

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

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PURDUE PHARMA L.P.,)	
)	
Plaintiff,)	
v.)	C.A. No. _____
)	
COLLEGIUM PHARMACEUTICAL, INC.,)	
)	
Defendant)	
)	
)	
)	

COMPLAINT

Plaintiff Purdue Pharma L.P., for its Complaint against Defendant Collegium Pharmaceutical, Inc., avers 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. Plaintiff seeks relief from infringement of U.S. Patent No. 9,155,717 (“the ’717 patent”), which relates to abuse-deterrent features of drugs susceptible to abuse, including extended-release opioid formulations. Defendant Collegium has infringed the ’717 patent under 35 U.S.C. § 271(e)(2)(A) by filing New Drug Application (“NDA”) No. 208090 on its proposed XTAMPZA ER™ product (“the proposed Collegium Product”).

THE PARTIES

2. 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 '717 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.

3. On April 10, 2002, Defendant Collegium Pharmaceutical, Inc. (“Collegium”) was incorporated as an entity under the laws of the State of Delaware, having its principal place of business at 780 Dedham Street, Suite 800, Canton, MA 02021.

4. 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.

5. On or about July 23, 2014, the Collegium entity that was incorporated in Delaware merged with the Collegium entity that was incorporated in Virginia.

6. 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

7. This action arises under the patent laws of the United States, including 35 U.S.C. § 271, and the Declaratory Judgment Act, 28 U.S.C §§ 2201 and 2202.

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

9. 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.

10. Pending before this Court is related consolidated case, Civil Action No. 15-cv-13099-FDS (Lead Docket No.), in which Purdue Pharma and other plaintiffs have accused

Collegium of infringing other U.S. patents, including related U.S. Patent No. 8,652,497, which is a parent patent to the '717 patent and also relates to abuse-deterrent features of drugs susceptible to abuse, including extended-release opioid formulations. Civil Action No. 15-cv-13099-FDS also involves Collegium's NDA No. 208090 and the proposed Collegium product. As of the filing of this complaint, the Rule 16 scheduling conference in Civil Action No. 15-cv-13099-FDS has yet to occur.

11. In Civil Action No. 15-cv-13099-FDS, Collegium admitted that this Court has personal jurisdiction over Collegium and that venue is proper in this Judicial District. Collegium also availed itself of the Court's jurisdiction by submitting counterclaims.

THE '717 PATENT

12. Plaintiff Purdue Pharma is the lawful owner of all right, title, and interest in the '717 patent, entitled "PHARMACEUTICAL FORMULATION CONTAINING IRRITANT," including all right to sue and to recover for past infringement thereof. The '717 patent was duly and legally issued on October 13, 2015, naming Richard Sackler as the inventor. A copy of the '717 patent is attached as Exhibit A.

DEFENDANT'S NDA

13. 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 the proposed Collegium Product prior to the expiration of the '717 patent.

14. Upon information and belief, the proposed Collegium Product has received tentative approval by the FDA.

15. Upon information and belief, Collegium has submitted a request for final approval of the proposed Collegium Product to the FDA.

16. Upon information and belief, Collegium is actively preparing to make and sell the proposed Collegium Product.

17. Upon information and belief, Collegium will launch the proposed Collegium Product if and when it receives final approval by the FDA.

CLAIMS FOR RELIEF:

COUNT I
(Patent Infringement of the '717 Patent)

18. Purdue Pharma incorporates by reference and realleges paragraphs 1-17 above as though fully restated herein.

19. Collegium's submission of its NDA was an act of infringement of the '717 patent under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

20. Upon information and belief, the proposed Collegium Product is covered by one or more claims of the '717 patent, including but not limited to independent claims 1, 23, and 28, which recite, *inter alia*, an oral dosage form comprising a therapeutically effective amount of a drug susceptible to abuse (or of oxycodone or a salt thereof).

21. 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 '717 patent under 35 U.S.C. § 271(a)-(c).

22. The proposed Collegium Product constitutes a material part of the inventions covered by the claims of the '717 patent and is not suitable for substantial noninfringing use.

23. Collegium, through at least its proposed labeling, will intentionally induce infringement by at least patients who will take the proposed Collegium Product.

24. 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.

COUNT II
(Declaratory Judgment as to the '717 Patent)

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

26. On information and belief, Collegium has made, and will continue to make, substantial preparation in the United States to manufacture, use, sell, offer to sell, or import the proposed Collegium Product prior to expiration of the '717 patent.

27. On information and belief, Collegium intends to engage in the commercial manufacture, use, sale, or offer for sale within the United States or importation into the United States of the proposed Collegium Product if and when it receives final approval by the FDA, unless enjoined by the Court.

28. On information and belief, Collegium's commercial manufacture, use, sale, or offer for sale within or importation into the United States of the proposed Collegium Product will constitute infringement of the '717 patent under 35 U.S.C. § 271(a)-(c).

29. There is a justiciable case or controversy between Purdue Pharma and Collegium regarding whether Collegium's commercial manufacture, use, sale, offer for sale, or importation into the United States of the proposed Collegium Product will infringe one or more claims of the '717 patent.

30. If Collegium's infringement of the '717 patent is not enjoined, Purdue Pharma will suffer substantial and irreparable harm from which there is no remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for judgment:

A. Adjudging that Collegium has infringed the '717 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 '717 patent;

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 date of expiration of the '717 patent 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 '717 patent;

D. 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

E. Awarding Plaintiff Purdue Pharma such other and further relief as this Court may deem just and proper.

Dated: June 10, 2016

Respectfully submitted,

PURDUE PHARMA L.P.,

By its counsel,

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