IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

FRESENIUS KABI USA, LLC and FRESENIUS KABI DEUTSCHLAND GMBH, Plaintiffs, v. SINTETICA S.A. Defendant.	Civil Action No. _____

COMPLAINT

Fresenius Kabi USA, LLC and Fresenius Kabi Deutschland GmbH (collectively, "Fresenius" or "Plaintiffs") bring this action for patent infringement against Sintetica S.A. ("Sintetica" or "Defendant").

NATURE OF THE ACTION

1. This is an action by Fresenius against Defendant for infringement of United States Patent No. 8,118,802 ("the '8,802 patent") ("the Patent-in-Suit"). This action arises out of Defendant Sintetica S.A.'s filing of an Abbreviated New Drug Application ("ANDA") seeking approval by the United States Food and Drug Administration ("FDA") to sell a generic version of Fresenius's ropivacaine hydrochloride injection product, Naropin®, prior to the expiration of the Patent-in-Suit.

THE PARTIES

Plaintiffs

2. Fresenius Kabi USA, LLC is a Delaware limited liability company with its principal place of business at Three Corporate Drive, Lake Zurich, Illinois 60047.

3. Fresenius Kabi Deutschland GmbH is a limited liability company organized and existing under the laws of Germany with a principal place of business at Else-Kröner-Straβe 1, 61352 Bad Homburg, Germany.

Defendant

4. Upon information and belief, Defendant Sintetica S.A. is a corporation organized and existing under the laws of Switzerland, with its principal place of business at Via Penate 5, 6850 Mendrisio, Switzerland.

5. Upon information and belief, Sintetica S.A. is a pharmaceutical company that develops, manufactures, markets and/or distributes pharmaceutical products around the world. Sintetica has taken steps to enable pharmaceutical products to be distributed and sold in the throughout the United States, including in this Judicial District.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

6. This action for patent infringement arises under 35 U.S.C. § 271.

7. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

Personal Jurisdiction Over Defendant

8. This Court has personal jurisdiction over Defendant because, *inter alia*, Defendant has maintained contacts with the State of Delaware such that Defendant could reasonably expect to be haled into court in the State of Delaware and at least for the reasons set forth below.

9. This Court has personal jurisdiction over Defendant because, *inter alia*, Defendant has committed, or aided, abetted, contributed to, or participated in the commission of the tortious action of patent infringement, which will lead to foreseeable harm and injury to Fresenius in the

State of Delaware, and by doing so, Defendant has purposefully directed its activities at the residents of this forum.

10. Upon information and belief, Sintetica has purposefully directed activities at residents of this Judicial District, and this action arises out of and relates to those activities. For example, Sintetica has taken the significant step of submitting its Abbreviated New Drug Application No. 215879 ("Sintetica's ANDA") to the FDA seeking approval to engage in the commercial manufacture, use, and/or sale of ropivacaine hydrochloride solution for injection, 200 mg/100 mL and 400 mg/200 mL ("Sintetica's proposed generic Naropin® product"), a generic version of Fresenius's Naropin® product, throughout the United States, including in this Judicial District. Upon information and belief, Sintetica will engage in the commercial manufacture, use, and/or sale of Sintetica's proposed generic Naropin® product upon approval of its ANDA. The submission of Sintetica's ANDA is therefore tightly tied, both in purpose and planned effect, to the deliberate commercial manufacture, use, and/or sale of Sintetica's proposed generic Naropin® product in the United States, including in this Judicial District, and reliably indicates that Sintetica's proposed generic Naropin® product will be marketed in this Judicial District.

11. Upon information and belief, Sintetica prepared and submitted Sintetica's ANDA and intends to directly benefit from the sale of Sintetica's proposed generic Naropin® product. Upon information and belief, Sintetica prepared, created, approved, and/or assembled the information and documentation in support of Sintetica's ANDA.

12. Upon information and belief, as a result of Defendant's marketing, selling, or offering for sale of Sintetica's generic version of Naropin® in the State of Delaware, Fresenius will lose sales of Naropin® and be injured in the State of Delaware.

13. On information and belief, if Sintetica's ANDA is approved, Sintetica's proposed generic Naropin® product will be administered to patients throughout the United States, including the State of Delaware. These activities, as well as Sintetica's manufacturing, marketing, selling, and/or distributing of Sintetica's proposed generic Naropin® product, will have a substantial effect within State of Delaware, and will constitute infringement of the Patent-in-Suit in the event that Sintetica's ANDA is approved before expiration of the Patent-in-Suit.

14. Upon information and belief, this Court may properly exercise personal jurisdiction over Defendant for the reasons stated herein, including, *inter alia*, Defendant's activities in the forum, activities directed at the forum, and substantial contacts with the forum, and the exercise of personal jurisdiction over Sintetica does not offend traditional notions of fair play and substantial justice.

Venue

15. Venue is proper in this district under 28 U.S.C. § 1391, including because, in*ter alia*, Sintetica is a foreign entity, and thus is subject to suit in any jurisdiction in the United States including in this Judicial District. 28 U.S.C. § 1391(c).

