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American Regent, Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

VIFOR (INTERNATIONAL) AG and AMERICAN REGENT, INC., Plaintiffs, v. MYLAN LABORATORIES LTD., Defendant.	Civil Action No. 19-13955 *Document Electronically Filed*

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Vifor (International) AG ("Vifor") and American Regent, Inc. ("American Regent") (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 Mylan Laboratories Ltd. ("Mylan"). This action relates to Abbreviated New Drug Application ("ANDA") No. 212572, filed by Mylan with the U.S. Food and Drug Administration ("FDA") for approval to market a generic version of Plaintiffs' Injectafer®, ferric carboxymaltose injection (750 mg/15 ml) ("Mylan's ANDA

Product") prior to the expiration of United States Patent Nos. 7,612,109 ("the '109 patent"); 7,754,702 ("the '702 patent"); 8,895,612 ("the '612 patent"); and 9,376,505 ("the '505 patent"). The '109, '702, '612, and '505 patents are listed in FDA's Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") for Injectafer®.

THE PARTIES

2. Plaintiff Vifor is a company organized and existing under the laws of Switzerland, having a principal place of business at Rechenstraβe 37, CH-9001, St. Gallen, Switzerland.

3. Vifor is engaged in the business of creating, developing, and bringing to market revolutionary drug products, including treatments for iron deficiency anemia.

4. Plaintiff American Regent is a corporation organized and existing under the laws of the State of New York, with a principal place of business at 5 Ramsey Road, Shirley, New York 11967. American Regent was formerly known as Luitpold Pharmaceuticals, Inc., until January 2, 2019, when its New York Certificate of Incorporation was amended to change the name of the corporation to American Regent, Inc. American Regent is a subsidiary of Daiichi Sankyo, Inc, which is located at 211 Mt. Airy Road, Basking Ridge, New Jersey 07920.

5. Vifor and American Regent developed Injectafer®. American Regent licenses Injectafer® from Vifor, and American Regent markets, distributes, and sells injectable pharmaceutical drug products, including Injectafer®, in this judicial district and throughout the United States.

6. On information and belief, Defendant Mylan is a company organized and existing under the laws of India, with a principal place of business at Plot No. 564/A/22, Road No. 92, Jubilee Hills 500034, Hyderabad, India.

7. On information and belief, Mylan is a generic pharmaceutical company that develops and manufactures generic pharmaceutical products that are marketed and sold throughout the United States.

JURISDICTION AND VENUE

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

9. On information and belief, this Court has personal jurisdiction over Mylan, under the New Jersey state long arm statute and consistent with due process of law, because it regularly does or solicits business in New Jersey, engages in other persistent courses of conduct in New Jersey, and/or derives substantial revenue from services or things used or consumed in New Jersey, demonstrating that Mylan has systematic and continuous contacts with this judicial district.

10. On information and belief, Mylan purposefully has conducted and continues to conduct business in this judicial district by manufacturing, importing, marketing, and distributing pharmaceutical products, including generic drug products, either by itself or through its parent corporation, subsidiaries and/or affiliates, throughout the United States, including in this judicial district.

11. On information and belief, Mylan is subject to personal jurisdiction in this judicial district through its pursuit of regulatory approval for Mylan's ANDA Product for the commercial manufacture, use, and/or sale of Mylan's ANDA Product, if approved, in this judicial district and to residents of this judicial district. Through at least these activities, Mylan has purposely

availed itself of the rights and benefits of New Jersey law such that it should reasonably anticipate being haled into court in this judicial district.

12. On information and belief, Mylan has been, and continues to be, wholly responsible for the drafting, submission, request for approval, and maintenance of ANDA No. 212572. Mylan's "Notice of Paragraph IV Certification" dated May 7, 2019 ("Mylan's Notice Letter") and sent to Plaintiffs pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act and § 314.95 of the Code of Federal Regulations, identified "Mylan Laboratories Ltd." as the entity which submitted ANDA No. 212572 to the FDA and the entity which seeks FDA approval of its ANDA prior to the expiration of the '109, '702, '612, and '505 patents.

