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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

VIFOR (INTERNATIONAL) AG and AMERICAN REGENT, INC., Plaintiffs, v. DR. REDDY'S LABORATORIES, LTD. and DR. REDDY'S LABORATORIES, INC., Defendants.	Case No. _____

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Vifor (International) AG ("Vifor") and American Regent, Inc. ("American Regent") (collectively, "Plaintiffs"), by their attorneys, through this Complaint, 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 Dr. Reddy's Laboratories, Ltd. ("DRL Ltd.") and Dr. Reddy's Laboratories, Inc. ("DRL Inc.") (DRL Ltd. and DRL Inc., collectively, "the

DRL Defendants"). This action relates to Abbreviated New Drug Application ("ANDA") No. 218848, filed by the DRL Defendants with the U.S. Food and Drug Administration ("FDA") for approval to market a generic version of Plaintiffs' Injectafer®, ferric carboxymaltose injection (100 mg Iron/2 mL; 500 mg Iron /10 mL; 750 mg Iron/15 mL; 1 g Iron /20 mL) ("DRL's ANDA Products") 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"); 11,364,260 ("the '260 patent"); 11,433,091 ("the '091 patent"); and 11,478,502 ("the '502 patent"). The '109, '702, '612, '260, '091, and '502 patents are listed in the 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."

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 DRL Ltd. is a company organized and

existing under the laws of the Republic of India and having a principal place of business at 8-2-337, Road No. 3, Banjara Hills, Hyderabad, Telangana, India, 500034.

7. On information and belief, DRL Ltd. itself, and through its subsidiary and agent DRL Inc., develops, manufactures, and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district.

8. On information and belief, Defendant DRL Inc. is a corporation organized and existing under the laws of the State of New Jersey, with a principal place of business at 107 College Road East, Princeton, New Jersey, 08540.

9. On information and belief, DRL Inc. is a wholly owned subsidiary of DRL Ltd. and is controlled and/or dominated by DRL Inc. On information and belief, DRL Ltd. established DRL Inc. for the purposes of developing, manufacturing, and distributing its generic drug products throughout the United States, including in this judicial district. On information and belief, DRL Inc. develops, manufactures, and/or distributes generic drug products for marketing, sale, and/or use throughout the United States, including in this judicial district.

JURISDICTION AND VENUE

10. 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).

11. On information and belief, this Court has personal jurisdiction over DRL Inc., under the New Jersey state long arm statute and consistent with due process of law, because DRL Inc. maintains its principal place of business in New Jersey.

12. On information and belief, this Court has personal jurisdiction over DRL Ltd., under the New Jersey state long arm statute and consistent with due process of law because DRL Ltd. has extensive contacts with the State of New Jersey, including through its subsidiary DRL

Inc., and regularly does business in this judicial district, including through its subsidiary DRL Inc. Further, the DRL Defendants plan to sell their ANDA product in the State of New Jersey, which provides an independent basis for personal jurisdiction here.

13. DRL Ltd. has previously availed itself of the legal protections of the State of New Jersey by, among other things, selecting the State of New Jersey as the place of incorporation and principal place of business for DRL Inc., admitting to jurisdiction in this judicial district, and/or pursuing counterclaims it this judicial district. *See, e.g.*, *Intra-Cellular Therapies, Inc. v. Dr. Reddy's Lab'ys, Inc. et al.*, C.A. No. 24-04314 (D.N.J.) (DRL Inc. and DRL Ltd. did not contest personal jurisdiction and asserted counterclaims); *Novo Nordisk Inc. et al. v. Dr. Reddy's Lab'ys, Ltd. et al.*, C.A. No. 23-22112 (D.N.J.) (same); *Bausch & Lomb Inc. et al., v. Dr. Reddy's Lab'ys, Ltd. et al.*, C.A. No. 23-03463 (D.N.J.) (same); *Eisai R&D Mgmt. Co., Ltd. et al. v. Dr. Reddy's Lab'ys, Inc. et al.*, C.A. No. 22-05950 (D.N.J.) (same); *Celgene Corp. v. Dr. Reddy's Lab'ys, Ltd. et al.*, C.A. No. 21-02111 (D.N.J.) (same); *Merck Sharp & Dohme BV et al. v. Dr. Reddy's Lab'ys, Inc. et al.*, C.A. No. 20-02909 (D.N.J.) (same); *Mitsubishi Tanabe Pharma Corp. et al. v. Dr. Reddy's Lab'ys, Inc. et al.*, C.A. No. 19-18764 (D.N.J.) (same); *AstraZeneca LP et al. v. Dr. Reddy's Lab'ys, Ltd. et al.*, C.A. No. 19-15739 (D.N.J.) (same); *see also Supernus Pharm., Inc. v. Dr. Reddy's Lab'ys, Ltd. et al.*, C.A. No. 22-04705 (D.N.J.) (DRL Inc. and DRL Ltd. did not contest personal jurisdiction); *Bausch & Lomb Inc. et al. v. Slayback Pharma LLC et al.*, C.A. No. 21-16766 (D.N.J.) (DRL Inc. did not contest personal jurisdiction and asserted counterclaims).

14. On information and belief, DRL Ltd. and DRL Inc. are subject to personal jurisdiction in New Jersey because they regularly do or solicit business in New Jersey, engage in other persistent courses of conduct in New Jersey, and/or derive substantial revenue from

services or things used or consumed in New Jersey, demonstrating that DRL Ltd. and DRL Inc. have systematic and continuous contacts with this judicial district.