BACKGROUND

The Patent-in-Suit

16. The '8,802 Patent, entitled "Connector for packaging containing medical fluids and packaging for medical fluids," was duly and lawfully issued on February 21, 2012 to inventors Torsten Brandenburger and Ismael Rahimy. The named inventors assigned the '8,802 Patent to Fresenius Kabi Deutschland GmbH. The '8,802 Patent is listed in the Orange Book with respect to Naropin®. The '8,802 Patent will expire on May 18, 2023. A true and accurate copy of the '8,802 Patent is attached hereto as Exhibit A.

The Naropin® Drug Product

17. Fresenius Kabi USA, LLC currently sells, promotes, distributes, and markets Naropin® in the United States.

18. Fresenius Kabi USA, LLC holds an approved New Drug Application ("NDA") No. 20553 under Section 505(b) of the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 355(a) in connection with Naropin®.

Defendant Sintetica S.A.'s ANDA

19. Defendant Sintetica S.A. filed with the FDA an ANDA under 21 U.S.C. § 355(j) seeking approval to manufacture, use, offer for sale, sell in and import into the United States a ropivacaine hydrochloride injection product that Defendant asserts is a generic copy of Naropin® prior to the expiration of the Patent-in-Suit.

20. The FDA assigned Defendant Sintetica S.A.'s ANDA number 215879.

21. Defendant filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the claims of the Patent-in-Suit are invalid, unenforceable and/or would not be infringed by the manufacture, use, importation, sale or offer for sale of Sintetica's proposed generic Naropin® product ("Defendant's Paragraph IV Certification").

22. Defendant Sintetica S.A. notified Fresenius of this certification in a letter dated January 4, 2022 (the "Notice Letter") sent by Federal Express. Fresenius received the Notice Letter on January 7, 2022. The Notice Letter stated that Defendant Sintetica S.A. had filed ANDA No. 215879 seeking FDA approval to market a generic Naropin® product prior to the expiration of the Patent-in-Suit.

23. A document entitled "Sintetica's Detailed Factual and Legal Bases in Support of Its Paragraph IV Certification for Ropivacaine for Injection, 200 mg/100 ml and 400 mg/200 ml" ("Detailed Statement") was attached to the Notice Letter.

24. In the Notice Letter, Defendant Sintetica offered Fresenius confidential access to ANDA No. 215879 on terms and conditions set forth in an attached "Offer of Confidential Access to Application and Confidential Disclosure Agreement" ("OCA").

25. On February 2, 2022, after the parties agreed to several revisions to the OCA, Fresenius executed the OCA. As part of the OCA, Sintetica agreed to produce portions of ANDA No. 215879 and samples of the packaging for Sintetica's proposed generic Naropin® product.

26. On February 2, 2022, Sintetica produced to Fresenius a limited portion of Sintetica's ANDA. On February 3, 2022, Fresenius received samples of the container Sintetica will purportedly use for its proposed generic Naropin® product. The samples Sintetica produced on February 3, 2022 did not reflect the container Sintetica proposes using for its proposed generic Naropin® product.

27. On February 15, 2022, merely a few business days before expiration of the 45-day statutory deadline to file suit set forth in 21 U.S.C. § 355(j)(5)(B)(iii), Fresenius received from Sintetica a supplemental production of samples of the packaging for Sintetica's proposed generic Naropin® product, including components that were not included in Sintetica's February 3, 2022 production of samples.

28. Given the 45-day statutory deadline to file suit set forth in 21 U.S.C. § 355(j)(5)(B)(iii) and the limited information provided by Defendant to date, Fresenius turns to the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to further confirm their allegations of infringement and to present to the Court evidence that Sintetica's proposed generic Naropin® product falls within the scope of one or more claims of the Patent-in-Suit.

COUNT I FOR INFRINGEMENT OF U.S. PATENT NO. 8,118,802 BY DEFENDANT

29. The allegations of paragraphs 1-28 are realleged and incorporated herein by reference.

30. Sintetica's proposed generic Naropin® product is covered by one or more claims of the '8,802 Patent.

31. Upon information and belief, the commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sintetica's proposed generic Naropin® product would infringe one or more claims of the '8,802 Patent.

32. Defendant has infringed the '8,802 Patent under 35 U.S.C. § 271(e)(2)(A) by, individually and/or in concert, submitting and maintaining Sintetica's ANDA before the FDA seeking approval to market Sintetica's proposed generic Naropin® product before the expiration of the '8,802 Patent.

33. Upon information and belief, Defendant actively and knowingly caused to be submitted, assisted with, participated in, encouraged, contributed to, aided and abetted, and/or directed the submission and maintenance of Sintetica's ANDA to the FDA.

34. Upon information and belief, Defendant induced the infringement of the '8,802 Patent by actively and knowingly aiding and abetting the preparation, submission, and maintenance of Sintetica's ANDA with the Paragraph IV Certification and the preparation to sell Sintetica's proposed generic Naropin® product in the United States.

