UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

MEDICURE INTERNATIONAL, INC.,	)	
	)	
Plaintiff,	)	
	)	C.A. No. _____
v.	)	
	)	*Document Filed Electronically*
NEXUS PHARMACEUTICALS, INC.,	)	
	)	
Defendant.	)	

COMPLAINT

Plaintiff Medicure International, Inc. ("Medicure" or "Plaintiff") by its undersigned attorneys, for its Complaint against defendant Nexus Pharmaceuticals, Inc. ("Nexus" 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, Nexus is a corporation organized and existing under the laws of the State of Illinois, having its principal place of business at 400 Knightsbridge Parkway, Lincolnshire, Illinois.

4. Upon information and belief, Nexus 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 Illinois.

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

JURISDICTION AND VENUE

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

7. In a letter to Medicure dated October 22, 2019, Nexus represented that "Nexus will not object to the personal jurisdiction in the Illinois courts."

8. This Court has personal jurisdiction over Nexus at least because, upon information and belief, Nexus is incorporated in Illinois; has its principal place of business in Lincolnshire, Illinois; regularly does or solicits business in Illinois; engages in other persistent courses of conduct in Illinois; and/or derives substantial revenue from services or things used or consumed in Illinois; thereby demonstrating that Nexus has continuous and systematic contacts with Illinois.

9. This Court has personal jurisdiction over Nexus at least because, upon information and belief, Nexus is the current owner of Abbreviated New Drug Application (ANDA) No. 213947 ("Nexus'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, 5 mg/100 mL and 12.5 mg/250 mL (50 mcg/mL) ("Nexus's ANDA Product") throughout the United States, including in Illinois, before the expiration of the '660 patent.

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

11. This Court has personal jurisdiction over Nexus at least because, upon information and belief, Nexus submitted its ANDA to the U.S. Food and Drug Administration (FDA) from Illinois.

12. Venue is proper in this district under 28 U.S.C. §§ 1391(b) and (c) and 1400(b).

BACKGROUND

13. Medicure is the owner of New Drug Application (NDA) No. 020913, which was approved by 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®.

14. NDA No. 020913 pertains to Aggrastat®'s 100 mL and 250 mL presentations, which have an active ingredient concentration of 50 μg/mL.

15. 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).

16. 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.

17. 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. Medicure is currently the sole assignee and owner of all right, title and interest in and to the '660 patent.

18. 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
(Nexus's Infringement of the '660 Patent)

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

20. Upon information and belief, Nexus prepared Nexus's ANDA.

21. Nexus submitted Nexus'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)). Nexus's ANDA seeks FDA approval to market Nexus's ANDA Product. Nexus's ANDA is based upon Aggrastat® injection, 5 mg/100 mL and 12.5 mg/250 mL (50 µg/mL), as its reference listed drug (RLD).

22. Nexus's ANDA includes a certification, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) ("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 Nexus's ANDA Product before the expiration of the '660 patent.

23. Upon information and belief, Nexus intends to obtain final FDA approval of Nexus's ANDA.

24. Upon information and belief, Nexus intends to obtain final FDA approval of Nexus's ANDA in about April 2022 or earlier.

25. Upon information and belief, Nexus is working towards obtaining final FDA approval of Nexus's ANDA in about April 2022 or earlier.

26. Upon information and belief, Nexus's ANDA contains proposed Prescribing Information.

27. Upon information and belief, the proposed Prescribing Information for Nexus's ANDA Product contains sections titled Indications and Usage, Dosage and Administration, and Dosage Forms and Strengths.

28. Upon information and belief, Nexus's ANDA contains a section titled Quality Overall Summary (QOS).

29. Upon information and belief, the QOS section of Nexus's ANDA includes, among other things, a list of the components of Nexus's ANDA Product and a comparison between Aggrastat® and Nexus's ANDA Product.

30. Upon information and belief, the QOS section of Nexus's ANDA provides a history of the development of Nexus's ANDA Product, including any alternate formulations that Nexus considered but did not select as the final formulation of Nexus's ANDA Product along with reasons why those alternate formulations were not selected.

31. Upon information and belief, Nexus's ANDA includes a biowaiver request.

32. Upon information and belief, Nexus's ANDA requests that FDA approve Nexus's ANDA without requiring Nexus to demonstrate bioequivalence between Nexus's ANDA Product and Aggrastat®.

33. Upon information and belief, Nexus and FDA have corresponded about Nexus's ANDA.

34. Upon information and belief, Nexus and FDA have corresponded regarding deficiencies in Nexus's ANDA.

35. Upon information and belief, Nexus and FDA have corresponded regarding reasons it has not approved Nexus's ANDA.

36. Under 35 U.S.C. § 271(e)(2)(A), Nexus's submission of Nexus'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 Nexus's ANDA Product before the expiration of the '660 patent is itself an act of infringement of the '660 patent.

