IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

ENDO OPERATIONS, LTD., *Plaintiff*, v. FRESENIUS KABI USA, LLC, *Defendant*.	Case No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Endo Operations Limited ("Endo" or "Plaintiff"), for its Complaint against FK Fresenius Kabi USA, LLC ("FK"), alleges as follows:

NATURE AND SUMMARY OF THIS ACTION

1. This is an action for patent infringement of Plaintiff's U.S. Patent Nos. 9,119,876 ("the '876 patent"), 9,295,657 ("the '657 patent") and 10,130,592 B2 ("the '592 patent"), (collectively, "the Patents-in-Suit") pursuant to the Patent Laws of the United States, 35 U.S.C. § 1, *et seq*.

THE PARTIES

2. Endo is an Irish company with offices located at First Floor, Minerva House, Simmonscourt Road, Ballsbridge, Dublin 4, Ireland.

3. Upon information and belief, FK is a limited liability company organized and existing under the laws of the State of Delaware, having its corporate headquarters at Three Corporate Drive, Lake Zurich, Illinois 60047.

4. Upon information and belief, FK is a healthcare company and pharmaceutical manufacturer that develops, manufactures, markets and/or distributes pharmaceutical products around the United States, including in this judicial district.

JURISDICTION AND VENUE

5. This Court has subject matter jurisdiction over this dispute pursuant to 28 U.S.C. §§ 1331 and 1338(a).

6. This Court has personal jurisdiction over FK at least because FK is a limited liability company organized and existing under the laws of the State of Delaware.

7. This Court has personal jurisdiction over FK at least because FK has continuous and systematic contacts within this Judicial District. On information and belief, FK at least sells certain FDA-approved pharmaceutical products that are regularly marketed and sold in this Judicial District.

8. This Court has personal jurisdiction over FK at least because FK has consented to jurisdiction in this Judicial District and purposefully availed itself of this Court by filing counterclaims in this jurisdiction. *See, e.g.*, *American Regent, Inc. f/k/a Luitpold Pharmaceuticals, Inc. v. Fresenius Kabi USA, LLC*, 1:24-cv-00824 (DDE), *Heron Therapeutics, Inc. v. Fresenius Kabi USA, LLC et al.*, 1:22-cv-00985 (DDE), *HQ Specialty Pharma Corporation et al v. Fresenius Kabi USA, LLC*, 1:21-cv-01714 (DDE).

9. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b). Venue is proper in this Judicial District at least because FK has committed acts of infringement in this Judicial District, including but not limited to selling and/or offering for sale products that infringe, or were made by a process that infringes, one or more claims of the Patents-in-Suit.

THE PATENTS-IN-SUIT

10. The ’876 patent, titled “Epinephrine Formulations,” was duly and legally issued by the United States Patent and Trademark Office on September 1, 2015. A true and correct copy of the ’876 patent is attached as Exhibit A.

11. The ’657 patent, titled “Epinephrine Formulations,” was duly and legally issued by the United States Patent and Trademark Office on March 29, 2016. A true and correct copy of the ’657 patent is attached as Exhibit B.

12. The ’592 patent, titled “Epinephrine Formulations,” was duly and legally issued by the United States Patent and Trademark Office on November 20, 2018. A true and correct copy of the ’592 patent is attached as Exhibit C.

13. Endo is the assignee of the Patents-in-Suit.

ENDO’S ADRENALIN® PRODUCT

14. Endo is the holder of New Drug Application (“NDA”) No. 204200 for epinephrine injection, Eq 1mg base/mL injectable solution (“Endo’s 1 mL Adrenalin® Product”), which the U.S. Food and Drug Administration (“FDA”) approved on December 7, 2012.

15. Endo is also the holder of New Drug Application (“NDA”) No. 204640 (together with NDA No. 204200, the “Adrenalin® NDAs”) for epinephrine injection, Eq 30 mg base/30 mL injectable solution (Eq 1 mg base/mL) (“Endo’s 30 mL Adrenalin® Product,” and, together with Plaintiff’s 1 mL Adrenalin® Product, “Adrenalin®”), which the U.S. Food and Drug Administration (“FDA”) approved on December 18, 2013.

