UNITED STATES DISTRICT COURT FOR THE EASTERN DISTRICT OF NEW YORK

MYLAN API US LLC and MYLAN INSTITUTIONAL LLC, Plaintiffs v. AMERICAN REGENT, INC., Defendant.	Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Mylan API US LLC ("Mylan API") and Mylan Institutional LLC ("Mylan Institutional") (collectively "Plaintiffs") for their Complaint for Patent Infringement against Defendant American Regent, Inc. ("American Regent"), herein 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, Sections 1 *et seq.*, and under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, involving United States Patent No. 9,353,050 ("the '050 Patent").

2. On information and belief, American Regent has filed an Abbreviated New Drug Application ("ANDA") seeking approval to market an isosulfan blue 1% injection product ("ANDA Product").

3. On information and belief, American Regent intends to manufacture, use, offer to sell, and/or sell within the United States and/or import into the United States the ANDA Product, upon receiving FDA approval and prior to the expiration of the '050 Patent.

4. On information and belief, the ANDA Product infringes at least one claim of the ’050 Patent.

THE PARTIES

5. Mylan API is a limited liability company organized and existing under the laws of the State of Delaware and having a place of business at 49 Napoleon Court, Somerset, New Jersey 08873.

6. Mylan API is a pharmaceutical company that provides innovative solutions to the pharmaceutical industry in the field of active pharmaceutical ingredient manufacturing.

7. Mylan API was previously known as Apicore US LLC. The company changed its name on July 12, 2019 and recorded the name change with the Delaware Division of Corporations.

8. Mylan API developed a process for manufacturing high purity isosulfan blue product that is superior to other methods of isosulfan blue synthesis and has entered into an exclusive arrangement with Mylan Institutional to commercialize this innovation.

9. Mylan Institutional is a limited liability company organized and existing under the laws of the State of Delaware and having a place of business at 1718 Northrock Court, Rockford, Illinois 61103.

10. Mylan Institutional is a pharmaceutical company that develops and commercializes injectable and other pharmaceutical products.

11. On information and belief, American Regent is a corporation organized and existing under the laws of the State of New York and having a principal place of business at 5 Ramsey Road, Shirley, New York 11967.

12. On information and belief, American Regent previously operated as Luitpold Pharmaceuticals, Inc. ("Luitpold"). On information and belief, on or about January 2, 2019, Luitpold changed its name to American Regent, Inc.

JURISDICTION AND VENUE

13. These claims arise under the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202, and under the patent laws of the United States, Title 35, United States Code, Sections 1 *et seq*.

14. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331 and 1338(a) in that it involves substantial claims arising under the patent laws of the United States, Title 35, United States Code, Sections 1 *et seq*.

15. This Court has subject matter jurisdiction over this action pursuant to 35 U.S.C. § 271(e)(2)(a) because Mylan API owns the '050 Patent and because, on information and belief, American Regent has filed an ANDA under section 505(j) of the Federal Food, Drug, and Cosmetic Act seeking FDA approval to market a product containing the same drug claimed in the '050 Patent.

16. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because this case involves an actual controversy within the Court's jurisdiction and because Plaintiffs seek a judgment that the '050 Patent will be infringed by American Regent's planned future acts.

17. This Court has personal jurisdiction over American Regent because, on information and belief, American Regent maintains a principal place of business within this District and is incorporated in the State of New York.

18. Venue is proper in this District under 28 U.S.C. § 1400(b) because, on information and belief, American Regent is organized under the laws of the State of New York and maintains a regular and established place of business in this District.

PATENT-IN-SUIT

19. The '050 Patent, entitled "Process for Preparation of Isosulfan Blue," was duly and legally issued by the USPTO on May 31, 2016. Apicore US LLC, which is now Mylan API, is the assignee of the patent. A true and correct copy of the '050 Patent is attached hereto as Ex. A.

20. Claim 1 of the '050 Patent recites:

> A compound N-[4-[[4-(diethyl amino)phenyl](2,5-disulfophenyl) methylene]-2,5-cyclohexadien-1-ylidene]-N-ethylethanaminium, sodium salt having a purity of at least 99.0% by HPLC.

21. Isosulfan blue is a triarylmethane dye used as a contrast agent for the delineation of lymphatic vessels and is used as a cancer diagnostic agent.

22. Mylan API is the lawful owner of the '050 Patent and has all right, title, and interest in and to it.

23. Mylan Institutional is an exclusive licensee of the '050 Patent.

24. Mylan Institutional's highly pure isosulfan blue 1% injection product is currently the Reference Standard product as designated by the FDA because the isosulfan blue Reference Listed Drug product previously sold by Covidien is no longer commercially available. *See* Ex. B (FDA Orange Book: Approved Drug Products with Therapeutic Equivalence Evaluations for isosulfan blue).

