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UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

AMERICAN REGENT, INC., Plaintiff, v. PHARMACOSMOS THERAPEUTICS INC. and PHARMACOSMOS A/S, Defendants.	Civil Action No. 20-1350 (BRM) (LHG) *Document Electronically Filed*

AMENDED COMPLAINT FOR PATENT INFRINGEMENT AND DEMAND FOR JURY TRIAL

Plaintiff American Regent, Inc. ("American Regent" or "Plaintiff"), by its attorneys, hereby alleges as follows:

NATURE OF THE ACTION

1. This is an action for infringement of U.S. Patent Nos. 8,431,549 ("the '549 patent") (Ex. 1) and 10,478,450 ("the '450 patent") (Ex. 2) (collectively, the "Patents-in-Suit") under the patent laws of the United States, Title 35, United States Code, against Pharmacosmos Therapeutics Inc. and Pharmacosmos A/S (collectively, "Pharmacosmos" or "Defendants"). This action relates to Pharmacosmos's Monoferric® (ferric derisomaltose) pharmaceutical drug product, which the

U.S. Food and Drug Administration ("FDA") recently approved for the treatment of iron deficiency anemia, and that, on information and belief, Pharmacosmos has commercially launched in the United States. Pharmacosmos's commercial manufacture, importation, offers to sell, and sales of Monoferric® actively induces and/or contributes to infringement of claims of each of the Patents-in-Suit.

THE PARTIES

2. Plaintiff American Regent, Inc. 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, NY 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.

3. American Regent manufactures and sells injectable pharmaceutical drug products, including Injectafer® (ferric carboxymaltose), an iron carbohydrate complex treatment for iron deficiency anemia, in this judicial district and throughout the United States. American Regent has contracted with Daiichi Sankyo, Inc. through a Marketing Services Agreement to market Injectafer® within the United States.

4. On information and belief, Defendant Pharmacosmos Therapeutics Inc. is a corporation organized and existing under the laws of the state of Delaware, with a principal place of business at 776 Mountain Blvd, Watchung, New Jersey 07069 and an office or facility at 65 Madison Avenue, Morristown, New Jersey 07960. On information and belief, Pharmacosmos Therapeutics Inc., a wholly-owned subsidiary of Pharmacosmos A/S, was "established to pursue FDA approval of and ultimately commercialize Pharmacosmos products in the US market." Ex. 3 at 1.

5. On information and belief, Defendant Pharmacosmos A/S is a company organized and existing under the laws of Denmark, with a principal place of business at Roervangsvej 30, DK-4300 Holbaek, Denmark. On information and belief, Pharmacosmos A/S is an international pharmaceutical company that develops and manufactures specialty carbohydrate products and veterinary products that are marketed and sold throughout the United States, including in this judicial district, either directly or through its United States partners, affiliates, and subsidiaries.

6. On information and belief, Pharmacosmos A/S and Pharmacosmos Therapeutics Inc. currently work in concert and will continue to work in concert with each other with respect to manufacturing, marketing, sale, and distribution of Monoferric® in New Jersey and throughout the United States.

JURISDICTION AND VENUE

7. 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).

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

9. On information and belief, this Court also has personal jurisdiction over Pharmacosmos Therapeutics Inc., 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 or engages in other persistent courses of conduct in New Jersey, demonstrating that Pharmacosmos Therapeutics Inc. has systematic and continuous contacts with this judicial district.

10. On information and belief, this Court has personal jurisdiction over Pharmacosmos A/S, 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 Pharmacosmos A/S has systematic and continuous contacts with this judicial district.

