THE UNITED STATES DISTRICT COURT FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

ASTELLAS US LLC; ASTELLAS PHARMA US, INC.; and GILEAD SCIENCES, INC. Plaintiffs, v. MYLAN PHARMACEUTICALS INC., Defendant.	C.A. No. **1:21-CV-32 (Kleeh)**

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Astellas US LLC and Astellas Pharma US, Inc. (collectively, "Astellas") and Gilead Sciences, Inc. ("Gilead") (Astellas and Gilead, collectively, "Plaintiffs"), by their attorneys, hereby allege as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, against Defendant Mylan Pharmaceuticals Inc. ("Mylan"). This action relates to Abbreviated New Drug Application ("ANDA") No. 213856 filed by Mylan with the U.S. Food and Drug Administration ("FDA").

2. In ANDA No. 213856, Mylan seeks approval to market 0.4 mg/5 mL (0.08 mg/mL) intravenous solution of regadenoson, a generic version of Plaintiffs' Lexiscan® drug product (the "Mylan ANDA product"), prior to expiration of U.S. Patent Nos. 8,106,183 (the "'183 patent"), RE 47,301 (the "'301 patent"), and 8,524,883 (the "'883 patent"). The '183 patent, '301 patent, and '883 patent are collectively referred to herein as the "patents-in-suit."

PARTIES

3. Astellas US LLC is a limited liability company organized and existing under the laws of the State of Delaware having its principal place of business at 1 Astellas Way, Northbrook, IL 60062.

4. Astellas Pharma US, Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 1 Astellas Way, Northbrook, IL 60062.

5. Gilead is a corporation organized and existing under the laws of Delaware, having its principal place of business at 333 Lakeside Drive, Foster City, CA 94404.

6. Plaintiffs are engaged in the business of creating, developing, and bringing to market revolutionary pharmaceutical products to help patients prevail against serious diseases, including diagnostic pharmacologic stress agents. Plaintiffs sell Lexiscan in this judicial district and throughout the United States.

7. Upon information and belief, Mylan is a corporation organized and existing under the laws of West Virginia, having its principal place of business at 781 Chestnut Ridge Road, Morgantown, WV, 26505.

JURISDICTION AND VENUE

8. This case arises under the patent laws of the United States, 35 U.S.C. §§ 100, *et seq.*, and this Court has jurisdiction over its subject matter under 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

9. On information and belief, Mylan has submitted, caused to be submitted, or aided and abetted in the preparation of Mylan's ANDA No. 213856. On information and belief, upon FDA approval of Mylan's ANDA No. 213856, Mylan intends to commercially manufacture, use, import, market, offer for sale, and/or sell Mylan's Proposed Product throughout the United States including in this district, prior to the expiration of the patents-in-suit.

10. This Court has personal jurisdiction over Mylan because of, among other things, its systematic and continuous contacts with the state of West Virginia. On information and belief, Mylan is a corporation organized and existing under the laws of West Virginia and has its principal place of business in West Virginia. On information and belief, Mylan regularly and continuously transacts business within West Virginia, including by making and selling pharmaceutical products in West Virginia. On information and belief, Mylan derives substantial revenue from the sale of those products in West Virginia and has availed itself of the privilege of conducting business within West Virginia. On information and belief, Mylan derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this judicial district.

11. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b), including because, among other things, Mylan is subject to personal jurisdiction in this judicial district, as set forth above; resides in this judicial district because it is organized under the laws of West Virginia and has its principal place of business in this judicial district; and has a regular and established place of business in this judicial district and has committed acts of infringement and, upon information and belief, will commit further acts of infringement in this judicial district.

12. By email dated February 9, 2021, Mylan's counsel agreed to accept service of a complaint related to a patent infringement action concerning Mylan's ANDA No. 213856 in West Virginia.