15. On information and belief, DRL Ltd. and DRL Inc. purposefully have conducted and continue to conduct business in this judicial district by manufacturing, importing, marketing, and distributing pharmaceutical products, including generic drug products, either alone or through their parent corporation, subsidiaries, and/or affiliates, throughout the United States, including in this judicial district. The DRL Defendants further intend to sell their generic ANDA product in the State of New Jersey.

16. On information and belief, DRL Inc. is registered to do business in the State of New Jersey under Entity Identification Number 0100518911, and DRL Inc. is also licensed to do business with the New Jersey Department of Health as a "Manufacturer and Wholesale[r]" of pharmaceuticals in the State of New Jersey (Registration Number 5002312). Moreover, on information and belief, DRL Inc. has appointed a registered agent in New Jersey for the receipt of service of process.

17. On information and belief, DRL Ltd. and DRL Inc. are subject to personal jurisdiction in this judicial district through their pursuit of regulatory approval for DRL's ANDA Products for the commercial manufacture, use, and/or sale of DRL's ANDA Products, if approved, in this judicial district and to residents of this judicial district. Through at least these activities, DRL Ltd. and DRL Inc. have purposely availed themselves of the rights and benefits of New Jersey law such that they should reasonably anticipate being haled into court in this judicial district.

18. On information and belief, consistent with their past practices, DRL Ltd. and DRL Inc. acted collaboratively in the preparation and submission of ANDA No. 218848.

19. On information and belief, and consistent with their past practices, following any FDA approval of ANDA No. 218848, DRL Ltd. and DRL Inc. will work in concert with one another to make, use, offer to sell, and/or sell the generic drug products that are the subject of ANDA No. 218848 throughout the United States and/or import such generic drug products into the United States, including in this judicial district.

20. On information and belief, if ANDA No. 218848 is approved, DRL's ANDA Products 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.

21. On information and belief, if ANDA No. 218848 is approved, DRL Ltd. and DRL Inc. will import, market, distribute, offer for sale, and/or sell DRL's ANDA Products, alone or through their 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 DRL's ANDA Products in the state of New Jersey.

22. If ANDA No. 218848 is approved, Vifor and American Regent will be harmed by the marketing, distribution, offer for sale, and/or sale of DRL's ANDA Products, including in New Jersey.

23. On information and belief, venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400(b) at least because DRL Inc. is incorporated in the State of New Jersey and therefore "resides" in this judicial district, and has committed acts of infringement in New Jersey and has a regular and established place of business in New Jersey. DRL Ltd. is a foreign company not residing in any United States judicial district and may be sued in any judicial

district. 28 U.S.C. § 1391(c)(3). Moreover, DRL Ltd. and DRL Inc. have litigated previous Hatch-Waxman patent infringement disputes in the District of New Jersey.

24. On information and belief, DRL Inc. has committed acts of infringement under the meaning of 28 U.S.C. § 1400(b) by submitting ANDA No. 218848 to the FDA, by taking steps indicating its intent to market DRL's ANDA Products in New Jersey, and by the acts that it non-speculatively intends to take in New Jersey if DRL's ANDA receives final FDA approval.

25. On information and belief, DRL Inc. has a regular and established place of business in New Jersey under the meaning of 28 U.S.C. § 1400(b) because, *inter alia*, its principal place of business is in New Jersey. As set forth above, on information and belief, DRL Inc. maintains regular and established places of business in New Jersey, including it headquarters, offices, laboratories, and/or facilities at 107 College Road East, Princeton, New Jersey, 08540.

26. On information and belief, DRL Ltd. and DRL Inc. have taken steps in New Jersey, including preparing ANDA No. 218848 and communicating with the FDA regarding ANDA No. 218848, that indicate their intent to market DRL's ANDA Products. As set forth above, on information and belief, if ANDA No. 218848 is approved, the DRL Defendants intend to commit acts of patent infringement in New Jersey, including marketing, distributing, offering for sale, and/or selling DRL's ANDA Products.

PATENTS-IN-SUIT

27. 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 current assignee of the '109 patent and has the right to enforce it. The '109 patent expires on February 5, 2025, subject to further extensions. 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**.

28. 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 issuance, 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**.

29. 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 issuance, 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**.

30. The PTO issued the ’260 patent entitled “Methods and Compositions For Administration of Iron,” on June 21, 2022 to inventors Mary Jane Helenek, Marc L. Tokars, and Richard P. Lawrence. American Regent is the current assignee of the ’260 patent and has the right to enforce it. The ’260 patent expires on January 8, 2027. The ’260 patent claims, *inter alia*, methods of treating iron deficiency or dysfunctional iron metabolism by the administration of an iron carboxymaltose complex. A true and correct copy of the ’260 patent is attached hereto as **Exhibit D**.

31. The PTO issued the ’091 patent entitled “Methods and Compositions For Administration of Iron,” on September 6, 2022 to inventors Mary Jane Helenek, Marc L. Tokars, and Richard P. Lawrence. American Regent is the current assignee of the ’091 patent and has the right to enforce it. The ’091 patent expires on January 8, 2027. The ’091 patent claims, *inter alia*, methods of treating a disease, disorder, or condition characterized by iron deficiency or dysfunctional iron metabolism by the administration of an iron carboxymaltose complex. A true and correct copy of the ’091 patent is attached hereto as **Exhibit E**.