11. On information and belief, Pharmacosmos A/S purposefully has conducted and continues to conduct business in this judicial district by importing, marketing, and selling specialty carbohydrate products and veterinary products, either directly and/or through its United States partners, affiliates, and subsidiaries throughout the United States, including in this judicial district. *See, e.g.*, Ex. 4 (noting that Pharmacosmos manufactures Dextran products that comply with United States Pharmacopeia ("USP") specifications and that "Pharmacosmos sells and ships directly to clients everywhere in the World."); *id.* (noting that Pharmacosmos holds a U.S. FDA certificate); Ex. 5 (providing "[o]rdering and product information for US customers"); Ex. 17 at 2-3 (noting that Pharmacosmos's Monofer® was "first approved in Europe," is "available in >30 countries," and that Monoferric® is now "approved in US").

12. On information and belief, Pharmacosmos A/S imports, markets, distributes, offers for sale, and/or sells Monoferric®, either directly or through its United States affiliate Pharmacosmos Therapeutics Inc., in the United States, including in New Jersey, and derives substantial revenue from the sale of its Monoferric® product in the state of New Jersey. Ex. 6 at 1 (noting on January 29, 2020, that Monoferric® is currently marketed, under different brand names, in over 30 countries worldwide and announcing FDA approval of Monoferric® in the U.S. for the treatment of iron deficiency anemia); Ex. 3 at 1 ("Pharmacosmos Therapeutics Inc., the US affiliate

of Pharmacosmos, has been established to pursue FDA approval of and ultimately commercialize Pharmacosmos products in the US market."); Ex. 7 at 1 ("Pharmacosmos Therapeutics Inc., a newly formed affiliate of Pharmacosmos, has been established to commercialize Monoferric® in the rapidly growing US high dose IV iron market."); Ex. 16 at 1 (Monoferric® main product webpage stating that it is "FDA approved" with links to the approved product labeling); Ex. 18 (Monoferric® "access & support" webpage providing information and resources to patients and healthcare professionals).

13. On information and belief, Pharmacosmos A/S imports, markets, distributes, offers for sale, and/or sells Monoferric® in New Jersey, and Monoferric® is prescribed by healthcare providers practicing in New Jersey and administered by healthcare providers to patients located within New Jersey, all of which has a substantial effect on New Jersey.

14. American Regent is harmed by the importation, marketing, distribution, offer for sale, and/or sale of Monoferric®, including in New Jersey.

15. Alternatively, this Court has personal jurisdiction over Pharmacosmos A/S 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 Pharmacosmos A/S 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, Pharmacosmos A/S has systematic and continuous contacts throughout the United States by manufacturing, importing, marketing, and/or distributing carbohydrate products and/or veterinary products, either directly to U.S. customers or through its subsidiaries and/or affiliates to U.S. customers.

16. On information and belief, Pharmacosmos Therapeutics 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, Pharmacosmos Therapeutics Inc. maintains regular and established places of business in New Jersey, including offices, laboratories, and/or facilities at 776 Mountain Blvd, Watchung, New Jersey 07069 and at 65 Madison Avenue, Morristown, New Jersey 07960. *See* Ex. 6 at 1. On information and belief, venue is proper in this judicial district with respect to Pharmacosmos Therapeutics Inc. under 28 U.S.C. § 1400(b) for at least the reason that it maintains a regular and established place of business in this judicial district and that it undertakes infringing activities in this judicial district by importing, marketing, distributing, offering for sale, and/or selling Monoferric® in the United States, including in New Jersey.

17. 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 Pharmacosmos A/S 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. 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).

PATENTS-IN-SUIT

18. The U.S. Patent and Trademark Office ("PTO") issued the '549 patent entitled "Methods and Compositions For Administration of Iron," on April 30, 2013, to inventors Mary Jane Helenek, Marc L. Tokars, and Richard P. Lawrence. As reflected in the assignment records of the PTO, American Regent is the assignee of the '549 patent and has the right to enforce it. The '549 patent claims, *inter alia*, methods of treating iron deficiency anemia by administering an iron carbohydrate complex. A true and correct copy of the '549 patent is attached hereto as Exhibit 1.

