IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ACTELION PHARMACEUTICALS LTD,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
GLAND PHARMA LIMITED,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Actelion Pharmaceuticals Ltd ("Actelion" or "Plaintiff"), for its Complaint for patent infringement against Gland Pharma Limited ("Gland" or "Defendant"), hereby alleges as follows:

NATURE OF THE ACTION

1. This is a civil action for infringement of United States Patent No. 8,598,227 ("the '227 patent") under the Patent Laws of the United States, 35 U.S.C. § 100 et seq. and the Declaratory Judgment Act, 28 U.S.C. §§ 2201-2202.

2. This action arises out of Gland's submission of Abbreviated New Drug Application ("ANDA") No. 219237 to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture, import, market, offer to sell, sell, and distribute a generic epoprostenol sodium for injection drug product, 1.5 mg/vial and 0.5 mg/vial (collectively, "Gland's ANDA Products"), prior to expiration of the '227 patent.

THE PARTIES

3. Plaintiff Actelion Pharmaceuticals Ltd is a Swiss corporation having a primary place of business at Gewerbestrasse 16, CH-4123 Allschwil, Switzerland.

4. On information and belief, Gland is a corporation organized and existing under the laws of India, having its principal place of business at Survey No. 143-148, 150 & 151, Near Gandimaisamma Cross Roads, D.P. Pally, Dundigal Gandimaisamma Mandal, Medchal-Malkajgiri District, Hyderabad 500043, Telangana, India.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

6. This Court has personal jurisdiction over Gland because, *inter alia*, it has purposefully availed itself of the benefits and protections of Delaware's laws such that it should reasonably anticipate being haled into court in Delaware. On information and belief, Gland manufactures and imports generic pharmaceutical products into the United States and directly or indirectly markets, offers to sell, and sells generic pharmaceutical products throughout the United States, including in Delaware.

7. This Court also has personal jurisdiction over Gland because, *inter alia*, Gland has purposely availed itself of the legal protections of the State of Delaware, has previously consented to personal jurisdiction in this Judicial District, and has asserted claims and/or counterclaims in this court. See, e.g., *Astellas US LLC et al. v. Gland Pharma Limited*, No. 20-347-CFC, D.I. 10 at 4-5 (D. Del. Apr. 17, 2020).

8. This Court also has personal jurisdiction over Gland because, on information and belief, Gland prepared, filed, and submitted ANDA No. 219237 for the purpose of seeking approval to engage in the commercial manufacture and/or importation of Gland's ANDA Products into the United States and the marketing, offer for sale, and sale of Gland's ANDA Products throughout the United States, including in Delaware. On information and belief, Gland knows and

intends that following any approval of Gland's ANDA No. 219237, Gland will manufacture and import into the United States Gland's ANDA Products and directly or indirectly market, offer for sale, and sell Gland's ANDA Products throughout the United States, including in Delaware. On information and belief, Gland regularly does business in Delaware, and its practices with other generic pharmaceutical products have involved placing those products into the stream of commerce for sale, distribution, use, and/or consumption throughout the United States, including in Delaware. On information and belief, Gland's ANDA Products will be prescribed by physicians practicing in Delaware, dispensed by pharmacies located within Delaware, and used by patients in Delaware. On information and belief, each of these future activities would be purposefully directed at Delaware and would have a substantial effect within Delaware and would constitute infringement of Actelion's patents in the event that Gland's ANDA Products are approved before the patents expire.

9. Alternatively, if Gland were not subject to personal jurisdiction in Delaware, this Court may exercise jurisdiction over Gland pursuant to Fed. R. Civ. P. 4(k)(2) because (1) Actelion's claims arise under federal law; (2) Gland is a foreign defendant not subject to personal jurisdiction in any state's court of general jurisdiction; and (3) Gland has sufficient contacts with the United States as a whole, including, but not limited to, submitting various ANDAs to the FDA and manufacturing, importing, offering to sell, or selling pharmaceutical products distributed throughout the United States, such that this Court's exercise of jurisdiction over Gland satisfies due process.

10. Venue is proper in this district as to Gland pursuant to 28 U.S.C. § 1391 at least because Gland is a foreign corporation organized and existing under the laws of the Republic of India and not resident in the United States.

VELETRI® AND THE '227 PATENT

11. Actelion holds approved New Drug Application ("NDA") No. 022260, under which the FDA granted approval on June 27, 2008 for epoprostenol sodium for injection, eq. 1.5 mg/vial and on June 28, 2012 for epoprostenol sodium for injection, eq. 0.5 mg/vial, both marketed in the United States under the trade name VELETRI®.

12. VELETRI® (epoprostenol) for Injection approved in NDA No. 022260 is indicated for the treatment of pulmonary arterial hypertension (PAH) (WHO Group 1) to improve exercise capacity.

13. Actelion owns the '227 patent, titled "Epoprostenol Formulation and Method of Making Thereof," and owns all rights to that patent, including the right to sue for infringement. The '227 patent was duly and legally issued on December 3, 2013. A copy of the '227 patent is attached as Exhibit A.

14. The '227 patent is listed in the FDA publication entitled *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book") for VELETRI®.

GLAND ANDA NO. 219237 AND NOTICE LETTER

15. On information and belief, Gland submitted ANDA No. 219237 to the FDA, including a certification with respect to the patent-in-suit under Section 505(j)(2)(A)(vii)(IV) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355) ("Paragraph IV Certification"), seeking approval to engage in the commercial manufacture, use, sale, or offer for sale within the United States, or importation into the United States, of Gland's ANDA Products prior to expiration of the patent-in-suit.

