IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS

MYLAN PHARMA ACQUISITION LTD., MYLAN TEORANTA, MYLAN INSTITUTIONAL LLC, Plaintiffs, v. FRESENIUS KABI USA, LLC, Defendant.	)))))))))))	Civil Action No.

COMPLAINT FOR PATENT INFRINGEMENT

Plaintiffs Mylan Pharma Acquisition Limited, Mylan Teoranta, and Mylan Institutional LLC (collectively, "Mylan" or "Plaintiffs") bring this Complaint for patent infringement against Fresenius Kabi USA, LLC ("Fresenius").

THE PARTIES

1. Mylan Pharma Acquisition Limited is a corporation organized and existing under the laws of Ireland, and having a place of business at Inverin, Co. Galway, Republic of Ireland.

2. Mylan Teoranta is a company organized and existing under the laws of the Republic of Ireland, having an address of Inverin, Co. Galway, Republic of Ireland.

3. Mylan Institutional LLC is a corporation organized and existing under the laws of the State of Delaware, and having a place of business at 1718 Northrock Court, Rockford, IL 61103. Mylan Institutional LLC is a pharmaceutical company that develops and commercializes injectable pharmaceutical products.

4. Upon information and belief, Fresenius is a corporation organized and existing under the laws of the State of Delaware, and having a principal place of business at 3 Corporate Dr, Lake Zurich, IL 60047.

5. On information and belief, Fresenius is engaged in the development, manufacture, marketing, and distribution of generic pharmaceutical products for sale throughout the United States.

NATURE OF THE ACTION

6. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, Sections 100 *et seq.*, involving United States Patent No. 5,866,591 ("the '591 patent").

7. This action arises out of Fresenius' submission of Abbreviated New Drug Application ("ANDA") No. 206223 to the United States Food and Drug Administration ("FDA") seeking approval, prior to the expiration of the '591 patent, to manufacture, market, and sell a generic copy of Mylan's Ultiva® (remifentanil hydrochloride) for Injection product, namely, EQ 1 mg base/vial, EQ 2 mg base/vial, and EQ 5 mg base/vial, that is sold in the United States.

JURISDICTION AND VENUE

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

9. Venue is proper in this district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

10. This Court has personal jurisdiction over Fresenius because Fresenius maintains its principal place of business in this judicial district. In addition, in a letter sent to Mylan dated June 16, 2015 purporting to be a notification of Paragraph IV Certification for its ANDA No. 206223 pursuant to § 505(j)(2)(B)(ii) of the Federal Food, Drug, and Cosmetic Act and 21

C.F.R. § 314.95 ("Fresenius' Notice Letter"), Fresenius stated that it "will not object to the personal jurisdiction of the Illinois courts."

BACKGROUND

11. The '591 patent, entitled "Stable Formulations of Remifentanil," was duly and legally issued by the United States Patent and Trademark Office on February 2, 1999. The named inventors of the '591 patent are Larry A. Gatlin, Shirley A. Heiman, and Janet S. Lewis. A true and correct copy of the '591 patent is attached hereto as Exhibit A.

12. Mylan Pharma Acquisition Limited is the lawful owner of the '591 patent by assignment of all right, title and interest in and to the '591 patent, including the right to sue for infringement thereof.

13. Mylan Teoranta owns approved New Drug Application ("NDA") No. 020630 for Ultiva® (remifentanil hydrochloride) for Injection product.

14. Mylan Institutional LLC is the acting applicant for NDA No. 020630 for Ultiva® (remifentanil hydrochloride) for Injection product, which Mylan Institutional LLC sells under the registered trademark Ultiva®.

ACTS GIVING RISE TO THIS ACTION

15. In its June 16, 2015 Notice Letter, Fresenius notified Mylan that it had filed ANDA No. 206223 with the FDA seeking approval to commercially manufacture, market, use, and sell generic remifentanil hydrochloride for injection product, EQ 1 mg base/vial, EQ 2 mg base/vial, and EQ 5 mg base/vial dosage strengths ("Fresenius ANDA Products") prior to the expiration of the '591 patent.

16. According to Fresenius' Notice Letter, Fresenius' ANDA No. 206223 contained a certification stating that in Fresenius' opinion the '591 patent is invalid and/or would not be

infringed by the manufacture, use, or sale of Fresenius' ANDA Products ("Paragraph IV Certification").