19. In 2015, Pharmacosmos filed a petition with the PTO for *inter partes* review ("IPR"), seeking to invalidate certain claims of the '549 patent. The Patent Trial and Appeal Board ("PTAB") declined to institute the IPR for at least claims 7, 17, and 21, concluding that Pharmacosmos had "not shown a reasonable likelihood of prevailing" in its validity challenge as to the non-instituted claims. *Pharmacosmos A/S v. Luitpold Pharm. Inc.*, IPR2015-01493, Paper No. 11 at 9 (PTAB Jan. 8, 2016). The PTAB instituted review for other of the challenged claims, and ultimately issued a final written decision finding only certain claims of the '549 patent unpatentable. *Pharmacosmos A/S v. Luitpold Pharm. Inc.*, IPR2015-01493, Paper No. 54 (PTAB Dec. 28, 2016).

20. In 2019, Pharmacosmos filed a second IPR petition against the '549 patent, again including claims 7 and 21 in its challenge. The Board denied the petition in its entirety. *Pharmacosmos A/S v. American Regent, Inc.*, No. IPR2019-01142, Paper No. 13 at 16 (PTAB Dec. 18, 2019).

21. Pharmacosmos is statutorily estopped from challenging the asserted claims of the '549 patent on grounds that Pharmacosmos raised or reasonably could have raised at least during IPR2015-01493. *See* 35 U.S.C. § 315(e).

22. Pharmacosmos is collaterally estopped from raising against the asserted claims of the '549 patent any issues of fact or law that, in Pharmacosmos's various post-grant challenges to American Regent's patents before the PTO (including but not limited to Pharmacosmos's challenges to the '549 and '450 patents), were actually litigated, determined by a valid and final judgment, and essential to such judgment.

23. The PTO issued the '450 patent entitled "Methods and Compositions For Administration of Iron," on November 19, 2019, to inventors Mary Jane Helenek, Marc L. Tokars,

and Richard P. Lawrence. As reflected in the assignment records of the PTO, American Regent is the assignee of the '450 patent and has the right to enforce it. The '450 patent claims, *inter alia*, methods of treating iron deficiency anemia by the administration of an iron carbohydrate complex. A true and correct copy of the '450 patent is attached hereto as Exhibit 2.

24. On January 6, 2020, Pharmacosmos filed a petition with the PTO for post-grant review ("PGR"), seeking to invalidate all claims of the '450 patent. The PTAB declined to institute the PGR in its entirety, concluding that "the same or substantially the same prior art and arguments previously were presented to the Office, and Petitioner [Pharmacosmos] has not shown that the Office erred in a manner material to patentability." *Pharmacosmos A/S v. American Regent, Inc.*, PGR2020-00009, Paper No. 17 at 28 (PTAB Aug. 14, 2020).

25. Pharmacosmos is collaterally estopped from raising against the asserted claims of the '450 patent any issues of fact or law that, in Pharmacosmos's various post-grant challenges to American Regent's patents before the PTO (including but not limited to Pharmacosmos's challenges to the '549 and '450 patents), were actually litigated, determined by a valid and final judgment, and essential to such judgment.

ACTS GIVING RISE TO THIS ACTION FOR DEFENDANTS' INFRINGEMENT OF THE PATENTS-IN-SUIT

26. Plaintiff realleges, and incorporates in full herein, each of the preceding paragraphs 1-25.

27. On March 21, 2019, Pharmacosmos A/S submitted New Drug Application ("NDA") No. 208171 to the FDA for approval to market Monoferric®, an iron carbohydrate complex injection product, for the treatment of iron deficiency anemia. Ex. 8 at 1.

28. On January 16, 2020, the FDA approved Pharmacosmos's NDA No. 208171 for Monoferric®, an iron carbohydrate complex injection product, for the treatment of iron deficiency

anemia, clearing the way for the commercial launch of Monoferric® in the United States. Ex. 8 at 1.

29. On September 11, 2020, the FDA approved Pharmacosmos's supplemental new drug application, NDA 208171/S-001, reflecting updated product safety information. Ex. 14 at 1.