13. On information and belief, if ANDA No. 212572 is approved, Mylan will import, market, distribute, offer for sale, and/or sell Mylan's ANDA Product, either by itself or through its parent corporation, subsidiaries and/or affiliates, in the United States, including in New Jersey, and will derive substantial revenue from the use or consumption of Mylan's ANDA Product in the state of New Jersey.

14. On information and belief, if ANDA No. 212572 is approved, Mylan's ANDA Product will be marketed, distributed, offered for sale, and/or sold in New Jersey; prescribed by physicians practicing in New Jersey; administered by healthcare professionals located within New Jersey; and/or used by patients in New Jersey, all of which will have a substantial effect on New Jersey.

15. If ANDA No. 212572 is approved, Vifor and American Regent will be harmed by the marketing, distribution, offer for sale, and/or sale of Mylan's ANDA Product, including in New Jersey.

16. On information and belief, Mylan has affirmatively availed itself of the jurisdiction of this Court by filing counterclaims in this judicial district. *See, e.g., AstraZeneca AB et al. v. Mylan Pharmaceuticals Inc. et al.*, Civil Action No. 13-04022 (D.N.J. Apr. 28, 2014), ECF No. 51 at 30.

17. Alternatively, this Court has personal jurisdiction over Mylan pursuant to Fed. R. Civ. P. 4(k)(2), to the extent it is not subject to personal jurisdiction in the courts of any state, because Mylan is a foreign entity, Plaintiffs' claims arise under federal patent law, and the exercise of jurisdiction satisfies due process requirements, at least because, upon information and belief, Mylan has systematic and continuous contacts throughout the United States by manufacturing, importing, marketing, and/or distributing pharmaceutical products, including generic drug products, either by itself or through its parent corporation, subsidiaries and/or affiliates.

18. On information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) for at least the reason that Mylan is a foreign corporation not residing in any United States district and may be sued in any judicial district that has personal jurisdiction, including this judicial district. Mylan has previously admitted, that as a foreign entity, venue is proper against it in New Jersey. *Valeant Pharm. N. Am. LLC v. Mylan Pharm. Inc.*, Civil Action No. 18-14305, ECF No. 21 at 6 n.1 ("MLL [Mylan Laboratories Ltd.] is incorporated in India. D.I. 1 ¶ 6. Under *In re HTC Corp.*, 889 F. 3d 1349 (Fed. Cir. 2018), venue for foreign corporations is governed by the general venue statute, which provides that 'a defendant not resident in the United States may be sued in any judicial district.' 28 U.S.C. § 1391(c)(3). The Mylan Defendants do not dispute that venue is proper over MLL as a foreign corporation in any judicial district ….").

PATENTS-IN-SUIT

19. The U.S. Patent and Trademark Office ("PTO") issued the '109 patent, entitled "Water-Soluble Iron-Carbohydrate Complexes, Production Thereof, and Medicaments Containing Said Complexes," on November 3, 2009 to inventors Peter Geisser, Erik Philipp, and Walter Richle. Vifor is the assignee of the '109 patent and has the right to enforce it. The '109 patent expires on February 5, 2024, excluding any patent term extension. The '109 patent claims, *inter alia*, compositions and methods of making iron carbohydrate complexes. A true and correct copy of the '109 patent is attached hereto as **Exhibit A**.

20. The PTO issued the '702 patent entitled "Methods and Compositions For Administration of Iron," on July 13, 2010 to inventors Mary Jane Helenek, Marc L. Tokars, and Richard P. Lawrence. At the time of its issue, the '702 patent was assigned to Luitpold Pharmaceuticals, Inc., and on January 11, 2019, the assignment records for the '702 patent were amended to reflect that Luitpold Pharmaceuticals, Inc. had changed its name to American Regent, Inc. The Change of Name of the assignee for the '702 patent is recorded by the PTO at Reel 048067, Frame 0271. American Regent is the current assignee of the '702 patent and has the right to enforce it. The '702 patent expires on February 15, 2028. The '702 patent claims, *inter alia*, methods of treating iron deficiency anemia by administering an iron carbohydrate complex. A true and correct copy of the '702 patent is attached hereto as **Exhibit B**.

