IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

PURDUE PHARMA L.P., THE P.F. LABORATORIES, INC., PURDUE PHARMACEUTICALS L.P., and RHODES TECHNOLOGIES,	)	
Plaintiffs,	)	C.A. No. _____
v.	)	
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 against Collegium Pharmaceutical, Inc. ("Collegium" or "Defendant"), aver as follows:

NATURE OF THE ACTION

1. This is an action for relief from patent infringement, arising under the patent laws of the United States, Title 35, United States Code. Plaintiffs seek relief from infringement of U.S. Patent Nos. 9,522,919 (the "'919 patent") and 9,073,933 (the "'933 patent") or, collectively, "patents-in-suit," which relate to improved oxycodone hydrochloride compositions and pharmaceutical formulations. Defendant Collegium has infringed the patents-in-suit under 35 U.S.C. § 271(e) by its submission of its supplemental New Drug Application No. 208090 ("Supplemental NDA") to the U.S. Food & Drug Administration ("FDA") under § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(b)(2)), seeking approval for revised labeling for its Xtampza® ER oxycodone extended release capsules, 9 mg, 13.5 mg, 18 mg, 27 mg, and 36 mg ("Collegium Supplemental NDA Products"), and to engage

in the commercial manufacture, use, sale, offer for sale, or importation of Collegium Supplemental NDA Products before the expiration of the '919 and '933 patents.

2. On March 24, 2015, Purdue filed a related complaint against Defendant, C.A. No. 1:15-cv-13624-FDS, for infringement of U.S. Patent Nos. 7,674,799 (the "'799 patent"); 7,674,800 (the "'800 patent"); 7,683,072 (the "'072 patent"); and 8,652,497 (the "'497 patent"). The previous action was filed in connection with Defendant's § 505(b)(2) NDA, which contained a "Paragraph IV" certification under 21 U.S.C. § 355(b)(2)(A)(vi) alleging that, *inter alia*, the '799, '800, and '072 patents, listed in the Orange Book (defined below) as covering OxyContin®, Purdue's extended-release oxycodone pain-relief medication, are "invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the product for which the 505(b)(2) NDA is submitted." The '497 patent is not listed in the FDA's Orange Book with respect to OxyContin®. On July 23, 2015, Purdue filed a notice of voluntary dismissal of this complaint.

3. On August 6, 2015, Purdue filed a related complaint against Defendant, C.A. No. 1:15-cv-13099-FDS, for infringement of the '799, '800, '072, and '497 patents. The previous action was filed in connection with Defendant's NDA, which contained a "Paragraph IV" certification under 21 U.S.C. § 355(b)(2)(A)(vi) alleging that, *inter alia*, the '799, '800, and '072 patents, listed in the Orange Book as covering OxyContin®, are "invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the product for which the 505(b)(2) NDA is submitted."

4. On November 6, 2015, Purdue filed a related complaint against Defendant, C.A. No. 1:15-cv-13783, for infringement of the '933 patent, which is related to the '799, '800, and '072 patents. The previous action was filed in connection with Defendant's

NDA, which contained a "Paragraph IV" certification under 21 U.S.C. § 355(b)(2)(A)(vi) alleging that, *inter alia*, the '933 patent, listed in the Orange Book as covering OxyContin®, is "invalid, unenforceable, and/or will not be infringed by the manufacture, use, or sale of the product for which the 505(b)(2) NDA is submitted."

5. On June 10, 2016, Purdue filed a related complaint against Defendant, C.A. No. 1:16-cv-11091, for infringement of U.S. Patent No. 9,155,717 (the "'717 patent"), which is related to the '497 patent. The previous action was filed in connection with Defendant's NDA filing. The '717 patent is not listed in the FDA's Orange Book.

6. On or about April 26, 2016, the FDA issued its final approval of Collegium's NDA. In June 2016, Collegium began commercial manufacture of Xtampza®, and began offering for sale, selling, and distributing Xtampza®.

7. On July 22, 2016, Purdue filed a Supplemental Complaint against Defendant in C.A. No. 1:15-cv-13099-FDS for infringement of the '497, '933, and '717 patents.[1] The Supplemental Complaint consolidated C.A. Nos. 15-13099 (lead docket no.), 15-13624, and 15-13783 referenced above.[2] The Supplemental Complaint also asserted new claims against Defendant for patent infringement under 35 U.S.C. §§ 271(a), (b), and (c) based on Collegium's actual marketing of Xtampza® after receiving FDA approval.

