organized and existing under the laws of the Republic of India with a principal place of business at Alembic Road, Vadodara 390003, Gujarat, India. On information and belief, Alembic Pharmaceuticals Limited is in the business of, among other things, manufacturing and selling generic versions of branded pharmaceutical drugs through various operating subsidiaries, including Alembic Pharmaceuticals, Inc., for the U.S. market, including in the State of Delaware.

6. On information and belief, defendant Alembic Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware with a principal place of business at 750 Highway 202, Bridgewater, New Jersey 08807. On information and belief, Alembic Pharmaceuticals, 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 the State of Delaware.

7. On information and belief, Alembic Pharmaceuticals, Inc. is a wholly owned subsidiary of Alembic Pharmaceuticals Limited and is controlled and/or dominated by Alembic Pharmaceuticals Limited.

8. On information and belief, Alembic Pharmaceuticals Limited and Alembic Pharmaceuticals, Inc. are in the business of, *inter alia*: (1) the development and manufacture of generic pharmaceutical products for sale and distribution throughout the world, including throughout the United States and in Delaware; (2) the preparation, submission, and filing of Abbreviated New Drug Applications ("ANDAs") seeking approval from the United States Food

and Drug Administration ("FDA") to market generic drugs throughout the United States, including in Delaware; and (3) the distribution of generic pharmaceutical products for sale and use throughout the United States, including in Delaware.

9. On information and belief, Alembic Pharmaceuticals Limited and Alembic Pharmaceuticals, Inc., acted in concert to prepare and submit ANDA No. 209290 (the "Alembic ANDA") to FDA for the manufacture, importation, marketing, and sale of the drug that is the subject of the Alembic ANDA if it is approved.

NATURE OF THE ACTION

10. This is a civil action for the infringement of U.S. Patent Nos. 8,664,215 (the "'215 patent") and 10,617,695 (the "'695 patent") under the Patent Laws of the United States, 35 U.S.C. § 100 et seq., arising from Alembic's filing of the Alembic ANDA with the FDA seeking approval to market a generic version of the pharmaceutical product LASTACAFT® ("Alembic's ANDA Product") before the expiration of the patents covering LASTACAFT® and its use. A copy of the '215 patent is attached as Exhibit A and a copy of the '695 patent is attached as Exhibit B.

JURISDICTION AND VENUE

11. This action arises under the patent laws of the United States. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a), 1391, 1400(b), 2201, and 2202.

12. This Court has personal jurisdiction over Alembic Pharmaceuticals, Limited and Alembic Pharmaceuticals, Inc.

13. Alembic Pharmaceuticals Limited is subject to personal jurisdiction in Delaware because, among other things, Alembic Pharmaceuticals Limited, itself and through its wholly-owned subsidiary Alembic Pharmaceuticals, Inc., has purposefully availed itself of the benefits

and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. On information and belief, Alembic Pharmaceuticals Limited, itself and through its wholly-owned subsidiary Alembic Pharmaceuticals, Inc., develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware, and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware. In addition, Alembic Pharmaceuticals Limited is subject to personal jurisdiction in Delaware because, on information and belief, it controls Alembic Pharmaceuticals, Inc. and therefore the activities of Alembic Pharmaceuticals, Inc. in this jurisdiction are attributed to Alembic Pharmaceuticals Limited.

14. Alembic Pharmaceuticals, Inc. is subject to personal jurisdiction in Delaware because, among other things, it has purposely availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court here. Alembic Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware, is qualified to do business in Delaware, and has appointed a registered agent for service of process in Delaware. It therefore has consented to general jurisdiction in Delaware. In addition, on information and belief, Alembic Pharmaceuticals, Inc. develops, manufactures, imports, markets, offers to sell, and/or sells generic drugs throughout the United States, including in the State of Delaware and therefore transacts business within the State of Delaware, and/or has engaged in systematic and continuous business contacts within the State of Delaware.

15. On information and belief, Alembic Pharmaceuticals Limited and Alembic Pharmaceuticals, Inc. are agents of each other, and/or operate in concert as integrated parts of the same business group, and enter into agreements with each other that are nearer than arm's length, including with respect to the development, regulatory approval, marketing, sale, offer for sale, and

distribution of generic pharmaceutical products throughout the United States, including into Delaware, and including with respect to Alembic's ANDA Product at issue. On information and belief, Alembic Pharmaceuticals Limited and Alembic Pharmaceuticals, Inc. together participated in, assisted, and cooperated in the acts complained of herein.