35. Upon information and belief, Defendant was aware of the '8,802 Patent when engaging in these knowing and purposeful activities and was aware that filing Sintetica's ANDA with the Paragraph IV Certification with respect to the '8,802 Patent constituted an act of infringement of the '8,802 Patent.

36. Upon information and belief, use of Sintetica's proposed generic Naropin® product in accordance with and as directed by Sintetica's proposed labeling for that product would infringe one or more claims of the '8,802 Patent.

37. Upon information and belief, Defendant intends to engage in the manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Sintetica's proposed generic Naropin® product with its proposed labeling immediately and imminently upon approval of Sintetica's ANDA.

38. Upon information and belief, Defendant plans and intends to, and will, actively induce infringement of the '8,802 Patent when Sintetica's ANDA is approved, and plans and intends to, and will, do so immediately and imminently upon approval.

39. Upon information and belief, Defendant knows that its generic Naropin® product and the proposed labeling for Sintetica's proposed generic Naropin® product are especially made or adapted for use in infringing the '8,802 Patent and that Sintetica's proposed generic Naropin® product and the proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Defendant plans and intends to, and will, contribute to the infringement of the '8,802 Patent immediately and imminently upon approval of Sintetica's ANDA.

40. The foregoing actions by Defendant constitute and/or would constitute infringement of the '8,802 Patent, active inducement of infringement of the '8,802 Patent and/or contribution to the infringement by others of the '8,802 Patent.

41. Upon information and belief, Defendant acted without a reasonable basis for believing that it would not be liable for infringing the '8,802 Patent, actively inducing infringement of the '8,802 Patent, and/or contributing to the infringement by others of the '8,802 Patent.

42. Fresenius will be substantially and irreparably harmed by Defendant's infringing activities unless the Court enjoins those activities. Fresenius will have no adequate remedy at law if Defendant is not enjoined from the commercial manufacture, use, offer to sell, sale in, and importation into the United States of Sintetica's proposed generic Naropin® product.

43. Defendant's activities render this case an exceptional one, and Fresenius is entitled to an award of its reasonable attorney fees under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Fresenius respectfully requests the following relief:

a. a judgment that the Patent-in-Suit is valid and enforceable;

b. a judgment that Sintetica S.A.'s submission of the ANDA No. 215879, was an act of infringement of one or more claims of the Patent-in-Suit and that the making, using, offering to sell, selling, marketing, distributing, or importing of Sintetica's proposed generic Naropin® product prior to the expiration of the Patent-in-Suit will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the Patent-in-Suit;

c. an Order pursuant to 35 U.S.C. § 271(e)(4)(A) providing that the effective date of any FDA approval of ANDA No. 215879 or any product the use of which infringes the Patent-in-Suit, shall be a date that is not earlier than the expiration of the Patent-in-Suit;

d. an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendant and all persons acting in concert with Defendant from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Sintetica's proposed generic Naropin® product, or any product the use of which infringes the Patent-in-Suit, or inducing or contributing to the infringement of the Patent-in-Suit until after the expiration of the Patent-in-Suit;

e. an Order pursuant to 35 U.S.C. § 283 permanently enjoining Defendant and all persons acting in concert with Defendant from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Sintetica's proposed generic Naropin® product, or any product or compound the use of which infringes the Patent-in-Suit, or inducing or contributing to the infringement of the Patent-in-Suit, until after the expiration of the Patent-in-Suit;

f. an Order enjoining Defendant and all persons acting in concert with Defendant from seeking, obtaining, or maintaining approval of Sintetica's ANDA No. 215879 before the expiration of the Patent-in-Suit;

g. an award of Fresenius's damages or other monetary relief to compensate Fresenius if Defendant engage in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Sintetica's proposed generic Naropin® product, or any product or compound the use of which infringes the Patent-in-Suit, or the inducement or contribution of the foregoing, prior to the expiration of the Patent-in-Suit in accordance with 35 U.S.C. § 271(e)(4)(C);

h. a judgment that this is an exceptional case and awarding Fresenius its attorneys' fees under 35 U.S.C. § 285;

i. an award of Fresenius's reasonable costs and expenses in this action; and

j. an award of any further and additional relief to Fresenius as this Court deems just and proper.

Date: February 18, 2022

Respectfully submitted,

FARNAN LLP

/s/ Michael J. Farnan

Brian E. Farnan (Bar No. 4089)
Michael J. Farnan (Bar No. 5165)
919 N. Market Str., 12th Floor
Wilmington, DE 19801
Tel: (302) 777-0300
Fax: (302) 777-0301
bfarnan@farnanlaw.com
mfarnan@farnanlaw.com

Attorneys for Plaintiffs Fresenius Kabi USA, LLC and Fresenius Kabi Deutschland GmbH

OF COUNSEL:

Daryl L. Wiesen
Shaobo Zhu
Goodwin Procter LLP
100 Northern Avenue
Boston, MA 02210
(617) 570-1000
(617) 523-1231 (Fax)
dwiesen@goodwinlaw.com
szhu@goodwinlaw.com