IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA PRODUCTS L.P. and NAPP PHARMACEUTICAL GROUP LTD.,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
SUN PHARMACEUTICAL INDUSTRIES LTD., SUN PHARMACEUTICALS INDUSTRIES, INC., SUN PHARMA GLOBAL FZE, and CARACO PHARMACEUTICAL LABORATORIES, LTD.,	)	
Defendants.	)	

COMPLAINT

Plaintiffs Purdue Pharma Products L.P. and Napp Pharmaceutical Group Ltd., for their Complaint herein, aver as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code.

THE PARTIES

2. Plaintiff Purdue Pharma Products L.P. ("Purdue") is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at One Stamford Forum, 201 Tresser Boulevard, Stamford, Connecticut 06901-3431. Purdue is an owner by assignment of the patents in suit identified in paragraph 17 below.

3. Plaintiff Napp Pharmaceutical Group Ltd. ("Napp") is a private limited company organized and existing under the laws of the United Kingdom, having a place of

business at Cambridge Science Park, Milton Road, Cambridge, CB4 0GW. Napp is an owner by assignment of the patents in suit identified in paragraph 17 below.

4. Upon information and belief, Defendant Sun Pharmaceutical Industries Ltd. ("Sun Ltd.") is a company organized and existing under the laws of India, having a place of business at Acme Plaza, Andheri-Kurla Road, Andheri (East), Mumbai-400 059, India.

5. Upon information and belief, Defendant Sun Pharmaceutical Industries, Inc. ("Sun USA") is a company organized and existing under the laws of the State of Michigan, having a principal place of business at 270 Prospect Plains Road, Cranbury, NJ 08512. Upon information and belief, Sun USA is a wholly owned subsidiary and agent of defendant Sun Ltd.

6. Upon information and belief, Defendant Sun Pharma Global FZE ("Sun FZE") is a company organized and existing under the laws of the United Arab Emirates, having a principal place of business at Office #43, Block Y, SAIF-Zone (Sharjah Airport International Free Zone), P.O. Box 122304, Sharjah, United Arab Emirates. Upon information and belief, Sun FZE is a wholly-owned subsidiary and agent of defendant Sun Ltd.

7. Upon information and belief, Defendant Caraco Pharmaceutical Laboratories, Ltd. ("Caraco") is a company organized and existing under the laws of the State of Michigan, having a principal place of business at 1150 Elijah McCoy Drive, Detroit, MI 48202. Upon information and belief, Caraco is a subsidiary of Sun Ltd., a majority of Caraco's common stock is owned by Sun Ltd., and Caraco is an agent of Sun Ltd.

8. Upon information and belief, the acts of Sun FZE complained of herein, were done at the direction of, with the authorization of, and with the cooperation, participation, and assistance of Sun Ltd., Sun USA and Caraco.

9. Sun Ltd., Sun USA, Sun FZE and Caraco are referred to hereinafter collectively as "Sun."

JURISDICTION AND VENUE

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

11. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has committed, or aided, abetted, contributed to, actively induced and/or participated in the commission of, the tortious action of patent infringement that has led to foreseeable harm and injury to Plaintiffs, one of which is a Delaware corporation. Further, each Defendant has purposefully availed itself of the rights and benefits of Delaware law, has engaged in continuous and systematic contact with the State of Delaware, and derives substantial revenue from things used or consumed in the State of Delaware. This Court has personal jurisdiction over each of the Defendants for the additional reasons set forth below and for other reasons that will be presented to the Court if such jurisdiction is challenged.

12. This Court has personal jurisdiction over Defendant Sun Ltd. by virtue of, *inter alia*, its systematic and continuous contacts with the State of Delaware. Among other things, upon information and belief, Sun Ltd., directly or through its subsidiaries and agents Sun USA, Sun FZE, and/or Caraco, purposefully manufactures goods for sale in the United States and the State of Delaware, derives substantial revenue from things used or consumed in the State of Delaware, has purposefully availed itself of this forum by filing claims and counterclaims in this Court, and has consented to jurisdiction in this Court on numerous occasions, including as recently as within the last month.