32. The PTO issued the ’502 patent entitled “Methods and Compositions For Administration of Iron,” on October 25, 2022 to inventors Mary Jane Helenek, Marc L. Tokars, and Richard P. Lawrence. American Regent is the current assignee of the ’502 patent and has the right to enforce it. The ’502 patent expires on January 8, 2027. The ’502 patent claims, *inter alia*, methods of treating iron deficiency anemia and functional iron deficiency by the administration of an iron carboxymaltose complex. A true and correct copy of the ’502 patent is attached hereto as **Exhibit F**.

NDA NO. 203565 AND INJECTAFER®

33. American Regent is the owner of New Drug Application (“NDA”) No. 203565 for Injectafer® (ferric carboxymaltose), which the FDA approved on July 25, 2013. The Orange

Book lists the NDA holder as "American Regent, Inc.," in accordance with the name change from "Luitpold Pharmaceuticals, Inc." to "American Regent, Inc.," effective January 2, 2019.

34. In conjunction with NDA No. 203565, American Regent listed with the FDA, *inter alia*, the '109, '702, and '612 patents. American Regent subsequently timely listed the '260, '091, and '502 patents with the FDA after those patents issued. All six patents—the '109, '702, '612, '260, '091, and '502 patents—are currently listed in the Orange Book for Injectafer®.

35. Injectafer® is covered by one or more claims of each of the '109, '702, '612, '260, '091, and '502 patents.

36. Injectafer® is currently approved to treat iron deficiency anemia in certain patients and iron deficiency in adult patents with heart failure and New York Heart Association class II/III to improve exercise capacity. A true and correct copy of the current Injectafer® label is attached as **Exhibit G**.

THE DRL DEFENDANTS' INFRINGING ANDA SUBMISSION

37. Plaintiffs received a letter from the DRL Defendants dated April 24, 2024, purporting to be a "Notice of Paragraph IV Certification Re: Dr. Reddy's Laboratories, Ltd.'s and/or Dr. Reddy's Laboratories, Inc.'s Ferric Carboxymaltose Injection; U.S. Patent Nos. 7,612,109; 7,754,702; 8,895,612; 11,364,260; 11,433,091, and 11,478,502" for ANDA No. 218848 pursuant to 21 U.S.C. § 355(j)(2)(B) and 21 § C.F.R. 314.95 ("DRL's Notice Letter").

38. DRL's Notice Letter states that DRL Inc. "on behalf of" DRL Ltd. "filed patent certifications . . . in support of DRL's Abbreviated New Drug Application" and is seeking approval to engage in the commercial manufacture, use, and/or sale of DRL's ANDA Products before the expiration of the '109, '702, '612, '260, '091, and '502 patents.

39. On information and belief, the DRL Defendants submitted ANDA No. 218848 to 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 DRL's ANDA Products, either by itself or through its parent corporation, subsidiaries, and/or affiliates, throughout the United States before the expiration of the '109, '702, '612, '260, '091, and '502 patents.

40. On information and belief, each of the DRL Defendants has made, and continues to make, substantial preparation in the United States to manufacture, use, import, offer to sell, and/or sell DRL's ANDA Products, either by itself or through its parent corporation, subsidiaries, and/or affiliates, before the expiration of the '109, '702, '612, '260, '091, and '502 patents.

41. By filing ANDA No. 218848, and as indicated in DRL's Notice Letter, the DRL Defendants have represented to the FDA that DRL's ANDA Products have the same active ingredient as Injectafer®, have the same dosage forms and strengths as Injectafer®, and are bioequivalent to Injectafer®.

42. On information and belief, the DRL Defendants are seeking approval to market DRL's ANDA Products for the same approved indications as Injectafer®.

43. DRL's Notice Letter states that it has attached a "[d]etailed statement of the legal and factual bases for the Paragraph IV Certification" and "has certified with the FDA that . . . the '109, '702, '612, '260, '091, and '502 patents are invalid, unenforceable, or will not be infringed by the manufacture, use, or sale of DRL's ANDA Products . . . pursuant to 21 U.S.C. § 355(j)(2)(B)(iv)(II) and 21 C.F.R. § 314.95(c)(7)."

COUNT I (INFRINGEMENT OF THE '109 PATENT)

44. Plaintiffs allege, and incorporate in full herein, each of the preceding paragraphs 1–43.

45. The claims of the '109 patent are presumed valid under 35 U.S.C. § 282.

46. Under 35 U.S.C. § 271(e)(2)(A), the DRL Defendants have infringed at least one

claim of the ’109 patent by submitting, or causing to be submitted to the FDA, ANDA No. 218848 seeking approval to engage in the commercial manufacture, use, or sale of DRL’s ANDA Products before the expiration date of the ’109 patent. On information and belief, the product described in ANDA No. 218848 would infringe, either literally or under the doctrine of equivalents, at least one claim of the ’109 patent under 35 U.S.C. § 271(e)(2)(A).

47. In DRL’s Notice Letter, the DRL Defendants did not provide any allegation that DRL’s ANDA Products do not fall within the scope of certain claims of the ’109 patent, and therefore admit infringement of the ’109 patent.