21. The PTO issued the '612 patent entitled "Methods and Compositions For Administration of Iron," on November 25, 2014 to inventors Mary Jane Helenek, Marc L. Tokars, and Richard P. Lawrence. At the time of its issue, the '612 patent was assigned to Luitpold Pharmaceuticals, Inc., and on January 11, 2019, the assignment records for the '612 patent were amended to reflect that Luitpold Pharmaceuticals, Inc. had changed its name to

American Regent, Inc. The Change of Name of the assignee for the '612 patent is recorded by the PTO at Reel 048067, Frame 0271. American Regent is the current assignee of the '612 patent and has the right to enforce it. The '612 patent expires on January 8, 2027. The '612 patent claims, *inter alia*, methods of treating iron deficiency anemia by the administration of an iron carboxymaltose complex. A true and correct copy of the '612 patent is attached hereto as **Exhibit C**.

22. The PTO issued the '505 patent entitled "Aqueous Iron Carbohydrate Complexes, Their Production, and Medicaments Containing Them," on June 28, 2016 to inventors Peter Geisser, Erik Philipp, and Walter Richle. Vifor is the assignee of the '505 patent and has the right to enforce it. The '505 patent expires on October 20, 2023. The '505 patent claims, *inter alia*, compositions and methods of making iron carbohydrate complexes comprising at least one oxidized maltodextrin. A copy of the '505 patent is attached hereto as **Exhibit D**.

23. American Regent is the owner of NDA No. 203565 for Injectafer® (ferric carboxymaltose) which the FDA approved on July 25, 2013. The Orange Book lists the NDA holder as Luitpold Pharmaceuticals, Inc. Luitpold Pharmaceuticals, Inc. changed its name to American Regent, Inc., effective January 2, 2019. The FDA has been informed of this name change. In conjunction with NDA No. 203565, the '109, '702, '612, and '505 patents are listed in the Orange Book.

MYLAN'S INFRINGING ANDA SUBMISSION

24. Plaintiffs reallege, and incorporate in full herein, each of the preceding paragraphs 1-23.

25. Plaintiffs received a letter from Mylan dated May 7, 2019, purporting to be a Notice of Paragraph IV Certification for ANDA No. 212572 pursuant to 21 U.S.C. § 355(j)(2)(B)(ii) and 21 § C.F.R. 314.95.

26. Mylan's Notice Letter states that "Mylan Laboratories Ltd." has submitted to the FDA ANDA No. 212572 seeking to engage in the commercial manufacture, use, and/or sale of Mylan's ANDA Product before the expiration of the '109, '702, '612, and '505 patents. Mylan's Notice Letter did not identify any other entity that is involved in the preparation, filing, and/or maintenance of ANDA No. 212572.

27. On information and belief, Mylan submitted ANDA No. 212572 to the FDA under Section 505(j) of the Act, 21 U.S.C. § 355(j), seeking approval to, and intending to, manufacture, use, import, offer to sell, and/or sell Mylan's ANDA Product, either by itself or through its parent corporation, subsidiaries and/or affiliates, throughout the United States before the expiration of the '109, '702, '612, and '505 patents.

28. By filing ANDA NO. 212572, and as indicated in Mylan's Notice Letter, Mylan has represented to the FDA that Mylan's ANDA Product has the same active ingredient as Injectafer®, has the same dosage form and strength as Injectafer®, and is bioequivalent to Injectafer®.

29. On information and belief, Mylan is seeking approval to market Mylan's ANDA Product for the same approved indications as Injectafer®.

30. Mylan's Notice Letter states that it has attached a "detailed statement of the present factual and legal bases for Mylan's belief that the '109, '702, '612, and '505 patents are invalid, unenforceable and/or will not be infringed" pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(6). Neither Mylan's Notice Letter nor its attached "Detailed

Statement of the Factual and Legal Bases for Mylan's Paragraph IV Certification Concerning United States Patents Nos. 7,612,109, 7,754,702, 8,895,612, AND 9,376,505" provide any substantive non-infringement allegation with respect to any claim of any of the '109, '702, '612, or '505 patents.

31. This Complaint is being filed before the expiration of the forty-five days from the date Plaintiffs received Mylan's Notice Letter.