13. This Court has personal jurisdiction over Defendant Sun USA by virtue of, *inter alia*, its systematic and continuous contacts with the State of Delaware. Among other things, upon information and belief, Sun USA, directly or though its sister companies and agents Caraco and Sun FZE, and parent company and agent Sun Ltd., purposefully manufactures goods for sale in the United States and the State of Delaware and derives substantial revenue from things used or consumed in the State of Delaware. Further, upon information and belief, Sun USA has previously consented to jurisdiction in this Court and has filed counterclaims in this Court.

14. This Court has personal jurisdiction over Defendant Sun FZE by virtue of, *inter alia*, its systematic and continuous contacts with the State of Delaware. Among other things, upon information and belief, Sun FZE, directly or though its sister companies and agents Caraco and Sun USA, and parent company and agent Sun Ltd., derives substantial revenue from things used or consumed in the State of Delaware. Further, Sun FZE has consented to jurisdiction in this Court as recently as within the last month.

15. This Court has personal jurisdiction over Defendant Caraco by virtue of, *inter alia*, its systematic and continuous contacts with the State of Delaware. Among other things, upon information and belief, Caraco, directly or though its sister companies and agents Sun FZE and Sun USA, and parent company and agent Sun Ltd., purposefully manufactures, sells, and distributes goods in the United States and the State of Delaware, and derives substantial revenue from things used or consumed in the State of Delaware.

16. Venue is proper in this Judicial District under 28 U.S.C. § 1391 and § 1400(b).

THE PATENTS-IN-SUIT

17. Purdue and Napp are the lawful owners of all right, title and interest in and to the following two United States patents, including all right to sue and to recover for past infringement thereof:

(a) United States Patent No. 6,254,887, entitled "CONTROLLED RELEASE TRAMADOL" ("the '887 patent"), a copy of which is attached hereto as Exhibit A, which was duly and legally issued on July 3, 2001, naming Ronald Brown Miller, Stewart Thomas Leslie, Sandra Therese Antoinette Malkowska, Kevin John Smith, Walter Wimmer, Horst Winkler, Udo Hahn and Derek Allan Prater as the inventors. The '887 patent is among the patents listed in the U.S. Food and Drug Administration's ("FDA") "Orange Book" (*Approved Drug Products With Therapeutic Equivalence Evaluation*) as covering Ryzolt®, a controlled-release tramadol hydrochloride pain relief medication.

(b) United States Patent No. 7,074,430, entitled "CONTROLLED RELEASE TRAMADOL TRAMADOL [sic] FORMULATION" ("the '430 patent"), a copy of which is attached hereto as Exhibit B, which was duly and legally issued on July 11, 2006, naming Ronald Brown Miller, Sandra Therese Antoinette Malkowska, Walter Wimmer, Udo Hahn, Stewart Thomas Leslie, Kevin John Smith, Horst Winkler and Derek Allan Prater as the inventors.

ANDA No. 91-607

18. Upon information and belief, Sun FZE submitted Abbreviated New Drug Application No. 91-607 ("ANDA") to the FDA, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval "to engage in the commercial manufacture, use or sale of tramadol hydrochloride extended release tablets," 100 mg, 200 mg, and 300 mg

("the Sun Tablets"), a generic version of Ryzolt®, before the expiration of the '887 and '430 patents.

19. Upon information and belief, in 1997, Sun Ltd. became Caraco's majority shareholder, and subsequently, the two companies entered into a technology transfer agreement. Further, upon information and belief, Caraco has recently entered into a definitive agreement to market Sun ANDAs that are either approved or awaiting approval at the FDA.

20. Upon information and belief, Sun Ltd., Sun USA, Sun FZE and Caraco are in the same corporate family, and Sun Ltd., Sun USA and Caraco were actively involved in the preparation of ANDA No. 91-607.