37. 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).

38. Nexus sent a copy of the required notice ("Nexus's Notice Letter") to Medicure International, Inc. at 1st Floor, Limegrove Centre, Holetown, St. James, Barbados; to Medicure Inc. at 2-1250 Waverley Street, Winnipeg, Manitoba, Canada R3T 6C6; and another copy to Medicure Pharma, Inc. at 116 Village Blvd., Suite 200, Princeton, New Jersey.

39. Upon information and belief, as of the date of Nexus's Notice Letter, Nexus 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).

40. Nexus's Notice Letter does not include any allegation that a physician using Nexus's ANDA product will not directly infringe the '660 patent's claims.

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

42. Upon information and belief, Nexus's ANDA Product will contain the active ingredient tirofiban hydrochloride.

43. Tirofiban hydrochloride is a pharmaceutically acceptable salt of tirofiban.

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

45. Upon information and belief, the proposed Prescribing Information for Nexus's ANDA Product includes the same recommended dosage as Aggrastat®.

46. Upon information and belief, the proposed Prescribing Information for Nexus's ANDA Product recommends a dosage of 25 mcg/kg administered intravenously within 5 minutes and then 0.15 mcg/kg/min for up to 18 hours.

47. Upon information and belief, the proposed Prescribing Information for Nexus's ANDA Product includes the same dose adjustment for renal impairment as Aggrastat®.

48. Upon information and belief, the proposed Prescribing Information for Nexus's ANDA Product recommends a dosage in patients with CrCl ≤ 60 mL/min (calculated using the

Cockcroft-Gault equation with actual body weight) of 25 mcg/kg intravenously within 5 minutes and then 0.075 mcg/kg/min, for up to 18 hours.

49. Upon information and belief, the proposed Prescribing Information for Nexus's ANDA Product does not include any recommended dosages or dose adjustments other than those described in ¶¶ 45–48, *supra*.

50. Upon information and belief, physicians will follow the proposed Prescribing Information for Nexus's ANDA Product when administering Nexus's ANDA Product 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).

51. Upon information and belief, administering Nexus's ANDA Product to a patient will inhibit platelet aggregation in that patient.

52. Upon information and belief, administering Nexus's ANDA Product to a patient at risk to acute coronary syndrome will reduce the risk of acute coronary syndrome in that patient.

53. Upon information and belief, the proposed Prescribing Information for Nexus's ANDA Product will recommend to physicians (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.

54. Upon information and belief, Nexus's commercial manufacture, use, offering to sell and/or sale within the United States, and/or importation into the United States of Nexus's

ANDA Product would infringe, literally and/or under the doctrine of equivalents, one or more of the ’660 patent’s claims under 35 U.S.C. § 271.

55. Upon information and belief, Nexus’s activities with respect to Nexus’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.

56. At least by the time it filed a Paragraph IV certification against the ’660 patent, Nexus was aware that the ’660 patent existed.

57. At least by the time it filed a Paragraph IV certification against the ’660 patent, Nexus, upon information and belief, possessed the specific intent to encourage physicians to infringe the ’660 patent.

58. At least by the time it filed a Paragraph IV certification against the ’660 patent, Nexus, upon information and belief, knew that physicians who acted according to the proposed Prescribing Information for Nexus’s ANDA Product would infringe the ’660 patent.

59. At least by the time it filed a Paragraph IV certification against the ’660 patent, Nexus, upon information and belief, knew that Nexus’s ANDA Product was not a staple article or commodity of commerce suitable for substantial noninfringing use.

60. At least by the time it filed a Paragraph IV certification against the ’660 patent, Nexus, upon information and belief, believed there was a high probability that physicians who acted according to the proposed Prescribing Information for Nexus’s ANDA Product would infringe the ’660 patent. Nexus, upon information and belief, has taken deliberate steps to avoid learning of that infringement.

61. At least by the time it filed a Paragraph IV certification against the ’660 patent, Nexus, 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.

62. The acts of infringement set forth above will cause Medicure irreparable harm for which there is no adequate remedy at law, unless Nexus 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 Nexus infringed the '660 patent by submitting to FDA Nexus's ANDA with a Paragraph IV certification for the purpose of obtaining approval for the commercial manufacture, use, or sale of Nexus'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 Nexus'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 Nexus'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 Nexus, its officers, agents, servants, employees, attorneys, and any person in active concert or participation or privy with Nexus, from engaging in the commercial manufacture, use, offering to sell, or sale within the United States, and/or importation into the

United States of Nexus'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 Nexus 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 Nexus's ANDA, before 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 Nexus's infringement of the '660 patent is willful and awarding Medicure enhanced damages if Nexus 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 Nexus's ANDA, before 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: December 5, 2019

Respectfully submitted,

By: */s/ Robert F. Green*

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