IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

HQ SPECIALTY PHARMA CORP. and WG CRITICAL CARE, LLC,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
FRESENIUS KABI USA, L.L.C.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs, HQ Specialty Pharma Corp. ("HQ Specialty Pharma") and WG Critical Care, LLC ("WG Critical Care") (collectively "Plaintiffs"), for their Complaint against Defendant Fresenius Kabi USA, LLC ("Fresenius USA"), allege as follows:

NATURE OF ACTION

1. This is an action arising under the patent laws of the United States, 35 U.S.C. § 100 et seq., including 35 U.S.C. §§ 271(a), (b), (c), and (e), for infringement by Defendants of United States Patent No. 10,130,646 (the "'646 patent") and United States Patent No. 10,342,813 (the "'813 patent") (together, the "Asserted Patents") and for a declaratory judgment of infringement under 28 U.S.C. §§ 2201 and 2202.

2. This action arises out of Fresenius USA's submission of its supplemental New Drug Application ("sNDA") No. 208418/S-007 ("Fresenius USA's sNDA") under Section 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 355(b)(2), to the U.S. Food and Drug Administration ("FDA") seeking approval to manufacture and sell calcium gluconate in sodium chloride injection solution in a bag prior to the expiration of the '646 patent and the '813 patent.

3. The FDA approved Fresenius USA's sNDA on June 17, 2021.

PARTIES

4. Plaintiff HQ Specialty Pharma is a corporation organized and existing under the laws of the state of New Jersey, having a place of business at 120 Route 17 North, Suite 130, Paramus, New Jersey 07652.

5. Plaintiff WG Critical Care is a limited liability company organized and existing under the laws of the state of New Jersey, having a principal place of business at 120 Route 17 North, Paramus, New Jersey 07652.

6. Upon information and belief, Defendant Fresenius USA is a limited liability company organized and existing under the laws of the state of Delaware, having its principal place of business at 3 Corporate Drive, Lake Zurich, Illinois 60047.

7. Upon information and belief, Fresenius USA is in the business of manufacturing, marketing, and selling generic drug products. As a part of this business, upon information and belief, Fresenius USA, directly or through agents, regularly files New Drug Applications ("NDAs"), sNDAs, and abbreviated new drug applications ("ANDAs") with the FDA seeking approval to engage in the commercial manufacture, use, offer for sale, sale and/or importation of generic versions of drug products that are covered by United States patents. Upon information and belief, Fresenius USA's ordinary business operations include litigating and filing claims in the courts of the United States, including this Court, regarding infringement, validity, and/or enforceability of United States patents that cover or are alleged to cover generic drug products that are the subject of NDAs, sNDAs, and ANDAs filed by Fresenius USA.

8. Upon information and belief, Fresenius USA manufactures and/or imports drug products for the purpose of sale within the United States, including Delaware.

9. Upon information and belief, Fresenius USA derives substantial revenue from services or things used or consumed in the Delaware.

JURISDICTION AND VENUE

10. Jurisdiction and venue are proper in this District pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, 2202, 1391, and 1400(b).

11. Fresenius USA is subject to personal jurisdiction in Delaware because, among other things, Fresenius USA is a limited liability company formed under the laws of the state of Delaware.

12. Upon information and belief, Fresenius USA has a registered agent in Delaware (Corporation Service Company, 251 Little Falls Drive, Wilmington, Delaware 19808); it is in the business of manufacturing drug products, which it manufactures, distributes, sells, or offers to sell throughout the United States, including in Delaware; it derives substantial revenue from services or things used or consumed in Delaware; it transacts business with companies located and/or headquartered in Delaware; as part of its ordinary business practice of engaging in U.S. patent litigation, it has regularly and routinely litigated ANDA and NDA cases without contesting jurisdiction in this District; it has, directly or through an agent, filed an NDA, and/or been actively involved in the preparation and submission of an NDA, for the purpose of approval to engage in the commercial manufacture, use, offer for sale, sale, and/or importation of the generic product described in sNDA No. 208418/S-007 in the United States, including in Delaware; and it intends to offer to sell and sell the generic product described in sNDA No. 208418/S-007 in the United States, including in Delaware.

