IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ASTELLAS US LLC; ASTELLAS PHARMA US, INC.; and GILEAD SCIENCES, INC. ,	)	
Plaintiffs,	)	C.A. No. 1:20-cv-01182-CFC
v.	)	
MEITHEAL PHARMACEUTICALS, INC.,	)	
Defendant.	)	

DEFENDANT MEITHEAL PHARMACEUTICALS, INC.'S
ANSWER, DEFENSES AND COUNTERCLAIMS TO PLAINTIFFS' COMPLAINT

Defendant Meitheal Pharmaceuticals, Inc. ("Meitheal"), by its undersigned counsel, for their Answer to the Complaint filed by Astellas US LLC and Astellas Pharma US, Inc. (collectively, "Astellas") and Gilead Sciences, Inc. ("Gilead") (Astellas and Gilead, collectively, "Plaintiffs"), states as follows:

GENERAL DENIAL

Pursuant to Fed. R. Civ. P. 8(b)(3), Meitheal denies all allegations in Plaintiffs' Complaint except those specifically admitted below:

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 Meitheal Pharmaceuticals, Inc. ("Meitheal"). This action relates to Abbreviated New Drug Application ("ANDA") No. 212806 filed by Meitheal with the U.S. Food and Drug Administration ("FDA").

ANSWER: Paragraph 1 of the Complaint contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal admits that Plaintiffs'

Complaint purports to assert an action for patent infringement, but Meitheal denies that Plaintiffs are entitled to any relief. Meitheal admits that Meitheal filed ANDA No. 212806 with the U.S. Food and Drug Administration ("FDA"). Meitheal denies any and all remaining allegations of Paragraph 1.

2. In ANDA No. 212806, Meitheal 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 "Meitheal 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."

ANSWER: Paragraph 2 contains legal conclusions to which no answer is required. To the extent, if any, Meitheal is required to answer, Meitheal admits Plaintiffs purport to bring this action for infringement of U.S. Patent Nos. 8,106,183 (the "'183 patent"), RE 47,301 (the "'301 patent"), and 8,524,883 (the "'883 patent"). Meitheal further admits that it filed ANDA No. 212806 with the FDA for approval to engage in the commercial manufacture, use or sale of 0.4 mg/5 mL (0.08 mg/mL) intravenous solution of regadenoson ("the Meitheal ANDA Product"), a generic version of Lexiscan®, prior to expiration of the '183 patent, '301 patent, and '883 patent (collectively, "the patents-in-suit"). Meitheal denies any and all remaining allegations of Paragraph 2.

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.

ANSWER: Paragraph 3 contains legal conclusions and allegations to which no answer is required. Meitheal is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of Paragraph 3 and therefore denies them.

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.

ANSWER: Paragraph 4 contains legal conclusions and allegations to which no answer is required. Meitheal is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of Paragraph 4 and therefore denies them.

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.

ANSWER: Paragraph 5 contains legal conclusions and allegations to which no answer is required. Meitheal is without sufficient information with which to form a belief as to the truth or accuracy of the allegations of Paragraph 5 and therefore denies them.

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.

ANSWER: Paragraph 6 contains legal conclusions and allegations to which no answer is required. Meitheal is without sufficient knowledge or information to form a belief as to the remaining allegations of this paragraph, and therefore denies the same.

7. Upon information and belief, Meitheal is a corporation organized and existing under the laws of Delaware, having its principal place of business at 8700 W. Bryn Mawr, Suite 600S, Chicago, IL 60631.

ANSWER: Meitheal admits that Meitheal Pharmaceuticals, Inc. is a corporation organized and existing under the laws of Delaware, having its principal place of business at 8700 W. Bryn Mawr Avenue, Suite 600S, Chicago, IL 60631. Meitheal denies any and all remaining allegations of Paragraph 7.

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.

ANSWER: Paragraph 8 contains legal conclusions to which no answer is required. To the extent an answer is required, Meitheal admits that the Complaint purports to assert a case under the patent laws of the United States, but denies that Plaintiffs are entitled to any relief. Meitheal denies the remaining allegations contained in this paragraph.

9. This Court has jurisdiction over Meitheal because Meitheal is incorporated in Delaware.

ANSWER: Paragraph 9 contains legal conclusions to which no answer is required. Meitheal does not contest personal jurisdiction solely for the limited purposes of this action only. Meitheal admits Meitheal is incorporated in Delaware. Meitheal denies the remaining allegations contained in this paragraph.