30. On information and belief, Pharmacosmos has launched Monoferric® in the United States and is actively importing, offering for sale, and selling Monoferric® throughout the United States, including in this judicial district, accompanied by the FDA-approved product labeling. *See* Ex. 16 at 1 (Monoferric® main product webpage stating that it is "FDA approved" with links to the approved product labeling); Ex. 17 at 3 (Monoferric® "global use" webpage stating that the drug is now "approved in US"); Ex. 18 (Monoferric® "access & support" webpage providing information and resources to patients and healthcare professionals).

31. On information and belief, Pharmacosmos A/S and Pharmacosmos Therapeutics Inc. are working together to import, market, distribute, offer for sale, and/or sell Monoferric® in the United States. *See, e.g.*, Ex. 7 at 1 (Pharmacosmos Therapeutics Inc. was founded by Pharmacosmos A/S in 2019 "to commercialize Monoferric® in the rapidly growing US high-dose IV iron market" and to "driv[e] the growth of Monoferric®" in the United States); Ex. 6 at 1 (CEO of Pharmacosmos Therapeutics Inc. stating "[w]e are excited to provide this new innovative treatment to US physicians").

32. On information and belief, as of January 2020, Pharmacosmos Therapeutics Inc. had hired a National Sales Director specializing in "commercial healthcare product launches" (Ex. 9) and was soliciting applications for the positions of "Marketing Director" and "Decision Support Director/Sr Director (Commercial Analytics & Sales Operations)" for the launch of Monoferric® (Exs. 7, 10). Since FDA approval of Monoferric®, Pharmacosmos Therapeutics Inc. has filled

numerous positions relating to its iron-deficiency product(s), including marketing and sales throughout the United States.

33. The FDA-approved Monoferric® Label states that it is "Manufactured under license from Pharmacosmos A/S," and distributed by Pharmacosmos A/S. Ex. 11 at 10; Ex. 15 at 10.

34. The Monoferric® Label states that "Monoferric® is indicated for the treatment of iron deficiency anemia (IDA) in adult patients: who have intolerance to oral iron or have had unsatisfactory response to oral iron or who have non-hemodialysis dependent chronic kidney disease (NDD-CKD)." Ex. 11 at 2; Ex. 15 at 2.

35. The Monoferric® Label states that Monoferric® is "an iron carbohydrate complex." Ex. 11 at 7; Ex. 15 at 7. On information and belief, Monoferric® has "very low immunogenic potential" and "low immunological activity." Ex. 12 at 480, 490.

36. The Monoferric® Label states that "Monoferric® is a sterile, dark brown, non-transparent aqueous solution available as: Injection: 1,000 mg iron/10 mL (100 mg/mL) single-dose vial" and "[t]he dosage of Monoferric® is expressed in mg of elemental iron. Each mL of Monoferric® contains 100 mg of elemental iron." Ex. 11 at 2; Ex. 15 at 2.

37. The Monoferric® Label instructs healthcare providers that "Monoferric® is indicated for the treatment of iron deficiency anemia (IDA) in adult patients: who have intolerance to oral iron or have had unsatisfactory response to oral iron who have non-hemodialysis dependent chronic kidney disease (NDD-CKD)." Ex. 11 at 2; Ex. 15 at 2.

38. The Monoferric® Label provides the following instructions to healthcare providers for the use of Monoferric® to treat iron deficiency anemia: "For patients weighing 50 kg or more: Administer 1,000 mg of Monoferric® by intravenous infusion over at least 20 minutes as a single dose. Repeat dose if iron deficiency anemia reoccurs." Ex. 11 at 2; Ex. 15 at 2.

39. On information and belief, healthcare providers administer Monoferric® according to the instructions provided in the Monoferric® Label, to treat patients with iron deficiency anemia.

