IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P. and RHODES TECHNOLOGIES,	)	
Plaintiffs,	)	
v.	)	C.A. No. _____
COLLEGIUM PHARMACEUTICAL, INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P., and Rhodes Technologies (collectively, "Purdue" or "Plaintiffs"), for their Complaint herein, aver as follows.

SUMMARY OF CLAIMS PRESENTED AND RELIEF SOUGHT

1. Plaintiffs seek relief from infringement of four U.S. patents, falling into two groups. First, Plaintiffs seek judgment that Defendant Collegium Pharmaceutical, Inc. ("Collegium") has infringed three patents relating to an improved active pharmaceutical ingredient ("API"), dosage forms including such API, or processes for making such API. These three API patents, U.S. Patent Nos. 7,674,799, 7,674,800, and 7,683,072 ("the Improved API patents"), are listed in the FDA's "Orange Book" as covering Purdue's OxyContin®, an extended-release pain medication. Collegium has infringed the Improved API patents under 35 U.S.C. § 271(e)(2)(A) by filing New Drug Application ("NDA") No. 208090 on its proposed XTAMPZA ER™ product. As set forth in paragraphs 21-26, these three patents have been

found infringed but invalid in a previous lawsuit not involving Collegium. Appeal from the judgment of invalidity is pending.

2. Second, Plaintiff Purdue Pharma L.P. seeks relief from infringement of U.S. Patent No. 8,652,497 ("the '497 Abuse-deterrence patent"), which relates to an abuse-deterrent feature of an extended-release opioid formulation. The '497 Abuse-deterrence patent is not listed in the FDA's "Orange Book" and has never been challenged in litigation. Collegium has infringed the '497 Abuse-deterrence patent under 35 U.S.C. § 271(e)(2)(A) by filing NDA No. 208090 on its proposed XTAMPZA ER™ product.

NATURE OF THE ACTION

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

THE PARTIES: PLAINTIFFS

4. Plaintiff Purdue Pharma L.P. ("Purdue Pharma") 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, CT 06901-3431. Purdue Pharma is an owner of (a) the Improved API patents, identified in paragraphs 18-20 below, and (b) the '497 Abuse-deterrence patent, identified in paragraph 38 below. Purdue Pharma is also the holder of NDA No. 022272 for the extended-release oxycodone pain-relief medication OxyContin® and is involved in the sale of OxyContin® in the United States.

5. Plaintiff The P.F. Laboratories, Inc. ("P.F. Labs") is a corporation organized and existing under the laws of the State of New Jersey, having a place of business at 700 Union Boulevard, Totowa, NJ 07512. P.F. Labs is an owner of the Improved API patents,

and is involved in the manufacture of extended-release oxycodone pain-relief medication under the brand name OxyContin®.

6. Plaintiff Purdue Pharmaceuticals L.P. ("Purdue Pharmaceuticals") is a limited partnership organized and existing under the laws of the State of Delaware, having a place of business at 4701 Purdue Drive, Wilson, NC 27893. Purdue Pharmaceuticals is an owner of the Improved API patents, and is involved in the manufacture of extended-release oxycodone pain-relief medication under the brand name OxyContin®.

7. Plaintiff Rhodes Technologies ("Rhodes") is a general partnership organized and existing under the laws of the State of Delaware, having a place of business at 498 Washington Street, Coventry, RI 02816. Rhodes is an owner of the Improved API patents, and is involved in the manufacture of the API used in the extended-release oxycodone pain-relief medication under the brand name OxyContin®.

THE PARTIES: DEFENDANT

8. Upon information and belief, Defendant Collegium incorporated as an entity under the laws of the State of Delaware on April 10, 2002, having its principal place of business at 780 Dedham Street, Suite 800, Canton, MA 02021.

9. Upon information and belief, on July 1, 2014, Collegium also incorporated as an entity under the laws of the Commonwealth of Virginia, having its principal place of business at 780 Dedham Street, Suite 800, Canton, MA 02021.

10. Upon information and belief, on or about July 23, 2014, the Collegium entity that was incorporated in Delaware merged with the Collegium entity that was incorporated in Virginia.

11. Upon information and belief, Collegium is currently a corporation organized and existing under the laws of the Commonwealth of Virginia, having its principal place of business at 780 Dedham Street, Suite 800, Canton, MA 02021.

