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Fresenius Kabi Deutschland GMBH*

**UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY**

FRESENIUS KABI USA, LLC)
and FRESENIUS KABI DEUTSCHLAND GMBH)
Plaintiffs,)
v.) Civil Action No. _____
WOCKHARDT USA LLC, WOCKHARDT BIO)
AG, and WOCKHARDT LIMITED)
Defendants.)

)

COMPLAINT

Fresenius Kabi USA, LLC and Fresenius Kabi Deutschland GmbH (collectively, “Fresenius” or “Plaintiffs”) bring this action for patent infringement against Wockhardt USA LLC, Wockhardt Bio AG, and Wockhardt Limited (collectively, “Wockhardt” or “Defendants”).

NATURE OF THE ACTION

1. This is an action by Fresenius against Defendants for infringement of United States Patent No. 8,118,802 (“the ‘802 Patent” or “the Patent-in-Suit”). This action arises out of Defendants’ filing, individually and/or in concert, 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-Straße 1, 61352 Bad Homburg, Germany.

Defendants

4. Upon information and belief, Defendant Wockhardt USA LLC limited liability company is organized and existing under the laws of New Jersey, with its corporate offices and a principal place of business at 20 Waterview Blvd., 3rd Floor Parsippany, NJ 07054.

5. Upon information and belief, Wockhardt USA LLC is a pharmaceutical company that, either by itself or through subsidiaries and/or partners, develops, manufactures, markets and/or distributes generic pharmaceutical products around the world, including in this Judicial District.

6. Upon information and belief, Defendant Wockhardt Bio AG is a corporation organized and existing under the laws of Switzerland, with its principal place of business at Grafenauweg 6, 6300 Zug, Switzerland.

7. Upon information and belief, Wockhardt Bio AG is a pharmaceutical company that, either by itself or through subsidiaries and/or partners, develops, manufactures, markets and/or distributes generic pharmaceutical products around the world, including in this Judicial District.

8. Upon information and belief, Defendant Wockhardt Limited is a corporation organized and existing under the laws of India, with its principal place of business at Wockhardt Towers, Bandra-Kurla Complex, Bandra East, Mumbai 400 051, India.

9. Upon information and belief, Wockhardt Limited is a pharmaceutical company that, either by itself or through subsidiaries and/or partners, develops, manufactures, markets and/or distributes generic pharmaceutical products around the world, including in this Judicial District.

10. Upon information and belief, Wockhardt USA LLC is a wholly owned subsidiary of Wockhardt Bio AG.

11. Upon information and belief, Wockhardt USA LLC and Wockhardt Bio AG are both wholly owned subsidiaries of Wockhardt Limited.

JURISDICTION AND VENUE

Subject Matter Jurisdiction

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

13. 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

14. This Court has personal jurisdiction over Defendants because, *inter alia*, they have maintained continuous and systematic contacts with the State of New Jersey.

15. This Court also has personal jurisdiction over Defendants because, *inter alia*, they have committed, or aided, abetted, contributed to, or participated in the commission of, tortious conduct which will lead to foreseeable harm and injury to Fresenius in the State of New Jersey, and by doing so, Defendants have purposefully directed their activities at the residents of this forum.

16. Upon information and belief, this Court has personal jurisdiction over Defendant Wockhardt USA LLC because it is incorporated and has its principal place of business in New Jersey.

17. Upon information and belief, this Court has personal jurisdiction over Defendant Wockhardt Bio AG because its U.S. agent of service, Wockhardt USA LLC, is located and incorporated in New Jersey.

18. Upon information and belief, Defendants have previously availed themselves of this Judicial District by not contesting personal jurisdiction in at least the following actions: *Jazz Pharm., Inc. et al. v. Wockhardt Bio AG et al.*, Civil Action No. 16-cv-00099-ES-JAD (D.N.J. filed Jan. 7, 2016); *BTG Int'l Ltd. et al. v. Actavis Labs. FL, Inc. et al.*, Civil Action No. 15-cv-05909-KM-JBC (D.N.J. filed July 31, 2015); and *Jazz Pharm., Inc. et al. v. Wockhardt Bio AG et al.*, Civil Action No. 15-cv-05619-ES-JAD (D.N.J. filed Jul. 17, 2015).