16. Alembic knows and intends that following any approval of the Alembic ANDA, Alembic will manufacture and import into the United States Alembic's ANDA Product and directly or indirectly market, sell, and distribute Alembic's ANDA Product throughout the United States, including in Delaware. Following any FDA approval of the ANDA, Alembic knows and intends that Alembic's ANDA Product will be marketed, used, distributed, offered for sale, and sold in the United States and within Delaware. Following any FDA approval of the Alembic ANDA, Alembic Pharmaceuticals Limited and Alembic Pharmaceuticals, Inc. will act in concert to distribute and sell Alembic's ANDA Product throughout the United States, including within Delaware.

17. Alembic has previously used the process contemplated by the Hatch-Waxman Act to challenge branded pharmaceutical companies' patents by filing a certification of the type described in Section 505(j)(2)(A)(vii)(IV) of the FDCA, 21 U.S.C. § 355(j)(2)(A)(vii)(IV), serving a notice letter on those companies, and engaging in patent litigation arising from the process contemplated by the Hatch-Waxman Act.

18. Alternatively, this Court may exercise jurisdiction over Alembic Pharmaceuticals Limited pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Alembic Pharmaceuticals Limited is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Alembic Pharmaceuticals Limited has sufficient contacts with the United States as a whole, including but not limited to

manufacturing and/or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Alembic Pharmaceuticals Limited satisfies due process.

19. Venue is proper in this district as to Alembic Pharmaceuticals, Inc. pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, inter alia, Alembic Pharmaceuticals, Inc. is a corporation organized and existing under the laws of the State of Delaware and is subject to personal jurisdiction in this judicial district.

20. Venue is proper in this district as to Alembic Pharmaceuticals Limited pursuant to 28 U.S.C. §§ 1391 and 1400(b) because, inter alia, Alembic Pharmaceuticals Limited is a corporation organized and existing under the laws of the Republic of India and is subject to personal jurisdiction in this judicial district.

ABBVIE'S NDA AND THE ASSERTED PATENTS

21. AbbVie holds all rights, title, and interest to NDA No. 022134, pursuant to which the FDA granted approval for alcaftadine ophthalmic solution 0.25% for the prevention of itching associated with allergic conjunctivitis. Alcaftadine ophthalmic solution 0.25% is sold by ASLLC under the trade name LASTACAFT®.

22. Following an internal corporate restructuring where Vistakon Pharmaceuticals, LLC ("Vistakon") merged with and into JJVCI, with JJVCI as the surviving entity, JJVCI owns U.S. Patent Nos. 8,664,215 (the "'215 Patent") and 10,617,695 (the "'695 Patent). The '215 patent discloses and claims compositions, kits, and methods of treating or preventing a clinical symptom of ocular allergies (including ocular itching, conjunctival redness, chemosis, and lid edema). The '215 patent claims are directed to the administration once daily of an ophthalmic solution comprising alcaftadine, its pharmaceutically acceptable salts, or mixtures thereof, wherein the

method comprises the administration of alcaftadine prior to and after exposure to a conjunctival allergen; the method of preventing ocular itching comprises inhibiting said ocular itching compared to a non-treated patient; and the method of preventing conjunctival redness, chemosis, and lid edema for a period exceeding 16 hours comprises inhibiting said conjunctival redness, chemosis, and lid edema compared to a non-treated patient. JJVCI as successor in interest exclusively licenses the ’215 patent to Allergan.

23. The ’695 patent discloses and claims compositions, kits, and methods of treating or preventing at least one clinical symptom of ocular allergies and inflammation. The ’695 patent claims are directed to the administration once daily of an ophthalmic solution comprising alcaftadine, its pharmaceutically acceptable salts, or mixtures thereof, wherein the composition is in the form of a solution or suspension; the pH of the composition ranges from 6.5 to 7.5; and the composition further comprises a pharmaceutically acceptable topical ophthalmic vehicle. JJVCI as successor in interest exclusively licenses the ’695 patent to Allergan.