48. On information and belief, based on DRL’s Notice Letter, the absence of any allegation that DRL’s ANDA Products do not fall within the scope of claims of the ’109 patent in DRL’s Notice Letter, the fact that the DRL Defendants have represented to the FDA that DRL’s ANDA Products are bioequivalent, pharmaceutically equivalent, and therapeutically equivalent to Injectafer®, and the fact that, pursuant to 21 C.F.R. § 314.94, the DRL Defendants are required to substantially copy the FDA-approved Injectafer® labeling, DRL’s ANDA Products comprise 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 one or more claim of the ’109 patent.

49. On information and belief, the DRL Defendants intend to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of DRL’s ANDA Products prior to the expiration of the ’109 patent immediately and imminently upon final approval of ANDA No. 218848. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of DRL’s ANDA Products prior to the

expiration of the ’109 patent would infringe one or more claims of the ’109 patent.

50. On information and belief, upon FDA approval of DRL’s ANDA Products, the DRL Defendants will infringe at least one claim 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 DRL’s ANDA Products in the United States, and/or will induce and/or contribute to infringement of one or more claims of the ’109 patent under 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

51. On information and belief, the DRL Defendants have knowledge of the ’109 patent and have filed ANDA No. 218848 seeking authorization to engage in the commercial manufacture, use, or sale of DRL’s ANDA Products in the United States. On information and belief, if the FDA approves ANDA No. 218848, 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 by the use DRL’s ANDA Products according to the DRL Defendants’ provided instructions and/or label.

52. On information and belief, the DRL Defendants know and intend that healthcare professionals and/or patients will use DRL’s ANDA Products according to the DRL Defendants’ 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).

53. Upon information and belief, upon approval, the DRL Defendants will take active steps to encourage the use of DRL’s ANDA Products 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 of the ’109 patent for the pecuniary benefit of the DRL

Defendants. Upon information and belief, the DRL Defendants will thus induce infringement of at least one claim of the '109 patent with the requisite intent under 35 U.S.C. § 271(b). Upon information and belief, the DRL Defendants will have actual knowledge of the '109 patent and will actively induce infringement of the '109 patent immediately and imminently upon approval of its ANDA.

54. On information and belief, if the FDA approves ANDA No. 218848, DRL's ANDA Products will be specifically labeled for use in practicing at least one claim of the '109 patent, wherein DRL's ANDA Products are a material part of the claimed invention, wherein the DRL Defendants know and intend that healthcare professionals and/or patients will use DRL's ANDA Products in accordance with the instructions and/or label provided by the DRL Defendants in practicing at least one claim of the '109 patent, and wherein DRL's ANDA Products are not a staple article or commodity of commerce suitable for substantial non-infringing use. Upon information and belief, the DRL Defendants will thus contribute to the infringement of at least one claim of the '109 patent under 35 U.S.C. § 271(c).

55. Upon information and belief, the DRL Defendants' actions relating to ANDA No. 218848 complained of herein were done by and for the benefit of the DRL Defendants.

56. If the DRL Defendants' marketing and sale of DRL's ANDA Products 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)

57. Plaintiffs allege, and incorporate in full herein, each of the preceding paragraphs 1–56.

58. Claims 4–9, 16–22, 24, 26, 31–40, and 44–57 of the '702 patent are presumed valid under 35 U.S.C. § 282.

59. Under 35 U.S.C. § 271(e)(2)(A), the DRL Defendants have infringed at least one claim of the '702 patent by submitting, or causing to be submitted to the FDA, ANDA No. 218848 seeking approval to engage in the commercial manufacture, use, or sale of DRL's ANDA Products before the expiration date of the '702 patent. On information and belief, the product described in ANDA No. 218848 would infringe, either literally or under the doctrine of equivalents, at least one claim of the '702 patent under 35 U.S.C. § 271(e)(2)(A).

60. In DRL's Notice Letter, the DRL Defendants did not provide any allegation that DRL's ANDA Products do not fall within the scope of the claims of the '702 patent, and therefore admit infringement of the '702 patent.

61. On information and belief, based on DRL's Notice Letter, the absence of any allegation that DRL's ANDA Products do not fall within the scope of the claims of the '702 patent in DRL's Notice Letter, the fact that the DRL Defendants have represented to the FDA that DRL's ANDA Products are bioequivalent, pharmaceutically equivalent, and therapeutically equivalent to Injectafer®, and the fact that, pursuant to 21 C.F.R. § 314.94, the DRL Defendants are required to substantially copy the FDA-approved Injectafer® labeling, DRL's ANDA Products comprise 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 DRL's ANDA Products 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 DRL's ANDA Products will satisfy all of the limitations of one or more claims of the '702 patent.

62. On information and belief, the DRL Defendants intend to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of

DRL's ANDA Products prior to the expiration of the '702 patent immediately and imminently upon final approval of ANDA No. 218848. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of DRL's ANDA Products prior to the expiration of the '702 patent would infringe one or more claims of the '702 patent.

63. On information and belief, upon FDA approval of DRL's ANDA Products, the DRL Defendants will induce and/or contribute to the infringement of one or more claims of the '702 patent under 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

64. On information and belief, the DRL Defendants have knowledge of the '702 patent and have filed ANDA No. 218848 seeking authorization to engage in the commercial manufacture, use, or sale of DRL's ANDA Products in the United States. On information and belief, if the FDA approves ANDA No. 218848, 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 by the use DRL's ANDA Products according to the DRL Defendants' provided instructions and/or label.