19. Upon information and belief, Defendants have engaged in continuous and systematic contacts with the State of New Jersey and/or purposefully have availed themselves of this forum by, *inter alia*, individually and/or in concert, making, marketing, shipping, using,

offering to sell or selling Wockhardt pharmaceutical products in this Judicial District, and deriving substantial revenue from such activities.

20. Upon information and belief, Defendants have engaged in and maintained systematic and continuous business contacts within the State of New Jersey, and have purposefully availed themselves of the benefits and protections of the laws of New Jersey, rendering them at home in New Jersey.

21. Upon information and belief, Defendants operate as a single vertically-integrated business with respect to the regulatory approval, manufacturing, marketing, sale, and distribution of pharmaceutical products throughout the United States including in this judicial district.

22. Upon information and belief, Defendants, individually and/or in concert, have committed, or aided, abetted, contributed to and/or participated in the commission of the tortious action of patent infringement that has led to foreseeable harm and injury to Fresenius, which manufactures Naropin® for sale and use throughout the United States, including the State of New Jersey.

23. Upon information and belief, Wockhardt Bio AG has applied for FDA approval to market and sell a generic version of Naropin® throughout the United States, including in New Jersey.

24. Wockhardt sent a letter dated October 4, 2019 (the “Notice Letter”) to Fresenius Kabi USA, LLC stating that Wockhardt Bio AG had filed ANDA No. 206320 seeking FDA approval to market a generic Naropin® product prior to the expiration of the Patents-in-Suit. The Notice Letter was signed by Serge Ilin-Schneider, general counsel to Wockhardt USA, LLC.

25. Upon information and belief, Defendants acted in concert to prepare and submit ANDA No. 206320.

26. Upon information and belief, Defendants, individually and/or in concert, will market, sell, and offer for sale Wockhardt's proposed generic version of Naropin® in the State of New Jersey following FDA approval of that product.

27. Upon information and belief, as a result of Defendants' marketing, selling, or offering for sale of Wockhardt's generic version of Naropin® in the State of New Jersey, Fresenius will lose sales of Naropin® and be injured in the State of New Jersey.

28. Upon information and belief, Defendants' systematic and continuous business contacts within New Jersey render them at home in New Jersey.

29. Upon information and belief, this Court has personal jurisdiction over Defendants for the reasons stated herein, including, *inter alia*, Defendants' activities in the forum, activities directed at the forum, and significant contacts with the forum, all of which render Defendants at home in the forum.

30. In the alternative, Defendants Wockhardt Bio AG and Wockhardt Limited are subject to personal jurisdiction in this forum under Fed. R. Civ. P. 4(k)(2).

Venue

31. Venue is proper in this district under 28 U.S.C. § 1391 and 1400(b). *In re HTC Corp.*, 889 F.3d 1349, 1354 (Fed. Cir. 2018).

32. Upon information and belief, Defendants have a regular and establish place of business in this Judicial District and have committed and/or will commit acts of infringement in this Judicial District.

33. Upon information and belief, Defendants have previously not contested venue in this Judicial District in at least the following actions: *Jazz Pharm., Inc. et al. v. Wockhardt Bio AG et al.*, Civil Action No. 16-cv-00099-ES-JAD (D.N.J. filed Jan. 7, 2016); *BTG Int'l Ltd. et al. v. Actavis Labs. FL, Inc. et al.*, Civil Action No. 15-cv-05909-KM-JBC (D.N.J. filed July 31,

2015); and *Jazz Pharm., Inc. et al. v. Wockhardt Bio AG et al.*, Civil Action No. 15-cv-05619-ES-JAD (D.N.J. filed Jul. 17, 2015).

34. Defendant Wockhardt USA LLC has a regular and established place of business in this Judicial District at least because, upon information and belief, it: (1) is incorporated in the State of New Jersey; (2) has a principal place of business in New Jersey; (3) has acted in concert with Wockhardt Bio AG and Wockhardt Limited to seek approval from the FDA to market and sell a proposed generic Naropin® in this Judicial District; (4) conducts business in this Judicial District; and (5) has engaged in regular and established business contacts with New Jersey by, individually and/or in concert, marketing, making, shipping, using, offering to sell, or selling, or causing others to market, make, ship, use, offer to sell, or sell Wockhardt products in this Judicial District, and deriving substantial revenue from such activities.

