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IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

PDL BIOPHARMA, INC.,

Plaintiff,

v.

SUN PHARMACEUTICAL INDUSTRIES LIMITED,

Defendant.
/

Case: 4:07-cv-11709
Assigned To: Gadola, Paul V
Referral Judge: Scheer, Donald A
Filed: 04-17-2007 At 02:33 PM
CMP PDL BIOPHARMA INC V. SUN PHARMACEUTICAL IND INC (TAM)

COMPLAINT FOR INFRINGEMENT OF U.S. PATENT NO. 5,164,405

Plaintiff PDL BioPharma Inc. ("PDL"), by way of Complaint against Defendant Sun Pharmaceutical Industries Ltd. ("SUN INDIA"), hereby alleges as follows:

PARTIES

1. PDL is a publicly held corporation organized and existing under the laws of the State of Delaware, having its headquarters at 34801 Campus Drive, Fremont, California 94555. PDL is engaged in the discovery, development, and commercialization of therapies for severe or life-threatening illness.

2. Upon information and belief, SUN INDIA is a public limited liability corporation organized under the laws of India, and its principal place of business is located at Acme Plaza, Andheri-Kurla Road, Mumbai, India 400-059. Upon information and belief, SUN INDIA through its wholly-owned subsidiary, Sun Pharmaceutical Industries Inc. ("SUN MI"), leases or owns an office at 29714 Orion Court, Farmington Hills, Michigan 48334, and maintains registered agents, Jayesh M. Shah and Jitendra Doshi, at the same address.

NATURE OF THE ACTION

3. This is a civil action for infringement of United States Patent Number 5,164,405 ("the '405 patent"), arising under the United States patent laws, Title 35, United States Code, §1 *et seq.*, including 35 U.S.C. §§271 and 281. This action relates to SUN INDIA's filing of an Abbreviated New Drug Application ("ANDA") under Section 505(j) of the Federal Food, Drug and Cosmetic Act ("the Act"), 21 U.S.C. §355(j) seeking U.S. Food and Drug Administration ("FDA") approval to market proposed ANDA product, "Injectable Nicardipine Hydrochloride" ("SUN INDIA's ANDA product").

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction under 28 U.S.C. §§1331 and 1338(a).

5. Upon information and belief, this Court has jurisdiction over SUN INDIA. Upon information and belief, SUN INDIA is in the business of manufacturing, marketing, importing and selling pharmaceutical drug products, including generic drug products. Upon information and belief, SUN INDIA directly, or through its subsidiaries, agents and/or alter-egos (including SUN MI), manufactures, markets and sells generic drugs throughout the United States and in this judicial district. Upon information and belief, SUN INDIA purposefully has conducted and continues to conduct business directly, and/or through its subsidiaries, agents and/or alter-egos (including SUN MI) in this judicial district, and this judicial district is a likely destination of SUN INDIA's ANDA product. Upon information and belief, SUN INDIA through its subsidiaries, agents, and/or alter-egos (primarily SUN MI) leases and owns facilities in this judicial district and retains a registered agent in this judicial district. Upon information and belief, SUN INDIA has previously submitted to the jurisdiction of this Court and has further previously availed itself of this Court by asserting counterclaims in other civil actions initiated in this jurisdiction.

6. Upon information and belief, venue is proper in this judicial district pursuant to 28 U.S.C. §§1391(c), 1391(d) and 1400(b).

CLAIM FOR RELIEF
(PATENT INFRINGEMENT U.S. PATENT NO. 5,164,405)

7. PDL here incorporates Paragraphs 1 through 6 above by reference.

8. The U.S. Patent and Trademark Office ("PTO") duly and legally issued the '405 patent on November 17, 1992, entitled "Nicardipine pharmaceutical composition for parenteral administration." A true and correct copy of the '405 patent is attached as Exhibit A.

9. In 2006, PDL acquired all rights to the '405 patent and CARDENE® I.V., the only U.S.-approved intravenous calcium channel blocker indicated for the treatment of hypertension.

10. PDL is the holder of New Drug Application ("NDA") No. 19-734, which the FDA approved on or about January 30, 1992. PDL lists the '405 patent in Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for NDA No. 19-734.

11. PDL manufactures and sells nicardipine hydrochloride pharmaceutical composition for parenteral administration in the United States under the trademark CARDENE® I.V.