65. On information and belief, the DRL Defendants know and intend that healthcare professionals and/or patients will use DRL's ANDA Products according to the DRL Defendants' 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).

66. Upon information and belief, upon approval, the DRL Defendants will take active steps to encourage the use of DRL's ANDA Products 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 of the '702 patent for the pecuniary benefit of the DRL

Defendants. Upon information and belief, the DRL Defendants will thus induce infringement of at least one claim of the '702 patent with the requisite intent under 35 U.S.C. § 271(b). Upon information and belief, the DRL Defendants will have actual knowledge of the '702 patent and will actively induce infringement of the '702 patent immediately and imminently upon approval of its ANDA.

67. On information and belief, if the FDA approves ANDA No. 218848, DRL's ANDA Products will be specifically labeled for use in practicing at least one claim of the '702 patent, wherein DRL's ANDA Products are a material part of the claimed invention, wherein the DRL Defendants know and intend that healthcare professionals and/or patients will use DRL's ANDA Products in accordance with the instructions and/or label provided by the DRL Defendants in practicing at least one claim of the '702 patent, and wherein DRL's ANDA Products are not a staple article or commodity of commerce suitable for substantial non-infringing use. Upon information and belief, the DRL Defendants will thus contribute to the infringement of at least one claim of the '702 patent under 35 U.S.C. § 271(c).

68. Upon information and belief, the DRL Defendants' actions relating to ANDA No. 218848 complained of herein were done by and for the benefit of the DRL Defendants.

69. If the DRL Defendants' marketing and sale of DRL's ANDA Products 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)

70. Plaintiffs allege, and incorporate in full herein, each of the preceding paragraphs 1–69.

71. The claims of the '612 patent are presumed valid under 35 U.S.C. § 282.

72. Under 35 U.S.C. § 271(e)(2)(A), the DRL Defendants have infringed at least one

claim of the ’612 patent by submitting, or causing to be submitted to the FDA, ANDA No. 218848 seeking approval to engage in the commercial manufacture, use, or sale of DRL’s ANDA Products before the expiration date of the ’612 patent. On information and belief, the product described in ANDA No. 218848 would infringe, either literally or under the doctrine of equivalents, at least one claim of the ’612 patent under 35 U.S.C. § 271(e)(2)(A).

73. In DRL’s Notice Letter, the DRL Defendants did not provide any allegation that DRL’s ANDA Products do not fall within the scope of any claim of the ’612 patent and therefore admit infringement of the ’612 patent.

74. On information and belief, based on DRL’s Notice Letter, the absence of any allegation that DRL’s ANDA Products do not fall within the scope of the claims of the ’612 patent in DRL’s Notice Letter, the fact that the DRL Defendants have represented to the FDA that DRL’s ANDA Products are bioequivalent, pharmaceutically equivalent, and therapeutically equivalent to Injectafer®, and the fact that, pursuant to 21 C.F.R. § 314.94, the DRL Defendants are required to substantially copy the FDA-approved Injectafer® labeling, DRL’s ANDA Products comprise 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 DRL’s ANDA Products 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 DRL’s ANDA Products will satisfy all of the limitations of one or more claims of the ’612 patent.

75. On information and belief, the DRL Defendants intend to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of

DRL's ANDA Products prior to the expiration of the '612 patent immediately and imminently upon final approval of ANDA No. 218848. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of DRL's ANDA Products prior to the expiration of the '612 patent would infringe one or more claims of the '612 patent.

76. On information and belief, upon FDA approval of DRL's ANDA Products, the DRL Defendants will induce and/or contribute to the infringement of one or more claims of the '612 patent under 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

77. On information and belief, the DRL Defendants have knowledge of the '612 patent and have filed ANDA No. 218848 seeking authorization to engage in the commercial manufacture, use, or sale of DRL's ANDA Products in the United States. On information and belief, if the FDA approves ANDA No. 218848, 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 '612 patent by the use DRL's ANDA Products according to the DRL Defendants' provided instructions and/or label.

78. On information and belief, the DRL Defendants know and intend that healthcare professionals and/or patients will use DRL's ANDA Products according to the DRL Defendants' 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).

79. Upon information and belief, upon approval, the DRL Defendants will take active steps to encourage the use of DRL's ANDA Products 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 of the '612 patent for the pecuniary benefit of the DRL

Defendants. Upon information and belief, the DRL Defendants will thus induce infringement of at least one claim of the '612 patent with the requisite intent under 35 U.S.C. § 271(b). Upon information and belief, the DRL Defendants will have actual knowledge of the '612 patent and will actively induce infringement of the '612 patent immediately and imminently upon approval of its ANDA.

80. On information and belief, if the FDA approves ANDA No. 218848, DRL's ANDA Products will be specifically labeled for use in practicing at least one claim of the '612 patent, wherein DRL's ANDA Products are a material part of the claimed invention, wherein the DRL Defendants know and intend that healthcare professionals and/or patients will use DRL's ANDA Products in accordance with the instructions and/or label provided by the DRL Defendants in practicing at least one claim of the '612 patent, and wherein DRL's ANDA Products are not a staple article or commodity of commerce suitable for substantial non-infringing use. Upon information and belief, the DRL Defendants will thus contribute to the infringement of at least one claim of the '612 patent under 35 U.S.C. § 271(c).