17. Upon information and belief, Fresenius submitted ANDA No. 206223 to the FDA seeking approval to commercially manufacture, market, use, and sell Fresenius' ANDA Products prior to the expiration of the '591 patent.

18. Upon information and belief, Fresenius' ANDA Products are the same, or substantially the same, as Mylan's approved Ultiva® product.

19. Upon information and belief, Fresenius represented to the FDA in ANDA No. 206223 that Fresenius' ANDA Products are bioequivalent to Mylan's approved Ultiva® product.

20. Upon information and belief, Fresenius was aware of the '591 patent when Fresenius filed ANDA No. 206223 containing a Paragraph IV certification.

21. This action is being commenced within 45 days from the date that Mylan received Fresenius' Notice Letter.

COUNT 1
INFRINGEMENT OF THE '591 PATENT

22. Mylan repeats and realleges each of the foregoing paragraphs as if fully set forth herein.

23. By submitting ANDA No. 206223 and a Paragraph IV Certification for the purpose of obtaining approval to engage in the commercial manufacture, use, sale, or importation of the Fresenius ANDA Products prior to the expiration of the '591 patent, Fresenius infringed one or more claims of the '591 patent under 35 U.S.C. § 271(e)(2).

24. Upon information and belief, the commercial manufacture, use, offer for sale, sale and/or importation of Fresenius' ANDA Products prior to the expiration of the '591 patent, and

the inducement of and/or contribution to such conduct, would infringe one or more claims of the '591 patent under 35 U.S.C. §§ 271(a), (b), and/or (c).

25. Upon information and belief, upon FDA approval of Fresenius' ANDA No. 206223, Fresenius will infringe one or more claims of the '591 patent by making, using, offering for sale, and/or selling the Fresenius ANDA Products in the United States and/or importing the Fresenius ANDA Products into the United States, or by actively inducing and contributing to infringement of the '591 patent by others, under 35 U.S.C. §§ 271(a), (b), and/or (c) unless enjoined by the Court.

26. Fresenius had knowledge of the '591 patent when it submitted ANDA No. 206223.

27. Upon information and belief, Fresenius was and is aware of the existence of the '591 patent and acted without a reasonable basis for believing that it would not be liable for infringement of the '591 patent, thus rendering this case "exceptional" under 35 U.S.C. § 285.

28. Mylan has and will continue to be substantially and irreparably damaged and harmed if Fresenius' infringement of the '591 patent is not enjoined by this Court. Mylan does not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Mylan requests the following relief:

1. A judgment that Defendant has infringed the '591 patent under 35 U.S.C. § 271(e)(2)(A) by submitting ANDA No. 206223 under the Federal Food, Drug, and Cosmetic Act, and that the commercial manufacture, use, offer for sale, sale in the United States, and/or importation into the United States, of the Fresenius ANDA Products prior to patent expiry will constitute an act of infringement of the '591 patent;

2. An order pursuant to 35 U.S.C. § 271(e)(4)(A) that the effective date of any FDA approval of ANDA No. 206223 shall be no earlier than the expiration date of the '591 patent, inclusive of any extension(s) and additional period(s) of exclusivity to which Mylan is or may become entitled;

3. An order permanently enjoining Defendant, its officer, agents, servants, employees, parents, subsidiaries, affiliate corporations, other business entities and all other persons acting or attempting to act in concert or privity with them, their successors, and assigns, or acting on their behalf, from infringing, contributorily infringing, or inducing others to infringe the '591 patent, including engaging in the commercial manufacture, use, sale, offer to sale in the United States, and/or importation into the United States, of the Fresenius ANDA Products that are the subject of ANDA No. 206223 until the expiration of the '591 patent, inclusive of any extension(s) and additional period(s) of exclusivity to which Mylan is or may become entitled;

4. A declaration that the '591 patent is valid and enforceable;

5. A judgment awarding Mylan damages or other monetary relief under 35 U.S.C. § 271(e)(4)(C) as appropriate;

6. That this is an exceptional case under 35 U.S.C. § 285, and that Mylan be awarded reasonable attorneys' fees and costs; and

7. Such further and other relief as this Court may deem just and proper.

Dated: July 30, 2015

Respectfully submitted,

/s/ Steven P. Mandell

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