16. Gland sent a Paragraph IV Certification Notice Letter to Actelion ("Notice Letter"). In its Notice Letter, Gland represented that ANDA No. 219237 contained a Paragraph IV Certification with respect to the '227 patent.

17. Actelion is commencing this action within 45 days of the date of receipt of the Gland Paragraph IV Certification Notice Letter.

INFRINGEMENT OF THE PATENT-IN-SUIT

18. Actelion re-alleges paragraphs 1-17 as if fully set forth herein.

19. Gland seeks approval of ANDA No. 219237 to engage in the commercial manufacture, use, sale, or offer for sale within the United States, and/or importation into the United States, of Gland's ANDA Products prior to the expiration of the '227 patent.

20. On information and belief, Gland's ANDA Products meet or embody all steps of one or more claims of the '227 patent.

21. Gland seeks FDA approval to market an epoprostenol sodium for injection drug product, 1.5 mg/vial (hereinafter, "Gland's 1.5 mg/vial ANDA Product").

22. Gland's 1.5 mg/vial ANDA Product is an epoprostenol composition.

23. Gland's 1.5 mg/vial ANDA Product contains an agent that provides an alkaline environment (pH > 7) when epoprostenol is dissolved in water along with the agent.

24. On information and belief, Gland's manufacturing process for its 1.5 mg/vial ANDA Product includes the step of providing a bulk solution that includes epoprostenol or a salt thereof and an agent that provides an alkaline environment (pH > 7) when epoprostenol is dissolved in water along with the agent.

25. On information and belief, Gland's manufacturing process for its 1.5 mg/vial ANDA Product includes the steps of adjusting to greater than 13 the pH of the bulk solution and lyophilizing the bulk solution.

26. Gland seeks FDA approval to market an epoprostenol sodium for injection drug product, 0.5 mg/vial (hereinafter, "Gland's 0.5 mg/vial ANDA Product").

27. Gland's 0.5 mg/vial ANDA Product is an epoprostenol composition.

28. Gland's 0.5 mg/vial ANDA Product contains an agent that provides an alkaline environment (pH > 7) when epoprostenol is dissolved in water along with the agent.

29. On information and belief, Gland's manufacturing process for its 0.5 mg/vial ANDA Product includes the step of providing a bulk solution that includes epoprostenol or a salt thereof and an agent that provides an alkaline environment (pH > 7) when epoprostenol is dissolved in water along with the agent.

30. On information and belief, Gland's manufacturing process for its 0.5 mg/vial ANDA Product includes the steps of adjusting to greater than 13 the pH of the bulk solution and lyophilizing the bulk solution.

31. Upon information and belief, Gland has made, and will continue to make, substantial preparations to manufacture, use, offer to sell, sell, or distribute in the United States, and/or import into the United States, Gland's ANDA Products prior to expiration of the '227 patent, or to induce or to contribute to such conduct.

32. Upon information and belief, Gland intends to, and will, engage in the commercial manufacture, use, offer for sale, or sale, within the United States, and/or importation into the United States, of Gland's ANDA Products, or induce or contribute to such conduct, upon receipt of final FDA approval of ANDA No. 219237.

33. If Gland manufactures, uses, offers to sell, or sells within the United States, or imports into the United States, Gland's ANDA Products prior to the expiration of the '227 patent, or induces or contributes to such conduct, Gland will infringe one or more claims of the '227 patent. Actelion therefore is entitled to a declaration that, if Gland commercially manufactures, uses, offers for sale, or sells Gland's ANDA Products within the United States, imports Gland's ANDA Products into the United States, or induces or contributes to such conduct, Gland will infringe the '227 patent, and an order that the effective date of the approval of Gland's ANDA be a date that is not earlier than the expiration date of the '227 patent, or any later expiration of any patent term extension or exclusivity for the '227 patent to which Actelion is or becomes entitled.

34. Actelion will be irreparably harmed by Gland's infringing activities unless those activities are enjoined by this Court. Plaintiff does not have an adequate remedy at law.

PRAYER FOR RELIEF

Actelion requests that the Court grant the following relief:

A. A judgment declaring that the commercial manufacture, use, offer for sale, sale or importation of Gland's ANDA Products prior to their expiration of the patent-in-suit, will infringe, induce the infringement of, and/or contribute to the infringement by others of, that patent;

B. A permanent injunction restraining and enjoining Gland, its affiliates, subsidiaries, successors, and each of its directors, officers, agents, attorneys, and employees, and those acting in concert with Gland, from infringing the '227 patent by the commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any pharmaceutical product claimed in the '227 patent;

C. An order decreeing that the effective date of any approval of ANDA No. 219237 be a date that is not earlier than the expiration date of the '227 patent, or any later expiration of

any patent term extension or exclusivity for the aforementioned patent to which Actelion is or becomes entitled;

D. An award of monetary relief to the extent Gland commercially manufactures, uses, offers for sale, or sells within the United States, or imports into the United States any product that infringes or induces or contributes to the infringement of the '227 patent prior to the expiration of the '227 patent, including any later expiration of any patent term extension or exclusivity for the patent to which Actelion is or becomes entitled, and that any such monetary relief be awarded to Actelion with prejudgment interest;

E. An award of costs; and

F. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP

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April 5, 2024