81. Upon information and belief, the DRL Defendants' actions relating to ANDA No. 218848 complained of herein were done by and for the benefit of the DRL Defendants.

82. If the DRL Defendants' marketing and sale of DRL's ANDA Products 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 '260 PATENT)

83. Plaintiffs allege, and incorporate in full herein, each of the preceding paragraphs 1–82.

84. The claims of the '260 patent are presumed valid under 35 U.S.C. § 282.

85. Under 35 U.S.C. § 271(e)(2)(A), the DRL Defendants have infringed at least one

claim of the ’260 patent by submitting, or causing to be submitted to the FDA, ANDA No. 218848 seeking approval to engage in the commercial manufacture, use, or sale of DRL’s ANDA Products before the expiration date of the ’260 patent. On information and belief, the product described in ANDA No. 218848 would infringe, either literally or under the doctrine of equivalents, at least one claim of the ’260 patent under 35 U.S.C. § 271(e)(2)(A).

86. In DRL’s Notice Letter, the DRL Defendants did not provide any allegation that DRL’s ANDA Products do not fall within the scope of the claims of the ’260 patent, and therefore admit infringement of the ’260 patent.

87. On information and belief, based on DRL’s Notice Letter, the absence of any allegation that DRL’s ANDA Products do not fall within the scope of the claims of the ’260 patent in DRL’s Notice Letter, the fact that the DRL Defendants have represented to the FDA that DRL’s ANDA Products are bioequivalent, pharmaceutically equivalent, and therapeutically equivalent to Injectafer®, and the fact that, pursuant to 21 C.F.R. § 314.94, the DRL Defendants are required to substantially copy the FDA-approved Injectafer® labeling, DRL’s ANDA Products comprise 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 or dysfunctional iron metabolism associated with cardiomyopathy, whereby DRL’s ANDA Products 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 DRL’s ANDA Products will satisfy all of the limitations of one or more claims of the ’260 patent.

88. On information and belief, the DRL Defendants intend to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of

DRL's ANDA Products prior to the expiration of the '260 patent immediately and imminently upon final approval of ANDA No. 218848. The commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of DRL's ANDA Products prior to the expiration of the '260 patent would infringe one or more claims of the '260 patent.

89. On information and belief, upon FDA approval of DRL's ANDA Products, the DRL Defendants will induce and/or contribute to the infringement of one or more claims of the '260 patent under 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

90. On information and belief, the DRL Defendants have knowledge of the '260 patent and have filed ANDA No. 218848 seeking authorization to engage in the commercial manufacture, use, or sale of DRL's ANDA Products in the United States. On information and belief, if the FDA approves ANDA No. 218848, 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 '260 patent by the use DRL's ANDA Products according to the DRL Defendants' provided instructions and/or label.

91. On information and belief, the DRL Defendants know and intend that healthcare professionals and/or patients will use DRL's ANDA Products according to the DRL Defendants' provided instructions and/or label in an infringing manner, and will therefore induce infringement of one or more claims of the '260 patent with the requisite intent under 35 U.S.C. § 271(b).

92. Upon information and belief, upon approval, the DRL Defendants will take active steps to encourage the use of DRL's ANDA Products 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 of the '260 patent for the pecuniary benefit of the DRL

Defendants. Upon information and belief, the DRL Defendants will thus induce infringement of at least one claim of the '260 patent with the requisite intent under 35 U.S.C. § 271(b). Upon information and belief, the DRL Defendants will have actual knowledge of the '260 patent and will actively induce infringement of the '260 patent immediately and imminently upon approval of its ANDA.

93. On information and belief, if the FDA approves ANDA No. 218848, DRL's ANDA Products will be specifically labeled for use in practicing at least one claim of the '260 patent, wherein DRL's ANDA Products are a material part of the claimed invention, wherein the DRL Defendants know and intend that healthcare professionals and/or patients will use DRL's ANDA Products in accordance with the instructions and/or label provided by the DRL Defendants in practicing at least one claim of the '260 patent, and wherein DRL's ANDA Products are not a staple article or commodity of commerce suitable for substantial non-infringing use. Upon information and belief, the DRL Defendants will thus contribute to the infringement of at least one claim of the '260 patent under 35 U.S.C. § 271(c).

94. Upon information and belief, the DRL Defendants' actions relating to ANDA No. 218848 complained of herein were done by and for the benefit of the DRL Defendants.

95. If the DRL Defendants' marketing and sale of DRL's ANDA Products prior to the expiration of the '260 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT V (INFRINGEMENT OF THE '091 PATENT)

96. Plaintiffs allege, and incorporate in full herein, each of the preceding paragraphs 1–95.

97. The claims of the '091 patent are presumed valid under 35 U.S.C. § 282.

98. Under 35 U.S.C. § 271(e)(2)(A), the DRL Defendants have infringed at least one

claim of the ’091 patent by submitting, or causing to be submitted to the FDA, ANDA No. 218848 seeking approval to engage in the commercial manufacture, use, or sale of DRL’s ANDA Products before the expiration date of the ’091 patent. On information and belief, the product described in ANDA No. 218848 would infringe, either literally or under the doctrine of equivalents, at least one claim of the ’091 patent under 35 U.S.C. § 271(e)(2)(A).