16. Adrenalin® was the first FDA-approved epinephrine injection product for use in a clinical setting available in the United States. Adrenalin® is a clear, colorless, sterile parenteral solution containing the active ingredient L-epinephrine and is intended for intramuscular or

subcutaneous administration. Adrenalin® is indicated for emergency treatment of allergic reactions (Type 1), including anaphylaxis and to increase mean arterial blood pressure in adult patients with hypotension associated with septic shock.

17. The chemical compound epinephrine is a well-known drug that has been in clinical use for over 100 years for the treatment of allergic reactions and anaphylaxis. Anaphylaxis is a serious and life threatening condition that can lead to death in minutes if not recognized and adequately treated. Epinephrine solution in vials for injection had been marketed as a drug product without FDA approval.

18. In March 2012, Endo's predecessor-in-interest to the Adrenalin® NDAs, JHP Pharmaceuticals ("JHP"), sought FDA approval of the epinephrine formulation it had marketed for over 100 years. Throughout its review of JHP's NDA No. 204200, FDA expressed concerns regarding the potency of the active ingredient in the product, L-epinephrine, in connection with the levels of certain impurities found therein. Epinephrine can potentially degrade through a variety of routes, and can react with other ingredients to form epinephrine sulfonic acid (ESA), or can racemize in aqueous solution to form D-epinephrine, both of which cause a decrease in the effective concentration of the active ingredient L-epinephrine and therefore decrease potency of the product.

19. Because of these concerns, FDA required JHP to meet strict purity requirements for Adrenalin®. In communications with JHP, FDA expressed that impurities reduced the potency of the product, which could be pharmaceutically unacceptable to patients suffering from emergency anaphylaxis who are in need of potent medication in a short amount of time. FDA ultimately required JHP to evaluate formulation and process improvements to reduce the levels of impurities and ensure adequate potency and stability of Adrenalin®.

20. Endo's predecessor-in-interest to the Adrenalin® NDAs, Par Sterile Products, Inc. ("Par Sterile"), undertook substantial efforts in response to FDA's requirement. Par Sterile committed both to investigate the cause of impurity formation and to take necessary measures to lower the limits for certain impurities. Par Sterile undertook a significant initiative to develop a new epinephrine formulation that could meet FDA's requirement to minimize the levels of impurities to address the issue of loss of potency.

21. Par Sterile developed new formulations with significantly lower levels of impurities. For example, Par Sterile developed compositions comprising epinephrine, tonicity regulating agent, pH raising agent, antioxidant comprising sodium bisulfite and/or sodium metabisulfite, pH lowering agent, and transition metal complexing agent, in certain ranges. Par Sterile balanced the compositions' properties, including isotonicity, pH, and stability, in light of the use of sodium bisulfite and/or sodium metabisulfite as an antioxidant. This reduced formation of D-epinephrine and ESA, without compromising pharmaceutical benefits. Thus, Par Sterile was able to maintain the racemic balance of the active ingredient, resulting in lower impurity levels and thus improved potency. The lower impurity levels and improved potency also allowed Par Sterile to extend the shelf life of its compositions.

22. After its successful reformulation effort, Par Sterile submitted supplemental NDAs to FDA for approval of a new formulation to provide a more stable Adrenalin® product, in March 2015 (for Endo's 30 mL Adrenalin® Product) and January 2016 (for Endo's 1 mL Adrenalin® Product). FDA approved the supplemental NDAs for the new formulation in January 2016 (for Endo's 30 mL Adrenalin® Product) and September 2016 (for Endo's 1 mL Adrenalin® Product).

23. Based on the significant research and development it had conducted in the course of reformulating and improving its Adrenalin® product, Endo's predecessor-in-interest to the Patents-in-Suit, Par Pharmaceutical, Inc., obtained several patents, including the Patents-in-Suit.

24. The '876 patent covers the technological advance achieved in its reformulation work. For example, the claims of the '876 patent are directed to compositions comprising epinephrine, tonicity regulating agent, pH raising agent, antioxidant comprising sodium bisulfite and/or sodium metabisulfite, pH lowering agent, and transition metal complexing agent, in certain ranges. The new Adrenalin® formulation is a composition that falls within the claims of the '876 patent.

