IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MERCK SHARP & DOHME CORP.,	)	
	)	
Plaintiff,	)	
	)	
v.	)	C.A. No. _____
	)	
FRESENIUS KABI USA, LLC,	)	
	)	
Defendant.	)	

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Merck Sharp & Dohme Corp. (hereinafter "Merck" or "Plaintiff"), for its Complaint against Fresenius Kabi USA, LLC (hereinafter "Fresenius"), alleges as follows:

THE PARTIES

1. Merck Sharp & Dohme Corp. is a subsidiary of Merck & Co., Inc., and is a corporation incorporated under the laws of the state of New Jersey, having its principal place of business at One Merck Drive, Whitehouse Station, New Jersey 08889.

2. Merck is a global research-driven pharmaceutical company that discovers, develops, manufactures and markets a broad range of innovative products to improve human and animal health.

3. On information and belief, Fresenius is a corporation organized and existing under the laws of Delaware, having its corporate headquarters at Three Corporate Drive, Lake Zurich, Illinois 60047.

4. On information and belief, Fresenius is in the business of, *inter alia*, marketing a portfolio of "pharmaceuticals and medical devices" including "intravenous specialty and generic medicines" and "infusion therapies." *Acetylcysteine Solution, USP 20% in 4 mL vials Now Available*, FRESENIUS KABI, http://www.fresenius-kabi.us/news-and-media/news-

releases/196-acetylcysteine-solution-usp-20-in-4-ml-vials-now-available.html (last visited August 2, 2014).

5. On information and belief, Fresenius is in the business of, *inter alia,* developing, manufacturing, selling, distributing, and/or importing generic pharmaceutical products, which are copies of products invented and developed by innovator pharmaceutical companies, throughout the United States, including in this Judicial District.

6. On information and belief, Fresenius Kabi expanded its presence in the United States in 2008 with the acquisition of APP Pharmaceuticals, which merged with Fresenius. On information and belief, Fresenius "bec[ame] a globally leading supplier in the field of intravenously administered generic drugs via the acquisition of the U.S. based APP Pharmaceuticals." *History,* FRESENIUS KABI, http://www.fresenius-kabi.us/company/history.html (last visited August 2, 2014). On information and belief, APP Pharmaceuticals was in the business of developing, manufacturing and/or marketing generic pharmaceutical products.

7. On information and belief, APP Pharmaceuticals, LLC was organized under the laws of the State of Delaware. On information and belief, in August 2012 APP Pharmaceuticals, LLC changed its name to Fresenius Kabi USA, LLC.

8. On information and belief, Fresenius expanded its presence in the United States in 2012 with the acquisition of Fenwal Inc. On information and belief, Fenwal Inc. was organized under the laws of the State of Delaware.

9. On information and belief, Fresenius assembled and caused to be filed with the United States Food and Drug Administration ("FDA"), pursuant to 21 U.S.C. § 355(b)(2) (§ 505(b)(2) of the Federal Food, Drug and Cosmetic Act), New Drug Application

("NDA") No. 206110 (hereinafter "the Fresenius 505(b)(2) application") concerning a proposed drug product, Caspofungin Acetate for Injection in 50 mg/vial and 70 mg/vial dosage strengths.

JURISDICTION AND VENUE

10. This action arises under the patent laws of the United States of America. This Court has jurisdiction over the subject matter of this action under 28 U.S.C. §§ 1331 and 1338(a).

11. Fresenius is subject to personal jurisdiction in Delaware because, *inter alia*, it (1) is a corporation organized and existing under the laws of the State of Delaware; (2) has affiliations with this Judicial District that are pervasive, continuous, and systematic, including direct marketing, distribution, and/or sale of generic pharmaceutical drugs within this Judicial District and to residents of this Judicial District, as well as the maintenance of corporate agents; and (3) has previously submitted to the jurisdiction of this Court and has availed itself of the legal protections of the State of Delaware, having asserted counterclaims in this jurisdiction, including in the matter of *Celgene Corp. v. Fresenius Kabi USA, LLC*, C.A. No. 14-571-RGA, D.I. 9, at 2, 8-14 (D. Del. May 9, 2014).

12. Fresenius is also subject to personal jurisdiction in Delaware because, *inter alia*, Fresenius has committed, aided, abetted, contributed to, and/or participated in the commission of a tortious act of patent infringement that has led to foreseeable harm and injury to Merck in this Judicial District. Fresenius states that it intends to engage in the commercial manufacture, use, and/or sale of caspofungin for injection before the expiration of U.S Patent Nos. 5,514,650 ("'650 patent") and 5,952,300 ("'300 patent"), including in this Judicial District.

13. Venue is proper in this Court at least pursuant to 28 U.S.C. § 1391(b), (c), and/or (d), and 1400(b).

CANCIDAS®

14. Merck holds approved New Drug Application ("NDA") 21-227 for CANCIDAS®, the active ingredient of which is caspofungin acetate. CANCIDAS® is approved for the treatment of certain types of fungal infections.