PATENTS-IN-SUIT

13. On January 31, 2012, the U.S. Patent and Trademark Office duly and legally issued the '183 patent, titled "Process for preparing an A_{2A}-adenosine receptor agonist and its polymorphs." A true and correct copy of the '183 patent is attached hereto as Exhibit A. The claims of the '183 patent are valid, enforceable, and not expired. Gilead is the owner of the '183 patent, and Astellas US LLC is the exclusive licensee of the '183 patent.

14. On March 19, 2019, the United States Patent and Trademark Office duly and legally issued the '301 patent, titled "Process for preparing an A_{2A}-adenosine receptor agonist and its polymorphs." The '301 patent is a reissue of U.S. Patent No. 9,085,601 (the "'601 patent"), which issued on July 21, 2015. A true and correct copy of the '301 patent is attached hereto as Exhibit B. The claims of the '301 patent are valid, enforceable, and not expired. Gilead is the owner of the '301 patent, and Astellas US LLC is the exclusive licensee of the '301 patent.

15. On September 3, 2013, the United States Patent and Trademark Office duly and legally issued the '883 patent, titled "Monohydrate of (1-{9-[4S,2R,3R,5R)-3,4-dihydroxy-5-(hydroxymethyl)oxolan-2-yl]-6-aminopurin-2-yl}pyrazol-4-yl)-N-methylcarboxamide." A true and correct copy of the '883 patent is attached hereto as Exhibit C. The claims of the '883 patent are valid, enforceable, and not expired. Gilead is the owner of the '883 patent, and Astellas US LLC is the exclusive licensee of the '883 patent.

16. Astellas Pharma US, Inc. is the holder of New Drug Application ("NDA") No. 022161, by which the FDA granted approval for the marketing and sale of 0.4 mg/5 mL (0.08 mg/mL) intravenous solution of regadenoson. Plaintiffs market 0.4 mg/5 mL (0.08 mg/mL) intravenous solution of regadenoson in the United States, under the trade name "Lexiscan®." The FDA's official publication of approved drugs (the "Orange Book") includes Lexiscan together with the '183 and '301 patents. Lexiscan is a pharmacologic agent used in a cardiac nuclear stress test. Lexiscan works by increasing blood flow in the coronary arteries. Lexiscan is given prior to a myocardial perfusion imaging (MPI) test, which provides physicians with detailed information about blood flow into a patient's heart. Approximately half of the people undergoing a cardiac stress test are unable to use a treadmill or a stationary bicycle because of medical conditions.

Lexiscan may be used when a person is unable to exercise enough to increase blood flow to the heart during a cardiac nuclear stress test.

17. The prescribing information for Lexiscan identifies the drug as "a pharmacologic stress agent indicated for radionuclide myocardial perfusion imaging (MPI) in patients unable to undergo adequate exercise stress." A copy of the complete prescribing information for Lexiscan approved in NDA No. 022161 is attached as Exhibit D.

18. The '883 patent claims processes for preparing a pharmaceutical composition of regadenoson with at least one pharmaceutically acceptable carrier.

INFRINGEMENT BY MYLAN

19. By a letter dated January 21, 2021, Mylan notified Plaintiffs that Mylan had submitted ANDA No. 213856 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)) ("the Lexiscan Notice Letter").

20. The Lexiscan Notice Letter states that Mylan has submitted an ANDA under 21 U.S.C. § 355(j) to engage in the commercial manufacture, use, importation, offer for sale, or sale of the Mylan ANDA product before the expiration of the '183 and '301 patents. Upon information and belief, Mylan intends to—directly or indirectly—engage in the commercial manufacture, use, and sale of the Mylan ANDA product.

21. By filing ANDA No. 213856, Mylan has necessarily represented to the FDA that the Mylan ANDA product has the same active ingredient as Lexiscan, has the same dosage form and strength as Lexiscan, and is bioequivalent to Lexiscan.

22. Upon information and belief, Mylan is seeking approval to market the Mylan ANDA product for the same approved indication as Lexiscan.

23. In the Lexiscan Notice Letter, Mylan stated that the '183 and '301 patents are invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, and sale of the Mylan ANDA product.

