

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS**

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

COMPLAINT

Plaintiffs Purdue Pharma L.P., 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 for infringement of U.S. Patent No. 10,407,434 (“the ’434 patent”). This action relates to Collegium’s submission of New Drug Application (“NDA”) No. 208090 (including any amendments and/or supplements thereto, “Collegium’s 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 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 Collegium NDA Products”) before the expiration of the ’434 patent.

2. Plaintiffs seek judgment that Defendant has infringed the ’434 patent. The ’434 patent is listed in the FDA *Approved Drug Products With Therapeutic Equivalence*

Evaluations (“Orange Book”) as covering Purdue’s OxyContin® (oxycodone hydrochloride) (“OxyContin”), an extended-release pain medication. Collegium has infringed the ’434 patent under 35 U.S.C. § 271(e)(2)(A) by filing the Collegium NDA on the Collegium NDA Products and under 35 U.S.C. §§ 271(a), (b), (c), and (g) by actual marketing of the Collegium NDA Products.

3. The present action is related to currently-pending patent infringement actions Purdue previously filed against Collegium that also relate to the filing of Collegium’s NDA and Collegium’s marketing of the Collegium NDA Products. These previously-filed actions include Case No. 15-cv-13099-FDS (“the Lead Action”), in which Purdue has asserted infringement of U.S. Patent Nos. 9,073,933 (“the ’933 patent”) and 9,522,919 (“the ’919 patent”), patents that are related to the ’434 patent. The ’434, ’933, and ’919 patents share, e.g., the same claim of priority, same inventors and same specification.

4. These previously-filed actions also include Case No. 17-cv-11814-FDS (the “’961 Patent Action”), in which Purdue has asserted infringement of U.S. Patent No. 9,693,961 (“the ’961 patent”). The ’961 Patent Action, which has been consolidated with the Lead Action for pretrial purposes, is related to the present action in that, *inter alia*, they both involve the same infringing product, the Collegium NDA Products.

5. Purdue and Collegium have agreed to consolidate the present action with the Lead Action for pretrial purposes, subject to the Court’s approval.

THE PARTIES

6. 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 '434 patent. 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.

7. 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 '434 patent, and is involved in the manufacture of OxyContin.

8. 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 '434 patent, and is involved in the manufacture of the active pharmaceutical ingredient ("API") used in OxyContin.

9. Upon 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

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

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

12. 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.

13. Collegium is in the business of preparing pharmaceuticals that it distributes in the Commonwealth of Massachusetts and throughout the United States.

14. Upon information and belief, once Collegium's NDA was approved, the Collegium NDA 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.

THE '434 PATENT

15. The 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 certain patents that cover a given drug product or the use thereof.

16. Purdue is the lawful owner of all right, title, and interest in the '434 patent, entitled "PROCESS FOR PREPARING 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. The '434 patent was duly and legally issued on September 10, 2019, naming Robert Chapman, Lon S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors. A copy of the '434 patent is attached as Exhibit A.

COLLEGIUM'S NDA

17. Upon information and belief, Collegium submitted Collegium's 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 NDA Products.

18. On or about April 26, 2016, the FDA issued its final approval of Collegium's NDA based on Collegium's filings as of that date.

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

20. Collegium has begun commercial manufacture of the Collegium NDA Products, has begun offering for sale and selling the Collegium NDA Products, and continues to manufacture (or have manufactured), offer for sale, sell, and distribute the Collegium NDA Products, including in this district.

21. After having already begun marketing the Collegium NDA Products, on or about October 4, 2016, Collegium filed a supplemental application relating to Collegium's NDA ("Collegium's sNDA").

22. On or about November 6, 2017, the FDA issued its final approval of Collegium's sNDA.

23. On information and belief, Collegium has marketed the Collegium NDA Products according to Collegium's sNDA.

CLAIMS FOR RELIEF:

COUNT I

(Collegium's Filing of Its NDA Constitutes Infringement of the '434 Patent)

24. Purdue incorporates by reference and realleges paragraphs 1-23 above as though fully restated herein.

25. Collegium's submission of its NDA for a drug claimed in the '434 patent was an act of infringement under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

26. Upon information and belief, the Collegium NDA Products use or, according to Collegium, contain oxycodone base. The oxycodone base and the process by which the oxycodone base is made is covered by one or more claims of the '434 patent, including but not limited to at least claims 1-7, 9, 13-15, 17, and 19, which recite, *inter alia*, a process of purifying oxycodone free base or oxycodone HCl that contains 8 α ,14-dihydroxy-7,8-dihydrocodeinone; a process of purifying oxycodone free base or oxycodone HCl that contains 8 α ,14-dihydroxy-7,8-

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