COUNT I (INFRINGEMENT OF THE '109 PATENT)

32. Plaintiffs reallege, and incorporate in full herein, each of the preceding paragraphs 1-31.

33. Under 35 U.S.C. § 271(e)(2)(A), Mylan has infringed at least one claim of the '109 patent, including for example claims 1 through 5, by submitting, or causing to be submitted to the FDA, ANDA No. 212572 seeking approval to manufacture, use, import, offer to sell and/or sell Mylan's ANDA Product before the expiration date of the '109 patent. On information and belief, the product described in ANDA No. 212572 would infringe, either literally or under the doctrine of equivalents, at least one claim, including for example claims 1 through 5, of the '109 patent under 35 U.S.C. § 271(e)(2)(A).

34. In Mylan's Notice Letter, Mylan did not provide any substantive non-infringement allegation of any of the claims of the '109 patent, and therefore admits infringement of the '109 patent.

35. On information and belief, based on Mylan's Notice Letter, the absence of any substantive non-infringement allegation in Mylan's Notice Letter, the fact that Mylan has represented to the FDA that Mylan's ANDA Product is bioequivalent, pharmaceutically equivalent, and therapeutically equivalent to Injectafer®, and the fact that, pursuant to 21 C.F.R.

§ 314.94, Mylan is required to substantially copy the FDA-approved Injectafer® labeling, Mylan's ANDA Product comprises an aqueous solution of ferric carboxymaltose which is formulated for parenteral application, wherein the ferric carboxymaltose, an iron carbohydrate complex, has a weight average molecular weight of 80,000 to 300,000 daltons, and satisfies all of the limitations of at least claims 1 through 5 of the '109 patent.

36. On information and belief, upon FDA approval of Mylan's ANDA Product, Mylan will infringe at least one claim, including for example claims 1 through 5, of the '109 patent under 35 U.S.C. § 271(a) either literally or under the doctrine of equivalents, by making, using, importing, offering to sell, and/or selling Mylan's ANDA Product in the United States, and/or will induce infringement of one or more claims of the '109 patent under 35 U.S.C. § 271(b), unless enjoined by the Court.

37. On information and belief, Mylan has knowledge of the '109 patent and has filed ANDA No. 212572 seeking authorization to commercially manufacture, use, offer for sale, and/or sell Mylan's ANDA Product in the United States. On information and belief, if the FDA approves ANDA No. 212572, healthcare professionals and/or patients will directly infringe under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, at least one claim of the '109 patent, including for example claims 1 through 5, by the use Mylan's ANDA Product according to Mylan's provided instructions and/or label.

38. On information and belief, Mylan knows and intends that health care professionals and/or patients will use Mylan's ANDA Product according to Mylan's provided instructions and/or label in an infringing manner, and will therefore induce infringement of one or more claims of the '109 patent with the requisite intent under 35 U.S.C. § 271(b).

39. Upon information and belief, upon approval, Mylan will take active steps to encourage the use of Mylan's ANDA Product by healthcare professionals and/or patients with the knowledge and intent that it will be used by healthcare professionals and/or patients in a manner that infringes at least one claim, including for example claims 1 through 5, of the '109 patent for the pecuniary benefit of Mylan. Upon information and belief, Mylan will thus induce infringement of at least one claim of the '109 patent with the requisite intent under 35 U.S.C. § 271(b).

40. Upon information and belief, Mylan's actions relating to Mylan's ANDA No. 212572 complained of herein were done by and for the benefit of Mylan.

41. If Mylan's marketing and sale of Mylan's ANDA Product prior to the expiration of the '109 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT II (INFRINGEMENT OF THE '702 PATENT)

42. Plaintiffs reallege, and incorporate in full herein, each of the preceding paragraphs 1-31.

43. Under 35 U.S.C. § 271(e)(2)(A), Mylan has infringed at least one claim of the '702 patent, including for example claims 17, 24, and 47, by submitting, or causing to be submitted to the FDA, ANDA No. 212572 seeking approval to manufacture, use, import, offer to sell and/or sell Mylan's ANDA Product before the expiration date of the '702 patent. On information and belief, the product described in ANDA No. 212572 would infringe, either literally or under the doctrine of equivalents, at least one claim including for example claims 17, 24, and 47 of the '702 patent under 35 U.S.C. § 271(e)(2)(A).