25. The '657 patent covers methods of using the inventive formulations to treat Type 1 allergic reactions, including anaphylaxis. For example, the claims of the '657 patent are directed to methods of treating certain conditions, including Type 1 allergic reactions and anaphylaxis, by administering to a patient in need a composition comprising epinephrine, tonicity regulating agent, pH raising agent, antioxidant comprising sodium bisulfite and/or sodium metabisulfite, pH lowering agent, and transition metal complexing agent, in certain ranges. The new Adrenalin® formulation, which is a composition that falls within the claims of the '657 patent, is used to treat Type 1 allergic reactions and anaphylaxis, as claimed in the '657 patent.

26. The '592 patent covers the novel compositions comprising epinephrine, methods of administration, and methods of making the same. Compositions may comprise at least one of an active agent, a pH raising agent, an antioxidant, a transition metal complexing agent, a pH lowering agent, a tonicity regulating agent, optionally a preservative, and optionally a solvent.

27. Pursuant to 21 U.S.C. § 355(b)(1) and attendant FDA regulations, the Patents-in-Suit are listed in the Approved Drug Products with Therapeutic Equivalence Evaluations ("Orange Book") with respect to Adrenalin® brand epinephrine injection.

FK'S NDA

28. Upon information and belief, FK is the purported holder of New Drug Application ("NDA") No. 215425 for epinephrine injection, 30 mg/30 mL, Multi-Dose Vial.

29. Upon information and belief, FK submitted to FDA a supplement to NDA No. 215425, under section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, seeking approval to engage in the commercial manufacture, use, sale, offer for sale, and/or importation of a 30 mg/30 mL Multi-Dose Vial presentation of Epinephrine Injection, USP, 1 mg/mL (the "FK Proposed Product"), prior to the expiration of the Patents-in-Suit.

30. By letter dated August 30, 2024 (the "Notice Letter"), FK sent Endo a correspondence stating that it had submitted an amendment to NDA No. 215425 for the FK Proposed Product.

31. Endo received the Notice Letter on September 3, 2024.

32. The Notice Letter purported to provide an Offer of Confidential Access to NDA No. 215425. The terms of the Offer of Confidential Access were unreasonable, not proportional to the purpose of the Offer of Confidential Access, and/or otherwise beyond the requirements of 21 U.S.C. § 355.

33. On information and belief, FK was aware of the Patents-in-Suit at the time the amendment to NDA No. 215425 was submitted to FDA.

34. Endo commenced this action within 45 days of receiving the Notice Letter.

COUNT I
INFRINGEMENT OF THE '876 PATENT

35. Endo re-alleges and incorporates Paragraphs 1-34 as if fully set forth herein.

36. The submission of the FK supplement to NDA No. 215425 to FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, importation, use, marketing, and sale of the FK Proposed Product prior to the expiration of the '876 Patent, constitutes infringement by FK of the '876 Patent under 35 U.S.C. § 271(e)(2)(A).

37. Upon FDA's approval of the supplement to NDA No. 215425, FK's commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of the FK Proposed Product will infringe at least claim 1 of the '876 patent, both directly under 35 U.S.C. §§ 271(a) and (g) and indirectly under 35 U.S.C. §§ 271(b) and 271(c), literally and/or under the doctrine of equivalents.

38. Claim 1 of the '876 patent reads as follows:

> A composition comprising:
>
> in the range of about 0.5 to 1.5 mg/mL of epinephrine and/or salts thereof,
>
> in the range of about 6 to 8 mg/mL of a tonicity regulating agent,
>
> in the range of about 2.8 to 3.8 mg/mL of a pH raising agent,
>
> in the range of about 0.1 to 1.1 mg/mL of an antioxidant,
>
> in the range of about 0.001 to 0.010 mL/mL of a pH lowering agent, and
>
> in the range of about 0.01 to 0.4 mg/mL of a transition metal complexing agent, wherein the antioxidant comprises sodium bisulfite and/or sodium metabisulfite.

39. Adrenalin® is an embodiment of one or more claims of the '876 patent.

40. On information and belief, the FK Proposed Product contains the same active ingredient and in the same concentration as Adrenalin®.

