

IN THE UNITED STATES DISTRICT COURT  
FOR THE SOUTHERN DISTRICT OF NEW YORK

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

COMPLAINT FOR DECLARATORY JUDGMENT

Plaintiff Collegium Pharmaceutical, Inc. (“Collegium”), for their Complaint herein, alleges as follows:

THE PARTIES

1. Collegium Pharmaceutical Inc. (“Collegium”) is a Virginia corporation, having its principal place of business at 780 Dedham Street, Suite 800, Canton, Massachusetts 02021.

Collegium is a small pharmaceutical development company that does not currently manufacture or sell any products.

2. Upon information and belief, Defendant Purdue Pharma L.P. (“Purdue Pharma”) is a Delaware limited partnership, having a principal place of business at One Stamford Forum, 201 Tressor Boulevard, Stamford, Connecticut 06901.

3. Upon information and belief, Defendant The P.F. Laboratories, Inc. (“P.F. Labs”) is a New Jersey corporation, having a principal place of business at 700 Union Boulevard, Totowa, New Jersey 07512.

4. Upon information and belief, Defendant Purdue Pharmaceuticals L.P. (“Purdue Pharmaceuticals”) is a Delaware limited partnership, having a principal place of business at 4701 Purdue Drive, Wilson, North Carolina 27893.

5. Upon information and belief, Defendant Rhodes Technologies (“Rhodes”) is a Delaware general partnership, having a principal place of business at 498 Washington Street, Coventry, Rhode Island 02816.

6. Upon information and belief, Defendants Purdue Pharma, P.F. Labs, Purdue Pharmaceuticals, and Rhodes are each owners of U.S. Patent Nos. 7,674,799 (“the ‘799 patent”), 7,674,800 (“the ‘800 patent”), and 7,683,072 (“the ‘072 patent”) (collectively “the Listed Patents”), copies of which are attached to the Complaint as Exhibits A–C. Upon information and belief, Purdue Pharma holds New Drug Application (“NDA”) No. 022272 for the extended-release oxycodone pain-relief medication OxyContin®.

7. Upon information and belief, Purdue Pharma is the owner of U.S. Patent No. 8,652,497 (“the ‘497 patent”), a copy of which is attached to the Complaint as Exhibit D.

#### JURISDICTION AND VENUE

8. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331 and 1338(a), in that it involves substantial claims arising under the United States Patent Act, 35 U.S.C. § 1 *et seq.*

9. This Court may declare the rights and other legal relations of the parties pursuant to 28 U.S.C. §§ 2201 and 2202 because this is a case of actual controversy within the Court’s jurisdiction seeking a declaratory judgment that the Patents in Suit are not infringed and/or are invalid. Pursuant to 21 U.S.C. Section 355, this is a a civil action to obtain patent certainty. All conditions of Section 355 have been met.

10. Venue is proper in this District pursuant to 28 U.S.C. § 1391.

THE CONTROVERSY

11. Collegium filed New Drug Application (“NDA”) No. 208090 under section 505(b)(2) of the Federal Food, Drug and Cosmetic Act with the United States Food and Drug Administration (“FDA”) to obtain approval to market a novel, abuse-deterrent formulation of oxycodone (the “proposed 505(b)(2) product”).

12. On or about March 24, 2015, Defendants filed an action in Delaware against Collegium alleging infringement of the Listed Patents and the ‘497 patent arising from Collegium’s submission of NDA No. 208090. That action was dismissed on August 6, 2015. The Listed Patents are listed in the FDA’s Orange Book as covering OxyContin®. The ‘497 patent is not listed in the FDA’s Orange Book.

13. On January 22, 2014, Judge Stein of the Southern District of New York entered judgment of invalidity based on obviousness against each of the three Listed Patents.

14. Each of the Listed Patents claims an oxycodone hydrochloride composition or intermediate for preparing oxycodone salts.

15. The ‘497 patent claims the addition of an effective amount of an “irritant” to an oral dosage form to impart an “irritating sensation” to an abuser upon administration after tampering.

16. On or about February 11, 2015 pursuant to 21 U.S.C. § 355(b)(3), Collegium provided written notice to Defendants that Collegium certified in NDA No. 208090 that the claims of the Listed Patents are not infringed by the commercial manufacture, use or sale the proposed 505(b)(2) product.

17. On or about February 11, 2015 Collegium provided Defendants a detailed statement of the factual and legal bases for Collegium's opinion of non-infringement of the Listed Patents ("Detailed Statement").

18. Collegium's Detailed Statement stated that no oxycodone hydrochloride is present in the proposed 505(b)(2) product or as an intermediate in preparing the proposed 505(b)(2) product.

19. Collegium's Detailed Statement stated that no equivalent of oxycodone hydrochloride is present in the proposed 505(b)(2) product or as an intermediate in preparing the proposed 505(b)(2) product.

20. Collegium's proposed 505(b)(2) product does not contain an "irritant."

COUNTERCLAIM COUNT I – NONINFRINGEMENT OF THE PATENTS-IN-SUIT

21. Collegium repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaims.

22. Collegium's commercial manufacture, use, offer for sale, sale or importation of its proposed 505(b)(2) product will not directly infringe any claim of the Patents-in-Suit.

23. Because Collegium has not infringed and will not infringe any claim of the Patents-in-Suit, Defendants are not entitled to damages or other relief against Collegium.

24. Accordingly, Collegium is entitled to a declaratory judgment that it does not infringe any valid, enforceable claim of the Patents-in-suit.

COUNTERCLAIM COUNT II – INVALIDITY OF THE PATENTS-IN-SUIT

25. Collegium repeats and incorporates by reference each of the foregoing paragraphs of its Counterclaims.

26. The claims of the Patents-in-Suit are invalid for failure to meet the requirements set forth in 35 U.S.C. §§ 1 *et seq.*, including without limitation §§ 101, 102, 103, and/or 112, and the rules, regulations, and laws pertaining thereto.

27. Because Collegium has not infringed and will not infringe any valid claim of the Patents-in-Suit, Defendants are not entitled to damages or other relief against Collegium.

28. Accordingly, Collegium is entitled to declaratory judgment that the Patents-in-Suit are invalid.

PRAYER FOR RELIEF

WHEREFORE, Collegium prays this Court:

A. Enter a judgment that Collegium has not infringed the Patents-in-Suit by filing its NDA No. 208090, and that Collegium's commercial manufacture, use, offer for sale, sale or importation of its proposed 505(b)(2) product will not directly or indirectly infringe any claim of the Patents-in-Suit.

B. Enter a judgment that the Patents-in-Suit are invalid and/or unenforceable.

C. Enter an order denying Defendants and any relief whatsoever.

D. Enter an order finding there is no 30-month stay prescribed by 21 U.S.C. § 355(c)(3)(c)

E. Find this case to be exceptional under 35 U.S.C. § 285 and award Collegium reasonable attorneys' fees and costs incurred in this litigation.

F. Award Collegium such other relief as the nature of this case may require and the court may deem just, proper, and equitable.

Dated: August 6, 2015

By /s/ \_\_\_\_\_  
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Pharmaceutical, Inc.*