COUNT I
(INFRINGEMENT OF THE '549 PATENT)

40. Plaintiff realleges, and incorporates in full herein, each of the preceding paragraphs 1-39.

41. On information and belief, Defendants are engaging in the commercial manufacture, offer for sale, sale, and/or importation of Monoferric®.

42. On information and belief, Defendants became aware of the '549 patent at least no later than January 30, 2015, when American Regent sent a letter to Pharmacosmos A/S regarding infringement of the '549 patent (Ex. 13), or at least no later than June 24, 2015, when Pharmacosmos A/S filed at the PTO a petition for *inter partes* review of the '549 patent.

43. On information and belief, upon awareness of the '549 patent, Defendants know of and intend the infringement of one or more claims of the '549 patent, at least because Defendants' Monoferric® Label provides instructions for infringement of at least one claim of the '549 patent, for example, the methods recited in claims 7, 17 and 21.

44. On information and belief, Defendants have included the Monoferric® Label within the packaging and promotion of Monoferric®, and have otherwise made it available to healthcare providers and patients, for example, on the product website. *See* Ex. 16.

45. On information and belief, healthcare providers that administer Monoferric® in accordance with the instructions provided in the Monoferric® Label directly infringe under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, at least one claim of the '549 patent, including for example claims 7, 17, and 21. On information and belief, Monoferric® is an

iron polyisomaltose complex having a substantially non-immunogenic carbohydrate component, and healthcare providers are instructed by the Monoferric® Label to use Monoferric® in a method of treating a disease characterized by iron deficiency (iron deficiency anemia) that is not Restless Leg Syndrome, whereby Monoferric® is administered in a single dosage unit of at least about 1.0 grams of elemental iron to a patient in need of such treatment, a second administration of such treatment to be administered upon recurrence of at least one symptom of such disease, and the use of Monoferric® satisfies all of the limitations of at least claims 7, 17, and 21 of the '549 patent. *See* Ex. 11; Ex. 15.

46. On information and belief, Defendants know and intend that healthcare providers and/or patients use Monoferric® according to Defendants' provided instructions and/or the Monoferric® Label in an infringing manner, and therefore induce infringement of one or more claims of the '549 patent with the requisite intent under 35 U.S.C. § 271(b).

47. On information and belief, Defendants are taking active steps to encourage the use of Monoferric® by healthcare providers and/or patients with the knowledge and intent that it be used by healthcare providers and/or patients in a manner that infringes at least one claim, including for example claims 7, 17, and 21 of the '549 patent, for the pecuniary benefit of Defendants. Upon information and belief, Defendants thus induce infringement of at least one claim of the '549 patent with the requisite intent under 35 U.S.C. § 271(b).

48. On information and belief, Defendants sell or offer to sell Monoferric® specifically labeled for use in practicing at least one claim including for example claims 7, 17, and 21 of the '549 patent, wherein Monoferric® is a material part of the claimed invention, wherein Defendants know that physicians prescribe and patients use Monoferric® in accordance with the instructions and/or Monoferric® Label provided by Defendants in practicing at least one claim, including for

example claims 7, 17, and 21 of the ’549 patent, and wherein Monoferric® is not a staple article or commodity of commerce suitable for substantial non-infringing use. Upon information and belief, Defendants thus contribute to the infringement of at least one claim of the ’549 patent under 35 U.S.C. § 271(c).

49. If Defendants’ marketing and sale of Monoferric® is not enjoined, Plaintiff will suffer substantial and irreparable harm for which there is no adequate remedy at law.

50. Plaintiff is entitled to a judgment that the manufacture, use, offer for sale, sale, and/or importation of Monoferric® constitutes active inducement of infringement and contributory infringement of at least claims 7, 17, and 21 of the ’549 patent.

COUNT II
(INFRINGEMENT OF THE ’450 PATENT)

51. Plaintiff realleges, and incorporates in full herein, each of the preceding paragraphs 1-50.

52. On information and belief, Defendants are engaging in the commercial manufacture, offer for sale, sale, and/or importation of the Monoferric®.

