IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA PRODUCTS L.P. and NAPP PHARMACEUTICAL GROUP LTD., Plaintiffs, v. LUPIN LTD. and LUPIN PHARMACEUTICALS, INC., Defendants.	C.A. No. _____

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 11 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 11 below.

4. Upon information and belief, Defendant Lupin Ltd. is a corporation organized and existing under the laws of India, having a principal place of business at B/4 Laxmi Towers, Bandra Kurla Complex, Bandra (W), Mumbai, 400 051, India.

5. Upon information and belief, Defendant Lupin Pharmaceuticals, Inc. ("LPI"), a wholly-owned subsidiary and agent of Lupin Ltd., is a Virginia corporation having a principal place of business at Harborplace Tower, 111 South Calvert Street, 21st Floor, Baltimore, Maryland 21202. Upon information and belief, LPI markets, sells, and distributes products for Lupin Ltd. in the United States, including this Judicial District.

JURISDICTION AND VENUE

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

7. This Court has personal jurisdiction over each of the Defendants by virtue of the fact that, *inter alia*, each Defendant has purposefully availed itself of the rights and benefits of Delaware law, regularly does and solicits business in Delaware, 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.

8. This Court has personal jurisdiction over Defendant Lupin Ltd. by virtue of, *inter alia*, its systematic and continuous contacts with the State of Delaware. Among other things, upon information and belief, Lupin Ltd., directly or through its wholly-owned subsidiary

and agent LPI, purposefully sells, markets, distributes, and 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, regularly does and solicits business in the State of Delaware, has purposefully availed itself of this forum by filing counterclaims in this Court, and has admitted and/or consented to jurisdiction in this Court on numerous occasions.

9. This Court has personal jurisdiction over Defendant LPI by virtue of, *inter alia*, its systematic and continuous contacts with the State of Delaware. Among other things, upon information and belief, LPI, directly or though its parent company Lupin Ltd., purposefully sells, markets, and distributes 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, is registered to do business in and regularly does and solicits business in the State of Delaware, has purposefully availed itself of this forum by filing counterclaims in this Court, and has admitted and/or consented to jurisdiction in this Court on numerous occasions.

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

THE PATENTS-IN-SUIT

11. 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 Ultram® ER, 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. The '430 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 Ultram® ER, a controlled-release tramadol hydrochloride pain relief medication.

ANDA No. 200503

12. Upon information and belief, Lupin Ltd. and LPI (collectively "Lupin") submitted Abbreviated New Drug Application No. 200503 ("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 controlled-release tablets, 100 mg, 200 mg, and 300 mg ("the Lupin Tablets"), a generic version of Ultram® ER, before the expiration of the '887 and '430 patents.

13. Upon information and belief, Lupin Ltd. and LPI are in the same corporate family and share directors and officers, and Lupin Ltd. and LPI were and continue to be actively involved in the preparation of ANDA No. 200503.

14. Upon information and belief, Lupin Ltd. and LPI will be involved in the manufacturing, marketing, selling and/or distribution of the Lupin Tablets if ANDA No. 200503 is approved by the FDA.

15. Upon information belief, Lupin Ltd. has specifically named LPI as its agent for ANDA No. 200503.

16. Upon information and belief, Lupin's ANDA contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the '887 and '430 patents, listed in the FDA's Orange Book as two of the patents covering Ultram® ER, "are invalid and/or will not be infringed by Lupin's tramadol tablets."

17. In a letter dated December 8, 2009 addressed to Purdue, Napp, Biovail Labs International SRL, Biovail Laboratories International SRL, Biovail Corporation, and Davidson, Davidson & Kappel, LLC, Lupin provided "notice" with respect to the Lupin Tablets and the '887 and '430 patents under 21 U.S.C. § 355(j)(2)(B)(ii) ("Lupin's Notice Letter").

PATENT INFRINGEMENT OF THE '887 & '430 PATENTS

18. Lupin's submission of its ANDA was an act of infringement of the '887 and '430 patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

19. Upon information and belief, the Lupin Tablets are covered by one or more claims of the '887 and '430 patents.

20. Upon information and belief, Lupin's commercial manufacture, use, sale, and/or offer for sale of the Lupin Tablets would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '887 and '430 patents.

21. Upon information and belief, Lupin has been aware of the existence of the '887 and '430 patents and has no reasonable basis for believing that the Lupin Tablets will not

infringe the '887 and '430 patents, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

22. The acts of infringement by Lupin 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.

***PURDUE v. PAR* CASE**

23. 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, C.A. 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.

24. On August 14, 2009, the District Court in *Par* issued a Judgment Order and Findings of Fact and Conclusions of Law on the asserted claims of the '887 and '430 patents that were at issue in the *Par* case. The Court found and adjudged, *inter alia*, that:

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

(b) Asserted claims 3, 13, 27, and 29 of the '887 patent and asserted 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.

25. 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. That appeal is currently pending.

THE FILING OF THIS SUIT

26. Under the Hatch-Waxman Act, Plaintiffs have 45 days after receipt of Lupin's Notice Letter to sue for infringement of the '887 and '430 patents to trigger a 30-month stay during which the FDA cannot approve Lupin'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 Lupin'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 Lupin'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.

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

28. Since initiating the *Par* case, seven other pharmaceutical companies, including Lupin, have provided "notice" to Plaintiffs of "Paragraph IV" certifications relating to seeking FDA approval of controlled-release tramadol products. In the interest of efficiency, Plaintiffs have moved the Judicial Panel on Multidistrict Litigation ("MDL Panel") to centralize five previously-filed actions in this Court. (*In re: Tramadol Hydrochloride Extended-Release Tablets Patent Litigation*, MDL No. 2126). That motion is pending.

29. Plaintiffs intend to notify the MDL Panel about this action as a tag-along action to be included in that multidistrict litigation. If and when Plaintiffs commence suit against the remaining two companies who have provided Paragraph IV notices, Plaintiffs will seek to have those actions included in the multidistrict litigation proceeding as well.

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

WHEREFORE, Plaintiffs pray for judgment:

A. Adjudging that Lupin has infringed the '887 and '430 patents, and that the commercial sale, offer for sale, and/or manufacture of the Lupin 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 Lupin's ANDA No. 200503, 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 Rule 65, Fed. R. Civ. P., Lupin, its partners, contractors, 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

Jack B. Blumenfeld (#1014)
Rodger D. Smith II (#3778)
1201 N. Market Street
Wilmington, DE 19899-1347
(302) 658-9200
rsmith@mnat.com
Attorneys for Plaintiffs
Purdue Pharma Products L.P.
and Napp Pharmaceutical Group Ltd.

OF COUNSEL

Robert J. Goldman
Sasha G. Rao
ROPES & GRAY LLP
1900 University Avenue
6th Floor
East Palo Alto, California 94303
(650) 617-4000

Pablo Hendler
Sona De
ROPES & GRAY LLP
1211 Avenue of the Americas
New York, New York 10036
(212) 596-9000

January 21, 2010
3348760