10. This Court has jurisdiction over Meitheal because, *inter alia*, Meitheal has committed an act of patent infringement under 35 U.S.C. § 271(e)(2) and intends a future course of conduct that includes acts of patent infringement in Delaware. These acts have led and will lead to foreseeable harm and injury to Plaintiffs, two Delaware corporations and a Delaware limited liability company, in Delaware. For example, on information and belief, following approval of ANDA No. 212806, Meitheal will make, use, import, sell, and/or offer for sale the Meitheal ANDA product in the United States, including in Delaware, prior to the expiration of the patents-in-suit.

ANSWER: Paragraph 10 contains legal conclusions to which no answer is required. Meitheal does not contest personal jurisdiction solely for the limited purposes of this action only. To the extent an answer is required, Meitheal denies the allegations contained in this paragraph.

11. This Court also has jurisdiction over Meitheal because, *inter alia*, this action arises from actions of Meitheal directed toward Delaware, and because Meitheal has purposefully availed itself of the rights and benefits of Delaware law by engaging in systematic and continuous contacts with Delaware. Upon information and belief, Meitheal regularly and continuously transacts business within Delaware, including by selling pharmaceutical products in Delaware either directly or indirectly through affiliated companies. Upon information and belief, Meitheal derives substantial revenue from the sale of those products in Delaware

ANSWER: Paragraph 11 contains legal conclusions to which no answer is required. Meitheal does not contest personal jurisdiction solely for the limited purposes of this action only. To the extent an answer is required, Meitheal denies the allegations contained in this paragraph.

12. Venue is proper in this Court under 28 U.S.C. §§ 1391 and/or 1400(b).

ANSWER: Paragraph 12 contains legal conclusions to which no answer is required. Meitheal does not contest venue solely for the limited purposes of this action only. To the extent an answer is required, Meitheal denies the allegations contained in this paragraph.

13. Meitheal, through its counsel, by e-mail dated September 2, 2020, agreed that it does not contest jurisdiction or venue in this Court in this matter.

ANSWER: Paragraph 13 contains legal conclusions and allegations to which no answer is required. Meitheal does not contest personal jurisdiction or venue solely for the limited purposes of this action only.

PATENTS-IN-SUIT

14. On January 31, 2012, the U.S. Patent and Trademark Office duly and legally issued the '183 patent, titled "Process for preparing an A2*A*-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.

ANSWER: Paragraph 14 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal admits that what purports to be a copy of the '183 patent is attached to the Complaint as Exhibit A, and that the copy bears an issue date of January 31, 2012, and bears the title "Process for preparing an A2*A*-adenosine receptor agonist and its polymorphs." Meitheal denies that '183 patent was duly or legally issued, and denies that the claims of the '183 patent are valid or enforceable. Meitheal denies the remaining allegations of this paragraph.

15. On March 19, 2019, the United States Patent and Trademark Office duly and legally issued the '301 patent, titled "Process for preparing an A2*A*-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.

ANSWER: Paragraph 15 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal admits that what purports to be a copy of the '301 patent is attached to the Complaint as Exhibit B, and that the copy bears a reissue date of March 19, 2019, bears the title "Process for preparing an A2*A*-adenosine receptor agonist and its polymorphs," and bears indication that the '301 patent is a reissue of U.S. Patent No. 9,085,601 (the "'601 patent"), which purportedly was issued on July 21, 2015. Meitheal denies that the'601

patent and the ’301 patent were duly or legally issued, and denies that the claims of the ’601 and ’301 patents are valid or enforceable. Meitheal denies the remaining allegations of this paragraph.

16. 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.

ANSWER: Paragraph 16 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal admits that what purports to be a copy of the ’883 patent is attached to the Complaint as Exhibit C, and that the copy bears an issue date of September 3, 2013, and bears the title “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.” Meitheal denies that ’883 patent was duly or legally issued, and denies that the claims of the ’883 patent are valid or enforceable. Meitheal denies the remaining allegations of this paragraph.

17. 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.

ANSWER: Paragraph 17 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal admits that, according to the electronic records of the FDA's publication *Approved Drug Products with Therapeutic Equivalence Evaluations* ("the Orange Book"), the applicant holder full name for NDA No. 022161 is Astellas Pharma US Inc., for 0.4 mg/5 mL (0.08 mg/mL) intravenous solution of regadenoson under the proprietary name of LEXISCAN, and that the '183 and '301 patents are listed in the Orange Book in connection with NDA No. 022161. Meitheal is without sufficient knowledge or information to form a belief as to the remaining allegations of this paragraph, and therefore denies the same.

