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Attorneys for Plaintiff
Sun Pharmaceutical Industries Limited

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

SUN PHARMACEUTICAL INDUSTRIES LIMITED, Plaintiff, v. PFIZER, INC. and PF PRISM C.V. Defendants.	Civil Action No. _____ JURY DEMAND

PLAINTIFF SUN PHARMACEUTICAL INDUSTRIES LIMITED'S COMPLAINT FOR PATENT INFRINGEMENT

Plaintiff Sun Pharmaceutical Industries Limited ("Sun"), by and through its counsel, respectfully submits this Complaint for Patent Infringement against Defendants Pfizer, Inc. and PF Prism C.V. (collectively, "Defendants"). In support thereof, Sun alleges as follows:

NATURE OF THE ACTION

1. This action is based on the patent laws of the United States, Title 35 of the United States Code.

2. Sun brings claims for patent infringement of U.S. Patent No. 9,393,205 ("the '205 patent'), relating to the manufacture, marketing, use and sale of LYRICA® CR extended-release tablets under Defendants' New Drug Application ("NDA") No. 209501 approved by the U.S. Food and Drug Administration ("FDA").

THE PARTIES

3. Plaintiff Sun is a corporation organized and existing under the laws of India, with its principal place of business in Mumbai, India.

4. On information and belief, Defendant Pfizer, Inc. is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business in New York, New York.

5. On information and belief, Defendant PF Prism C.V. is a limited partnership organized under the laws of the Netherlands, having its registered seat in Rotterdam, the Netherlands, and registered at the Trade Register held by the Chamber of Commerce in Rotterdam, the Netherlands, under number 51840456. On information and belief, PF Prism C.V. is a subsidiary of Pfizer, Inc.

6. PF Prism C.V. is the holder of NDA 209501 and sells LYRICA® CR extended-release tablets in this judicial district and throughout the United States.

JURISDICTION AND VENUE

7. This is a civil action regarding allegations of patent infringement arising under the patent laws of the United States, Title 35 of the United States Code. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1338, 2201 and 2202.

8. An actual controversy exists for patent infringement between Sun and Defendants by virtue of Defendants' making, using, offering to sell and selling LYRICA® CR extended-release tablets.

9. This Court has personal jurisdiction over Defendants because Defendants conduct substantial business in, and have regular and systematic contact with, the state of New Jersey, including this District. Defendants have committed acts of patent infringement and induced acts of patent infringement by others in this District and in the state of New Jersey; Defendants engage in other persistent courses of conduct and derive substantial revenue from products and/or services provided to individuals in this District and in the state of New Jersey; and Defendants have purposefully established systematic and continuous contacts with this District and should reasonably expect to be brought into Court here.

10. Venue is proper in this Court pursuant to 28 U.S.C. § 1391 because Defendants are subject to personal jurisdiction in this District.

BACKGROUND AND SPECIFIC FACTUAL ALLEGATIONS

11. When FDA approves a brand-name manufacturer's NDA, FDA publishes in the "Orange Book" any patents the brand-name manufacturer alleges can be reasonably asserted against a generic equivalent. 21 U.S.C. § 355(j)(7)(A)(iii). The listing of patents in the Orange Book by FDA is a ministerial act. FDA does not check the facts supplied to it by the brand-name manufacturer.

12. After NDA approval by FDA, the NDA holder may list additional new patents in the Orange Book as being related to the drug the subject of the NDA. The brand-name manufacturer must certify the new patents claim either the approved drug or approved methods of using the drug.

13. The ’205 patent, entitled “Gastroretentive Tablets,” was issued on July 19, 2016. As per the face of the patent, the inventors of the subject matter claimed in the ’205 patent are Varinder Kumar, Shavej Ahman and Romi Barat Singh. Sun Pharmaceutical Industries Limited is listed as the Assignee. A true and correct copy of the ’205 patent is attached hereto as Exhibit A. The claims of the ’205 patent are valid, enforceable and not expired.

14. The ’205 patent claims a gastroretentive tablet comprising pregabalin and the preparation of the same.

15. Defendants issued a press release on October 12, 2017, announcing FDA approval of LYRICA® CR extended-release tablets as once-daily therapy for the management of neuropathic pain associated with diabetic peripheral neuropathy and the management of postherpetic neuralgia.