15. Merck is the owner of U.S. Patent No. 5,514,650 and U.S. Patent No. 5,952,300 (Attached as Exhibit A and B, respectively).

16. CANCIDAS® is an embodiment of one or more claims of each of the '650 and '300 patents.

FRESENIUS 505(b)(2) APPLICATION

17. On June 25, 2014, Merck received from Fresenius's counsel a letter, dated June 23, 2014 (the "June 23 letter"), stating that Fresenius had submitted to the FDA a §505(b)(2) application or NDA, assigned as NDA No. 206110, seeking approval to market Caspofungin Acetate for Injection, in 50 mg/vial and 70 mg/vial dosage strengths ("the Fresenius Products").

18. The June 23 letter stated that the Fresenius 505(b)(2) application was amended to include a certification pursuant to 21 U.S.C. § 355(b)(2)(A)(iv) that each claim of the '650 and '300 patents is invalid, unenforceable, and/or would not be infringed by the manufacture, use, or sale of the Fresenius Products.

19. The Fresenius 505(b)(2) application refers to and relies upon the Merck NDA for CANCIDAS®.

20. The June 23 letter fails to comply with the requirements of 21 U.S.C. § 355(b)(3)(D) because, *inter alia*, it contains very limited information about the Fresenius

Products. For example, the June 23 letter does not list any of the ingredients in the proposed Fresenius Products, apart from caspofungin diacetate, or the amounts of those ingredients.

21. In the June 23 letter, Fresenius offered confidential access to portions of NDA No. 206110 (the Fresenius 505(b)(2) application) on terms and conditions set forth in paragraph VII of the June 23 letter ("Fresenius Offer"). Fresenius requested that Merck accept the Fresenius Offer before receiving access to any portion of the Fresenius 505(b)(2) application. The Fresenius Offer contained unreasonable restrictions on who could view the Fresenius 505(b)(2) application, above and beyond those that would apply under a protective order. 21 U.S.C. § 355(c)(3)(D)(i)(III). For example, the Fresenius Offer did not allow any access to Merck's in-house counsel, did not provide a reasonable provision for access by experts, and unreasonably limited the fields of practice of outside counsel.

22. Under 21 U.S.C. § 355(c)(3)(D)(i)(III), an "offer of confidential access shall contain such restrictions as to persons entitled to access, and on the use and disposition of any information accessed, as would apply had a protective order been entered for the purpose of protecting trade secrets and other confidential business information."

23. Since rejecting the Fresenius Offer, Merck attempted to negotiate with Fresenius to procure a copy of the Fresenius 505(b)(2) application under restrictions "as would apply had a protective order been issued." Those negotiations were unsuccessful. For example, Fresenius's final proposal continued to either deny access to in-house counsel, or as an alternative, to unreasonably limit the fields of practice of in-house counsel who would be provided access to the Fresenius 505(b)(2) application. Fresenius refused to remove these unreasonable restrictions despite their being wholly inconsistent with any protective order that has been entered in other cases pertaining to Cancidas® and the patents in suit in this action,

including in this and other jurisdictions. *See Merck & Co. Inc., et al, v. Teva Parenteral Medicines, Inc., et al.*, Civil Action. No. 09-6026, D.I. 50 (SRC)(PS) (consolidated) (D.N.J. June 9, 2010); *Merck Sharp & Dohme v. Xellia Pharmaceuticals ApS*, Civil Action No. 14-199, D.I. 20 (RGA) (D. Del. April 25, 2014).

24. Merck is not aware of any other means of obtaining information regarding the Fresenius Products within the 45-day statutory period. Without such information, Merck will use the judicial process and the aid of discovery to obtain, under appropriate judicial safeguards, such information as is required to confirm its allegations of infringement and to present to the Court evidence that the Fresenius Products fall within the scope of one or more claims of the '650 and '300 patents.

INFRINGEMENT OF U.S. PATENT NO. 5,514,650

25. Plaintiff repeats and realleges paragraphs 1-24 above as if fully set forth herein.

26. By filing its NDA No. 206110 under 21 U.S.C. § 355(b)(2) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of the Fresenius Products before the expiration of the '650 patent, Fresenius committed an act of infringement under 35 U.S.C. § 271(e)(2).

27. If Fresenius commercially makes, uses, offers to sell, or sells the Fresenius Products within the United States, or imports the Fresenius Products into the United States, or induces or contributes to any such conduct during the term of the '650 patent, it would further infringe the '650 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

28. Merck will be irreparably harmed if Fresenius is not enjoined from infringing the '650 patent. Merck does not have an adequate remedy at law.

29. Fresenius's certification under 21 U.S.C. § 355(b)(2)(A)(iv) against the '650 patent was wholly unjustified, and thus this case is exceptional under 35 U.S.C. § 285.