18. 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.

ANSWER: Paragraph 18 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal admits that, according its current prescribing information, LEXISCAN is a pharmacologic stress agent indicated for radionuclide myocardial perfusion imaging (MPI) in patients unable to undergo adequate exercise stress. Meitheal admits that what purports to be a copy of the prescribing information for NDA No. 022161 is attached to the Complaint as Exhibit D. Meitheal is without sufficient knowledge or information to form a belief as to the remaining allegations of this paragraph, and therefore denies the same.

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

ANSWER: Paragraph 19 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal denies the allegations of this paragraph.

INFRINGEMENT BY MEITHEAL

20. By a letter dated August 17, 2020, Meitheal notified Plaintiffs that Meitheal had submitted ANDA No. 212806 to the FDA under Section 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301(j)) ("the Lexiscan Notice Letter").

ANSWER: Paragraph 20 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal admits that Meitheal sent a letter dated August 17, 2020, to Plaintiffs, which served as written notification that Meitheal had submitted ANDA No. 212806 to the FDA, and which satisfied all statutory, legal, and regulatory requirements. Meitheal denies any remaining allegations of this paragraph.

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

ANSWER: Paragraph 21 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal admits that the Lexiscan Notice Letter states that the FDA has received an ANDA from Meitheal for Meitheal's ANDA Product containing a paragraph IV certification to obtain approval to engage in the commercial manufacture, use, or sale of the Meitheal ANDA product before the expiration of the '183 and '301 patents. Meitheal is without sufficient knowledge or information to form a belief as to the remaining allegations of this paragraph, and therefore denies the same.

22. By filing ANDA No. 212806, Meitheal has necessarily represented to the FDA that the Meitheal ANDA product has the same active ingredient as Lexiscan, has the same dosage form and strength as Lexiscan, and is bioequivalent to Lexiscan.

ANSWER: Paragraph 22 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal is without sufficient knowledge or information to form a belief as to the remaining allegations of this paragraph, and therefore denies the same.

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

ANSWER: Meitheal admits that ANDA No. 212806 lists the proposed indication of its product as a pharmacologic stress agent indicated for radionuclide myocardial perfusion imaging (MPI) in patients unable to undergo adequate exercise stress. Meitheal is without sufficient knowledge or information to form a belief as to the remaining allegations of this paragraph, and therefore denies the same.

24. In the Lexiscan Notice Letter, Meitheal 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 Meitheal ANDA product.

ANSWER: Meitheal admits the allegations of this paragraph.

25. In the Lexiscan Notice Letter, Meitheal offered confidential access to portions of its ANDA No. 212806, on terms and conditions set forth in the Lexiscan Notice Letter ("the Meitheal Offer"). Meitheal requested that Plaintiffs accept the Meitheal Offer before receiving access to Meitheal's ANDA No. 212806. The Meitheal Offer contained unreasonable restrictions well beyond those that would apply under a protective order on who could view the ANDA. For example, the Meitheal Offer contained a broad patent prosecution bar, which, among other things, does not have a carve out for post-grant proceedings. The Meitheal Offer unreasonably restricted the ability of counsel to seek the opinions of Plaintiffs' employees and outside experts. The restrictions Meitheal has placed on access to ANDA No. 212806 contravene 21 U.S.C. § 301(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).

ANSWER: Paragraph 25 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal admits that the Lexiscan Notice Letter included an offer of confidential access pursuant to 21 U.S.C. § 301(j)(5)(C)(i)(III), which satisfied all statutory, legal, and regulatory requirements. Meitheal denies the remaining allegations of this paragraph.

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

ANSWER: Paragraph 26 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal denies the allegations of this paragraph.

27. 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.

ANSWER: Paragraph 27 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal denies the allegations of this paragraph.

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

ANSWER: Paragraph 28 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal denies the allegations of this paragraph.

29. Upon information and belief, Meitheal intends to import into the United States and/or offer to sell, sell, make, and/or use within the United States the Meitheal

ANDA product, which is made by the process patented by the '883 patent, prior to the expiration of the '883 patent.

ANSWER: Paragraph 29 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal denies the allegations of this paragraph.

30. Upon information and belief, Meitheal 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. Meitheal's preparations include, but are not limited to, developing Meitheal's generic product and filing ANDA No. 212806.

ANSWER: Paragraph 30 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal admits that Meitheal filed ANDA No. 212806. Meitheal denies the remaining allegations of this paragraph.