53. On information and belief, Defendants became aware of the ’450 patent at least no later than January 6, 2020, when they filed at the PTO a petition for post-grant review of the ’450 patent listing as real parties-in-interest Pharmacosmos A/S and Pharmacosmos Therapeutics Inc.

54. On information and belief, upon awareness of the ’450 patent, Defendants know of and intend the infringement of one or more claims of the ’450 patent, at least because Defendants’ Monoferric® Label provides instructions for infringement of at least one claim of the ’450 patent, for example, the methods recited in claims 6, 14, and 22.

55. On information and belief, Defendants have included the Monoferric® Label within the packaging and promotion of Monoferric®, and have otherwise made it available to healthcare

providers and patients, for example, on the product website. *See* Ex. 16.

56. On information and belief, healthcare providers that administer Monoferric® in accordance with the instructions provided in the Monoferric® Label directly infringe under 35 U.S.C. § 271(a), either literally or under the doctrine of equivalents, at least one claim of the '450 patent, including for example claims 6, 14, and 22. On information and belief, Monoferric® is an iron polyisomaltose complex having a substantially non-immunogenic carbohydrate component and substantially no cross reactivity with anti-dextran antibodies, and healthcare providers are instructed by the Monoferric® Label to use Monoferric® in a method of treating a disease characterized by iron deficiency (iron deficiency anemia), whereby Monoferric® is administered in a single dosage unit of at least 0.7 grams of elemental iron to a patient in need of such treatment, a second administration of such treatment to be administered upon recurrence of at least one symptom of such disease, and the use of Monoferric® satisfies all of the limitations of at least claims 6, 14, and 22 of the '450 patent. *See* Ex. 11; Ex. 15.

57. On information and belief, Defendants know and intend that healthcare providers and/or patients use Monoferric® according to Defendants' provided instructions and/or the Monoferric® Label in an infringing manner, and therefore induce infringement of one or more claims of the '450 patent with the requisite intent under 35 U.S.C. § 271(b).

58. On information and belief, Defendants are taking active steps to encourage the use of Monoferric® by healthcare providers and/or patients with the knowledge and intent that it be used by healthcare providers and/or patients in a manner that infringes at least one claim, including for example claims 6, 14, and 22 of the '450 patent, for the pecuniary benefit of Defendants. Upon information and belief, Defendants thus induce infringement of at least one claim of the '450 patent with the requisite intent under 35 U.S.C. § 271(b).

59. On information and belief, Defendants sell or offer to sell Monoferric® specifically labeled for use in practicing at least one claim including for example claims 6, 14, and 22 of the '450 patent, wherein Monoferric® is a material part of the claimed invention, wherein Defendants know that physicians prescribe and patients use Monoferric® in accordance with the instructions and/or Monoferric® Label provided by Defendants in practicing at least one claim, including for example claims 6, 14, and 22 of the '450 patent, and wherein Monoferric® is not a staple article or commodity of commerce suitable for substantial non-infringing use. Upon information and belief, Defendants thus contribute to the infringement of at least one claim of the '450 patent under 35 U.S.C. § 271(c).

60. If Defendants' marketing and sale of Monoferric® is not enjoined, Plaintiff will suffer substantial and irreparable harm for which there is no adequate remedy at law.

61. Plaintiff is entitled to a judgment that the manufacture, use, offer for sale, sale, and/or importation of Monoferric® constitutes active inducement of infringement and contributory infringement of at least claims 6, 14, and 22 of the '450 patent.

