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 No. 9,522,919 (the "'919 patent" or "patent-in-suit"), which relates to improved oxycodone hydrochloride compositions and pharmaceutical formulations. Defendant Collegium has infringed the '919 patent under 35 U.S.C. § 271(e) by its submission of New Drug Application ("NDA") No. 208090 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 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 before the expiration of the '919 patent. Defendant Collegium has also infringed the '919 patent

under 35 U.S.C. §§ 271(a), (b), and (c) by manufacturing, using, selling, offering for sale and/or importing of its Xtampza® ER products ("the Collegium Products").

2. On March 26, 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 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." The '497 patent is not listed in the FDA's Orange Book. 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." The '497 patent is not listed in the FDA's Orange Book.

4. On November 6, 2015, Purdue filed a related complaint against Defendant, C.A. No. 1:15-cv-13783, for infringement of U.S. Patent No. 9,073,933 ("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 the Collegium Products, and began offering for sale, selling, and distributing the Collegium Products.

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 the Collegium Products after receiving FDA approval.

THE PARTIES

8. 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 patent. Purdue Pharma is also the holder of NDA No. 022272

[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 id.* at 2.)

for the extended-release oxycodone pain-relief medication OxyContin® and is involved in the sale of OxyContin® in the United States.

9. 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 patent.

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

11. 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 patent, 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®.

12. 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

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

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

15. 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.

16. 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.

17. On information and belief, once NDA No. 208090 was approved, the Collegium Products were, 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.

18. 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 NDA

19. 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 Collegium Products.

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

21. On June 20, 2016, Collegium issued a press release announcing the commercial launch of the Collegium Products.

22. Collegium has begun commercial manufacture of the Collegium Products, has begun offering for sale and selling the Collegium Products, and continues to manufacture (or have manufactured), offer for sale, sell, and distribute the Collegium Products.

THE '919 PATENT

23. 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.

24. 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.

25. Upon information and belief, the Collegium 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.

CLAIM FOR RELIEF:

COUNT I
(Collegium's Filing of NDA No. 208090 Constitutes Infringement of the '919 patent)

26. Plaintiffs incorporate by reference and reallege paragraphs 1-25 above as though fully restated herein.

27. 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 Collegium Products.

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

29. Collegium's submission of its 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 Marketing of the Collegium Products Has Infringed the '919 patent)

30. Plaintiffs incorporate by reference and reallege paragraphs 1-25 above as though fully restated herein.

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

32. On June 20, 2016, Collegium issued a press release announcing the commercial launch of the Collegium Products.

33. Collegium has begun commercial manufacture of the Collegium Products, has begun offering for sale and selling the Collegium Products, and continues to manufacture (or have manufactured), offer for sale, sell, and distribute the Collegium Products.

34. Since at least December 20, 2016, Collegium has been infringing the '919 patent by making, using, offering for sale, selling, and distributing products embodying the patented inventions in violation of 35 U.S.C. § 271(a), by inducing others to make, use, sell, or offer for sale products and methods embodying the patented inventions in violation of 35 U.S.C. § 271(b), and/or by contributing to the manufacture, use, sale, or offer for sale of products embodying the patented inventions in violation of 35 U.S.C. § 271(c).

35. Collegium, through at least its labeling and manufacturing process, has intentionally induced infringement of the '919 patent by at least patients who take the Collegium Products and manufacturers who manufacture the Collegium Products.

36. The Collegium Products constitute a material part of the inventions covered by the claims of the '919 patent and are not suitable for substantial noninfringing use.

37. Collegium's infringement of the '919 patent has been willful, egregious, and in disregard of the '919 patent.

38. Since at least December 20, 2016, when Collegium continued to offer the Collegium Products for sale following the issuance of the '919 patent, Collegium had knowledge that it had no good-faith non-infringement and invalidity positions.

39. Plaintiffs have been and will continue to be substantially and irreparably damaged and harmed by Collegium's manufacture, use, sale, or offer for sale of the Collegium Products in this Judicial District if such infringement is not enjoined by this Court. Plaintiffs do not have an adequate remedy at law.

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 Products infringes, induces infringement of, and/or contributes to the infringement of the '919 patent;

B. Adjudging that Collegium has infringed the '919 patent, and that Collegium's commercial sale, offer for sale, use, manufacture, and/or importation of the Collegium Products infringes, induces infringement of, and/or contributes to the infringement of the '919 patent;

C. 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)), be revised to a date not earlier than the date of expiration of the '919 patent plus any additional periods of exclusivity;

D. 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 infringes the '919 patent;

E. Awarding, pursuant to 35 U.S.C. §§ 271(e)(4)(C) and 284, damages to Plaintiffs resulting from Collegium's commercial manufacture, use, importation into the United States, offer for sale, or sale of the Collegium Products prior to the expiration of the '919 patent, increased to treble the amount found or assessed, together with interest;

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

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

Dated: April 21, 2017

/s/ Christopher M. Morrison

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CERTIFICATE OF SERVICE

I, Christopher M. Morrison, hereby certify that I have on this 21st day of April 2017 filed a copy of the foregoing through the Court's CM/ECF system, which will serve an electronic copy on counsel of record identified in the Notice of Electronic Filing.

/s/ Christopher M. Morrison