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

ANSWER: Paragraph 31 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal denies the allegations of this paragraph.

32. Upon information and belief, Meitheal had actual and/or constructive notice of the '883 patent prior to filing ANDA No. 212806.

ANSWER: Paragraph 32 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal admits it had knowledge of the '883 patent when Meitheal filed ANDA No. 212806. Meitheal denies the remaining allegations of this paragraph.

COUNT I
(INFRINGEMENT OF THE '183 PATENT)

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

ANSWER: Meitheal incorporates each of its responses to each of the preceding paragraphs as if fully set forth herein.

34. Meitheal's submission of ANDA No. 212806 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Meitheal 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).

ANSWER: Paragraph 34 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal admits it submitted ANDA No. 212806, and Meitheal denies the remaining allegations of this paragraph.

35. Meitheal's commercial manufacture, use, offer to sell, sale, or importation of the Meitheal 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).

ANSWER: Paragraph 35 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal denies the allegations of this paragraph.

36. Upon FDA approval of Meitheal's ANDA No. 212806, Meitheal 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 Meitheal 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.

ANSWER: Paragraph 36 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal denies the allegations of this paragraph.

37. If Meitheal's marketing and sale of the Meitheal 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.

ANSWER: Paragraph 37 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal denies the allegations of this paragraph.

COUNT II
(INFRINGEMENT OF THE '301 PATENT)

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

ANSWER: Meitheal incorporates each of its responses to each of the preceding paragraphs as if fully set forth herein.

39. Meitheal's submission of ANDA No. 212806 to obtain approval to engage in the commercial manufacture, use, offer to sell, or sale of the Meitheal 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, 11, and 17, under 35 U.S.C. § 271(e)(2)(A).

ANSWER: Paragraph 39 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal admits it submitted ANDA No. 212806, and Meitheal denies the remaining allegations of this paragraph.

40. Meitheal's commercial manufacture, use, offer to sell, sale, or importation of the Meitheal 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, 11, and 17, under 35 U.S.C. § 271(a), (b), (c) and/or (g).

ANSWER: Paragraph 40 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal denies the allegations of this paragraph.

41. Upon FDA approval of Meitheal's ANDA No. 212806, Meitheal 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, 11, and 17, by making, using, offering to sell, and selling the Meitheal 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.

ANSWER: Paragraph 41 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal denies the allegations of this paragraph.

42. If Meitheal's marketing and sale of the Meitheal 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.

ANSWER: Paragraph 42 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal denies the allegations of this paragraph.

COUNT III
(DECLARATORY JUDGMENT OF INFRINGEMENT OF THE '883 PATENT)

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

ANSWER: Meitheal incorporates each of its responses to each of the preceding paragraphs as if fully set forth herein.

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

ANSWER: Paragraph 44 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal denies the allegations of this paragraph.

45. Upon information and belief, Meitheal 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.

ANSWER: Paragraph 45 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal denies the allegations of this paragraph.

46. Meitheal's conduct including, but not limited to, the filing of ANDA No. 212806 and attempting to meet the regulatory requirements for approval of ANDA No. 212806, demonstrate a refusal to change its course of action.

ANSWER: Paragraph 46 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal admits it filed ANDA No. 212806, and Meitheal denies the remaining allegations of this paragraph.

47. Meitheal'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 Meitheal'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).

ANSWER: Paragraph 47 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal denies the allegations of this paragraph.

48. 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).

ANSWER: Paragraph 48 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal denies the allegations of this paragraph.

49. If Meitheal's marketing and sale of the Meitheal 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.

ANSWER: Paragraph 49 contains legal conclusions and allegations to which no answer is required. To the extent an answer is required, Meitheal denies the allegations of this paragraph.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs request 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 Meitheal's submission of ANDA No. 212806, either literally or under the doctrine of equivalents, under 35 U.S.C. § 271(e)(2)(A), and that Meitheal's making, using, offering to sell, or selling in the United States, or importing into the United States the Meitheal 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. 212806 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 Meitheal's importing, selling, offering to sell, and/or using the generic product described in ANDA No. 212806, 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 Meitheal, 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 Meitheal 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 Meitheal engages in commercial manufacture, use, offers to sell, sale, or

importation in or into the United States of the Meitheal 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.