41. On information and belief, the FK Proposed Product infringes at least one claim, including at least claim 1 of the '876 patent, literally and/or by the doctrine of equivalents.

42. On information and belief, the FK Proposed Product comprises epinephrine, a tonicity regulating agent, a pH raising agent, an antioxidant comprising sodium bisulfite and/or sodium metabisulfite, a pH lowering agent, and a transition metal complexing agent, in the ranges claimed in at least one claim, including at least claim 1 of the '876 patent, literally and/or by the doctrine of equivalents.

43. Unless enjoined by the Court, upon FDA's approval of the supplement to NDA No. 215425, FK will infringe at least one claim, including at least claim 1 of the '876 patent, literally and/or by the doctrine of equivalents, under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing FK Proposed Product into the United States.

44. Unless enjoined by the Court, upon FDA's approval of the supplement to NDA No. 215425, FK will infringe at least one claim, including at least claim 1 of the '876 patent, literally and/or by the doctrine of equivalents, under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing the FK Proposed Product into the United States. On information and belief, FK will knowingly encourage direct infringement of the '876 patent, and possesses specific intent to encourage another's direct infringement of the '876 patent.

45. Unless enjoined by the Court, upon FDA's approval of the supplement to NDA 215425, FK will infringe at least one claim, including at least claim 1 of the '876 patent, literally and/or by the doctrine of equivalents, under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing the FK Proposed Product into the United States. On information

and belief, the act of direct infringement of the '876 patent is attributed to a single entity. On information and belief, the FK Proposed Product is a material part of the claimed invention, and is not suitable for substantial non-infringing uses.

46. Endo is entitled to a declaratory judgment that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of the FK Proposed Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the FK Proposed Product before expiration of the '876 patent by FK, will constitute infringement, inducement of infringement, and/or contributory infringement of the '876 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

47. Endo will be irreparably harmed if FK is not enjoined from infringing, inducing, or contributing to infringement of the '876 patent. Endo does not have an adequate remedy at law to fully compensate Endo for its damages.

48. This case is exceptional and Endo is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT II
INFRINGEMENT OF THE '657 PATENT

49. Endo re-alleges and incorporates Paragraphs 1-48 as if fully set forth herein.

50. The submission of the FK supplement to NDA No. 215425 to FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, importation, use, marketing, and sale of the FK Proposed Product prior to the expiration of the '657 Patent, constitutes infringement by FK of the '657 Patent under 35 U.S.C. § 271(e)(2)(A).

51. Upon FDA's approval of the supplement to NDA No. 215425, the FK commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of the FK Proposed Product will infringe at least claim 1 of the '657 patent, both directly under 35 U.S.C. §§ 271(a) and (g) and indirectly under 35 U.S.C. §§ 271(b) and 271(c), literally and/or under the doctrine of equivalents.

52. Claim 1 of the '657 patent reads as follows:

> A method of treating a condition comprising administering to a patient in need thereof a composition comprising:
>
> in the range of about 0.5 to 1.5 mg/mL of epinephrine and/or salts thereof,
>
> in the range of about 6 to 8 mg/mL of a tonicity regulating agent,
>
> in the range of about 2.8 to 3.8 mg/mL of a pH raising agent,
>
> in the range of about 0.1 to 1.1 mg/mL of an antioxidant,
>
> in the range of about 0.001 to 0.010 mL/mL of a pH lowering agent, and
>
> in the range of about 0.01 to 0.4 mg/mL of a transition
>
> metal complexing agent;
>
> wherein the antioxidant comprises sodium bisulfite and/or sodium metabisulfite,
>
> and wherein the condition is selected from the group consisting of anaphylaxis, bronchospasm, sensitivity reactions, cardiac arrhythmias, GI and renal hemorrhage, superficial bleeding, premature labor, hypoglycemia,

53. Upon FDA approval of the supplement to NDA No. 215425, FK will induce infringement of at least one claim, including at least claims 1 and 20 of the '657 patent, by promoting, encouraging, and/or recommending that medical personnel perform methods of treating certain conditions, including Type 1 allergic reactions and anaphylaxis, by administering

to a patient in need a composition comprising epinephrine, tonicity regulating agent, pH raising agent, antioxidant comprising sodium bisulfite and/or sodium metabisulfite, pH lowering agent, and transition metal complexing agent, in certain ranges and/or by contributing to the performance of said method, in violation of 35 U.S.C. §§ 271(a), (b), and/or (c), literally and/or by the doctrine of equivalents.