25. According to 21 C.F.R. § 314.3, a "[r]eference standard is the drug product selected by FDA that an applicant seeking approval of an ANDA must use in conducting an in vivo bioequivalence study required for approval."

26. Because Mylan Institutional's isosulfan blue 1% injection product is listed as the Reference Standard, any new ANDA for isosulfan blue, including American Regent's, would be compared to the Mylan Institutional product in any required *in vivo* bioequivalence studies.

27. Mylan API's isosulfan blue active pharmaceutical ingredient and Mylan Institutional's isosulfan blue 1% injection product, which incorporates Mylan API's active pharmaceutical ingredient, are at least 99.0% pure by HPLC as disclosed in the '050 Patent and in Mylan Institutional's Drug Substance specifications.

28. As such, on information and belief, American Regent's isosulfan blue 1% injection product will match or exceed 99.0% purity by HPLC to show bioequivalence to Mylan Institutional's isosulfan blue 1% injection product, which showing of bioequivalence is necessary for obtaining FDA approval.

29. Neither Mylan API nor Mylan Institutional has authorized or licensed American Regent to make, use, sell, or offer for sale and/or import into the United States any isosulfan blue products covered by the claims of the '050 Patent.

ACTS GIVING RISE TO THIS ACTION

30. On August 31, 2018, American Regent f/k/a Luitpold filed a petition for *inter partes* review of the '050 Patent at the Patent Trial and Appeal Board ("PTAB"). On March 6, 2019, PTAB issued a decision denying institution of *inter partes* review.

31. On information and belief, American Regent spent significant time and money on its petition for *inter partes* review of the '050 Patent.

32. On information and belief, American Regent filed its petition for *inter partes* review of the '050 Patent because it had already filed or intended to file imminently an ANDA for an infringing isosulfan blue injection product.

33. On May 1, 2019, Mylan API sent American Regent a letter stating Mylan API's belief that American Regent had filed an ANDA for an isosulfan blue injection product. The letter requested American Regent to disclose certain information about its manufacturing process and to provide batch records so that counsel for Mylan API could evaluate whether the ANDA Product would infringe the '050 Patent. The letter included an offer to enter into a confidential disclosure agreement concerning any information American Regent provided. *See* Ex. C.

34. On May 8, 2019, American Regent sent a response letter in which it refused to produce the requested information. American Regent also refused to confirm or deny that it had filed an ANDA for an isosulfan blue product, stating the information was "not public information." *See* Ex. D.

35. On June 27, Mylan API sent another letter to American Regent notifying American Regent of certain pending U.S. patent applications owned by Mylan API, also relating to isosulfan blue. The letter reiterated Mylan API's request for American Regent to disclose certain information about its manufacturing process for the ANDA Product. *See* Ex. E.

36. In its response letter of July 26, 2019, American Regent again refused to produce the requested information and remained equivocal as to whether it had filed an ANDA for an isosulfan blue product. *See* Ex. F.

37. On August 13, 2019, Mylan API sent a final letter to American Regent asking it to produce information regarding its ANDA Product and asking that American Regent "engage in good faith negotiations with [Mylan API] on a process that ensures sufficient time for [Mylan API] to seek an injunction prior to the launch of [American Regent's] product." *See* Ex. G. The letter requested a response by August 15, 2019.

38. Counsel for American Regent responded by email on August 15 and requested additional time because in-house counsel for American Regent were unavailable. The email stated that American Regent would "respond substantively to [Mylan API's] request after Labor Day." Mylan API agreed to the extension provided that American Regent refrain from launching any isosulfan blue product during the intervening time. American Regent agreed to this condition. *See* Ex. H.

39. American Regent provided a final response by email on September 13, 2019. Contrary to what was assured in the August 15 email, American Regent provided no information and refused to engage in discussions at that time. Nor did American Regent state whether it had filed an ANDA for isosulfan blue, stating only that "American Regent will consider engaging in pre-suit discussions in the event a more appropriate time arises." *See* Ex. I.

40. On October 4, 2019, Mylan API sent a letter to American Regent notifying it that two of Mylan API's pending U.S. patent applications had received notices of allowance. The letter asked American Regent to "disclose whether it has filed an ANDA for isosulfan blue" and "disclose documents showing the manufacturing process and HPLC purity of American Regent's isosulfan blue product and active pharmaceutical ingredient." *See* Ex. J.