24. In the Lexiscan Notice Letter, Mylan offered confidential access to portions of its ANDA No. 213856, on terms and conditions set forth in the Lexiscan Notice Letter ("the Mylan Offer"). Mylan requested that Plaintiffs accept the Mylan Offer before receiving access to Mylan's ANDA No. 213856. The Mylan Offer contained unreasonable restrictions well beyond those that would apply under a protective order on who could view the ANDA. For example, the Mylan Offer contained a broad patent prosecution bar, which, among other things, does not have a carve out for post-grant proceedings. The Mylan Offer unreasonably restricted the ability of counsel to seek the opinions of Plaintiffs' employees and outside experts. The restrictions Mylan has placed on access to ANDA No. 213856 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***" (emphasis added).

25. Upon information and belief, Mylan uses processes covered by the claims of the '883 patent to prepare Mylan's ANDA product.

26. Upon information and belief, the product resulting from the process claimed in the '883 patent is made, used, offered for sale, and/or sold without material change to the product resulting from the process claimed by the '883 patent.

27. The product resulting from the process claimed by the '883 patent is not a nonessential and/or trivial component of another product.

28. Upon information and belief, Mylan intends to import into the United States and/or offer to sell, sell, make, and/or use within the United States the Mylan ANDA product, which is made by the process patented by the '883 patent, prior to the expiration of the '883 patent.

29. Upon information and belief, Mylan has made and will continue to make substantial and meaningful preparations to practice the method claimed in the '883 patent and/or import, offer to sell, sell, make, and/or use within the United States its ANDA product, which is made by the process covered by the '883 patent, prior to the expiration of the '883 patent. Mylan's preparations include, but are not limited to, developing Mylan's generic product and filing ANDA No. 213856.

30. Upon information and belief, Mylan plans to continue to use the processes claimed in the '883 patent to make its ANDA product.

31. Upon information and belief, Mylan had actual and/or constructive notice of the '883 patent prior to filing ANDA No. 213856.

COUNT I

(INFRINGEMENT OF THE '183 PATENT)

32. Each of the preceding paragraphs 1 to 31 is incorporated as if fully set forth herein.

33. Mylan's submission of ANDA No. 213856 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Mylan ANDA product prior to the expiration of the '183 patent constituted a technical act of infringement of at least one of the claims of the '183 patent, either literally or under the doctrine of equivalents, including but not limited to claims 1-3 and 8-9, under 35 U.S.C. § 271(e)(2)(A).

34. Mylan's commercial manufacture, use, offer to sell, sale, or importation of the Mylan ANDA product prior to the expiration of the '183 patent, and its inducement of and/or contribution to such conduct, would further infringe at least one of the claims of the '183 patent,

either literally or under the doctrine of equivalents, including at least claims 1-3 and 8-9, under 35 U.S.C. §§ 271(a), (b), (c) and/or (g).

35. Upon FDA approval of Mylan's ANDA No. 213856, Mylan will infringe one or more claims of the '183 patent, either literally or under the doctrine of equivalents, including at least claims 1-3 and 8-9, by making, using, offering to sell, and selling the Mylan ANDA product in the United States and/or importing said product into the United States, and/or by actively inducing and contributing to infringement of the '183 patent by others, under 35 U.S.C. § 271(a), (b), (c) and/or (g), unless enjoined by the Court.

36. If Mylan's marketing and sale of the Mylan ANDA product prior to expiration of the '183 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT II

(INFRINGEMENT OF THE '301 PATENT)

37. Each of the preceding paragraphs 1 to 36 is incorporated as if fully set forth herein.

38. Mylan's submission of ANDA No. 213856 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Mylan ANDA product prior to the expiration of the '301 patent constituted a technical act of infringement of at least one of the claims of the '301 patent, either literally or under the doctrine of equivalents, including but not limited to claims 6 and 17, under 35 U.S.C. § 271(e)(2)(A).