54. Adrenalin® is an embodiment of one or more claims of the '657 patent. The use of Adrenalin® to treat Type 1 allergic reactions, including anaphylaxis, falls within one or more claims of the '657 patent.

55. As part of its supplement to NDA No. 215425, FK must show that "the labeling proposed for the new drug is the same as the labeling approved for the listed drug," except for changes indicating that the drug is produced or distributed by different manufacturers. 21 U.S.C. § 355(j)(2)(A)(v).

56. The label for Adrenalin® states that Adrenalin® is indicated for emergency treatment of allergic reactions (Type 1), including anaphylaxis. *See* Exhibit D.

57. On information and belief, the label for FK's supplement to NDA No. 215425 is substantially identical to the approved label for Adrenalin®, and the FK Proposed Product, if approved, will be marketed, sold, and/or distributed with labeling that is substantially identical to the labeling for Adrenalin®.

58. On information and belief, the label for the FK Proposed Product also states that the FK Proposed Product is indicated for emergency treatment of allergic reactions (Type 1), including anaphylaxis. Therefore, the label promotes or encourages medical personnel to administer the FK Proposed Product to treat Type 1 allergic reactions and anaphylaxis.

59. On information and belief, the FK Proposed Product contains the same active ingredient and in the same concentration as Adrenalin®, epinephrine 30 mg/30 mL (1 mg/mL) dose vial.

60. On information and belief, the FK Proposed Product infringes at least one claim, including at least claim 1 of the '657 patent, literally and/or by the doctrine of equivalents.

61. On information and belief, the FK Proposed Product comprises epinephrine, tonicity regulating agent, pH raising agent, antioxidant comprising sodium bisulfite and/or sodium metabisulfite, pH lowering agent, and transition metal complexing agent, in the ranges claimed in at least one claim, including at least claim 1 of the '657 patent, literally and/or by the doctrine of equivalents.

62. On information and belief, FK knowingly provides instruction in the label for medical personnel to administer the FK Proposed Product to treat allergic reactions (Type 1) including anaphylaxis, and the label reflects a specific intent to encourage medical personnel to directly infringe at least one claim, including at least claim 1 of the '657 patent, literally and/or by the doctrine of equivalents.

63. Unless enjoined by the Court, upon FDA's approval of the supplement to NDA No. 215425, FK will infringe at least one claim, including at least claim 1 of the '657 patent, literally and/or by the doctrine of equivalents, under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing the FK Proposed Product into the United States.

64. Unless enjoined by the Court, upon FDA's approval of the supplement to NDA No. 215425, FK will infringe at least one claim, including at least claim 1 of the '657 patent, literally and/or by the doctrine of equivalents, under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing the FK Proposed Product into the United States. On

information and belief, FK will knowingly encourage direct infringement of the '657 patent, and possesses specific intent to encourage another's direct infringement of the '657 patent.

65. Unless enjoined by the Court, upon FDA's approval of the supplement to NDA 215425, FK will infringe at least one claim, including at least claim 1 of the '657 patent, literally and/or by the doctrine of equivalents, under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing the FK Proposed Product into the United States. On information and belief, the act of direct infringement of the '657 patent is attributed to a single entity. On information and belief, the FK Proposed Product is a material part of the claimed invention, and is not suitable for substantial non-infringing uses.

66. Endo is entitled to a declaratory judgment that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of the FK Proposed Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the FK Proposed Product before expiration of the '657 patent by FK, will constitute infringement, inducement of infringement, and/or contributory infringement of the '657 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

67. Endo will be irreparably harmed if FK is not enjoined from infringing, inducing, or contributing to infringement of the '657 patent. Endo does not have an adequate remedy at law to fully compensate Endo for its damages.