RESPONSE TO PRAYER FOR RELIEF

Meitheal denies all allegations not expressly admitted herein. Meitheal further denies that Plaintiffs are entitled to any of the relief requested in paragraphs 1-6 of Plaintiffs' Prayer for Relief, and requests that Plaintiffs' Complaint be dismissed with prejudice and that Meitheal be awarded its fees and costs incurred defending this suit under 35. U.S.C. § 285.

MEITHEAL'S ADDITIONAL DEFENSES

FIRST SEPARATE DEFENSE

(Invalidity of the '183 Patent)

The claims of the '183 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, et seq. or under other judicially-created bases for invalidation.

SECOND SEPARATE DEFENSE

(Invalidity of the '301 Patent)

The claims of the '301 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, et seq. or under other judicially-created bases for invalidation.

THIRD SEPARATE DEFENSE

(Invalidity of the '883 Patent)

The claims of the '883 patent are invalid and/or unenforceable under 35 U.S.C. §§ 101, et seq. or under other judicially-created bases for invalidation.

FOURTH SEPARATE DEFENSE

(No Direct Infringement of the '183 Patent)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 212806 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '183 patent.

FIFTH SEPARATE DEFENSE

(No Direct Infringement of the '301 Patent)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 212806 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '301 patent.

SIXTH SEPARATE DEFENSE

(No Direct Infringement of the '883 Patent)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 212806 do not and will not infringe, either literally or under the doctrine of equivalents, any valid and enforceable claim of the '883 patent.

SEVENTH SEPARATE DEFENSE

(No Indirect Infringement of the '183 Patent)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 212806 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '183 patent.

EIGHTH SEPARATE DEFENSE

(No Indirect Infringement of the '301 Patent)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 212806 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '301 patent.

NINTH SEPARATE DEFENSE

(No Indirect Infringement of the '883 Patent)

The manufacture, use, offer for sale, sale, or importation of the products described in ANDA No. 212806 do not and will not induce the infringement of, and have not, do not, and will not contribute to the infringement of any valid and enforceable claim of the '883 patent.

TENTH SEPARATE DEFENSE

(Failure to State a Claim)

Plaintiffs' complaint, in whole and/or in part, fails to state a claim upon which relief can be granted.

ELEVENTH SEPARATE DEFENSE

(Failure to State a Claim for Exceptional or Willful Infringement)

Plaintiffs fail to state a proper claim for an exceptional case and/or willful infringement.

RESERVATION OF ADDITIONAL DEFENSES

Meitheal reserves the right to plead additional affirmative defenses or counterclaims that may be revealed through the course of discovery, including unenforceability.

COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Meitheal Pharmaceuticals, Inc. ("Meitheal"), by way of its attorneys, hereby states for its Counterclaims against Plaintiffs, Astellas US LLC and Astellas Pharma US, Inc. (collectively, "Astellas") and Gilead Sciences, Inc. ("Gilead") (Astellas and Gilead, collectively, "Plaintiffs/Counterclaim-Defendants"), the following:

THE PARTIES

1. Meitheal repeats and incorporates by reference each of the foregoing paragraphs of Meitheal's Answer and Separate Defenses to the Complaint.

2. Meitheal Corp. is a corporation organized and existing under the laws of the State of Delaware, with a place of business at 8700 W. Bryn Mawr Avenue, Suite 600S, Chicago, IL 60631.

3. Upon information and belief, Plaintiff/Counterclaim-Defendant 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. Upon information and belief, Plaintiff/Counterclaim-Defendant 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. Upon information and belief, Plaintiff/Counterclaim-Defendant Gilead Sciences, Inc. 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.

JURISDICTION

6. These Counterclaims arise under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*., and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (2003) ("MMA") (21 U.S.C. § 301(j) and 35 U.S.C. § 271(e)(5)).

7. This Court has original jurisdiction over the subject matter of these Counterclaims under 28 U.S.C. §§ 1331 and 1338(a); under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202; and under the MMA (21 U.S.C. § 301(j) and 35 U.S.C. § 271(e)(5)).

8. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1337(a), 1338(a), 2201(a) and (b), and 2202, based on an actual controversy between Meitheal, and Plaintiffs/Counterclaim-Defendants, arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq*.

9. This Court has personal jurisdiction over Plaintiffs/Counterclaim-Defendants based on, *inter alia*, the filing of this lawsuit in this jurisdiction and because Plaintiffs/Counterclaim-Defendants are doing business in this jurisdiction.