35. Defendant Wockhardt Bio AG has a regular and established place of business in this Judicial District at least because, upon information and belief, it: (1) has sought approval from the FDA to market and sell its proposed generic Naropin® in this Judicial District; (2) conducts business, individually and/or in concert with its U.S. agent of service, which is located and incorporated in New Jersey, in this Judicial District; (3) has engaged in regular and established business contacts with New Jersey by, *inter alia*, marketing, making, shipping, using, offering to sell or selling Wockhardt products in this Judicial District, and deriving substantial revenue from such activities.

36. Defendant Wockhardt Limited has a regular and established place of business in this Judicial District at least because, upon information and belief, it: (1) conducts business, individually and/or in concert with its U.S. subsidiary, which is located and incorporated in New Jersey, in this Judicial District; and (2) has engaged in regular and established business contacts

with New Jersey by, *inter alia*, marketing, making, shipping, using, offering to sell or selling Wockhardt products in this Judicial District, and deriving substantial revenue from such activities.

BACKGROUND

The Patents-in-Suit

37. The ‘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 ‘802 Patent to Fresenius Kabi Deutschland GmbH. The ‘802 Patent is listed in the Orange Book with respect to Naropin®. The ‘802 Patent will expire on May 18, 2023. A true and accurate copy of the ‘802 Patent is attached hereto as Exhibit A.

The Naropin® Drug Product

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

39. 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’s ANDA

40. Wockhardt Bio AG 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 Wockhardt asserts is a generic copy of Naropin® (“Defendants’ generic Naropin® product”) prior to the expiration of the Patents-in-Suit.

41. The FDA assigned Wockhardt’s ANDA number 206320.

42. Wockhardt filed with the FDA, pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV), a certification alleging that the claims of the Patents-In-Suit are invalid, unenforceable and/or

would not be infringed by the manufacture, use, importation, sale or offer for sale of Wockhardt's generic Naropin® product ("Wockhardt's Paragraph IV Certification"). Wockhardt notified Fresenius of this certification in a letter dated October 4, 2019 sent by Certified Mail.

43. A document entitled "Detailed Statement of the Factual and Legal Bases of Wockhardt's Opinion that the '787 Patent, '7802 Patent, '8802 Patent and the 915 Patent is Invalid, Unenforceable and/or Not Infringed" ("Detailed Statement") was attached to Wockhardt's Paragraph IV Certification. The Detailed Statement provided only a cursory two-sentence description of Defendant's generic Naropin® product that was not supported with any technical documentation. The Detailed Statement also states that "[a]dditional details of Wockhardt's ANDA product and/or the process by which Wockhardt's ANDA product is made may be made available pursuant to the terms of the Offer for Confidential Access."

44. In the Notice Letter, Wockhardt offered Fresenius confidential access to ANDA No. 206320 on terms and conditions set forth in an attached "Offer of Confidential Access to Application" ("OCA"). The OCA provided by Wockhardt contained various terms and conditions, several of which went above and beyond protections typically afforded in a protective order.

45. On October 18, 2019, Fresenius provided Wockhardt with a revised draft of the OCA. Over two weeks later on November 5, 2019, Wockhardt provided Fresenius with counter-revisions to the OCA, and indicated that it would produce the document referenced in the OCA "promptly" after execution of the OCA. A final OCA was signed on November 7, 2019. Fresenius requested production of the relevant documents on November 7, 2019, and again, on November 11, 2019.

46. On November 12, 2019, Wockhardt indicated to Fresenius that it was still gathering the relevant documents and would produce them to Fresenius as soon as it is able.

47. As of the filing of this Complaint, Fresenius has still not received the documents Wockhardt agreed to produce under the executed OCA.

48. 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 Wockhardt 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 Defendants' generic Naropin® product falls within the scope of one or more claims of the Patents-in-Suit.

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

49. The allegations of paragraphs 1-48 are realleged and incorporated herein by reference.

50. The use of Wockhardt's generic Naropin® product is covered by one or more claims of the '802 Patent.

51. The commercial manufacture, use, offer for sale, sale, marketing, distribution, and/or importation of Wockhardt's generic Naropin® product would infringe one or more claims of the '802 Patent.

