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UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

MEDICURE INTERNATIONAL, INC.,	)	
	)	
Plaintiff,	)	
	)	C.A. No. _____
v.	)	
	)	*Document Filed Electronically*
GLAND PHARMA LTD.,	)	
	)	
Defendant.	)	

COMPLAINT

Plaintiff Medicure International, Inc. ("Medicure" or "Plaintiff") by its undersigned attorneys, for its Complaint against defendant Gland Pharma Ltd. ("Gland" or "Defendant") herein, allege as follows:

NATURE OF THE ACTION

1. This is a civil action for patent infringement arising under the patent laws of the United States, Title 35 of the United States Code, involving U.S. Patent No. 6,770,660 ("the '660 patent" or "the patent in suit"), attached hereto as Exhibit A.

THE PARTIES

2. Medicure is a corporation organized and existing under the laws of the country of Barbados, having its principal place of business at 1st Floor, Limegrove Centre, Holetown, St. James, Barbados. Medicure is a wholly-owned subsidiary of Medicure Inc., which is a publicly traded company having its principal place of business at 2-1250 Waverley Street, Winnipeg, Manitoba, Canada.

3. Upon information and belief, Gland is a corporation organized and existing under the laws of India, having its principal place of business in Hyderabad, India.

4. Upon information and belief, Gland is in the business of, among other things, the development, manufacture, marketing, sale, and distribution of generic pharmaceutical products throughout the United States, including in New Jersey.

5. Upon information and belief, Gland derives substantial revenue from the sale of generic pharmaceutical products in the United States and New Jersey.

JURISDICTION AND VENUE

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

7. This Court has personal jurisdiction over Gland at least because, upon information and belief, Gland is the current owner of Abbreviated New Drug Application (ANDA) No. 206888 ("Gland's ANDA") and is seeking final approval of that ANDA to engage in the commercial use, sale, and/or distribution of generic tirofiban hydrochloride injection premixed,

12.5 mg/250 ml (50 mcg/mL) ("Gland's ANDA Product") throughout the United States, including in New Jersey, before the expiration of the '660 patent.

8. This Court has personal jurisdiction over Gland at least because, upon information and belief, if Gland's ANDA receives final approval, Gland's ANDA Product will be manufactured, sold, distributed, and/or used by Gland in New Jersey; prescribed by physicians practicing in New Jersey; and/or administered to patients in New Jersey.

9. This Court has personal jurisdiction over Gland at least because Gland's ANDA was amended to include a paragraph-IV certification to the '660 patent and Gland sent notice of the paragraph-IV certification to, among other locations, an address in New Jersey.

10. This Court has personal jurisdiction over Gland at least because, upon information and belief, Gland manufactures generic pharmaceutical products that are imported into and distributed throughout the United States—including in New Jersey—and, thus, Gland has availed itself of the privileges and benefits of the laws and commerce of New Jersey. *See* Gland Pharma Ltd.'s Answer ¶ 13, *Novartis Pharms. Corp. v. Actavis LLC*, No. 13-1028 (D.N.J. May 15, 2013), ECF No. 241 (admitting that Gland "manufactures products that are sold throughout the United States, including in New Jersey").

11. This Court has personal jurisdiction over Gland at least because, upon information and belief, Gland regularly does or solicits business in New Jersey, engages in other persistent courses of conduct in New Jersey, and/or derives substantial revenue from services or things used or consumed in New Jersey, thereby demonstrating that Gland has continuous and systematic contacts with New Jersey.

12. This Court has personal jurisdiction over Gland at least because Gland has previously submitted to the jurisdiction of this Court and has availed itself of New Jersey's legal

protections in at least three prior litigations. *See Novartis Pharma Corp. v. Gland Pharma Ltd.*, No. 14-1841 (D.N.J. filed Mar. 21, 2014); *Novartis Pharms. Corp. v. Actavis LLC*, No. 13-1028 (D.N.J. filed Feb. 20, 2013); *Novartis Pharma Corp. v. Wockhardt USA LLC*, No. 12-3967 (D.N.J. filed June 27, 2012).

13. This Court has personal jurisdiction over Gland at least because Gland has previously invoked this Court's jurisdiction by asserting counterclaims in at least two prior litigations. *See Novartis Pharms. Corp. v. Actavis LLC*, No. 13-1028 (D.N.J. filed Feb. 20, 2013); *Novartis Pharma Corp. v. Wockhardt USA LLC*, No. 12-3967 (D.N.J. filed June 27, 2012).

14. Federal venue rules do not restrict the locations in which alien corporations, like Gland, may be sued. *In re HTC Corp.*, 889 F.3d 1349, 1354–61 (Fed. Cir. 2018) (citing *TC Heartland LLC v. Kraft Foods Grp. Brands LLC*, 137 S. Ct. 1514 (2017); *Brunette Mach. Works, Ltd. v. Kockum Indus., Inc.*, 406 U.S. 706 (1972); and *In re Hohorst*, 150 U.S. 653 (1893)). For that reason, venue is proper in this Court.