41. On information and belief, information regarding the purity of the ANDA Product and its method of manufacture is uniquely in the possession of American Regent and is not publicly available.

42. On information and belief, American Regent submitted an ANDA for an isosulfan blue 1% injection product and intends to market that product upon receiving FDA approval, while the '050 Patent remains enforceable.

43. On information and belief, based on when American Regent filed its petition for *inter partes* review, FDA approval of American Regent's ANDA is now imminent.

44. American Regent has known of the '050 Patent at least as early as August 31, 2018, when American Regent filed its petition for *inter partes* review of the '050 Patent.

COUNT I: INFRINGEMENT OF U.S. PATENT NO. 9,353,050 UNDER 35 U.S.C. § 271(e)(2)

45. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

46. On information and belief, American Regent has infringed one or more claims of the '050 Patent under 35 U.S.C. § 271(e)(2), either literally or under the doctrine of equivalents.

47. On information and belief, American Regent submitted an ANDA for approval to market an isosulfan blue 1% injection product, with intent to market the product upon receiving FDA approval.

48. On information and belief, upon securing FDA approval for its ANDA, American Regent will continue to infringe the '050 Patent by making, using, selling, offering for sale, and/or importing the infringing isosulfan blue 1% injection product in or into the United States.

49. On information and belief, American Regent's isosulfan blue active pharmaceutical ingredient has a purity of at least 99.0% by HPLC, and the ANDA Product is a solution containing isosulfan blue with a purity of at least 99.0% by HPLC.

50. As such, on information and belief, the ANDA Product and its active pharmaceutical ingredient together will infringe, either literally or under the doctrine of equivalents, at least Claims 1, 11, and 15 of the '050 Patent.

51. Plaintiffs will be substantially and irreparably harmed if American Regent's infringement of the '050 Patent's claims is not enjoined by the Court.

COUNT II: DECLARATORY JUDGMENT OF FUTURE INFRINGEMENT OF U.S. PATENT NO. 9,353,050 UNDER 35 U.S.C. § 271(a)

52. Plaintiffs repeat and reallege each of the foregoing paragraphs as if fully set forth herein.

53. On information and belief, American Regent submitted an ANDA for approval to market an isosulfan blue 1% injection product, with intent to market the product upon receiving FDA approval.

54. On information and belief, upon securing FDA approval for its ANDA, American Regent will continue to infringe the '050 Patent under 35 U.S.C. § 271(a) by making, using, selling, offering for sale, and/or importing the infringing isosulfan blue 1% injection product in or into the United States.

55. On information and belief, American Regent's isosulfan blue active pharmaceutical ingredient has a purity of at least 99.0% by HPLC, and the ANDA Product is a solution containing isosulfan blue with a purity of at least 99.0% by HPLC.

56. As such, on information and belief, the ANDA Product and its active pharmaceutical ingredient together will infringe, either literally or under the doctrine of equivalents, at least Claims 1, 11, and 15 of the '050 Patent.

57. Plaintiffs will be substantially and irreparably harmed if American Regent's infringement of the '050 Patent's claims is not enjoined by the Court.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that the Court enter judgment in their favor and against Defendant American Regent as follows:

a) A judgment that American Regent has infringed the ’050 Patent under 35 U.S.C. § 271(e)(2) by filing an ANDA for approval to market an infringing drug product;

b) A judgment that the future manufacture, use, sale, offer for sale, and/or importation of the ANDA Product in or into the United States will infringe the ’050 Patent under 35 U.S.C. § 271(a).

c) A judgment that the ’050 Patent is valid and enforceable;

d) An order that the effective date of any FDA approval for the ANDA Product shall be a date which is not earlier than the expiration date of the ’050 Patent, inclusive of any extension(s) and additional period(s) of exclusivity to which Plaintiffs are or may become entitled;

e) An order preliminarily and permanently enjoining American Regent, its officers, agents, servants, employees, parents, subsidiaries, affiliates, other business entities, and all other persons acting or attempting to act in concert or privity with American Regent, their successors, and assigns, or anyone acting on their behalf, from directly and/or indirectly infringing the ’050 Patent, including by engaging in the manufacture, use, sale, and offer for sale in the United States, and/or importation into the United States, of the ANDA Product until expiration of the ’050 Patent, inclusive of any extension(s) and additional period(s) of exclusivity to which Plaintiffs are or may become entitled;

f) A judgment that this is an exceptional case under 35 U.S.C. § 285 and that Plaintiffs be awarded reasonable attorneys’ fees and costs; and

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

Dated: October 8, 2019

Respectfully submitted,

/s/ Morris J. Fodeman

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*Pro hac vice application to be submitted