8. On April 21, 2017, Purdue filed a related complaint against Defendant in C.A. No. 1:17-cv-10690-FDS for infringement of the '919 patent, which is related to the '933 patent. This previous action was filed in connection with Defendant's NDA filing. On May 22,

[1] The parties entered into a stipulated judgment and dismissal of Purdue's allegations of infringement of the '799, '800, and '072 patents. (*See* C.A. No. 15-13099, D.I. 81 at 1 n.1.)

[2] In view of the Supplemental Complaint's allegations of infringement of the '717 patent, the parties agreed to dismiss the 16-11091 action. (*See* C.A. No. 15-13099, D.I. 81 at 2.)

2017, pursuant to the Court's order, C.A. No. 1:17-cv-10690 was consolidated with C.A. No. 1:15-cv-13099.

9. On September 21, 2017, Purdue filed a related complaint against Defendant in C.A. No. 1:17-cv-11814-FDS for infringement of U.S. Patent No. 9,693,961 (the "'961 patent"). The action was filed in connection with Defendant's actual marketing of Xtampza® and Defendant's NDA filing. The '961 patent is not listed in the FDA's Orange Book with respect to OxyContin®.

THE PARTIES

10. 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 the '919 and '933 patents. Purdue Pharma is also the holder of NDA No. 022272 for OxyContin® and is involved in the sale of OxyContin® in the United States.

11. 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 One Stamford Forum, 201 Tresser Boulevard, Stamford, CT 06901-3431. P.F. Labs is an owner of the '919 and '933 patents.

12. 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 '919 and '933 patents, and is involved in the manufacture of extended-release oxycodone pain-relief medication under the brand name OxyContin®.

13. 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 '919 and '933 patents, and is involved in the manufacture of the active pharmaceutical ingredient ("API") used in the extended-release oxycodone pain-relief medication under the brand name OxyContin®.

14. On information and belief, Collegium is 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

15. This action arises under the patent laws of the United States, including 35 U.S.C. § 271.

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

17. This Court has personal jurisdiction over Collegium, and venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b), because Collegium has its principal place of business in this Judicial District and has committed an act of patent infringement in this Judicial District.

18. On information and belief, Defendant is in the business of preparing pharmaceuticals that it distributes in the Commonwealth of Massachusetts and throughout the United States.

19. On information and belief, once NDA No. 208090 was approved, Xtampza® was, among other things, marketed and distributed in Massachusetts, and/or prescribed by physicians practicing and dispensed by pharmacies located within Massachusetts, all of which have a substantial effect on Massachusetts.

20. In C.A. No. 15-cv-13099-FDS (*consol.*), Collegium admitted that this Court has personal jurisdiction over Collegium and that venue is proper in this Judicial District. Collegium also availed itself of this Court's jurisdiction by submitting counterclaims.

DEFENDANT'S SUPPLEMENTAL NDA

21. 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 the products described in NDA No. 208090.

22. On or about April 26, 2016, the FDA issued its final approval of Collegium's NDA.

23. On June 20, 2016, Collegium issued a press release announcing the commercial launch of Xtampza®.

24. Collegium has begun commercial manufacture of Xtampza®, has begun offering for sale and selling Xtampza®, and continues to manufacture (or has manufactured), offer for sale, sell, and distribute Xtampza®.

25. Upon information and belief, on or before August 25, 2017, Collegium submitted its Supplemental NDA pursuant to 21 U.S.C. § 355(b)(2) and § 505(b)(2) of the Federal Food, Drug, and Cosmetic Act, seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of the Collegium Supplemental NDA Products.

26. Upon information and belief, the Collegium Supplemental NDA contains a "Paragraph IV" certification under 21 U.S.C § 355(b)(2)(A)(iv) alleging that the patents-in-suit, 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 product for which the 505(b)(2) NDA is submitted."

27. In a letter dated August 25, 2017 addressed to Plaintiffs Purdue Pharma, P.F. Labs, Purdue Pharmaceuticals, and Rhodes, and received on August 28, 2017, Collegium provided "Notice" with respect to the proposed Collegium Supplemental NDA Products and the patents-in-suit under 21 U.S.C. § 355(b)(3).