44. In Mylan's Notice Letter, Mylan did not provide any substantive non-infringement allegation of any of the claims of the '702 patent, and therefore admits infringement of the '702 patent.

45. On information and belief, based on Mylan's Notice Letter, the absence of any substantive non-infringement allegation in Mylan's Notice Letter, the fact that Mylan has represented to the FDA that Mylan's ANDA Product is bioequivalent, pharmaceutically equivalent, and therapeutically equivalent to Injectafer®, and the fact that, pursuant to 21 C.F.R. § 314.94, Mylan is required to substantially copy the FDA-approved Injectafer® labeling, Mylan's ANDA Product is an iron carboxymaltose complex having a molecular weight of about 100,000 daltons to about 350,000 daltons, and will be used in a method of treating iron deficiency anemia, whereby Mylan's ANDA Product will be administered intravenously in about 15 minutes or less to a subject in need thereof in a single dosage unit of at least about 0.6 grams of elemental iron, and the use of Mylan's ANDA Product will satisfy all of the limitations of at least claims 17, 24, and 47 of the '702 patent.

46. On information and belief, upon FDA approval of Mylan's ANDA Product, Mylan will induce and/or contribute to the infringement of one or more claims, including for example claims 17, 24, and 47, of the '702 patent under 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

47. On information and belief, Mylan has knowledge of the '702 patent and has filed ANDA No. 212572 seeking authorization to commercially manufacture, use, offer for sale, and sell Mylan's ANDA Product in the United States. On information and belief, if the FDA approves ANDA No. 212572, healthcare professionals and/or patients will directly infringe under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, at least one claim

of the ’702 patent, including for example claims 17, 24, and 47, by the use Mylan’s ANDA Product according to Mylan’s provided instructions and/or label.

48. On information and belief, Mylan knows and intends that health care professionals and/or patients will use Mylan’s ANDA Product according to Mylan’s provided instructions and/or label in an infringing manner, and will therefore induce infringement of one or more claims of the ’702 patent with the requisite intent under 35 U.S.C. § 271(b).

49. Upon information and belief, upon approval, Mylan will take active steps to encourage the use of Mylan’s ANDA Product by healthcare professionals and/or patients with the knowledge and intent that it will be used by healthcare professionals and/or patients in a manner that infringes at least one claim, including for example claims 17, 24, and 47, of the ’702 patent for the pecuniary benefit of Mylan. Upon information and belief, Mylan will thus induce infringement of at least one claim of the ’702 patent with the requisite intent under 35 U.S.C. § 271(b).

50. On information and belief, if the FDA approves ANDA No. 212572, Mylan’s ANDA Product will be specifically labeled for use in practicing at least one claim including for example claims 17, 24, and 47 of the ’702 patent, wherein Mylan’s ANDA Product is a material part of the claimed invention, wherein Mylan knows and intends that healthcare professionals and/or patients will use Mylan’s ANDA Product in accordance with the instructions and/or label provided by Mylan in practicing at least one claim, including for example claims 17, 24, and 47 of the ’702 patent, and wherein Mylan’s ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use. Upon information and belief, Mylan will thus contribute to the infringement of at least one claim of the ’702 patent under 35 U.S.C. § 271(c).

51. Upon information and belief, Mylan's actions relating to Mylan's ANDA No. 212572 complained of herein were done by and for the benefit of Mylan.

52. If Mylan's marketing and sale of Mylan's ANDA Product prior to the expiration of the '702 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT III (INFRINGEMENT OF THE '612 PATENT)

53. Plaintiffs reallege, and incorporate in full herein, each of the preceding paragraphs 1-31.

54. Under 35 U.S.C. § 271(e)(2)(A), Mylan has infringed at least one claim of the '612 patent, including for example claims 2, 4, and 5, by submitting, or causing to be submitted to the FDA, ANDA No. 212572 seeking approval to manufacture, use, import, offer to sell and/or sell Mylan's ANDA Product before the expiration date of the '612 patent. On information and belief, the product described in ANDA No. 212572 would infringe, either literally or under the doctrine of equivalents, at least one claim including for example claims 2, 4, and 5 of the '612 patent under 35 U.S.C. § 271(e)(2)(A).

