IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

ALLERGAN, INC., ALLERGAN SALES, LLC, and VISTAKON PHARMACEUTICALS, LLC,	)	
Plaintiffs,	)	
	)	C.A. No. 20-cv-4094
v.	)	
GLAND PHARMA LIMITED,	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Allergan, Inc., Allergan Sales, LLC, and Vistakon Pharmaceuticals, LLC (collectively, "Plaintiffs"), for their Complaint against Defendant Gland Pharma Limited ("Defendant" or "Gland"), hereby allege as follows:

THE PARTIES

1. Plaintiff Allergan, Inc. is a corporation organized and existing under the laws of the State of Delaware and has a place of business at 2525 DuPont Drive, Irvine, California 92612. Allergan, Inc. is an affiliate of AbbVie Inc., a Delaware corporation with its principal place of business at 1 North Waukegan Road, North Chicago, Illinois 60064-6400.

2. Plaintiff Allergan Sales, LLC ("Allergan Sales," and collectively with Allergan, Inc., "Allergan") is a Delaware limited liability company having a place of business at 5 Giralda Farms, Madison, New Jersey 07940. Allergan Sales is an affiliate of AbbVie Inc.

3. Plaintiff Vistakon Pharmaceuticals, LLC ("Vistakon") is a Florida limited liability company, having a place of business at 7500 Centurion Parkway, Jacksonville, Florida, 32256.

4. On information and belief, Gland is a corporation organized and existing under the laws of India, having a principal place of business at Survey No: 143-148, 150 & 151, Near Gandimaisamma Cross Roads, D.P.Pally, Dundigal Post, Dundigal - Gandimaisamma Mandal, Medchal - Malkajgiri District, Hyderabad, Telangana 500 043, India.

5. On information and belief, Gland, by itself and/or through its affiliates and agents, is 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 Illinois; (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 Illinois; and (3) the distribution of generic pharmaceutical products for sale and use throughout the United States, including in Illinois.

6. On information and belief, Gland has prepared and filed ANDA No. 209706 and will be involved in the manufacture, importation, marketing, and sale of the drug that is the subject of ANDA No. 209706 (the "Gland ANDA") if it is approved.

NATURE OF THE ACTION

7. 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 Gland's filing of the Gland ANDA with the FDA seeking approval to market a generic version of the pharmaceutical product LASTACAFT® 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

8. 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).

9. Plaintiffs believe this case belongs in Delaware. Upon information and belief, Gland is aware that three other related actions involving generic versions of LASTACAFT® and the '215 patent were instituted in Delaware, including *Allergan, Inc., et al. v. Aurobindo Pharma Ltd. et al.*, Civil Action No. 17-01290 (D. Del.); *Allergan, Inc. et al. v. Somerset Therapeutics, LLC*, Civil Action No. 16-00392 (D. Del.); and *Allergan, Inc., et al. v. Wilshire Pharm. Inc.*, Civil Action No. 14-01461 (D. Del.).

10. To avoid burdening the courts and the parties during the COVID-19 pandemic, Plaintiffs asked Gland on July 6, 2020 and again on July 8, 2020 to confirm that it would not contest jurisdiction or venue in Delaware, but Gland refused. As a result, Plaintiffs file this case in this District out of an abundance of caution.

11. Upon information and belief, this Court has personal jurisdiction over Gland by virtue of the fact that in the letter ("Gland Notice Letter") dated May 27, 2020 in which Gland gave notice that it had submitted the Gland ANDA to the FDA under 21 U.S.C. § 355(j) seeking approval to manufacture, use or sell alcaftadine ophthalmic solution 0.25% prior to the expiration of the '215 patent and the '695 patent, Gland affirmatively stated that it "will not object to personal jurisdiction in the Illinois courts" and therefore, Gland has affirmatively consented to personal jurisdiction in Illinois.