15. Venue is otherwise proper in this Court under 28 U.S.C. § 1400(b).

BACKGROUND

16. Medicure is the owner of New Drug Application (NDA) No. 020913, which was approved by the U.S. Food and Drug Administration (FDA) for the manufacture and sale of tirofiban hydrochloride injection for intravenous use. Tirofiban hydrochloride is a platelet aggregation inhibitor. Medicure markets its tirofiban products under the trade name Aggrastat®.

17. NDA No. 020913 pertains to Aggrastat®'s 250 mL bag presentation, which has an active ingredient concentration of 50 µg/mL.

18. Aggrastat® is indicated to reduce the rate of thrombotic cardiovascular events (combined endpoint of death, myocardial infarction, or refractory ischemia/repeat cardiac procedure) in patients with non-ST elevation acute coronary syndrome (NSTE-ACS).

19. Aggrastat®'s recommended dosage is 25 mcg/kg administered intravenously within 5 minutes and then 0.15 mcg/kg/min for up to 18 hours.

20. The '660 patent, titled "Method for Inhibiting Platelet Aggregation," was duly and legally issued by the U.S. Patent and Trademark Office on August 3, 2004. The '660 patent was subsequently assigned to Medicure.

21. Pursuant to 21 U.S.C. § 355(b)(1), the '660 patent was submitted to FDA with NDA No. 020913. The '660 patent was subsequently listed in FDA's publication titled "Approved Drug Products with Therapeutic Equivalence Evaluations" (commonly known as the Orange Book) as covering Aggrastat®.

FIRST COUNT
(Gland's Infringement of the '660 Patent)

22. Medicure repeats and re-alleges each of the foregoing paragraphs as if fully set forth herein.

23. Upon information and belief, Gland prepared Gland's ANDA.

24. Gland submitted Gland's ANDA to FDA pursuant to § 505(j) of the Federal Food, Drug, and Cosmetic Act ("FDCA") (codified at 21 U.S.C. § 355(j)). Gland's ANDA seeks FDA approval to market Gland's ANDA Product. Gland's ANDA is based upon Aggrastat® injection, 12.5 mg/250 mL (50 µg/mL), as its reference listed drug (RLD).

25. On January 31, 2017, FDA tentatively approved Gland's ANDA, pending the expiration of Aggrastat®'s Orange-Book-listed patents, including U.S. Patent No. 6,136,794 and the '660 patent.

26. Gland subsequently amended Gland's ANDA to include a paragraph IV certification to the '660 patent to obtain approval to engage in the commercial manufacture, use, sale, offering for sale, and/or importation of Gland's ANDA Product before the expiration of the '660 patent.

27. Under 35 U.S.C. § 271(e)(2)(A), Gland's submission of Gland's ANDA with a paragraph IV certification to the '660 patent for the purpose of obtaining approval to engage in the commercial manufacture, use, or sale of Gland's ANDA Product before the expiration of the '660 patent is itself an act of infringement of the '660 patent.

28. Under 21 U.S.C. § 355(j)(2)(B), the filer of an ANDA containing a paragraph IV certification must provide notice of the filing to each patent owner and each NDA holder. Under 21 U.S.C. § 355(j)(2)(B)(iv)(II), such notice must "include a detailed statement of the factual and legal basis of the opinion of the applicant that the patent is invalid or will not be infringed." Likewise, 21 C.F.R. § 314.95(c)(7) requires that such notice include a "detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid, unenforceable, or will not be infringed." The detailed statement must include: "For each claim of a patent alleged not to be infringed, a full and detailed explanation of why the claim is not infringed" and "For each claim of a patent alleged to be invalid or unenforceable, a full and detailed explanation of the ground supporting the allegation." 21 C.F.R. § 314.95(c)(7)(i)–(ii).

29. Upon information and belief, as of the date of Gland's Notice Letter, Gland was aware of the statutory provisions and regulations set out in 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7).

30. Purportedly in accordance with 21 U.S.C. § 355(j)(2)(B)(iv) and 21 C.F.R. § 314.95(d)(1), Gland sent a copy of the required notice ("Gland's Notice Letter") to Medicure

International, Inc. at 1st Floor, Limegrove Centre, Holetown, St. James, Barbados and at 2-1250 Waverley St., Winnipeg MB R3T 6C6, Canada; and another copy of Gland's Notice Letter to Medicure Pharma, Inc. at 116 Village Blvd., Suite 200, Princeton, N.J. 08540.

31. Gland's Notice Letter does not include any allegation that a physician and/or caretaker using Gland's ANDA product will not directly infringe the '660 patent's claims.