55. In Mylan's Notice Letter, Mylan did not provide any substantive non-infringement allegation of any of the claims of the '612 patent, and therefore admits infringement of the '612 patent.

56. On information and belief, based on Mylan's Notice Letter, the absence of any substantive non-infringement allegation in Mylan's Notice Letter, the fact that Mylan has represented to the FDA that Mylan's ANDA Product is bioequivalent, pharmaceutically equivalent, and therapeutically equivalent to Injectafer®, and the fact that, pursuant to 21 C.F.R. § 314.94, Mylan is required to substantially copy the FDA-approved Injectafer® labeling,

Mylan's ANDA Product is an iron carboxymaltose complex having a substantially non-immunogenic carbohydrate component and substantially no cross reactivity with anti-dextran antibodies, and will be used in a method of treating iron deficiency anemia associated with chronic kidney disease and/or heavy uterine bleeding, whereby Mylan's ANDA Product will be administered in about 15 minutes or less to a subject in need thereof in a single dosage unit of at least about 0.6 grams of elemental iron, and the use of Mylan's ANDA Product will satisfy all of the limitations of at least claims 2, 4, and 5 of the '702 patent.

57. On information and belief, upon FDA approval of Mylan's ANDA Product, Mylan will induce and/or contribute to the infringement of one or more claims, including for example claims 2, 4, and 5 of the '612 patent under 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

58. On information and belief, Mylan has knowledge of the '612 patent and has filed ANDA No. 212572 seeking authorization to commercially manufacture, use, offer for sale, and/or sell Mylan's ANDA Product in the United States. On information and belief, if the FDA approves ANDA No. 212572, health care professionals and/or patients will directly infringe under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, at least one claim of the '612 patent, including for example claims 2, 4, and 5, by the use Mylan's ANDA Product according to Mylan's provided instructions and/or label.

59. On information and belief, Mylan knows and intends that healthcare professionals and/or patients will use Mylan's ANDA Product according to Mylan's provided instructions and/or label in an infringing manner, and will therefore induce infringement of one or more claims of the '612 patent with the requisite intent under 35 U.S.C. § 271(b).

60. Upon information and belief, upon approval, Mylan will take active steps to encourage the use of Mylan's ANDA Product by healthcare professionals and/or patients with the knowledge and intent that it will be used by healthcare professionals and/or patients in a manner that infringes at least one claim, including for example claims 2, 4, and 5, of the '612 patent for the pecuniary benefit of Mylan. Upon information and belief, Mylan will thus induce infringement of at least one claim of the '612 patent with the requisite intent under 35 U.S.C. § 271(b).

61. On information and belief, if the FDA approves ANDA No. 212572, Mylan's ANDA Product will be specifically labeled for use in practicing at least one claim including for example claims 2, 4, and 5, of the '612 patent, wherein Mylan's ANDA Product is a material part of the claimed invention, wherein Mylan knows and intends that healthcare professionals and/or patients will use Mylan's ANDA Product in accordance with the instructions and/or label provided by Mylan in practicing at least one claim, including for example claims 2, 4, and 5, of the '612 patent, and wherein Mylan's ANDA Product is not a staple article or commodity of commerce suitable for substantial non-infringing use. Upon information and belief, Mylan will thus contribute to the infringement of at least one claim of the '612 patent under 35 U.S.C. § 271(c).

62. Upon information and belief, Mylan's actions relating to Mylan's ANDA No. 212572 complained of herein were done by and for the benefit of Mylan.

63. If Mylan's marketing and sale of Mylan's ANDA Product prior to the expiration of the '612 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT IV (INFRINGEMENT OF THE '505 PATENT)

64. Plaintiffs reallege, and incorporate in full herein, each of the preceding paragraphs 1-31.

65. In Mylan's Notice Letter, Mylan did not provide any substantive non-infringement allegation of any of the claims of the '505 patent, and therefore admits infringement of the '505 patent.