JURISDICTION AND VENUE

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

13. This Court has personal jurisdiction over Collegium because, inter alia, Collegium has purposefully availed itself of the rights and benefits of the laws of this State and this Judicial District. Upon information and belief, Collegium was a corporation organized and existing under the laws of the State of Delaware from 2002 to 2014, during which time it made and tested the DETERx® extended-release mechanism used in the XTAMPZA ER™ capsules, which are the subject of this action, as further described in paragraph 27 below.

14. This Court also has personal jurisdiction over Collegium because this action arises out of Collegium's purposefully directed activities toward residents of Delaware. Specifically, as set forth in paragraphs 27-30 below, this action arises out of Collegium's filing of NDA No. 208090 and out of Collegium's sending a Notice of Paragraph IV Certification ("Notice Letter") to Plaintiffs. Plaintiffs Purdue Pharma, Purdue Pharmaceuticals, and Rhodes are Delaware partnerships. Collegium knew or should have known that its filing of NDA No. 208090, which constitutes patent infringement under 35 U.S.C. § 271(e)(2)(A), would cause injury to Delaware residents in Delaware. Accordingly, Collegium should have reasonably anticipated that its actions would cause injury in Delaware and that it would be liable for suit in Delaware to redress that injury.

15. Moreover, as explained in paragraphs 27-30 below, upon information and belief, Collegium is actively preparing to make XTAMPZA ER™, which is the subject of its NDA No. 208090, and to use, sell, and offer for sale XTAMPZA ER™ in this State and in this Judicial District. Upon information and belief, if NDA No. 208090 is approved, XTAMPZA ER™ will, among other things, be marketed and distributed in Delaware, and/or prescribed by physicians practicing and dispensed by pharmacies located within Delaware, all of which will have a substantial effect in Delaware. Upon information and belief, Collegium knows and intends that XTAMPZA ER™ will be distributed and sold in the United States, including in Delaware.

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

THE IMPROVED API PATENTS

17. The U.S. Food and Drug Administration's ("FDA") *Approved Drug Products with Therapeutic Equivalence Evaluations* ("Orange Book") identifies drug products that have been approved by the FDA under the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 301 et seq.). The Orange Book also provides a listing of patents that cover a given drug product.

18. Plaintiffs Purdue Pharma, P.F. Labs, Purdue Pharmaceuticals, and Rhodes are the lawful owners of all right, title and interest in United States Patent No. 7,674,799 entitled "OXYCODONE HYDROCHLORIDE HAVING LESS THAN 25 PPM 14-HYDROXYCODEINONE" ("the '799 patent"), including all right to sue and to recover for past infringement thereof, which patent is listed in the FDA's Orange Book as covering the drug OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '799 patent is

attached hereto as Exhibit A, which was duly and legally issued on March 9, 2010, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

19. Plaintiffs Purdue Pharma, P.F. Labs, Purdue Pharmaceuticals, and Rhodes are the lawful owners of all right, title and interest in United States Patent No. 7,674,800 entitled "OXYCODONE HYDROCHLORIDE HAVING LESS THAN 25 PPM 14-HYDROXYCODEINONE" ("the '800 patent"), including all right to sue and to recover for past infringement thereof, which patent is listed in the FDA's Orange Book as covering the drug OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '800 patent is attached hereto as Exhibit B, which was duly and legally issued on March 9, 2010, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

20. Plaintiffs Purdue Pharma, P.F. Labs, Purdue Pharmaceuticals, and Rhodes are the lawful owners of all right, title and interest in United States Patent No. 7,683,072 entitled "OXYCODONE HYDROCHLORIDE HAVING LESS THAN 25 PPM 14-HYDROXYCODEINONE" ("the '072 patent"), including all right to sue and to recover for past infringement thereof, which patent is listed in the FDA's Orange Book as covering the drug OxyContin®, which is the subject of approved NDA No. 022272. A copy of the '072 patent is attached hereto as Exhibit C, which was duly and legally issued on March 23, 2010, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

21. The Improved API patents have been the subject of previous District Court litigation in which they were found infringed by an API that, upon information and belief, is substantially similar to the API to be used in the proposed Collegium Product. The Improved API patents were also found invalid for obviousness, a judgment that is currently being appealed.

22. On March 23, 2011 and June 28, 2012, Plaintiffs Purdue, along with Grunenthal GmbH ("Grunenthal"), filed suit against Teva Pharmaceuticals USA, Inc. ("Teva") in the Southern District of New York, Civil Action Nos. 11-cv-2037-SHS and 12-cv-5083-SHS, alleging infringement of, inter alia, the Improved API patents ("the *Teva* case"). In response, Teva denied infringement and asserted that the claims of the Improved API patents were invalid. A twelve-day bench trial relating, inter alia, to these patents was held in September and October 2013.