THE '919 PATENT

28. The 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 the patents that cover a given drug product.

29. Plaintiffs Purdue Pharma, P.F. Labs, Purdue Pharmaceuticals, and Rhodes are the lawful owners of all right, title, and interest in the '919 patent, entitled "OXYCODONE COMPOSITIONS," 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 '919 patent is attached hereto as Exhibit A, which was duly and legally issued on December 20, 2016, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

30. Upon information and belief, the Collegium Supplemental NDA Products are covered by one or more claims of the '919 patent, including, but not limited to, independent claims 1, 4, 12, and 18, which recite, *inter alia*, an oxycodone hydrochloride composition or pharmaceutically acceptable formulation comprising oxycodone HCl and 8α,4-dihydroxy-7,8-dihydrocodeinone, wherein the ratio of 8α,4-dihydroxy-7,8-dihydrocodeinone to oxycodone HCl is 0.04% or less as measured by HPLC.

THE '933 PATENT

31. Plaintiffs Purdue Pharma, P.F. Labs, Purdue Pharmaceuticals, and Rhodes are the lawful owners of all right, title, and interest in the '933 patent, entitled "OXYCODONE COMPOSITIONS HAVING LESS THAN 25 PPM 14-HYDROXYCODEINONE," 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 '933 patent is attached hereto as Exhibit B, which was duly and legally issued on December 20, 2016, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

32. Upon information and belief, the Collegium Supplemental NDA Products are covered by one or more claims of the '933 patent, including, but not limited to, independent claims 1 and 10, which recite, *inter alia*, an oxycodone hydrochloride composition, which comprises at least 95% oxycodone hydrochloride, 8α,14-dihydroxy-7,8-dihydrocodeinone, and less than 25 ppm of 14-hydroxycodeinone, and claim 16, which recites, *inter alia*, an oxycodone hydrochloride composition, which comprises at least 95% oxycodone hydrochloride, 8α,14-dihydroxy-7,8-dihydrocodeinone, and less than 5 ppm of 14-hydroxycodeinone .

CLAIM FOR RELIEF:

COUNT I
(Collegium's Filing of its Supplemental NDA Constitutes Infringement of the '919 patent)

33. Plaintiffs incorporate by reference and reallege paragraphs 1-32 above as though fully restated herein.

34. Collegium submitted its Supplemental NDA 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 the Collegium Supplemental NDA Products.

35. Upon information and belief, the Collegium Supplemental NDA Products are covered by one or more claims of the '919 patent, including, but not limited to, independent claims 1, 4, 12, and 18.

36. Collegium's submission of its Supplemental NDA is an act of infringement of the '919 patent under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

COUNT II
(Collegium's Filing of Supplemental NDA Constitutes Infringement of the '933 patent)

37. Plaintiffs incorporate by reference and reallege paragraphs 1-36 above as though fully restated herein.

38. Collegium submitted its Supplemental NDA 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 the Collegium Supplemental NDA Products.

39. Upon information and belief, the Collegium Supplemental NDA Products are covered by one or more claims of the '933 patent, including, but not limited to, independent claims 1, 10, and 16.

40. Collegium's submission of its Supplemental NDA is an act of infringement of the '933 patent under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment:

A. Adjudging that the commercial sale, offer for sale, use, manufacture, and/or importation of the Collegium Supplemental NDA Products will infringe, induce infringement of, and/or contribute to the infringement of the ’919 and ’933 patents;

B. Adjudging that Collegium has infringed the ’919 and ’933 patents, and that Collegium’s commercial sale, offer for sale, use, manufacture, and/or importation of the Collegium Supplemental NDA Products will infringe, induce infringement of, and/or contribute to the infringement of the ’919 and ’933 patent;

C. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Collegium’s Supplemental NDA 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 ’919 and ’933 patents, plus any additional periods of extension or exclusivity;

D. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Fed. R. Civ. P. 65, 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 is the subject of the Collegium Supplemental NDA, including the Collegium Supplemental NDA Products or any other drug product that infringes the ’919 and ’933 patent;

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

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

Dated: October 6, 2017

Respectfully submitted,

PURDUE PHARMA L.P.,
THE P.F. LABORATORIES, INC.,
PURDUE PHARMACEUTICALS L.P.,
and RHODES TECHNOLOGIES,

By their counsel,

/s/ Christopher M. Morrison

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