99. In DRL’s Notice Letter, the DRL Defendants did not provide any allegation that DRL’s ANDA Products do not fall within the scope of the claims of the ’091 patent, and therefore admit infringement of the ’091 patent.

100. On information and belief, based on DRL’s Notice Letter, the absence of any allegation that DRL’s ANDA Products do not fall within the scope of the claims of the ’091 patent in DRL’s Notice Letter, the fact that the DRL Defendants have represented to the FDA that DRL’s ANDA Products are bioequivalent, pharmaceutically equivalent, and therapeutically equivalent to Injectafer®, and the fact that, pursuant to 21 C.F.R. § 314.94, the DRL Defendants are required to substantially copy the FDA-approved Injectafer® labeling, DRL’s ANDA Products comprise an iron carboxymaltose complex, and will be used in a method of treating anemia, whereby DRL’s ANDA Products will be administered intravenously to a human subject in need thereof in a single dosage unit of at least about 0.7 grams of elemental iron in 15 minutes or less, and the use of DRL’s ANDA Products will satisfy all of the limitations of one or more claims of the ’091 patent.

101. On information and belief, the DRL Defendants intend to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of DRL’s ANDA Products prior to the expiration of the ’091 patent immediately and imminently upon final approval of ANDA No. 218848. The commercial manufacture, use, offer for sale,

sale, marketing, distributing, and/or importation of DRL's ANDA Products prior to the expiration of the '091 patent would infringe one or more claims of the '091 patent.

102. On information and belief, upon FDA approval of DRL's ANDA Products, the DRL Defendants will induce and/or contribute to the infringement of one or more claims of the '091 patent under 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

103. On information and belief, the DRL Defendants have knowledge of the '091 patent and have filed ANDA No. 218848 seeking authorization to engage in the commercial manufacture, use, or sale of DRL's ANDA Products in the United States. On information and belief, if the FDA approves ANDA No. 218848, 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 '091 patent by the use DRL's ANDA Products according to the DRL Defendants' provided instructions and/or label.

104. On information and belief, the DRL Defendants know and intend that healthcare professionals and/or patients will use DRL's ANDA Products according to the DRL Defendants' provided instructions and/or label in an infringing manner, and will therefore induce infringement of one or more claims of the '091 patent with the requisite intent under 35 U.S.C. § 271(b).

105. Upon information and belief, upon approval, the DRL Defendants will take active steps to encourage the use of DRL's ANDA Products 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 of the '091 patent for the pecuniary benefit of the DRL Defendants. Upon information and belief, the DRL Defendants will thus induce infringement of at least one claim of the '091 patent with the requisite intent under 35 U.S.C. § 271(b). Upon

information and belief, the DRL Defendants will have actual knowledge of the ’091 patent and will actively induce infringement of the ’091 patent immediately and imminently upon approval of its ANDA.

106. On information and belief, if the FDA approves ANDA No. 218848, DRL’s ANDA Products will be specifically labeled for use in practicing at least one claim of the ’091 patent, wherein DRL’s ANDA Products are a material part of the claimed invention, wherein the DRL Defendants know and intend that healthcare professionals and/or patients will use DRL’s ANDA Products in accordance with the instructions and/or label provided by the DRL Defendants in practicing at least one claim of the ’091 patent, and wherein DRL’s ANDA Products are not a staple article or commodity of commerce suitable for substantial non-infringing use. Upon information and belief, the DRL Defendants will thus contribute to the infringement of at least one claim of the ’091 patent under 35 U.S.C. § 271(c).

107. Upon information and belief, the DRL Defendants’ actions relating to ANDA No. 218848 complained of herein were done by and for the benefit of the DRL Defendants.

108. If the DRL Defendants’ marketing and sale of DRL’s ANDA Products prior to the expiration of the ’091 patent is not enjoined, Plaintiffs will suffer substantial and irreparable harm for which there is no adequate remedy at law.

COUNT VI (INFRINGEMENT OF THE ’502 PATENT)

109. Plaintiffs allege, and incorporate in full herein, each of the preceding paragraphs 1–108.

110. The claims of the ’502 patent are presumed valid under 35 U.S.C. § 282.

111. Under 35 U.S.C. § 271(e)(2)(A), the DRL Defendants have infringed at least one claim of the ’502 patent by submitting, or causing to be submitted to the FDA, ANDA No. 218848 seeking approval to engage in the commercial manufacture, use, or sale of DRL’s

ANDA Products before the expiration date of the ’502 patent. On information and belief, the product described in ANDA No. 218848 would infringe, either literally or under the doctrine of equivalents, at least one claim of the ’502 patent under 35 U.S.C. § 271(e)(2)(A).

112. In DRL’s Notice Letter, the DRL Defendants did not provide any allegation that DRL’s ANDA Products do not fall within the scope of the claims of the ’502 patent, and therefore admit infringement of the ’502 patent.