68. This case is exceptional and Endo is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

COUNT III
INFRINGEMENT OF THE '592 PATENT

69. Endo re-alleges and incorporates Paragraphs 1-68 as if fully set forth herein.

70. The submission of the FK supplement to NDA No. 215425 to FDA, including the Paragraph IV Certifications submitted therewith, which seeks approval to engage in the commercial manufacture, importation, use, marketing, and sale of the FK Proposed Product prior to the expiration of the '592 Patent, constitutes infringement by FK of the '592 Patent under 35 U.S.C. § 271(e)(2)(A).

71. Upon FDA's approval of the supplement to NDA No. 215425, FK's commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of the FK Proposed Product will infringe at least claim 1 of the '592 patent, both directly under 35 U.S.C. §§ 271(a) and (g) and indirectly under 35 U.S.C. §§ 271(b) and 271(c), literally and/or under the doctrine of equivalents.

72. Claim 1 of the '592 patent reads as follows:

> A composition comprising:
>
> epinephrine and/or salts thereof,
>
> an antioxidant present at a concentration of in the range of about 0.1 to 0.9 mg/mL,
>
> a buffer system, the buffer system comprising tartaric acid,
>
> sodium chloride as a tonicity regulating agent at a concentration of in the range of about 6 to 7.5 mg/mL,
>
> a preservative, and
>
> disodium edetate dihydrate as a transition metal complexing agent at a concentration of in the range of about 0.01 to 0.4 mg/mL,
>
> wherein the buffer system provides a resistance to a pH change such that the composition has a pH of in the range of about 3.5 and 4.0 after 18 months of shelf life, and wherein after 18 months of storage at between 23° C. and 32° C. and between 55% RH and 70% RH, the composition comprises about 3% or less of D-Epinephrine.

73. 73. Endo's 30 mL Adrenalin® Product is an embodiment of one or more claims of the '592 patent.

74. On information and belief, the FK Proposed Product contains the same active ingredient and in the same concentration as Adrenalin®.

75. On information and belief, the FK Proposed Product infringes at least one claim, including at least claim 1 of the '592 patent, literally and/or by the doctrine of equivalents.

76. On information and belief, the FK Proposed Product comprises epinephrine, a tonicity regulating agent comprising sodium chloride, a buffer system comprising tartaric acid, an antioxidant, a preservative, and a transition metal complexing agent comprising disodium edetate dihydrate, and a pH in the ranges claimed in at least one claim, including at least claim 1 of the '592 patent, literally and/or by the doctrine of equivalents.

77. Unless enjoined by the Court, upon FDA's approval of the supplement to NDA No. 215425, FK will infringe at least one claim, including at least claim 1 of the '592 patent, literally and/or by the doctrine of equivalents, under 35 U.S.C. § 271(a) by making, using, offering to sell, selling, and/or importing the FK Proposed Product into the United States.

78. Unless enjoined by the Court, upon FDA's approval of the supplement to NDA No. 215425, FK will infringe at least one claim, including at least claim 1 of the '592 patent, literally and/or by the doctrine of equivalents, under 35 U.S.C. § 271(b) by making, using, offering to sell, selling, and/or importing the FK Proposed Product into the United States. On information and belief, FK will knowingly encourage direct infringement of the '592 patent, and possesses specific intent to encourage another's direct infringement of the '592 patent.

79. Unless enjoined by the Court, upon FDA's approval of the supplement to NDA 215425, FK will infringe at least one claim, including at least claim 1 of the '592 patent, literally and/or by the doctrine of equivalents, under 35 U.S.C. § 271(c) by making, using, offering to sell, selling, and/or importing the FK Proposed Product into the United States. On information

and belief, the act of direct infringement of the '592 patent is attributed to a single entity. On information and belief, the FK Proposed Product is a material part of the claimed invention, and is not suitable for substantial non-infringing uses.

80. Endo is entitled to a declaratory judgment that the commercial manufacture, use, offer to sell, or sale within the United States, and/or importation into the United States, of the FK Proposed Product, or the inducement of and/or contribution to the commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States, of the FK Proposed Product before expiration of the '592 patent by FK, will constitute infringement, inducement of infringement, and/or contributory infringement of the '592 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

81. Endo will be irreparably harmed if FK is not enjoined from infringing, inducing, or contributing to infringement of the '592 patent. Endo does not have an adequate remedy at law to fully compensate Endo for its damages.