12. Upon information and belief, this Court also has personal jurisdiction over Gland by virtue of the fact that in the Gland Notice Letter, Gland purported to offer confidential access only to "certain information" of the Gland ANDA on terms and conditions set forth in the

Gland Notice Letter ("the Gland Offer"), and Gland affirmatively stated that the Gland Offer "shall be governed by the laws of the State of Illinois."

13. Upon information and belief, this Court also has personal jurisdiction over Gland by virtue of the fact that Gland has committed the tortious act of patent infringement pursuant to 35 U.S.C. § 271(e)(2)(A) that has led to foreseeable harm and injury to Plaintiffs throughout the United States, including in Illinois. The policy behind the Hatch-Waxman Act dictates that Gland's very act of filing the Gland ANDA provides a formal, reliable, and non-speculative prediction of Gland's activities in Illinois, including its plans to market its generic version of LASTACAFT®. Gland filed its ANDA with the deliberate and purposeful objective of benefiting from the consequences of its ANDA should it be approved by the FDA. Upon information and belief, following approval of the Gland ANDA, Gland will make, use, sell, offer for sale, and/or import its generic version of LASTACAFT® into the United States, including into Illinois, a product that infringes claims of the '215 patent and the '695 patent.

14. Upon information and belief, this Court also has personal jurisdiction over Gland because, *inter alia*: (1) Gland filed its ANDA for the purpose of seeking approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the generic version of LASTACAFT® throughout the United States, including in Illinois; (2) upon any approval of the Gland ANDA, Gland will market, distribute, offer for sale, and/or sell the generic version of LASTACAFT® throughout the United States, including in Illinois, and will derive substantial revenue from the use or sale of the products in Illinois; (3) upon any approval of the Gland ANDA, the generic version of LASTACAFT® will be prescribed by physicians practicing in Illinois and dispensed by pharmacies located within Illinois; and (4) the resolution of this action will directly affect when the Gland ANDA can be approved to allow the marketing of

Gland's generic version of LASTACAFT® in or directed at Illinois, and when such marketing can lawfully take place.

15. Alternatively, if the above facts do not establish personal jurisdiction over Gland, then this Court may exercise jurisdiction over Gland pursuant to Federal Rule of Civil Procedure 4(k)(2) because: (a) Plaintiffs' claims arise under federal law; (b) Gland is a foreign defendant not subject to general personal jurisdiction in the courts of any state; and (c) Gland 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 Gland satisfies due process.

16. Venue is proper in this judicial district pursuant to 28 U.S.C. § 1391 and 28 U.S.C. § 1400(b). Specifically, venue is proper in Illinois because upon information and belief, Gland is not incorporated anywhere in the United States and does not have a regular and established place of business in the United States and thus may be sued in any judicial district.

ALLERGAN, INC.'S NDA AND THE ASSERTED PATENTS

17. Vistakon filed New Drug Application ("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. Vistakon assigned all rights, title, and interest to NDA No. 022134 to Allergan, Inc. Alcaftadine ophthalmic solution 0.25% is sold by an affiliate of Allergan under the trade name LASTACAFT®.

18. Vistakon is the assignee of the '215 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. Vistakon exclusively licensed the ’215 patent to Allergan.

19. Vistakon is the assignee of the ’695 patent. 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. Vistakon exclusively licensed the ’695 patent to Allergan.

20. Pursuant to 21 U.S.C. § 355(b)(1), Allergan, Inc. 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, Inc. 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, Inc. 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®.

GLAND'S ANDA AND NOTICE LETTER

21. In the Gland Notice Letter dated May 27, 2020 and received by Plaintiffs no earlier than May 28, 2020, Gland gave notice that it had submitted the Gland ANDA to the FDA under 21 U.S.C. § 355(j) seeking approval to manufacture, use or sell alcaftadine ophthalmic solution 0.25% (the "Gland Generic Product"), prior to the expiration of the '215 patent and the '695 patent.