12. CARDENE® I.V. is covered under multiple patents, including the '405 patent.

13. The '405 patent expires on or about November 17, 2009.

14. The '405 patent claims, inter alia, a stable pharmaceutical composition including nicardipine hydrochloride, a non-chloride isotonicity agent, a buffering agent and a pharmaceutically acceptable aqueous vehicle for parenteral administration, and methods to produce such a composition.

15. Upon information and belief, SUN INDIA filed with the FDA ANDA No. 78-405, under Section 505(j) of the Act, 21 U.S.C. §355(j).

16. Upon information and belief, SUN INDIA's ANDA No. 78-405 seeks FDA approval to sell in the United States generic product "Injectable Nicardipine Hydrochloride" with a proposed dosage strength of 2.5 mg/mL (i.e., SUN INDIA's ANDA product).

17. On March 5,2007, PDL received a letter from SUN INDIA, dated March 2, 2007, purporting to be a Notice of Certification for ANDA No. 78-405 ("SUN INDIA's Letter") under Sections 505(j)(2)(B)(i) and (ii) of the Act, 21 U.S.C. §355(j)(2)(B)(i) and (ii), and 21 C.F.R. §314.95(c). Upon information and belief, ANDA No. 78-405 alleges under Section 505(j)(2)(A)(vii)(IV) of the Act, 21 U.S.C. §355(A)(vii)(IV), that the claims of the '405 patent are not infringed by the manufacture, use, or sale of SUN INDIA's ANDA product.

18. SUN INDIA's Letter alleges that the active ingredient in SUN INDIA's ANDA product for which it seeks approval is nicardipine hydrochloride in injectable form.

19. Upon information and belief, SUN INDIA's ANDA product will, if approved and marketed, infringe, either literally and/or under the doctrine of equivalents, at least one claim of the '405 patent.

20. Under 35 U.S.C. §271(e)(2)(A), SUN INDIA has infringed, either literally and/or under the doctrine of equivalents, at least one claim of the '405 patent by submitting, or causing to be submitted to the FDA, ANDA No. 78-405 seeking approval for the commercial marketing of SUN INDIA's ANDA product before the expiration date of the '405 patent.

21. This case is an exceptional one, and PDL is entitled to an award of its reasonable attorney fees under 35 U.S.C. §285.

22. PDL has sought to enjoin Defendant SUN INDIA's infringement of the

'405 patent by filing suit in the District of New Jersey on April 17, 2007. SUN INDIA is properly subject to personal jurisdiction in the District of New Jersey and judicial economy would be promoted by PDL's claims for infringement of the '405 patent being addressed in that court. Upon information and belief, PDL understands that SUN INDIA may nevertheless contest jurisdiction in that venue. Given the possible consequences, PDL has filed this Complaint in this jurisdiction.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff PDL respectfully requests that the Court enter judgment in its favor and against Defendant SUN INDIA on the patent infringement claims set forth above and respectfully requests that this Court:

1) enter judgment that, under 35 U.S.C. §271(e)(2)(A), SUN INDIA has infringed at least one claim of the '405 patent through SUN INDIA's submission of ANDA No. 78-405 to the FDA to obtain approval for the commercial manufacture, use, import, offer for sale and/or sale in the United States of SUN INDIA's ANDA product before expiration of the '405 patent, either literally and/or under the doctrine of equivalents;

2) order that the effective date of any approval by the FDA of SUN INDIA's ANDA product be a date that is not earlier than the expiration of the '405 patent, or such later date as the Court may determine;

3) enjoin SUN INDIA, its subsidiaries, agents and alter-egos, their officers, servants and employees, and those persons in active concert or participation with any of them, from the commercial manufacture, use, import, offer for sale and/or sale of SUN INDIA's ANDA product until the expiration of the '405 patent, or such later date as the Court may determine;

4) enjoin SUN INDIA, its subsidiaries, agents and alter-egos, their officers, servants and employees, and those persons in active concert or participation with any of

them, from seeking, obtaining or maintaining approval of SUN INDIA's ANDA No. 78-405 until expiration of the '405 patent;

5) declare this to be an exceptional case under 35 U.S.C. §§285 and 271(e)(4) and award PDL costs, expenses and disbursements in this action, including reasonable attorneys' fees; and

6) award PDL such further and additional relief as this Court deems just and proper.

Dated: April 17, 2007

Respectfully submitted,

By: _____

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