39. Mylan's commercial manufacture, use, offer to sell, sale, or importation of the Mylan ANDA product prior to the expiration of the '301 patent, and its inducement of and/or contribution to such conduct, would further infringe at least one of the claims of the '301 patent, either literally or under the doctrine of equivalents, including but not limited to claims 6 and 17, under 35 U.S.C. § 271(a), (b), (c) and/or (g).

40. Upon FDA approval of Mylan's ANDA No. 213856, Mylan will infringe one or more claims of the '301 patent, either literally or under the doctrine of equivalents, including but not limited to claims 6 and 17, by making, using, offering to sell, and selling the Mylan ANDA product in the United States and/or importing said product into the United States, and/or by actively inducing and contributing to infringement of the '301 patent by others, under 35 U.S.C. § 271(a), (b), (c) and/or (g), unless enjoined by the Court.

41. If Mylan's marketing and sale of the Mylan ANDA product prior to expiration of the '301 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

COUNT III

(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '883 PATENT)

42. Each of the preceding paragraphs 1 to 41 is incorporated as if fully set forth herein.

43. A definite and concrete, real and substantial, justiciable controversy of sufficient immediacy and reality exists between Plaintiffs and Mylan regarding infringement of the '883 patent.

44. Upon information and belief, Mylan has made and will continue to make substantial and meaningful preparations to perform the processes claimed in the '883 patent or to import a product which is made by a process claimed by the '883 patent into the United States prior to the expiration of the '883 patent.

45. Mylan's conduct including, but not limited to, the filing of ANDA No. 213856 and attempting to meet the regulatory requirements for approval of ANDA No. 213856, demonstrate a refusal to change its course of action.

46. Mylan's performance of the processes claimed in the '883 patent and/or importation in the United States, offers to sell, sale, and/or use of Mylan's products made by the patented process prior to the expiration of the '883 patent, and its inducement of and/or contribution to such conduct, would infringe claims 1-5 of the '883 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), (c) and/or (g).

47. Plaintiffs should be granted a judicial declaration that the claims of the '883 patent are not invalid, are not unenforceable and that the importation into the United States, use, offer for sale, and/or sale in the United States of a product made using the processes claimed in the '883 patent, the use of the processes claimed in the '883 patent, and/or actively inducing and contributing to infringement of the '883 patent by others will constitute infringement of the '883 patent under 35 U.S.C. § 271(a), (b), (c) and/or (g).

48. If Mylan's marketing and sale of the Mylan ANDA product prior to expiration of the '883 patent and all other relevant exclusivities are not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court grant the following relief:

1. A judgment that the claims of the '183 and '301 patents are not invalid, are not unenforceable, and are infringed by Mylan's submission of ANDA No. 213856, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(e)(2)(A), and that Mylan's making, using, offering to sell, or selling in the United States, or importing into the United States the Mylan ANDA product will infringe the claims of the '183 and '301 patents, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), (c) and/or (g).

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval of ANDA No. 213856 shall be a date which is not earlier than the latest expiration

date of the ’183 and ’301 patents, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

3. A judgment declaring that the claims of the ’883 patent are not invalid, are not unenforceable and that Mylan’s importing, selling, offering to sell, and/or using the generic product described in ANDA No. 213856, or inducing or contributing to such conduct, will infringe the ’883 patent, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(a), (b), (c) and/or (g);

4. An order permanently enjoining Mylan, its affiliates, subsidiaries, and each of its officers, agents, servants and employees and those acting in privity or concert with them, from making, using, offering to sell, or selling in the United States, or importing into the United States the Mylan ANDA product until after the latest expiration date of the patents-in-suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

5. Damages or other monetary relief, including costs, fees, pre- and post-judgment interest, to Plaintiffs if Mylan engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of the Mylan ANDA product prior to the latest expiration date of the patents-in-suit, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled.

6. Such further and other relief as this Court deems proper and just, including any appropriate relief under 35 U.S.C. § 285.

Dated March 4, 2021

ASTELLAS US LLC, ASTELLAS PHARMA US, INC., AND GILEAD SCIENCES, INC.m

By Counsel

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