113. On information and belief, based on DRL’s Notice Letter, the absence of any allegation that DRL’s ANDA Products do not fall within the scope of the claims of the ’502 patent in DRL’s Notice Letter, the fact that the DRL Defendants have represented to the FDA that DRL’s ANDA Products are bioequivalent, pharmaceutically equivalent, and therapeutically equivalent to Injectafer®, and the fact that, pursuant to 21 C.F.R. § 314.94, the DRL Defendants are required to substantially copy the FDA-approved Injectafer® labeling, DRL’s ANDA Products comprise a polynuclear iron (III)-hydroxide 4(R)-(poly-(1→4)-O-α-D-glucopyranosyl)-oxy-2(R),3(R),5(R),6-tetrahydroxy-hexanoate, and will be used in a method of treating iron deficiency anemia or functional iron deficiency and result in increased transferrin saturation, whereby DRL’s ANDA Products will be administered intravenously in about 15 minutes or less to an adult human subject in need thereof in a single dosage unit of at least about 0.6 grams of elemental iron, and the use of DRL’s ANDA Products will satisfy all of the limitations of one or more claims of the ’502 patent.

114. On information and belief, the DRL Defendants intend to engage in the commercial manufacture, use, offer for sale, sale, marketing, distributing, and/or importation of DRL’s ANDA Products prior to the expiration of the ’502 patent immediately and imminently upon final approval of ANDA No. 218848. The commercial manufacture, use, offer for sale,

sale, marketing, distributing, and/or importation of DRL's ANDA Products prior to the expiration of the '502 patent would infringe one or more claims of the '502 patent.

115. On information and belief, upon FDA approval of DRL's ANDA Products, the DRL Defendants will induce and/or contribute to the infringement of one or more claims of the '502 patent under 35 U.S.C. §§ 271(b) and/or (c), unless enjoined by the Court.

116. On information and belief, the DRL Defendants have knowledge of the '502 patent and have filed ANDA No. 218848 seeking authorization to engage in the commercial manufacture, use, or sale of DRL's ANDA Products in the United States. On information and belief, if the FDA approves ANDA No. 218848, 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 '502 patent by the use DRL's ANDA Products according to the DRL Defendants' provided instructions and/or label.

117. On information and belief, the DRL Defendants know and intend that healthcare professionals and/or patients will use DRL's ANDA Products according to the DRL Defendants' provided instructions and/or label in an infringing manner, and will therefore induce infringement of one or more claims of the '502 patent with the requisite intent under 35 U.S.C. § 271(b).

118. Upon information and belief, upon approval, the DRL Defendants will take active steps to encourage the use of DRL's ANDA Products 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 of the '502 patent for the pecuniary benefit of the DRL Defendants. Upon information and belief, the DRL Defendants will thus induce infringement of at least one claim of the '502 patent with the requisite intent under 35 U.S.C. § 271(b). Upon

information and belief, the DRL Defendants will have actual knowledge of the '502 patent and will actively induce infringement of the '502 patent immediately and imminently upon approval of its ANDA.

119. On information and belief, if the FDA approves ANDA No. 218848, DRL's ANDA Products will be specifically labeled for use in practicing at least one claim of the '502 patent, wherein DRL's ANDA Products are a material part of the claimed invention, wherein the DRL Defendants know and intend that healthcare professionals and/or patients will use DRL's ANDA Products in accordance with the instructions and/or label provided by the DRL Defendants in practicing at least one claim of the '502 patent, and wherein DRL's ANDA Products are not a staple article or commodity of commerce suitable for substantial non-infringing use. Upon information and belief, the DRL Defendants will thus contribute to the infringement of at least one claim of the '502 patent under 35 U.S.C. § 271(c).

120. Upon information and belief, the DRL Defendants' actions relating to ANDA No. 218848 complained of herein were done by and for the benefit of the DRL Defendants.

121. If the DRL Defendants' marketing and sale of DRL's ANDA Products prior to the expiration of the '502 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, '260, '091, and '502 patents are not invalid or unenforceable, and are infringed by the DRL Defendants' submission of ANDA No. 218848 under 35 U.S.C. §271(e)(2)(A), and that the DRL Defendants' making, using, offering to sell, or selling in the United States, or importing into the United States, DRL's ANDA Products will infringe the '109, '702, '612, '260, '091, and '502 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. 218848 shall be a date that is not earlier than the latest expiration date of the '109, '702, '612, '260, '091, and '502 patents, including any extensions and/or additional periods of exclusivity to which Plaintiffs are or become entitled;

3. An order permanently enjoining each of the DRL Defendants and 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 DRL's ANDA Products until after the last expiration date of the '109, '702, '612, '260, '091, and '502 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 the DRL Defendants engage in commercial manufacture, use, offers to sell, sale, or importation in or into the United States of DRL's ANDA Products prior to the latest expiration date of the '109, '702, '612, '260, '091, and '502 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 7, 2024

Respectfully submitted,

McCARTER & ENGLISH, LLP

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LOCAL RULE 11.2 CERTIFICATION

Pursuant to Local Civil Rule 11.2, I hereby certify that the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

United States Patent Nos. 7,612,109 ("the '109 patent"); 7,754,702 ("the '702 patent"); and 8,895,612 ("the '612 patent") were the subject of now-closed proceedings before this Court including those cases consolidated under the matter *VIFOR (INTERNATIONAL) AG et al v. MYLAN LABORATORIES Ltd*., 3:19-cv-13955-FLW-DEA. The Defendants in this matter were not involved in those cases.

I certify under penalty of perjury under the laws of the United States of America that the foregoing is true and correct.

Dated: June 7, 2024

/s/ Cynthia S. Betz
Cynthia S. Betz