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

23. In the Gland Notice Letter, Gland purported to offer the Gland Offer, in which Gland would offer confidential access to only "certain information" of the Gland ANDA on terms and conditions set forth in the Gland Notice Letter. Gland requested that Allergan and Vistakon accept the Gland Offer before receiving access to the Gland ANDA. The Gland Offer contained unreasonable restrictions on who could view the ANDA, well beyond those that would apply under a protective order. The Gland Offer did not permit any Allergan or Vistakon in-house attorneys to access and portion of the Gland ANDA, and only allowed "one outside law firm representing the Requestor" to access certain portions of the Gland ANDA. Nor did it permit any scientific experts to access any portion of the Gland ANDA. Additionally, the Gland

Offer contained provisions that unreasonably restricted the ability of the one outside law firm receiving certain portions of the Gland ANDA to engage in any patent prosecution (including reexaminations, reissues and patent review proceedings) or work before or involving the FDA. The restrictions the Gland Offer placed on access to the Gland ANDA contravene 21 U.S.C. § 355(j)(5)(C)(i)(III), which states that an offer of confidential access "shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

24. Beginning on July 2, 2020, outside counsel for Plaintiffs negotiated in good faith with counsel for Gland in an attempt to reach agreement on reasonable terms of confidential access to the Gland ANDA. Gland responded by letter on July 7, 2020 (received at 11:05 PM ET) indicating that it would not compromise on all of Plaintiffs' concerns.

25. For at least one claim of the '695 Patent, the Gland Notice Letter failed to allege that the Gland Generic Product or the proposed administration of the Gland Generic Product will not meet the limitations of that claim. As for the '215 Patent, Gland did not contest that all limitations of claims 4-6 will be met by the administration of the Gland Generic Product. Representative claim 4 reads, "A method of preventing ocular itching in a human patient exposed to a conjunctival allergen, comprising administering once daily to the eye of said human patient an ophthalmic composition comprising alcaftadine, its pharmaceutically acceptable salts, or mixtures thereof, wherein prevention comprises inhibiting said ocular itching compared to a non-treated patient." Gland only contended that it does not induce infringement of representative claim 4 and claims 5-6. However, on information and belief, Gland will copy the FDA approved label for LASTACAFT®. This label accompanying the marketing of the Gland Generic Product

will encourage, recommend, and promote infringement by instructing physicians and patients to administer the Gland Generic 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.

26. On information and belief, Gland intends to manufacture, import, use, sell, or offer to sell the Gland Generic Product for uses that would infringe the claims of the ’215 patent and the ’695 patent.

27. This action is being filed within 45 days of Plaintiffs’ receipt of the Gland 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 GLAND

28. Plaintiffs reallege, as if fully set forth herein, the averments contained in paragraphs 1-27.

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

30. On information and belief, the commercial manufacture, use, or sale of the Gland Generic 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). Gland 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.

31. On information and belief, the Gland Generic Product will have instructions for use that substantially copy the instructions for LASTACAFT®. Upon information and belief, the proposed labeling for the Gland Generic Product directs the use of the Gland Generic Product for the following indication: prevention of itching associated with allergic conjunctivitis.

32. Upon information and belief, Gland 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, Gland has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of the Gland Generic Product immediately and imminently upon approval of the Gland ANDA. Upon information and belief, through such activities, Gland specifically intends infringement of the '215 patent.

33. Upon information and belief, if the FDA approves the Gland ANDA, Gland 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.

34. Upon information and belief, Gland knows that the Gland Generic Product is especially made or adapted for use in infringing the '215 patent, and that the Gland Generic Product is not suitable for substantial noninfringing use. Upon information and belief, Gland plans and intends to, and will, contribute to infringement of the '215 patent immediately and imminently upon approval of the Gland ANDA.

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

36. 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 Gland 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.

37. On information and belief, Gland lacked a good faith basis for alleging invalidity of the '215 patent when it filed the Gland ANDA and made the Paragraph IV certification. Accordingly, Gland's Paragraph IV certification was wholly unjustified.