66. On information and belief, based on Mylan's Notice Letter, the absence of any substantive non-infringement allegation in Mylan's Notice Letter, the fact that Mylan has represented to the FDA that Mylan's ANDA Product is bioequivalent, pharmaceutically equivalent, and therapeutically equivalent to Injectafer®, and the fact that, pursuant to 21 C.F.R. § 314.94, Mylan is required to substantially copy the FDA-approved Injectafer® labeling, Mylan's ANDA Product is an aqueous solution comprising an iron (III) carbohydrate complex comprising at least one oxidized maltodextrin, wherein the iron (III) carbohydrate complex has a weight average molecular weight of 118,000 to 400,000 daltons, wherein the aqueous solution of the iron (III) carbohydrate has an iron content of between 1% and 20% weight/volume of the solution, and satisfies all of the limitations of at least claims 1, 10, 19, and 28 of the '505 patent.

67. On information and belief, upon FDA approval of Mylan's ANDA Product, Mylan will infringe at least one claim, including for example claims 1, 10, 19, and 28, of the '505 patent under 35 U.S.C. § 271(a) either literally or under the doctrine of equivalents, by making, using, importing, offering to sell, and/or selling Mylan's ANDA Product in the United States, and/or will induce infringement of one or more claims of the '505 patent under 35 U.S.C. § 271(b), unless enjoined by the Court.

68. On information and belief, Mylan has knowledge of the '505 patent and has filed ANDA No. 212572 seeking authorization to commercially manufacture, use, offer for sale, and/or sell Mylan's ANDA Product in the United States. On information and belief, if the FDA approves ANDA No. 212572, healthcare professionals and/or patients will directly infringe under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, at least one claim of the '505 patent, including for example claims 1, 10, 19, and 28, by the use of Mylan's ANDA Product according to Mylan's provided instructions and/or label.

69. On information and belief, Mylan knows and intends that health care professionals and/or patients will use Mylan's ANDA Product according to Mylan's provided instructions and/or label in an infringing manner, and will therefore induce infringement of one or more claims of the '505 patent with the requisite intent under 35 U.S.C. § 271(b).

70. Upon information and belief, upon approval, Mylan will take active steps to encourage the use of Mylan's ANDA Product by healthcare professionals and/or patients with the knowledge and intent that it will be used by healthcare professionals and/or patients in a manner that infringes at least one claim, including for example claims 1, 10, 19, and 28, of the '505 patent for the pecuniary benefit of Mylan. Upon information and belief, Mylan will thus induce infringement of at least one claim of the '505 patent with the requisite intent under 35 U.S.C. § 271(b).

71. Upon information and belief, Mylan's actions relating to Mylan's ANDA No. 212572 complained of herein were done by and for the benefit of Mylan.

72. If Mylan's marketing and sale of Mylan's ANDA Product prior to the expiration of the '505 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request that this Court grant the following relief:

1. A judgment that the claims of the '109, '702, '612, and '505 patents are not invalid or unenforceable, and are infringed by Mylan's submission of ANDA No. 212572 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, Mylan's ANDA Product will infringe the '109, '702, '612, and '505 patents under 35 U.S.C. §§ 271(a), (b), and/or (c);

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any approval by the FDA of ANDA No. 212572 shall be a date that is not earlier than the latest expiration date of the '109, '702, '612, and '505 patents, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

3. An order permanently enjoining Mylan, its parent corporation, affiliates, subsidiaries, and each of its officers, agents, servants, 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 Mylan's ANDA Product until after the last expiration date of the '109, '702, '612, and '505 patents, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled, in accordance with 35 U.S.C. § 271(e)(4)(B) and 35 U.S.C. § 283;

4. Damages or other monetary relief to Plaintiffs if Mylan engages in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of Mylan's ANDA Product prior to the latest expiration date of the '109, '702, '612, and '505 patents, including any extensions and/or additional periods of exclusivity to which Plaintiffs is or becomes entitled, in accordance with 35 U.S.C. § 271(e)(4)(C); and

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

Dated: June 18, 2019
Newark, New Jersey

Respectfully submitted,

s/ William P. Deni, Jr.

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