COUNT III
(WILLFUL INFRINGEMENT OF THE '549 PATENT)

62. Plaintiff realleges, and incorporates in full herein, each of the preceding paragraphs 1-61.

63. On information and belief, Defendants' infringement of the '549 patent is willful. Indeed, Defendants have been aware of the '549 patent at least no later than January 30, 2015, when American Regent sent a letter to Pharmacosmos A/S regarding infringement of the '549 patent, or at least no later than June 24, 2015, when Pharmacosmos A/S filed a petition for *inter partes* review of the '549 patent. The PTAB declined to institute IPR for claims 7, 17, and 21, concluding that Pharmacosmos A/S had "not shown a reasonable likelihood of prevailing" in its

validity challenge. *Pharmacosmos A/S v. Luitpold Pharm. Inc.*, IPR2015-01493, Paper No. 11 at 9 (PTAB Jan. 8, 2016).

64. On information and belief, Defendants challenged the validity of the '549 patent with full knowledge that its development and commercialization of Monoferric® in the United States when prescribed by treating healthcare providers in accordance with instructions provided in the Monoferric® Label would induce and/or contribute to infringement of the asserted claims of the '549 patent.

65. Defendants' continued development and commercialization of Monoferric® in the United States constitutes willful and blatant infringement.

66. For the same reasons set forth above in paragraphs 26-50, Defendants have knowledge of the '549 patent and that their acts constitute infringement. Defendants have acted and are continuing to act in the face of an objectively high likelihood that their actions constitute infringement of valid claims of the '549 patent or with reckless disregard of that likelihood.

COUNT IV
(WILLFUL INFRINGEMENT OF THE '450 PATENT)

67. Plaintiff realleges, and incorporates in full herein, each of the preceding paragraphs 1-66.

68. On information and belief, Defendants' infringement of the '450 patent is willful. Indeed, Defendants have been aware of the '450 patent at least no later than January 6, 2020, the date on which Defendants filed a petition for post grant review of claims of the '450 patent. The PTAB declined the institute the PGR in its entirety, concluding that "the same or substantially the same prior art and arguments previously were presented to the Office, and Petitioner [Pharmacosmos] has not shown that the Office erred in a manner material to patentability." *Pharmacosmos A/S v. American Regent, Inc.*, PGR2020-00009, Paper No. 17 at 28 (PTAB Aug.

14, 2020).

69. On information and belief, Defendants challenged the validity of the '450 patent with full knowledge that its development and commercialization of Monoferric® in the United States when prescribed by treating healthcare providers in accordance with instructions provided in the Monoferric® Label would induce and/or contribute to infringement of the asserted claims of the '450 patent.

70. Defendants' continued development and commercialization of Monoferric® in the United States constitutes willful and blatant infringement.

71. For the same reasons set forth above in paragraphs 26-39, 51-61, Defendants have knowledge of the '450 patent and that their acts constitute infringement. Defendants have acted and are continuing to act in the face of an objectively high likelihood that their actions constitute infringement of valid claims of the '450 patent or with reckless disregard of that likelihood.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests that this Court grant the following relief:

1. A judgment that the manufacture, use, offer for sale, sale, and/or importation of Monoferric® before expiration of the '549 and '450 patents infringes the Patents-in-Suit;

2. An order enjoining Defendants and their affiliates, subsidiaries, officers, agents, employees, attorneys, and all persons in active concert or participation with any of them, or acting on their behalf, from infringing the '549 and '450 patents;

3. An award for Plaintiff of damages in an amount sufficient to compensate for Defendants' infringement of the '549 and '450 patents, together with prejudgment and post-judgment interest and costs under 35 U.S.C. § 284;

4. An award for Plaintiff, of enhanced damages pursuant to 35 U.S.C. § 284 for

Defendants' willful infringement of the '549 and '450 patents;

5. A finding that this case is an exceptional case under 35 U.S.C. § 285, and an award for Plaintiff of reasonable attorneys' fees and costs;

6. An order requiring Defendants to provide an accounting of Defendants' infringing activities through trial and judgment; and

7. An award of such other and further relief as this Court may deem just and proper.

JURY DEMAND

Under Rule 38 of the Federal Rules of Civil Procedure, Plaintiff hereby demands trial by jury of all issues so triable by a jury in this action.

Dated: January 8, 2021
Newark, New Jersey

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