INFRINGEMENT OF U.S. PATENT NO. 5,952,300

30. Plaintiff repeats and realleges paragraphs 1-29 above as if fully set forth herein.

31. By filing its NDA No. 206110 under 21 U.S.C. § 355(b)(2) for the purpose of obtaining approval to engage in the commercial manufacture, use or sale of the Fresenius Products before the expiration of the '300 patent, Fresenius committed an act of infringement under 35 U.S.C. § 271(e)(2).

32. If Fresenius commercially makes, uses, offers to sell, or sells the Fresenius Products within the United States, or imports the Fresenius Products into the United States, or induces or contributes to any such conduct during the term of the '300 patent, it would further infringe the '300 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

33. Merck will be irreparably harmed if Fresenius is not enjoined from infringing the '300 patent. Merck does not have an adequate remedy at law.

34. Fresenius's certification under 21 U.S.C. § 355(b)(2)(A)(iv) against the '300 patent was wholly unjustified, and thus this case is exceptional under 35 U.S.C. § 285.

STATEMENT REGARDING CO–FILED SUIT

35. Merck has also filed, on August 7, 2014, an action in the United States District Court for the District of New Jersey seeking to enjoin Fresenius from infringing the '650 and '300 patents. ("Merck-Fresenius D.N.J. Action"). That action has not yet been assigned a Civil Action Number.

36. In the Merck-Fresenius D.N.J. Action, Merck alleged that the District Court for the District of New Jersey has personal jurisdiction over Fresenius with regard to Merck's claim of patent infringement.

37. Fresenius has recently admitted to personal jurisdiction in New Jersey for the purpose of a Hatch-Waxman Act litigation in, *inter alia*, the matters of *Merck Sharp & Dohme Corp. v. Fresenius Kabi USA, LLC.*, Civil Action No. 3:14-cv-03917 (PGS)(LHG), D.I. 12, 4-5 (D.N.J. Aug. 4, 2014) and *Novartis Pharmaceuticals Corporation v. Fresenius Kabi USA, LLC*, Civil Action No. 2:13-cv-7914 (SDW)(MCA), D.I. 10, at 3 (D.N.J. Feb. 13, 2014).

38. Pursuant to 21 U.S.C. § 355(c)(3)(C), a patent owner has 45 days from receipt of a 505(b)(2) Notice Letter to file suit in order to perfect its statutory right to a stay of FDA approval of a 505(b)(2) application pending resolution of litigation regarding the submission of such 505(b)(2) application. Plaintiff filed this action as a further protective measure with regard to this statutory right in light of Fresenius's statement that Fresenius does not believe it is subject to personal jurisdiction in New Jersey. Plaintiff expects that personal jurisdiction will be maintained in the District of New Jersey and that the action will proceed in that forum. In that circumstance, this action would be unnecessary and may be voluntarily dismissed without prejudice in favor of continued prosecution of the Merck-Fresenius D.N.J. Action, transferred to the District of New Jersey for consolidation with the Merck-Fresenius D.N.J. Action, or such other non-substantive disposition that would ensure maintenance of Merck's rights pursuant to 21 U.S.C. § 355(c)(3)(C).

PRAYER FOR RELIEF

WHEREFORE, Plaintiff respectfully requests:

A. Judgment that Fresenius Kabi USA, LLC has infringed one or more claims of the '650 patent by filing NDA No. 206110 relating to Fresenius's caspofungin acetate products;

B. A permanent injunction restraining and enjoining Fresenius Kabi USA, LLC, and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of caspofungin products as claimed in the '650 patent;

C. An order that the effective date of any approval of NDA No. 206110 relating to Fresenius's caspofungin acetate products be a date that is not earlier than the expiration date of the '650 patent as extended plus any other regulatory exclusivity to which Plaintiff is or becomes entitled;

D. Judgment that Fresenius Kabi USA, LLC has infringed one or more claims of the '300 patent by filing NDA No. 206110 relating to Fresenius's caspofungin acetate products;

E. A permanent injunction restraining and enjoining Fresenius Kabi USA, LLC, and its officers, agents, attorneys and employees, and those acting in privity or concert with them, from engaging in the commercial manufacture, use, offer for sale, or sale within the United States, or importation into the United States, of caspofungin products as claimed in the '300 patent;

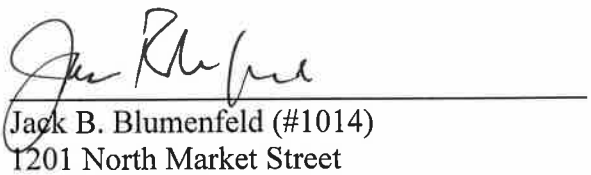
F. An order that the effective date of any approval of NDA No. 206110 relating to Fresenius's caspofungin acetate products be a date that is not earlier than the

expiration date of the '300 patent plus any other regulatory exclusivity to which Plaintiff is or becomes entitled;

G. A declaration that this case is exceptional within the meaning of 35 U.S.C. § 285 and an award of reasonable attorney fees, expenses, and disbursements of this action; and

H. Such other and further relief as the Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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August 7, 2014