21. Upon information and belief, Sun Ltd., Sun USA and Caraco will be involved in the manufacturing, marketing, selling and/or distribution of the Sun Tablets if ANDA No. 91-607 is approved by the FDA.

22. Upon information and belief, Sun's ANDA contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '887 patent, listed in the FDA's Orange Book as one of the patents covering Ryzolt®, "will not be infringed by the proposed drug products in [Sun's ANDA] and/or [is] invalid."

23. In a letter dated September 24, 2009 addressed to Purdue, Napp, Labopharm Canada, Inc. and Labopharm (Barbados) Limited, Sun provided "notice" with respect to the Sun Tablets and the '887 patent under 21 U.S.C. § 355(j)(2)(B)(ii) ("Sun's Notice Letter").

FIRST CLAIM FOR RELIEF:
PATENT INFRINGEMENT OF THE '887 PATENT

24. Sun's submission of its ANDA was an act of infringement of the '887 patent under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

25. Upon information and belief, the Sun Tablets are covered by one or more claims of the '887 patent.

26. Upon information and belief, Sun's commercial manufacture, use, sale, and/or offer for sale of the Sun Tablets would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '887 patent.

27. Upon information and belief, Sun has been aware of the existence of the '887 patent, and has no reasonable basis for believing that the Sun Tablets will not infringe the '887 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

28. The acts of infringement by Sun set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

SECOND CLAIM FOR RELIEF: DECLARATORY JUDGMENT OF PATENT INFRINGEMENT OF THE '430 PATENT

29. The filing of Sun's ANDA under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)) is a defined act sufficient to create case or controversy jurisdiction under 35 U.S.C. § 271(e)(2) to enable this Court to promptly resolve any dispute concerning infringement.

30. Additionally, upon information and belief, once the FDA grants approval of Sun's ANDA, Sun will undertake substantial activities directed toward engaging in infringement, contributory infringement, and active inducement of infringement of the '430 patent by making, using and undertaking substantial preparation for offering to sell, without authority from Plaintiffs, the Sun Tablets, which are covered by one or more claims of the '430 patent.

31. Upon information and belief, Sun has been aware of the existence of the '430 patent but, once the FDA grants approval of Sun's ANDA, Sun will nevertheless engage in substantial activities directed towards infringing, contributorily infringing, and actively inducing the infringement of the '430 patent. These activities will be in total disregard for Plaintiff's lawful rights under the '430 patent, thus rendering the case "exceptional," as that term is set forth in 35 U.S.C. § 285.

32. Once the FDA grants approval of Sun's ANDA, these substantial activities engaged in by Sun directed toward infringement, contributory infringement, and active inducement of infringement as set forth above demonstrate the existence of an actual and justiciable controversy, and, if allowed to continue and progress, will inevitably constitute infringement, contributory infringement, and active inducement of infringement of the '430 patent, will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless preliminarily and permanently enjoined by this Court.

***PURDUE v. PAR* CASE**

33. On May 5, 2007, Plaintiffs Purdue and Napp, along with Ortho-McNeil, Inc. ("Ortho") and Biovail Laboratories International, SRL ("Biovail"), filed suit against Par Pharmaceutical, Inc. and Par Pharmaceutical Companies, Inc. (collectively "Par") in the District of Delaware, Civil Action No.07-255-KAJ, alleging infringement of the '887 patent ("the *Par* case"). On March 28, 2008, Plaintiffs Purdue and Napp, along with Ortho and Biovail, filed an amended complaint against Par additionally seeking declaratory judgment of patent infringement of the '430 patent. In response, Par denied infringement and asserted that the claims of the patents-in-suit were invalid and unenforceable due to inequitable conduct. Biovail was

dismissed by consent on November 10, 2008. Ortho was dismissed for lack of standing on December 3, 2008. A five-day bench trial was held from April 16 to April 22, 2009.

