IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA PRODUCTS L.P., NAPP PHARMACEUTICAL GROUP LTD., and ORTHO-MCNEIL-JANSSEN PHARMACEUTICALS, INC.,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
PADDOCK LABORATORIES, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Purdue Pharma Products L.P. and Napp Pharmaceuticals Group Ltd., and Ortho-McNeil-Janssen Pharmaceuticals, Inc., 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 9 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 9 below.

4. Plaintiff Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("Ortho") is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having a place of business at 1000 Route 202 South, Raritan, New Jersey 08869. Ortho, previously Ortho-McNeil, Inc., is a licensee of the patents in suit identified in paragraph 9 below and Ortho, through its divisions, markets and distributes Ultram® ER in the United States.

5. Upon information and belief, defendant Paddock Laboratories, Inc. ("Paddock") is a corporation organized and existing under the laws of the State of Minnesota, having a place of business at 3940 Quebec Avenue North, Minneapolis, Minnesota 55427-1244.

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 Paddock because, *inter alia*, Paddock has purposefully availed itself of the rights and benefits of Delaware law. Upon information and belief, defendant Paddock engages in the manufacture and sale of a range of generic pharmaceutical products within the United States generally and the State of Delaware specifically, including to Walmart and Walgreens pharmacy stores in the State of Delaware. 10 Del. C. § 3104(c)(4).

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

THE PATENTS IN SUIT

9. 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, which patents are 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) 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.

(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.

ULTRAM® ER

10. Biovail Laboratories International, SRL ("Biovail") is the holder of New Drug Application ("NDA") No. 21-692 and manufactures the controlled-release tramadol hydrochloride pain relief medication Ultram® ER.

11. Plaintiff Ortho is a licensee of the patents in suit identified in paragraph 9 above, and markets and distributes Ultram® ER in the United States.

12. In compliance with 21 U.S.C. § 355(b)(1), Biovail certified to the FDA that the '887 and '430 patent claims cover Ultram® ER.

PADDOCK'S ANDA

13. Upon information and belief, Paddock submitted Abbreviated New Drug Application No. 91-460 ("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, and sale of tramadol hydrochloride extended release tablets, 100 mg, 200 mg, and 300 mg ("Paddock's 100 mg, 200 mg, and 300 mg Tablets"), a generic version of Biovail's Ultram® ER, before the expiration of the '887 and '430 patents.

14. Upon information and belief, Paddock'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 patents covering the drug Ultram® ER, are invalid and/or will not be infringed by the commercial manufacture, use or sale of Paddock's 100 mg, 200 mg, and 300 mg Tablets.

15. In a letter dated July 21, 2009 addressed to Purdue, Napp, and Biovail, Paddock provided "notice" with respect to its 100 mg, 200 mg, and 300 mg Tablets and the '887 and '430 patents under 21 U.S.C. § 355(j)(2)(B)(ii) ("Paddock's Notice Letter").

16. Paddock'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).

17. Upon information and belief, the composition of Paddock's 100 mg, 200 mg, and 300 mg Tablets is covered by one or more claims of the '887 and '430 patents.

18. Upon information and belief, Paddock's commercial manufacture, use, sale, and/or offer for sale of its 100 mg, 200 mg, and 300 mg Tablets would infringe, contribute

to the infringement of, and/or induce the infringement of one or more claims of the '887 and '430 patents.

19. Upon information and belief, Paddock has been aware of the existence of the '887 and '430 patents, and has no reasonable basis for believing that its 100 mg, 200 mg, and 300 mg 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.

20. The acts of infringement by Paddock 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**

21. On May 5, 2007, Plaintiffs Purdue, Napp and Ortho-McNeil, Inc., along with 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, Napp and Ortho-McNeil, Inc. and Biovail filed an amended complaint against Par additionally seeking declaratory judgment of patent infringement of the '430 patent, which was not listed in the Orange Book for Ultram® ER at that time.[1] 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.

[1] The '430 was added to the Orange Book prior to Paddock's Paragraph IV certification, which certifies against both the '887 and '430 patents listed in the Orange Book for Ultram® ER.

22. On August 14, 2009, the District Court in *Par* 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.

23. 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.

24. On September 3, 2009, Plaintiff Ortho filed a Notice of Appeal appealing the District Court's order dismissing Ortho from the *Par* case to the U.S. Court of Appeals for the Federal Circuit to request reversal of the District Court's finding that Ortho lacked standing.

25. Under the Hatch-Waxman Act, Plaintiffs have 45 days after receipt of Paddock'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 Paddock'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 Paddock'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 Paddock'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.

26. Accordingly, Plaintiffs must file suit against Paddock for infringement of its 100 mg, 200 mg, and 300 mg Tablets within the 45-day timeframe provided by statute, in order to perfect their rights to a 30-month stay prohibiting FDA approval of Paddock's ANDA if the Federal Circuit vacates or reverses the District Court's judgment in *Par*.

27. To conserve the resources of the Court and the parties, Plaintiffs will move promptly for a stay of this action against Paddock until the earlier of (a) a final adjudication of the appeal in the *Par* case or (b) a decision by the FDA to tentatively approve Paddock's product.

WHEREFORE, Plaintiffs pray for judgment:

A. Adjudging that Paddock has infringed the '887 and '430 patents, and that the commercial sale, offer for sale, and/or manufacture of Paddock's 100 mg, 200 mg, and 300 mg 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 Paddock's ANDA No. 91-460, 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., Paddock, 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

/s/ Rodger D. Smith II

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

CONNOLLY BOVE LODGE & HUTZ LLP

/s/ Mary W. Bourke

Mary W. Bourke (#2356)
The Nemours Building
1007 N. Orange Street
P.O. Box 2207
Wilmington, DE 19899
(302) 658-9141
mbourke@cblh.com
Attorneys for Plaintiff
Ortho-McNeil-Janssen Pharmaceuticals, Inc.

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