23. On January 14, 2014, the Southern District of New York (Stein, J.) issued Findings of Fact and Conclusions of Law in the *Teva* case. The accused products were found to infringe the asserted claims of the Improved API patents and the claims were found to satisfy the disclosure and claiming requirements of 35 U.S.C. § 112. However, the asserted claims of the Improved API patents were also found invalid for obviousness. On January 22, 2014, the Court entered Judgment, inter alia, that: (a) Claims 3 and 19 of the '799 patent are invalid; (b) Claims 30-34 and 76-79 of the '800 patent are invalid; and (c) Claims 1, 4, and 5 of the '072 patent are invalid.

24. On February 12, 2014, Plaintiffs Purdue and Grunenthal filed a notice of appeal appealing the Southern District of New York's judgment of invalidity in the *Teva* case, including the judgment with respect to the claims of the Improved API patents, to the Court of Appeals for the Federal Circuit ("the Federal Circuit"). The District Court's judgment was amended on April 16, 2014 and July 14, 2014, and notices of appeal were filed by Purdue and Grunenthal on May 20, 2014 and July 23, 2014, respectively.

25. The July 14, 2014 Amended Judgment stated, "Teva's counterclaims for declaratory judgment of non-infringement of claims 3 and 19 of U.S. Patent No. 7,674,799;

claims 30-34 and 76-79 of U.S. Patent No. 7,674,800; claims 1, 4, and 5 of U.S. Patent No. 7,683,072; and claims 1, 2, 5, 7, and 8 of U.S. Patent No. 8,114,383 are denied."

26. Under a scheduling order issued by the Federal Circuit and pursuant to the Federal Rules of Appellate Procedure, briefing of Purdue's appeal is currently scheduled to close in late April 2015. No date has yet been set for oral argument.

DEFENDANT'S NDA

27. Upon information and belief, Collegium submitted NDA No. 208090 to the FDA, under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(b)(2)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale or importation of XTAMPZA ER™ oxycodone extended release capsules, 9 mg, 13.5 mg, 18 mg, 27 mg, and 36 mg ("the proposed Collegium Product") before the expiration of the Improved API patents. The proposed Collegium Product is in the late stages of development and Collegium is actively preparing to make and sell that product if and when it is approved by the FDA.

28. Upon information and belief, the proposed Collegium Product does not include oxycodone hydrochloride salt. However, the proposed Collegium Product does include a different salt, oxycodone myristate, which is equivalent to oxycodone hydrochloride for purposes of the inventions claimed in the Improved API patents.

29. Upon information and belief, Collegium's NDA No. 208090 contains a "Paragraph IV" certification under 21 U.S.C. § 355(b)(2)(A)(iv) alleging that the Improved API patents, listed in the FDA's Orange Book as covering the drug OxyContin®, which is the subject of approved NDA No. 022272, are "invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of [the proposed Collegium Product]."

30. In a letter dated February 11, 2015 addressed to Plaintiffs Purdue Pharma, P.F. Labs, Purdue Pharmaceuticals, and Rhodes, and received on February 12, 2015, Collegium provided "Notice" with respect to the proposed Collegium Product and the Improved API patents under 21 U.S.C. § 355(b)(3).

THE FILING OF THIS SUIT

31. Under 21 U.S.C. § 355(c)(3)(C), Plaintiffs have 45 days after receipt of Collegium's Notice Letter to sue for infringement of the Improved API patents to trigger a 30-month stay during which the FDA cannot approve Collegium's NDA. There is no mechanism in the statute by which, pending appeal, Plaintiffs can toll the statutory requirement that the suit be filed within 45 days of receipt of Collegium's Notice Letter in order for Plaintiffs to obtain such a stay, or to revive Plaintiffs' right to such a stay upon successful resolution of the appeal, if suit is not filed within 45 days.

32. Accordingly, Plaintiffs must file suit against Collegium for the infringement of the Improved API patents by the proposed Collegium Product within the 45-day timeframe provided by 21 U.S.C. § 355(c)(3)(C) in order to perfect their rights to a 30-month stay prohibiting FDA approval of Collegium's NDA if the Federal Circuit vacates or reverses the judgment in the *Teva* case.