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

FACTS COMMON TO ALL COUNTS

11. This is an action for a declaratory judgment of non-infringement and invalidity of one or more claims of U.S. Patent Nos. 8,106,183 (the "'183 patent"), RE 47,301 (the "'301

patent"), and 8,524,883 (the "'883 patent") (collectively, the "Patents-In-Suit"). Upon information and belief, true and correct copies of the Patents-in-Suit were attached to the Complaint as Exhibits A-C.

12. On or about January 31, 2012, the U.S. Patent & Trademark Office ("USPTO") issued the '183 patent.

13. On or about March 19, 2019, the USPTO issued the '301 patent.

14. On or about September 3, 2013, the USPTO issued the '883 patent.

15. Upon information and belief, Plaintiff/Counterclaim-Defendant Gilead is the assignee of the '183 Patent, the '301 Patent, and the '883 Patent.

16. Upon information and belief, Plaintiff/Counterclaim-Defendant Astellas US LLC is the exclusive licensee of the '183 Patent, the '301 Patent, and the '883 Patent.

17. Upon information and belief, Plaintiff/Counterclaim-Defendant Astellas Pharma US, Inc. is the holder of New Drug Application ("NDA") No. 022161 for 0.4 mg/5 mL (0.08 mg/mL) intravenous solution of regadenoson.

18. Upon information and belief, at least one of the Plaintiffs/Counterclaim-Defendants markets and sells 0.4 mg/5 mL (0.08 mg/mL) intravenous solution of regadenoson in the United States, under the trade name "Lexiscan®."

19. Plaintiffs/Counterclaim-Defendants purport and claim to have the rights to enforce the Patents-in-Suit.

20. Astellas Pharma US, Inc. has listed the '183 and '301 patents in the FDA's *Approved Drug Products and Therapeutic Equivalence Evaluations* (the "Orange Book") in connection with NDA No. 022161 for Lexiscan®.

21. Meitheal has filed the Abbreviated New Drug Application ("ANDA) No. 212806 with the U.S. Food and Drug Administration (the "FDA") seeking approval for Meitheal's proposed regadenoson product described therein (the "Meitheal ANDA product"), identifying NDA No. 022161 as the Reference Listed Drug pursuant to 21 C.F.R. § 314.3 ("Meitheal's ANDA").

22. Meitheal's ANDA seeks FDA approval to market the Meitheal ANDA product described within ANDA No. 212806 before the expiration of the Patents-in-Suit that are listed in the Orange Book, and Meitheal's ANDA includes a certification under 21 U.S.C. § 301(j)(2)(A)(vii)(IV) (also called a "Paragraph IV Certification") as to the Patents-in-Suit that are listed in the Orange Book.

23. Plaintiffs/Counterclaim-Defendants sued Meitheal in this District for alleged infringement of each one of the Patents-in-Suit.

COUNT I

(Declaratory Judgment of Invalidity of The '183 Patent)

24. Meitheal realleges and incorporates by reference the allegations of paragraphs 1-23 as though fully set forth herein.

25. There is an actual, substantial, and continuing case or controversy between Meitheal and the Plaintiffs/Counterclaim-Defendants regarding, *inter alia,* the invalidity of the '183 patent, and a judicial declaration of invalidity is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties regarding the invalidity of the claims of the '183 patent.

26. The claims of the '183 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation.

27. The claims of the '183 patent are invalid under 35 U.S.C. § 103 because they are obvious to a person of ordinary skill in the art, as set forth in Meitheal's Notice of Certification Under § 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95 dated August 17, 2020, because each and every element of each and every claim of the '183 patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the '183 patent, including, but not limited to, those references and/or products disclosed in Meitheal's Notice of Certification Under § 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95 dated August 17, 2020, namely:

(1) Zablocki, J.A. et al., WO2000078779, entitled "N-Pyrazole A_2A Receptor Agonists," published December 28, 2000; and

(2) Niiya K. et al., "2 -(N' -Alkylidenehydrazino) Adenosines: Potent and Selective Coronary Vasodilators," J. Med. Chem. 35 (1992), pp. 4557-4561;

together with the general knowledge of a person of skill in the art.

28. Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act, dated September 12, 2016, any person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the '183 patent, and would have had a reasonable expectation of success in doing so.

29. There is no objective evidence of non-obviousness of the claims of the '183 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '183 patent.

30. Meitheal is entitled to a judicial declaration that the claims of the '183 patent are invalid.

31. Meitheal reserves the right to provide additional bases for invalidity of each claim of the '183 patent in its contentions, responses to discovery requests, expert reports or pleadings filed or served as this action progresses.