16. Upon information and belief, Defendants have not sought to have the ’205 listed in the Orange Book.

17. Prior to selling LYRICA® CR extended-release tablets in the United States, Defendants did not seek a license to the ’205 patent, nor have they done so to date.

18. By letter dated February 6, 2019, Sun informed Pfizer, Inc. of its infringement of the ’205 patent, demanding Defendants discontinue infringement of the ’205 patent in the form of the unlicensed sale of LYRICA® CR extended-release tablets. Sun requested a response by February 19, 2019, but as of today, Sun has not received a response.

19. The use, marketing, offer to sell or sale of LYRICA® CR extended-release tablets in the United States infringes one or more claims of the '205 patent. For example, Claim 1 of the '205 patent recites "[a] gastroretentive tablet comprising pregabalin, at least one swellable polymer, and other pharmaceutically acceptable excipients." (The '205 patent at claim 1).

20. Swellable polymer as per the '205 patent includes cellulose polymers, gums, polyethylene oxide, carbomer, superdisintegrant polymers, and combinations thereof.

21. The Prescribing Information of LYRICA® CR states that each tablet contains pregabalin, along with Kollidon SR (polyvinyl acetate, povidone, sodium lauryl sulphate, and silica), crospovidone, polyethylene oxide, carbomer, magnesium stearate, polyvinyl alcohol, titanium dioxide, talc, polyethylene glycol, and colorants as inactive ingredients.

22. The continued unlicensed use, marketing and sale of LYRICA® CR extended-release tablets in the United States by Defendants is in violation of Sun's rights as the holder of the '205 patent and causes damage to Sun.

COUNT I

Infringement of the '205 Patent

23. Sun hereby incorporates by reference its allegations contained in paragraphs 1 through 22 of this Complaint as though fully set forth herein

24. Defendants' commercial manufacture, use, offer to sell, sale or import of LYRICA® CR extended-release tablets prior to the expiration of the '205 patent, and its inducement and/or contribution to such conduct infringes at least one of the claims of the '205 patent, either literally or under the doctrine of equivalents, including but not limited to claim 1.

25. On information and belief, Defendants have had knowledge and notice of the '205 patent, as well as of its own infringement of the '205 patent.

26. Defendants have had knowledge and notice of the ’205 patent, as well as its own infringement of the ’205 patent since at least February 7, 2019, by virtue of the letter sent by Sun on February 6, 2019, informing Defendants of the ’205 patent and Defendants’ infringement.

27. Sun has been and continues to be damaged by Defendants’ infringement of the ’205 patent.

28. Defendants’ infringement of the ’205 patent has been and continues to be willful.

29. Defendants’ infringement of the ’205 patent renders this case exceptional under 35 U.S.C. § 285.

PRAYER FOR RELIEF

WHEREFORE, Sun prays for a judgment as follows:

A. Judgment that the claims of the ’205 patent are infringed by Defendants’ making, using, offering to sell or selling, either literally or under the doctrine of equivalents, and that Defendants’ making, using, offering to sell, or selling in the United States, or importing into the United States Defendants’ LYRICA® CR extended-release tablets infringes the claims of the ’205 patent, either literally or under the doctrine of equivalents.

B. Awarding Sun all damages adequate to compensate it for Defendants’ infringement of the ’205 patent, such damages to be determined by a jury and an accounting, if necessary, to adequately compensate Sun for Defendants’ infringement;

C. Awarding Sun a reasonable royalty from Defendants for all future infringing sales;

D. Awarding Sun treble damages, pre-judgment and post-judgment interest;

E. Awarding Sun its costs, expenses and reasonable attorneys’ fees pursuant to 35 U.S.C. § 285; and

F. Awarding Sun such other and further relief as the Court deems just and reasonable.

JURY DEMAND

Pursuant to Rule 38 of the Federal Rules of Civil Procedure, Sun demands a trial by jury in this action for all issues so triable.

Dated: April 5, 2019

Respectfully Submitted:

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULES 11.2 & 40.1

Pursuant to Local Civil Rules 11.2 and 40.1, I hereby certify that, to the best of my knowledge, the matter in controversy is not the subject of any other action pending in any court or of any pending arbitration or administrative proceeding.

Dated: April 5, 2019

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

I hereby certify that the above-captioned matter is not subject to compulsory arbitration in that Sun seeks, *inter alia*, in excess of $150,000 in damages, exclusive of interest and costs.

Dated: April 5, 2019

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