IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PH HEALTH LIMITED, *Plaintiff*, v. FRESENIUS KABI USA, LLC, *Defendant*.	C.A. No. _____

COMPLAINT

Plaintiff PH Health Limited ("Par Health"), for its Complaint against Defendant Fresenius Kabi USA, LLC ("FK"), alleges as follows:

NATURE AND SUMMARY OF THIS ACTION

1. This is an action for patent infringement arising under 35 U.S.C. § 271 regarding Defendant FK's infringement of U.S. Patent No. 10,869,845 ("the '845 patent") by manufacturing, using, offering for sale, or selling within the United States, and/or importing into the United States FK's ephedrine sulfate injection, 50 mg/10mL single-dose vial.

THE PARTIES

2. Par Health is an Irish company with offices located at First Floor, Minerva House, Simmonscourt Road, Ballsbridge, Dublin 4, D04 H9P8, Ireland.

3. Upon information and belief, FK is a corporation 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 corporation 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 develops, manufactures, seeks approval for, and sells certain FDA-approved pharmaceutical products that are regularly marketed and sold in Delaware.

8. This Court has personal jurisdiction over FK at least because FK has previously submitted to the jurisdiction of this Court and purposefully availed itself of this Court by filing claims and counterclaims in this jurisdiction. *See, e.g.*, *American Regent, Inc. v. Fresenius Kabi USA, LLC*, No. 1:24-cv-00824-MN; *Fresenius Kabi USA, LLC v. Natco Pharma USA LLC*, No. 1:24-cv-00472; *Fresenius Kabi USA, LLC v. Caplin Steriles Ltd.*, No. 1:23-cv-01144.

9. Venue is proper in this judicial district under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b) at least because FK is incorporated in the State of Delaware. On further information and belief, FK has committed acts of infringement in this judicial district, including but not limited to making, selling, and/or offering for sale products that infringe one or more claims of the ’845 patent.

THE PATENT-IN-SUIT

10. The ’845 patent, titled “Ephedrine Compositions and Methods,” was duly and legally issued by the United States Patent and Trademark Office on December 22, 2020. A true and correct copy of the ’845 patent is attached as Exhibit A.

11. Par Health is an exclusive licensee of the '845 patent and has the ability and proper standing to enforce the '845 patent.

PLAINTIFF'S READY-TO-USE EPHEDRINE SULFATE PRODUCT

12. Par Health is the holder of New Drug Application ("NDA") No. 213994 ("Plaintiff's NDA") for Ephedrine Sulfate Injection, 50 mg/10 mL vials ("Plaintiff's Ephedrine SD Vials"), which the U.S. Food and Drug Administration ("FDA") approved on October 16, 2020. Commercial marketing of Plaintiff's Ephedrine SD Vials began in March 2022.

13. Plaintiff's Ephedrine SD Vials are ready-to-use ("RTU") formulations, stored in glass vials, that require no further dilution prior to administration to a patient. Plaintiff's Ephedrine SD Vials are indicated for the treatment of clinically important hypotension occurring in the setting of anesthesia.

14. FDA-approved, ready-to-use formulations of ephedrine were not commercially available prior to the effective filing date of the '845 patent. Then-available FDA-approved ephedrine products were concentrated formulations that had to be diluted prior to administration to a patient. The diluted solutions of ephedrine were not pH stable and, therefore, were not recommended to be stored for any period of time.

15. The '845 patent describes stable, ready-to-administer ephedrine products that avoid the need for dilution prior to use and can be stored for up to 24 months. Avoiding the dilution step provides many benefits for hospitals, including avoiding the potential for dilution errors, avoiding the risk of contamination, and saving time and resources.

FK'S READY-TO-USE EPHEDRINE SULFATE PRODUCT

16. FK is the holder of Abbreviated New Drug Application ("ANDA") No. 219991 ("FK's ANDA") for ephedrine sulfate injection, 50 mg/10mL single-dose vial ("FK's Proposed ANDA Product").

17. In a letter dated July 17, 2025 ("Notice Letter"), FK stated that it had sought FDA approval to commercially manufacture, use, or sell FK's Proposed ANDA Product prior to the expiration of the Patents-in-Suit. The Notice Letter further stated that FK's ANDA contained a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) (a "Paragraph IV Certification") that the '845 patent is invalid, unenforceable, and/or will not be infringed by the commercial manufacture, use, offer for sale, sale, and/or importation of FK's Proposed ANDA Product.

18. FK was aware of the '845 patent when it submitted FK's ANDA with a Paragraph IV Certification.

19. On information and belief, FK's Proposed ANDA Product contains ephedrine sulfate, 50 mg/10 mL, that is covered by the claims of the '845 patent.

20. On information and belief, FK's ANDA refers to and relies upon Endo's NDA and contains data that demonstrates the bioequivalence of FK's Proposed ANDA Product and Plaintiff's Ephedrine SD Vials.

21. On information and belief, FDA has not yet approved FK's ANDA.

22. Plaintiff commenced this action within 45 days of receipt of the Notice Letter.

COUNT I
INFRINGEMENT OF THE '845 PATENT

23. Plaintiff re-alleges and incorporates Paragraphs 1-22 as if fully set forth herein.

24. The submission of FK's ANDA to FDA under 21 U.S.C. § 355(b)(2) for purposes of obtaining approval to commercially manufacture, use, offer for sale, sell, and/or import FK's ANDA Product before the expiration of the '845 patent constitutes infringement of one or more claims of the '845 patent under 35 U.S.C. § 271(e)(2).