COUNT II

(Declaratory Judgment of Invalidity of The '301 Patent)

32. Meitheal realleges and incorporates by reference the allegations of paragraphs 1-31 as though fully set forth herein.

33. There is an actual, substantial, and continuing case or controversy between Meitheal and the Plaintiffs/Counterclaim-Defendants regarding *inter alia,* the invalidity of the '301 patent, and a judicial declaration of invalidity is necessary and appropriate at this time so that

the parties may ascertain their respective rights and duties regarding the invalidity of the claims of the '301 patent.

34. The claims of the '301 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation.

35. The claims of the '301 patent are invalid under 35 U.S.C. § 103 because they are obvious to a person of ordinary skill in the art, as set forth in Meitheal's Notice Letter to Plaintiffs/Counterclaim-Defendants, namely Meitheal's Notice of Certification Under § 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95 dated August 17, 2020, because each and every element of each and every claim of the '301 patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the '301 patent, including, but not limited to, those references and/or products disclosed in Meitheal's Notice of Certification Under § 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95 dated August 17, 2020, namely:

(1) Zablocki, J.A. et al., WO2000078779, entitled "N-Pyrazole A_2A Receptor Agonists," published December 28, 2000; and

(2) Niiya K. et al., "2 -(N' -Alkylidenehydrazino) Adenosines: Potent and Selective Coronary Vasodilators," J. Med. Chem. 35 (1992), pp. 4557-4561;

together with the general knowledge of a person of skill in the art.

36. Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act, dated September 12, 2016, any person of ordinary skill in the art would have been motivated to combine

those references and/or products as of the earliest possible priority date of the '301 patent, and would have had a reasonable expectation of success in doing so.

37. There is no objective evidence of non-obviousness of the claims of the '301 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the '301 patent.

38. Meitheal is entitled to a judicial declaration that the claims of the '301 patent are invalid.

39. Meitheal reserves the right to provide additional bases for invalidity of each claim of the '301 patent in its contentions, responses to discovery requests, expert reports or pleadings filed or served as this action progresses.

COUNT III

(Declaratory Judgment of Invalidity of The '883 Patent)

40. Meitheal realleges and incorporates by reference the allegations of paragraphs 1-39 as though fully set forth herein.

41. There is an actual, substantial, and continuing case or controversy between Meitheal and the Plaintiffs/Counterclaim-Defendants regarding *inter alia,* the invalidity of the '883 patent, and a judicial declaration of invalidity is necessary and appropriate at this time so that the parties may ascertain their respective rights and duties regarding the invalidity of the claims of the '883 patent.

42. The claims of the ’883 patent are invalid for failure to satisfy one or more of the conditions for patentability in Title 35 of the United States Code, or under judicially-created bases for invalidation.

43. The claims of the ’883 patent are invalid under 35 U.S.C. § 103 because they are obvious to a person of ordinary skill in the art, because each and every element of each and every claim of the ’883 patent was disclosed expressly in one or more references and/or products which were publicly available before the earliest possible priority date of the ’883 patent, including, but not limited to, those references identified in Meitheal’s Notice of Certification Under § 505(j)(2)(B) of the Federal Food, Drug and Cosmetic Act and 21 C.F.R. § 314.95 dated August 17, 2020, pertaining to the ’183 patent and the ’301 patent, namely:

(1) Zablocki, J.A. et al., WO2000078779, entitled “N-Pyrazole A_2A Receptor Agonists,” published December 28, 2000; and

(2) Niiya K. et al., “2 -(N' -Alkylidenehydrazino) Adenosines: Potent and Selective Coronary Vasodilators,” J. Med. Chem. 35 (1992), pp. 4557-4561;

together with the general knowledge of a person of skill in the art.

44. Pursuant to § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act, dated September 12, 2016, any person of ordinary skill in the art would have been motivated to combine those references and/or products as of the earliest possible priority date of the ’883 patent, and would have had a reasonable expectation of success in doing so.

45. There is no objective evidence of non-obviousness of the claims of the ’883 patent, nor would any such evidence, should it exist, have any nexus to the claimed purported inventions of the ’883 patent.

46. Meitheal is entitled to a judicial declaration that the claims of the '883 patent are invalid.

47. Meitheal reserves the right to provide additional bases for invalidity of each claim of the '883 patent in its contentions, responses to discovery requests, expert reports or pleadings filed or served as this action progresses.

COUNT IV

(Declaratory Judgment of Noninfringement of the '183 Patent)

48. Meitheal realleges and incorporates by reference the allegations of paragraphs 1-47 as though fully set forth herein.