13. Upon information and belief, Fresenius USA has availed itself of the legal protections of Delaware by filing claims or counterclaims affirmatively seeking relief in other prior

actions in this Court, including in *Millennium Pharmaceuticals, Inc. v. Fresenius Kabi USA, LLC, et al.*, 13-467-GMS (D. Del.); *Fresenius Kabi USA, LLC v. Dr. Reddy's Laboratories Ltd., et al.*, 13-925-SLR (D. Del.); *Fresenius Kabi USA, LLC v. Watson Laboratories Inc., et al.*, 13-1015-SLR (D. Del.); *Celgene Corp. v. Fresenius Kabi USA, LLC, et al.*, 14-571-RGA (D. Del.); and *Shire Orphan Therapies, LLC v. Fresenius Kabi USA, LLC, et al.*, 15-1102-GMS (D. Del).

14. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b) and (c) and § 1400(b) because Fresenius USA is organized, and thus resides, in Delaware.

BACKGROUND

15. On October 29, 2018, Plaintiff HQ Specialty Pharma received FDA approval for its NDA 210906. NDA 210906 covers calcium gluconate in sodium chloride solution in bags for intravenous administration.

16. Plaintiffs' calcium gluconate in sodium chloride injection is a solution indicated for the treatment of acute symptomatic hypocalcemia. It is provided in a ready-to-use flexible plastic bag to be administered intravenously without dilution.

17. The '646 patent, entitled "Calcium Gluconate Solutions in Flexible Containers" (Exhibit A hereto), was duly and legally issued on November 20, 2018 to HQ Specialty Pharma as assignee. HQ Specialty Pharma is the owner and assignee of the '646 patent. Calcium gluconate in sodium chloride solution and the use thereof are covered by one or more claims of the '646 patent, and HQ Specialty Pharma has caused the '646 patent to be listed in connection with calcium gluconate in sodium chloride solutions in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the "Orange Book."

18. The '646 has one independent claim. Independent claim 1 of the '646 patent states:

1. A terminally sterilized aqueous calcium gluconate solution comprising:

sodium chloride; and

1 to 15 wt. % calcium gluconate and from 1 to 19 wt. parts of calcium saccharate per 100 wt. parts of calcium gluconate packaged in a flexible plastic container with the remainder water,

wherein

the flexible plastic container is a bag, and

the solution has a pH of from 6 to 8.2.

19. The '813 patent, entitled "Calcium Gluconate Solutions in Flexible Containers" (Exhibit B hereto), was duly and legally issued on July 9, 2019 to HQ Specialty Pharma as assignee. HQ Specialty Pharma is the owner and assignee of the '813 patent. Calcium gluconate in sodium chloride solution and the use thereof are covered by one or more claims of the '813 patent. HQ Specialty Pharma has caused the '813 patent to be listed in connection with calcium gluconate in sodium chloride solutions in the FDA's Approved Drug Products with Therapeutic Equivalence Evaluations, also known as the "Orange Book."

20. The '813 has one independent claim. Independent claim 1 states:

1. A terminally sterilized aqueous calcium gluconate solution comprising 1 to 15 wt.% calcium gluconate and from 1 to 19 wt. parts of calcium saccharate per 100 wt. parts of calcium gluconate packaged in a flexible plastic container with the remainder water,

wherein the solution has a pH of from 6.0 to 8.2.

21. WG Critical Care has an exclusive license from HQ Specialty Pharma to sell products covered by the Asserted Patents in the United States. WG Critical Care also has the right to enforce the Asserted Patents. WG Critical Care is responsible for the marketing and sale of HQ Specialty Pharma's calcium gluconate in sodium chloride solution in the United States.

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