82. This case is exceptional and Endo is entitled to an award of reasonable attorneys' fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Endo respectfully requests the following relief:

A. A judgment declaring that FK has infringed, contributed to, or induced the infringement of one or more claims of the '876 patent, literally and/or by the doctrine of equivalents, by submitting the supplement to NDA No. 215425 to FDA for the FK Proposed Product;

B. A judgment declaring that FK has infringed, contributed to, or induced the infringement of one or more claims of the '657 patent, literally and/or by the doctrine of

equivalents, by submitting the supplement to NDA No. 215425 to FDA for the FK Proposed Product;

C. A judgment declaring that FK has infringed, contributed to, or induced the infringement of one or more claims of the ’592 patent, literally and/or by the doctrine of equivalents, by submitting the supplement to NDA No. 215425 to FDA for the FK Proposed Product;

D. A judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of the FK Proposed Product within the United States, prior to expiration, infringes the ’657 patent;

E. A judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of the FK Proposed Product within the United States, prior to expiration, infringes the ’876 patent;

F. A judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of the FK Proposed Product within the United States, prior to expiration, infringes the ’657 patent;

G. A judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of the FK Proposed Product within the United States, prior to expiration, infringes the ’592 patent;

H. A permanent injunction restraining and enjoining FK, and its officers, agents, attorneys, servants and employees, and those in active concert or participation with any of them, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation within the United States, of the FK Proposed Product, until the expiration of the ’876 patent, including any extensions and/or additional periods of exclusivity to which Endo is or becomes entitled;

I. A permanent injunction restraining and enjoining FK, and its officers, agents, attorneys, servants and employees, and those in active concert or participation with any of them, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation within the United States, of the FK Proposed Product, until the expiration of the '657 patent, including any extensions and/or additional periods of exclusivity to which Endo is or becomes entitled;

J. A permanent injunction restraining and enjoining FK, and its officers, agents, attorneys, servants and employees, and those in active concert or participation with any of them, from engaging in the commercial manufacture, use, offer for sale, sale, and/or importation within the United States, of the FK Proposed Product, until the expiration of the '592 patent, including any extensions and/or additional periods of exclusivity to which Endo is or becomes entitled;

K. An order that the effective date of any approval of the supplement to NDA No. 215425 for the FK Proposed Product under 21 U.S.C. § 355(j) shall not be earlier than the expiration date of the '876 patent, including any extensions and/or additional periods of exclusivity to which Endo is or becomes entitled;

L. An order that the effective date of any approval of the supplement to NDA No. 215425 for the FK Proposed Product under 21 U.S.C. § 355(j) shall not be earlier than the expiration date of the '657 patent, including any extensions and/or additional periods of exclusivity to which Endo is or becomes entitled;

M. An order that the effective date of any approval of the supplement to NDA No. 215425 for the FK Proposed Product under 21 U.S.C. § 355(j) shall not be earlier than the expiration date of the '592 patent, including any extensions and/or additional periods of exclusivity to which Endo is or becomes entitled;

N. An award of compensatory damages, together with pre-judgment and post-judgment interest, to Endo for FK's infringement of the '876 patent;

O. An award of compensatory damages, together with pre-judgment and post-judgment interest, to Endo for FK's infringement of the '657 patent;

P. An award of compensatory damages, together with pre-judgment and post-judgment interest, to Endo for FK's infringement of the '592 patent;

Q. An award of increased damages to Endo under 35 U.S.C. § 284 for FK's willful and deliberate infringement of the '876 patent;

R. An award of increased damages to Endo under 35 U.S.C. § 284 for FK's willful and deliberate infringement of the '657 patent;

S. An award of increased damages to Endo under 35 U.S.C. § 284 for FK's willful and deliberate infringement of the '592 patent;

T. A judgment declaring this to be an exceptional case under 35 U.S.C. § 285 in Endo's favor and awarding Endo its reasonable attorneys' fees;

U. An award of Endo's costs and expenses; and

V. An award to Endo of such other and further relief as the Court may deem just and proper.

Dated: September 24, 2024

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