33. To conserve the resources of the Court and the parties, Plaintiffs will seek a stay of this action against Collegium with respect to the Improved API patents until a final adjudication of the appeal in the *Teva* case.

FIRST CLAIM FOR RELIEF:
PATENT INFRINGEMENT OF THE IMPROVED API PATENTS

34. Collegium's submission of its NDA was an act of infringement of the Improved API patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

35. Upon information and belief, the proposed Collegium Product is covered by one or more claims of the Improved API patents.

36. Upon information and belief, Collegium's commercial manufacture, use, sale, offer for sale and/or importation of the proposed Collegium Product would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the Improved API patents.

37. The acts of infringement by Collegium 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.

THE '497 ABUSE-DETERRENCE PATENT

38. Plaintiff Purdue Pharma is the lawful owner of all right, title and interest in United States Patent No. 8,652,497 entitled "PHARMACEUTICAL FORMULATION CONTAINING IRRITANT" ("the '497 Abuse-deterrence patent"), including all right to sue and to recover for past infringement thereof. A copy of the '497 Abuse-deterrence patent is attached hereto as Exhibit D, which was duly and legally issued on February 18, 2014, naming Richard Sackler as the inventor.

SECOND CLAIM FOR RELIEF:
PATENT INFRINGEMENT OF THE '497 ABUSE-DETERRENCE PATENT

39. Collegium's submission of its NDA was an act of infringement of the '497 Abuse-deterrence patent under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

40. Upon information and belief, the proposed Collegium Product is covered by one or more claims of the '497 Abuse-deterrence patent.

41. Upon information and belief, Collegium's commercial manufacture, use, sale, offer for sale and/or importation of the proposed Collegium Product would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '497 Abuse-deterrence patent.

42. The acts of infringement by Collegium set forth above will cause Plaintiff Purdue Pharma irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

WHEREFORE, Plaintiffs pray for judgment:

ON PLAINTIFFS' FIRST CLAIM FOR RELIEF,
AS SET FORTH IN THE COMPLAINT:

A. Adjudging that Collegium has infringed U.S. Patent Nos. 7,674,799, 7,674,800, and 7,683,072 ("the Improved API patents"), and that the commercial sale, offer for sale, use, manufacture and/or importation of the proposed Collegium Product described in NDA No. 208090 would infringe, induce infringement of, and/or contribute to the infringement of the Improved API patents;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of NDA No. 208090, under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(b)(2)), to be a date not earlier than the dates of expiration of the Improved API 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., Collegium, its officers, partners, 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 Improved API 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.

ON PLAINTIFF PURDUE PHARMA'S SECOND CLAIM FOR RELIEF, AS SET FORTH IN THE COMPLAINT:

F. Adjudging that Collegium has infringed U.S. Patent No. 8,652,497 ("the '497 Abuse-deterrence patent"), and that the commercial sale, offer for sale, use, manufacture, and/or importation of the proposed Collegium Product described in NDA No. 208090 would infringe, induce infringement of, and/or contribute to the infringement of the '497 Abuse-deterrence patent;

G. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of NDA No. 208090, under § 505(b)(2) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(b)(2)), to be a date not earlier than the date of expiration of the '497 Abuse-deterrence patent plus any additional periods of exclusivity;

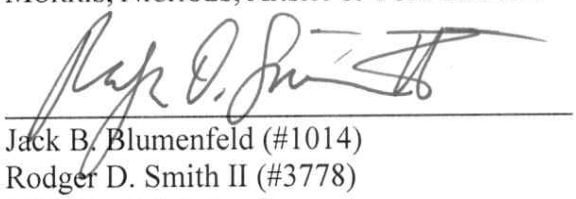
H. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., Collegium, its officers, partners, agents, servants, employees, parents, subsidiaries, divisions, affiliate corporations, other related business entities and all other persons acting 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 '497 Abuse-deterrence patent;

I. Declaring this an exceptional case and awarding Plaintiff Purdue Pharma its attorneys' fees, as provided by 35 U.S.C. §§ 271(e)(4) and 285; and

J. Awarding Plaintiff Purdue Pharma 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 North Market Street
P.O. Box 1347
Wilmington, DE 19899
(302) 658-9200
jblumenfeld@mnat.com
rsmith@mnat.com

Attorneys for Plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue Pharmaceuticals L.P. and Rhodes Technologies

OF COUNSEL:

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

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

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