52. Defendants have infringed the '802 Patent by, individually and/or in concert, submitting and maintaining Wockhardt's ANDA before the FDA seeking approval to market Defendants' generic Naropin® product before the expiration of the '802 Patent.

53. Upon information and belief, Defendants 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 Wockhardt's ANDA to the FDA.

54. Defendants induced the infringement of the '802 Patent by, individually and/or in concert, actively and knowingly aiding and abetting the preparation, submission, and maintenance of Defendant's ANDA with the Paragraph IV Certification and the preparation to sell Defendants' generic Naropin® product in the United States.

55. Defendants were aware of the '802 Patent when engaging in these knowing and purposeful activities and were aware that filing Wockhardt's ANDA with the Paragraph IV Certification with respect to the '802 Patent constituted an act of infringement of the '802 Patent.

56. Use of Defendants' generic Naropin® product in accordance with and as directed by Wockhardt's proposed labeling for that product would infringe one or more claims of the '802 Patent.

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

58. Upon information and belief, Defendants, individually and/or in concert, plan and intend to, and will, actively induce infringement of the '802 Patent when Wockhardt's ANDA is approved, and plan and intend to, and will, do so immediately and imminently upon approval.

59. Upon information and belief, Defendants know that Defendants' generic Naropin® product and the proposed labeling for Defendant's generic Naropin® product are especially made or adapted for use in infringing the '802 Patent and that Defendants' generic Naropin® product

and the proposed labeling are not suitable for substantial noninfringing use. Upon information and belief, Defendants plan and intend to, and will, contribute to the infringement of the ‘802 Patent immediately and imminently upon approval of Wockhardt’s ANDA.

60. The foregoing actions by Defendants constitute and/or would constitute infringement of the ‘802 Patent, active inducement of infringement of the ‘802 Patent and/or contribution to the infringement by others of the ‘802 Patent.

61. Upon information and belief, Defendants acted without a reasonable basis for believing that they would not be liable for infringing the ‘802 Patent, actively inducing infringement of the ‘802 Patent, and/or contributing to the infringement by others of the ‘802 Patent.

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

63. Defendants’ 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.

PRAAYER FOR RELIEF

WHEREFORE, Fresenius respectfully requests the following relief:

- a. a judgment that the ‘802 Patent is valid and enforceable;
- b. a judgment that Wockhardt’s submission of the ANDA No. 206320, was an act of infringement of one or more claims of the ‘802 Patent and that the making, using, offering to sell, selling, marketing, distributing, or importing of Defendants’ generic Naropin® product prior to the expiration of the ‘802 Patent will infringe, actively induce infringement and/or contribute to the infringement of one or more claims of the ‘802 Patent;

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. 206320 or any product the use of which infringes the ‘802 Patent, shall be a date that is not earlier than the expiration of the ‘802 Patent;

d. an Order pursuant to 35 U.S.C. § 271(e)(4)(B) permanently enjoining Defendants and all persons acting in concert with Defendants from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Defendants’ generic Naropin® product, or any product the use of which infringes the ‘802 Patent, or inducing or contributing to the infringement of the ‘802 Patent until after the expiration of the ‘802 Patent;

e. an Order pursuant to 35 U.S.C. § 283 permanently enjoining Defendants and all persons acting in concert with Defendants from commercially manufacturing, using, offering for sale, selling, marketing, distributing, or importing Defendants’ generic Naropin® product, or any product or compound the use of which infringes the ‘802 Patent, or inducing or contributing to the infringement of the ‘802 Patent, until after the expiration of the ‘802 Patent;

f. an Order enjoining Defendants and all persons acting in concert with Defendants from seeking, obtaining, or maintaining approval of Wockhardt’s ANDA No. 206320 before the expiration of the ‘802 Patent;

g. an award of Fresenius’s damages or other monetary relief to compensate Fresenius if Defendants engage in the commercial manufacture, use, offer to sell, sale or marketing or distribution in, or importation into the United States of Defendants’ generic Naropin® product, or any product or compound the use of which infringes the ‘802 Patent, or the inducement or contribution of the foregoing, prior to the expiration of the ‘802 Patent 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.

Dated: November 15, 2019

Respectfully submitted,

/s/ Eric I. Abraham
ERIC I. ABRAHAM

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