32. Gland's Notice Letter does not include any allegation that Gland will not indirectly infringe the '660 patent's claims.

33. Upon information and belief, Gland will commercially manufacture, use, offer to sell, and/or sell within the United States, and/or import into the United States Gland's ANDA Product upon receiving final FDA approval.

34. Upon information and belief, Gland's ANDA Product will have the same indication(s) as Aggrastat®.

35. Upon information and belief, the prescribing information for Gland's ANDA Product will recommend the same dosage or dosages as Aggrastat®.

36. Upon information and belief, administering Gland's ANDA Product, will be used to inhibit platelet aggregation in a patient in need thereof.

37. Upon information and belief, administering Gland's ANDA Product, will be used to reduce the risk of acute coronary syndrome in a patient at risk to acute coronary syndrome.

38. Upon information and belief, the prescribing information for Gland's ANDA Product will recommend (1) administering to a patient a bolus injection of the active drug, in an amount of about 25 μg/kg, and (2) administering to the patient, after the bolus injection, an intravenous infusion for a period of between about 12 hours and about 72 hours, of the active drug, in an amount of about 0.15 μg/kg/min.

39. Upon information and belief, Gland's commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States of Gland's ANDA Product would infringe, directly and/or indirectly, one or more of the '660 patent's claims under 35 U.S.C. § 271.

40. Upon information and belief, Gland's commercial offering for sale and/or sale of Gland's ANDA Product would induce and/or contribute to third-party infringement of one or more claims of the '660 patent under 35 U.S.C. § 271.

41. At least by the time it filed a paragraph-IV certification against the '660 patent, Gland was aware of that patent's existence and, upon information and belief, acted without a reasonable basis for believing that it would not be liable for infringement of the '660 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

42. The acts of infringement set forth above will cause Medicure irreparable harm for which there is no adequate remedy at law, unless Gland is preliminarily and permanently enjoined by this Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests the following relief:

(A) A judgment declaring that the '660 patent is valid and enforceable;

(B) A judgment, pursuant to 35 U.S.C. § 271(e)(2)(A), declaring that Gland infringed the '660 patent by submitting to FDA Gland's ANDA with a paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, or sale of Gland's ANDA Product before the expiration of the '660 patent;

(C) A judgment, pursuant to 35 U.S.C. § 271(a), (b), and/or (c), declaring that the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of Gland's ANDA Product before the expiration of the '660

patent (including any regulatory extension), would directly and/or indirectly infringe the '660 patent;

(D) An order, pursuant to 35 U.S.C. § 271(e)(4)(A), § 281, and § 283, that the effective date of any final approval of Gland's ANDA shall be no earlier than the date on which the '660 patent expires (including any regulatory extension);

(E) An order, pursuant to 35 U.S.C. § 271(e)(4)(B), § 281, and § 283, preliminarily and permanently enjoining Gland, its officers, agents, servants, employees, attorneys, and any person in active concert or participation or privy with Gland, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the United States of Gland's ANDA Product until the expiration of the '660 patent (including any regulatory extension);

(F) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, awarding Medicure damages or other monetary relief if Gland commercially manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States any product that is the subject of Gland's ANDA, prior to the expiration of the '660 patent (including any regulatory extension);

(G) A judgment, pursuant to 35 U.S.C. § 271(e)(4)(C) and § 284, declaring that Gland's infringement of the '660 patent is willful and awarding Medicure enhanced damages if Gland commercially manufactures, uses, offers to sell, or sells within the United States, and/or imports into the United States any product that is the subject of Gland's ANDA, prior to the expiration of the '660 patent (including any regulatory extension);

(H) A judgment, pursuant to 35 U.S.C. § 285, declaring that this is an exceptional case and awarding Medicure its attorneys' fees and costs;

(I) Such other and further relief as this Court may deem just and proper.

Dated: November 16, 2018

Respectfully submitted,

SAIBER LLC

Attorneys for Plaintiff
Medicure International, Inc.

By: /s/ Arnold B. Calmann

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LOCAL CIVIL RULE 11.2 CERTIFICATION

Under Local Civil Rule 11.2, the undersigned counsel for Plaintiff Medicure International, Inc. hereby certifies that this matter is not the subject of any other action in any other court, or of any pending arbitration or administrative proceeding.

Dated: November 16, 2018

s/ Arnold B. Calmann
Arnold B. Calmann

LOCAL CIVIL RULE 201.1 CERTIFICATION

Under Local Civil Rule 201.1, the undersigned counsel for Plaintiff Medicure International, Inc. hereby certifies that Plaintiff seeks injunctive relief and therefore, this action is not appropriate for compulsory arbitration.

Dated: November 16, 2018

s/ Arnold B. Calmann
Arnold B. Calmann