IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF VIRGINIA

PURDUE PHARMA PRODUCTS L.P. and
NAPP PHARMACEUTICAL GROUP LTD.,

Plaintiffs,

v.

CIPHER PHARMACEUTICALS INC.,

Defendant.

Civ. No. 2:09CV544

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 8 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 8 below.

4. Upon information and belief, defendant Cipher Pharmaceuticals Inc. ("Cipher") is a corporation organized and existing under the laws of Canada, having a place of business at 5650 Tomken Rd., Unit 16, Mississauga, ON L4W 4P1.

JURISDICTION AND VENUE

5. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202.

6. This Court has personal jurisdiction over Cipher because, *inter alia*, Cipher has consented to personal jurisdiction for purposes of this action in the United States District Court for the Eastern District of Virginia.

7. Venue is proper in this Judicial District under 28 U.S.C. § 1391 and E.D. Va. Local Civil Rule 3(C).

THE PATENTS IN SUIT

8. 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

9. 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.

10. Ortho-McNeil-Janssen Pharmaceuticals, Inc. is a licensee of the patents in suit identified in paragraph 8 above, and markets and distributes Ultram® ER in the United States.

11. 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.

CIPHER'S NDA

12. Upon information and belief, Cipher submitted New Drug Application No. 22-370 ("NDA") to the FDA, under § 505(b) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(b)), seeking approval to engage in the commercial manufacture, use, and sale of "finished dosage capsule forms containing tramadol hydrochloride," in strengths of 100 mg, 200 mg, and 300 mg ("Cipher's NDA Products"), before the expiration of the '887 and '430 patents.

13. Upon information and belief, Cipher's NDA contains a "Paragraph IV" certification under 21 U.S.C. § 355(b)(2)(A)(IV) alleging that the '887 patent, listed in the FDA's Orange Book as one of the patents covering the drug Ultram® ER, is invalid and/or will not be infringed by the commercial manufacture, use or sale of Cipher's NDA Products.

14. In a letter dated September 15, 2009 addressed to Purdue, Napp, and Biovail, Cipher provided "notice" with respect to Cipher's NDA Products and the '887 patent under 21 U.S.C. §§ 355(b)(2), (b)(3)(B) and 21 C.F.R § 314.52(c) ("Cipher's Notice Letter").

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

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

16. Upon information and belief, the compositions of Cipher's NDA Products are covered by one or more claims of the '887 patent.

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

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

19. The acts of infringement by Cipher 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

20. The filing of Cipher's NDA under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(b)(2)) 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.

21. Additionally, upon information and belief, once the FDA grants tentative approval of Cipher's NDA, Cipher 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, Cipher's NDA Products, whose compositions are covered by one or more claims of the '430 patent.

22. Upon information and belief, Cipher has been aware of the existence of the '430 patent but, once the FDA grants tentative approval of Cipher's NDA, Cipher 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.

23. Once the FDA grants tentative approval of Cipher's NDA, these substantial activities engaged in by Cipher 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**

24. On May 5, 2007, Plaintiffs Purdue and Napp along with Ortho-McNeil, Inc., and 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-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. 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-McNeil, Inc. was dismissed for lack of standing on December 3, 2008. A five-day bench trial was held from April 16 to April 22, 2009.

25. 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.

26. 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.

27. Under the Hatch-Waxman Act, Plaintiffs have 45 days after receipt of Cipher's Notice Letter to sue for infringement of the '887 patent to trigger a 30-month stay during which the FDA cannot approve Cipher's NDA. 21 U.S.C. § 355(c)(3)(C). 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 Cipher's NDA 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 Cipher'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.

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

29. To conserve the resources of the Court and the parties, Plaintiffs will move promptly for a stay of this action against Cipher 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 Cipher's NDA Products.

WHEREFORE, Plaintiffs pray for judgment:

A. Adjudging that Cipher has infringed the '887 and '430 patents, and that the commercial sale, offer for sale, and/or manufacture of Cipher's NDA Products 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 Cipher's NDA No. 22-370, under § 505(b) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(b)), 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., Cipher, 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 and '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

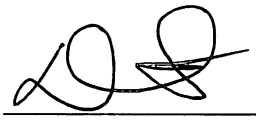
E. Awarding Plaintiffs such other and further relief as this Court may deem just and proper.

Dated: October 30, 2009

Respectfully submitted

PURDUE PHARMA L.P. and
NAPP PHARMACEUTICAL GROUP LTD.

By Counsel



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October 30, 2009