38. This case is an exceptional one, and Plaintiffs are entitled to an award of reasonable attorney fees under 35 U.S.C. §§ 271(e)(4) and 285.

COUNT II – INFRINGEMENT OF '695 PATENT BY GLAND

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

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

41. On information and belief, the commercial manufacture, use, or sale of the Gland Generic 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). Gland will infringe or aid another in the infringement of at least one or more of the following claims of the ’695 patent: claims 1-20.

42. On information and belief, the Gland Generic Product will have instructions for use that substantially copy the instructions for LASTACAFT®. Upon information and belief, the proposed labeling for the Gland Generic Product directs the use of the Gland Generic Product for the following indication: prevention of itching associated with allergic conjunctivitis.

43. Upon information and belief, Gland 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, Gland has continued to assert its intent to engage in the manufacture, use, offer for sale, sale, marketing, distribution and/or importation of the Gland Generic Product immediately and imminently upon approval of the Gland ANDA. Upon information and belief, through such activities, Gland specifically intends infringement of the ’695 patent.

44. Upon information and belief, if the FDA approves the Gland ANDA, Gland 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.

45. Upon information and belief, Gland knows that the Gland Generic Product is especially made or adapted for use in infringing the ’695 patent, and that the Gland Generic Product is not suitable for substantial noninfringing use. Upon information and belief, Gland

plans and intends to, and will, contribute to infringement of the ’695 patent immediately and imminently upon approval of the Gland ANDA.

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

47. 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 Gland 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.

48. On information and belief, Gland lacked a good faith basis for alleging invalidity of the ’695 patent when it filed the Gland ANDA and made the Paragraph IV certification. Accordingly, Gland’s Paragraph IV certification was wholly unjustified.

49. This case is an exceptional one, and Plaintiffs are entitled to an award of reasonable attorney fees under 35 U.S.C. §§ 271(e)(4) and 285.

STATEMENT REGARDING PRIOR-FILED SUIT

50. Plaintiffs previously filed, on July 9, 2020, an action (“the Delaware Action”) in the District of Delaware, Case No. 20-932, seeking to enjoin Gland from infringing the ’215 patent and ’695 patent.

51. In the Delaware Action, Plaintiffs alleged that the District Court for the District of Delaware has personal jurisdiction over Gland with regard to Plaintiffs’ claim of patent infringement.

52. Judicial economy would be promoted, and Plaintiffs' choice of forum respected, if the claims related to Plaintiffs' action for infringement of the '215 patent and '695 patent are addressed in the District of Delaware.

53. Pursuant to 21 U.S.C. § 355(j)(5)(B)(iii), a patent owner has 45 days from receipt of an ANDA Notice Letter to file suit in order to perfect its statutory right to a stay of FDA approval of an ANDA pending resolution of litigation regarding the submission of such ANDA. Plaintiffs filed this action within 45 days of receipt of the Gland Notice Letter as a further protective measure with regard to this statutory right.

54. Plaintiffs expect that Gland will be subject to personal jurisdiction in the District of Delaware and that the claims of this lawsuit will proceed in that forum. In that circumstance, this lawsuit could be unnecessary and may be voluntarily dismissed without prejudice in favor of continued prosecution of the Delaware Action, transferred to the District of Delaware for consolidation with the Delaware Action, or subject to such other non-substantive disposition that would ensure maintenance of Plaintiffs' rights pursuant to 21 U.S.C. § 355(j)(5)(B)(iii).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request that:

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

b. Judgment be entered that the commercial manufacture, use, offer for sale, and/or sale of the Gland Generic Product in the United States, and/or the importation of the Gland Generic 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 Defendant, 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 the Gland Generic 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 Defendant commercially makes, uses, sells, or offers to sell the Gland Generic Product within the United States, or imports the Gland Generic 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 Gland 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;

f. Judgment be entered that this is an exceptional case, and that Plaintiffs are entitled to its reasonable attorney fees pursuant to 35 U.S.C. §§ 271(e)(4) and 285;

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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