25. On information and belief, FK's Proposed ANDA Product infringes one or more claims of the '845 patent, either literally or under the doctrine of equivalents, because FK's

Proposed ANDA Product is an ephedrine ready-to-use solution composition as covered by one or more claims of the ’845 patent.

26. On information and belief, FK plans to, intends to, and will commercially manufacture, use, offer for sale, sell, and/or import FK’s Proposed ANDA Product immediately upon approval of FK’s ANDA.

27. On information and belief, upon FDA approval of FK’s ANDA, FK will infringe one or more claims of the ’845 patent by making, using, offering to sell, selling, and/or importing FK’s Proposed ANDA Product in the United States, and by actively inducing and/or contributing to infringement by others under 35 U.S.C. §§ 271(b) and/or 271(c).

28. On information and belief, FK had knowledge of the ’845 patent when it submitted FK’s ANDA to FDA, FK knew or should have known that it will induce or contribute to another’s direct infringement of the ’845 patent, and FK acted with the specific intent to induce or contribute to another’s direct infringement of the ’845 patent. Plaintiff will be substantially and irreparably harmed by the infringing activities described above unless those activities are enjoined by this Court.

29. FK’s commercial manufacture, use, offer for sale, or sale within the United States, and/or importation into the United States of FK’s Proposed ANDA Product constitutes infringement of at least claim 1 of the ’845 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.

30. Claim 1 of the ’845 patent reads as follows:

A storage-stable, sterile ephedrine ready-to-use solution composition, comprising:

about 5 mg/mL of ephedrine or a pharmaceutically acceptable salt thereof;

about 9 mg/mL of sodium chloride;

a pH adjuster comprising acetic acid; and

water,

wherein the initial adjusted pH of the composition is in the range of 4.6 to 4.8;

wherein the pH drift of the composition is less than 0.5 after storage for 6 months at 25° C. and 60% relative humidity; and

wherein the composition contains about 5% or less total impurities after storage for 6 months at 25° C. and 60% relative humidity as determined by HPLC.

31. Plaintiff's Ephedrine SD Vials are an embodiment of one or more claims of the '845 patent.

32. On information and belief, FK's Proposed ANDA Product contains the same active ingredient, in the same concentration, as Plaintiff's Ephedrine SD Vials.

33. On information and belief, FK's Proposed ANDA Product is a storage-stable, sterile ephedrine ready-to-use solution composition that comprises ephedrine, sodium chloride, a pH adjuster comprising acetic acid, and water, in the ranges claimed in at least one claim, including at least claim 1 of the '845 patent, literally and/or under the doctrine of equivalents.

34. On information and belief, FK's Proposed ANDA Product is a storage-stable, sterile ephedrine ready-to-use solution composition having an initial adjusted pH, pH drift of the composition after storage for 6 months at 25° C. and 60% relative humidity, and total impurities after storage for 6 months at 25° C. and 60% relative humidity as determined by HPLC, in the ranges claimed in at least one claim, including at least claim 1 of the '845 patent, literally and/or under the doctrine of equivalents.

35. Plaintiff 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 FK's Proposed ANDA 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 FK's Proposed ANDA Product before expiration of the '845 patent by FK or its agents, constitutes infringement, inducement of infringement, and/or contributory infringement of the '845 patent under 35 U.S.C. §§ 271(a), (b), (c), and/or (g).

36. Plaintiff will be irreparably harmed if FK is not enjoined from infringing, or inducing or contributing to infringement of, the '845 patent. Plaintiff does not have an adequate remedy at law to fully compensate Plaintiff for its damages.

DEMAND FOR JUDGMENT

WHEREFORE, Plaintiff respectfully requests the following relief:

A. A judgment declaring that FK has infringed, or induced or contributed to the infringement of, one or more claims of the '845 patent, literally and/or by the doctrine of equivalents, by submitting FK's ANDA to FDA for FK's Proposed ANDA Product;

B. A judgment that the commercial manufacture, use, offer for sale, sale, and/or importation of FK's Proposed ANDA Product within the United States, prior to expiration of the '845 patent, infringes the '845 patent;

C. A judgment permanently enjoining FK, its officers, agents, servants and employees, and those in active concert or participation with any of them, from engaging, whether directly or indirectly, in the commercial manufacture, use, offer for sale, sale, and/or importation within the United States, of FK's Proposed ANDA Product, until the expiration of the '845 patent, including any extensions and/or additional periods of exclusivity to which Plaintiff is or becomes entitled;

D. An order that the effective date of any approval of FK's ANDA for FK's Proposed ANDA Product under 21 U.S.C. § 355(j) shall not be earlier than the expiration date of

the ’845 patent, including any extensions and/or additional periods of exclusivity to which Plaintiff is or becomes entitled;

E. An award of compensatory damages to Plaintiff for FK’s infringement of the ’845 patent;

F. An award of increased damages to Plaintiff under 35 U.S.C. § 284 for FK’s willful and deliberate infringement of the ’845 patent;

G. A judgment declaring this to be an exceptional case under 35 U.S.C. § 285 in Plaintiff’s favor and awarding Plaintiff its reasonable attorneys’ fees;

H. An award of Plaintiff’s costs and expenses for defending this action, together with pre-judgment and post-judgment interest; and

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

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