49. There is an actual, substantial, and continuing case or controversy between Meitheal and the Plaintiffs/Counterclaim-Defendants regarding, *inter alia*, non-infringement of the claims of the '183 patent.

50. The manufacture, use, offer for sale, sale, importation, and/or marketing of Meitheal's ANDA Product described in Meitheal's ANDA has not infringed, does not infringe, and would not —if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '183 patent, either literally or under the doctrine of equivalents.

51. Meitheal is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Meitheal's ANDA Product described in Meitheal's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported

or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '183 patent, either literally or under the doctrine of equivalents.

COUNT V

(Declaratory Judgment of Noninfringement of the '301 Patent)

52. Meitheal realleges and incorporates by reference the allegations of paragraphs 1-51 as though fully set forth herein.

53. There is an actual, substantial, and continuing case or controversy between Meitheal and the Plaintiffs/Counterclaim-Defendants regarding, *inter alia*, non-infringement of the claims of the '301 patent.

54. The manufacture, use, offer for sale, sale, importation, and/or marketing of Meitheal's ANDA Product described in Meitheal's ANDA has not infringed, does not infringe, and would not —if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '301 patent, either literally or under the doctrine of equivalents.

55. Meitheal is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Meitheal's ANDA Product described in Meitheal's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '301 patent, either literally or under the doctrine of equivalents.

COUNT VI

(Declaratory Judgment of Noninfringement of the '883 Patent)

56. Meitheal realleges and incorporates by reference the allegations of paragraphs 1-55 as though fully set forth herein.

57. There is an actual, substantial, and continuing case or controversy between Meitheal and the Plaintiffs/Counterclaim-Defendants regarding, *inter alia*, non-infringement of the claims of the '883 patent.

58. The manufacture, use, offer for sale, sale, importation, and/or marketing of Meitheal's ANDA Product described in Meitheal's ANDA has not infringed, does not infringe, and would not —if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '883 patent, either literally or under the doctrine of equivalents.

59. Meitheal is entitled to a judicial declaration that the manufacture, use, offer for sale, sale, importation, and/or marketing of Meitheal's ANDA Product described in Meitheal's ANDA has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported or marketed—infringe, either directly or indirectly, any valid or enforceable claim of the '883 patent, either literally or under the doctrine of equivalents.

PRAYER FOR RELIEF

WHEREFORE, Meitheal seeks judgment awarding it the following relief:

A. Dismissing Plaintiffs/Counterclaim-Defendants' Complaint with prejudice and denying Plaintiffs/Counterclaim-Defendants the relief requested in their Complaint, and denying Plaintiffs/Counterclaim-Defendants any relief whatsoever;

B. Declaring that the claims of the '183, '301, and '883 patents are invalid;

C. Declaring that the manufacture, use, sale, offer for sale, importation, and/or marketing of the Meitheal ANDA Product in Meitheal's ANDA 212806 has not infringed, does not infringe, and would not—if made, used, sold, offered for sale, imported, or marketed—infringe, either directly or indirectly, any valid and/or enforceable claims of the '183, '301, and '883 patents, either literally or under the doctrine of equivalents;

D. Ordering that Plaintiffs/Counterclaim-Defendants' Complaint be dismissed with prejudice and judgment entered in favor of Meitheal;

E. If the facts so demonstrate, declaring this case exceptional and awarding Meitheal its reasonable attorneys' fees, expenses, and costs under 35 U.S.C. § 285, this Court's inherent authority and/or any other applicable authority;

F. Ordering that Plaintiffs/Counterclaim-Defendants and their respective officers, agents, servants, employees, attorneys, successors and any person who acts in concert or participation with it or any of them, be preliminarily and permanently enjoined from using the Patents-in-Suit to block, hamper, hinder or obstruct FDA approval of the products described in Meitheal's ANDA; and

G. Awarding such other and further relief as the Court may deem just and proper.

Dated: September 25, 2020

/s/ Kenneth L. Dorsney
Kenneth L. Dorsney (#3726)
MORRIS JAMES LLP
500 Delaware Avenue, Suite 1500
Wilmington, DE 19801
(302) 888-6800
kdorsney@morrisjames.com

Of Counsel:

Stephen R. Auten
Taft Stettinius & Hollister LLP
111 East Wacker Drive, Suite 2800
Chicago, IL 60601
312-527-4000
sauten@taftlaw.com

Attorneys for Defendant
Meitheal Pharmaceuticals, Inc.