34. On August 14, 2009, the District Court issued a Judgment Order and Findings of Fact and Conclusions of Law in the *Par* case. The Court found and adjudged, *inter alia*, that:

(a) Par has literally infringed Claims 3, 13, 27, and 29 of the '887 patent, and Par's manufacture, use, and offer to sell tramadol extended release tablets in 100 mg, 200 mg, and 300 mg dosage strengths would infringe claims 5, 7, and 11 of the '430 patent;

(b) Claims 3, 13, 27, and 29 of the '887 patent and claims 5, 7, and 11 of the '430 patent are invalid for obviousness; and

(c) The '887 patent and '430 patents are not unenforceable due to inequitable conduct.

35. On September 3, 2009, Plaintiffs Purdue and Napp filed a Notice of Appeal appealing the District Court's judgment of invalidity in the *Par* case to the U.S. Court of Appeals for the Federal Circuit.

THE FILING OF THIS SUIT

36. Under the Hatch-Waxman Act, Plaintiffs have 45 days after receipt of Sun's Notice Letter to sue for infringement of the '887 patent to trigger a 30-month stay during which the FDA cannot approve Sun's ANDA. 21 U.S.C. § 355(j)(5)(B)(iii). There can be no such stay while the patents remain invalid. The law is unclear as to whether, following a successful appeal of the District Court's decision in the *Par* case, Plaintiffs would have a right to a statutory stay of FDA approval of Sun's ANDA if they were to file suit at that time. However, there appears to be no mechanism in the Hatch-Waxman Act by which Plaintiffs can toll the

statutory requirement that suit be filed within 45 days of receipt of Sun's Notice Letter in order for Plaintiffs to obtain such a stay, or to revive Plaintiffs' right to such a stay, if suit is not filed within 45 days.

37. Accordingly, Plaintiffs must file suit against Sun for the infringement of the Sun Tablets within the 45-day timeframe provided by statute, in order to perfect their rights to a 30-month stay prohibiting FDA approval of Sun's ANDA if the Federal Circuit vacates or reverses the District Court's judgment in *Par*.

38. Since initiating the *Par* case, four other pharmaceutical companies, including Sun, have provided "notice" to Plaintiffs of "Paragraph IV" certifications relating to seeking FDA approval of extended-release tramadol products. In the interest of efficiency, Plaintiffs have moved the Judicial Panel on Multidistrict Litigation ("MDL Panel") to centralize three cases in this Court. (*In re: Tramadol Hydrochloride Extended-Release Tablets Patent Litigation*, MDL No. 2126). That motion is pending. Plaintiffs intend to move the MDL Panel to include this action as part of that multidistrict litigation.

39. To conserve the resources of the Court and the parties, Plaintiffs will move promptly for a stay of this action against Sun until (1) Plaintiffs' motion requesting that the MDL Panel centralize this action with the other extended-release tramadol cases is resolved; and (2) the earlier of (a) a final adjudication of the appeal in the *Par* case or (b) a decision by the FDA to tentatively approve the Sun Tablets.

WHEREFORE, Plaintiffs pray for judgment:

A. Adjudging that Sun has infringed the '887 and '430 patents, and that the commercial sale, offer for sale, and/or manufacture of the Sun Tablets would infringe, induce infringement of, and/or contribute to the infringement of the '887 and '430 patents;

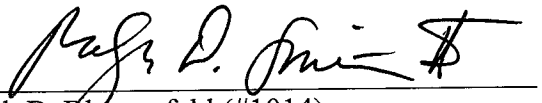
B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Sun's ANDA No. 91-607, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), to be a date not earlier than the date of expiration of the '887 and '430 patents plus any additional periods of exclusivity;

C. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Fed. R. Civ. P. 65, Sun, its officers, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting in concert, participation, or in privity with them, and their successors and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product that infringes the '887 or '430 patents;

D. Declaring this an exceptional case and awarding Plaintiffs their attorneys' fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

E. Awarding Plaintiffs such other and further relief as this Court may deem just and proper.

MORRIS, NICHOLS, ARSHT & TUNNELL LLP



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November 5, 2009
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