24. Pursuant to 21 U.S.C. § 355(b)(1), Allergan previously submitted information concerning the ’215 patent and the ‘695 patent to the FDA in connection with NDA No. 022134, identifying it as a patent “with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.” Pursuant to 21 U.S.C. § 355(c)(2), Allergan also timely filed with the FDA’s Secretary of Health and Human Services the patent number and expiration date of the ’695 patent, which issued after NDA No. 022134 was approved, not later than thirty days after the ’695 patent issued; Allergan further identified the patent “with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug.” The ’215 patent and the ’695 patent have been listed in the FDA publication

entitled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the "Orange Book") as covering LASTACAFT®.

ALEMBIC'S ANDA AND NOTICE LETTER

25. By letter ("Alembic Notice Letter") dated February 15, 2024, and received by Plaintiffs no earlier than February 20, 2024, Alembic gave notice that it had submitted the Alembic ANDA to the FDA under 21 U.S.C. § 355(j) seeking approval to manufacture, use or sell Alembic's ANDA Product, prior to the expiration of the '215 patent and the '695 patent.

26. The Alembic Notice Letter informed Plaintiffs that Alembic's ANDA contained a "Paragraph IV Certification" alleging that the claims of the '215 patent and the '695 patent are invalid.

27. The Alembic Notice Letter failed to allege that Alembic's ANDA Product or the proposed administration of the Alembic's ANDA Product will not meet the limitations of claims 1-3 and 7 of the '215 Patent and claims 1-12 of the '695 Patent.

28. On information and belief, Alembic will copy the FDA approved label for LASTACAFT®. This label accompanying the marketing of Alembic's ANDA Product will encourage, recommend, and promote infringement by instructing physicians and patients to administer Alembic's ANDA Product, which will include 0.25% alcaftadine, to a human patient with allergic conjunctivitis for prevention of ocular itching, thus inducing infringement of at least claims 4-6 of the '215 Patent. A copy of the LASTACAFT® label is attached as Exhibit C.

29. On information and belief, Alembic intends to manufacture, import, use, sell, or offer to sell Alembic's ANDA Product for uses that would infringe the claims of the '215 patent and the '695 patent.

30. This action is being filed within 45 days of Plaintiffs' receipt of the Alembic Notice Letter. Accordingly, Plaintiffs are entitled to a stay of FDA approval pursuant to 21 U.S.C. § 355(j)(5)(B)(iii) and U.S.C. 355(j)(5)(F)(ii).

COUNT I – INFRINGEMENT OF '215 PATENT BY ALEMBIC

31. Plaintiffs reallege, as if fully set forth herein, the averments contained in paragraphs 1-30.

32. Alembic submitted the Alembic ANDA to the FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use, or sale of Alembic's ANDA Product prior to the expiration of the '215 patent. By submitting the Alembic ANDA, Alembic has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

33. The commercial manufacture, use, or sale of Alembic's ANDA Product prior to the expiration of the '215 patent will directly infringe the '215 patent under 35 U.S.C. § 271(a), will actively induce infringement of the '215 patent under 35 U.S.C. § 271(b), and will constitute contributory infringement of the '215 patent under 35 U.S.C. § 271(c). Alembic will infringe or aid another in the infringement of at least one or more of the following claims of the '215 patent: claims 1-11.

34. Upon information and belief, Alembic has acted with full knowledge of the '215 patent and its claims and without a reasonable basis for believing that it would not be liable for indirect infringement, induced infringement, and contributory infringement of the '215 patent. Notwithstanding this knowledge, Alembic has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Alembic's ANDA Product immediately and imminently upon approval of the Alembic ANDA. Upon

information and belief, through such activities, Alembic specifically intends infringement of the '215 patent.

35. If FDA approves the Alembic ANDA, Alembic intends to, and will, infringe, actively induce infringement of, and contribute to the infringement of the '215 patent, and plans and intends to, and will, do so immediately and imminently upon approval.

36. Alembic knows that Alembic's ANDA Product is especially made or adapted for use in infringing the '215 patent, and that Alembic's ANDA Product is not suitable for substantial noninfringing use. Alembic plans and intends to, and will, contribute to infringement of the '215 patent immediately and imminently upon approval of the Alembic ANDA.

37. Plaintiffs will be substantially and irreparably harmed if Alembic's infringement of the '215 patent is not enjoined. Plaintiffs do not have an adequate remedy at law.

38. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of the Alembic ANDA be a date which is not earlier than the later of the expiration dates of the '215 patent or '695 patent, or the date of any later expiration of exclusivity to which Plaintiffs are or become entitled.

COUNT II – INFRINGEMENT OF '695 PATENT BY ALEMBIC

39. Plaintiffs reallege, as if fully set forth herein, the averments contained in paragraphs 1-38.

40. Alembic submitted the Alembic ANDA to the FDA under 21 U.S.C. § 355(j) to obtain approval to engage in the commercial manufacture, use, or sale of Alembic's ANDA Product prior to the expiration of the '695 patent. By submitting the Alembic ANDA, Alembic has committed an act of infringement under 35 U.S.C. § 271(e)(2)(A).

41. The commercial manufacture, use, or sale of Alembic's ANDA Product prior to the expiration of the '695 patent will directly infringe the '695 patent under 35 U.S.C. § 271(a), will actively induce infringement of the '695 patent under 35 U.S.C. § 271(b), and will constitute contributory infringement of the '695 patent under 35 U.S.C. § 271(c). Alembic will infringe or aid another in the infringement of at least one or more claims of the '695 patent.

42. Alembic has acted with full knowledge of the '695 patent and its claims and without a reasonable basis for believing that it would not be liable for direct infringement, induced infringement, and contributory infringement of the '695 patent. Notwithstanding this knowledge, Alembic has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of Alembic's ANDA Product immediately and imminently upon approval of the Alembic ANDA. Upon information and belief, through such activities, Alembic specifically intends infringement of the '695 patent.

43. If the FDA approves the Alembic ANDA, Alembic intends to, and will, infringe, actively induce infringement of, and contribute to the infringement of the '695 patent, and plans and intends to, and will, do so immediately and imminently upon approval.

44. Alembic knows that Alembic's ANDA Product is especially made or adapted for use in infringing the '695 patent, and that Alembic's ANDA Product is not suitable for substantial noninfringing use. Alembic plans and intends to, and will, contribute to infringement of the '695 patent immediately and imminently upon approval of the Alembic ANDA.

45. Plaintiffs will be substantially and irreparably harmed if Alembic's infringement of the '695 patent is not enjoined. Plaintiffs do not have an adequate remedy at law.

46. Plaintiffs are entitled to the relief provided by 35 U.S.C. § 271(e)(4), including an order of this Court that the effective date of the approval of the Alembic ANDA be a date which

is not earlier than the later of the expiration dates of the ’215 patent or ’695 patent, or the date of any later expiration of exclusivity to which Plaintiffs are or become entitled.

REQUEST FOR RELIEF

WHEREFORE, Plaintiffs request that:

a. Judgment be entered that Alembic has infringed the ’215 patent and ’695 patent under 35 U.S.C. § 271(e)(2)(A) by submitting the Alembic ANDA;

b. Judgment be entered that the commercial manufacture, use, offer for sale, and/or sale of Alembic’s ANDA Product in the United States, and/or the importation of Alembic’s ANDA Product into the United States, will infringe the ’215 patent and ’695 patent under 35 U.S.C. §§ 271(a), (b), and/or (c);

c. A permanent injunction be issued, pursuant to 35 U.S.C. § 271(e)(4)(B), restraining and enjoining Alembic, its officers, agents, attorneys, and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of Alembic’s ANDA Product prior to the later of the expiration dates of the ’215 patent and ’695 patent, or the date of any later expiration of exclusivity to which Plaintiffs are or become entitled;

d. If Alembic commercially makes, uses, sells, or offers to sell Alembic’s ANDA Product within the United States, or imports Alembic’s ANDA Product into the United States, prior to the later of the expiration dates of the ’215 patent and ’695 patent, including any extensions, that Plaintiffs be awarded monetary damages for those infringing acts to the fullest extent allowed by law, and be awarded prejudgment interest based on those monetary damages;

e. An order be issued pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any approval of the Alembic ANDA be a date which is not earlier than the later of the expiration

dates of the ’215 patent and ’695 patent, or the date of any later expiration of exclusivity to which Plaintiffs are or become entitled;

g. Costs and expenses in this action; and

h. The Court grant such other and further relief as it may deem just and proper under the circumstances.

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