IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF WEST VIRGINIA

PURDUE PHARMA L.P., PURDUE PHARMACEUTICALS L.P., THE P.F. LABORATORIES, INC., and RHODES TECHNOLOGIES,	)	
Plaintiffs,	)	C.A. No. 1:15-CV-232 (Keeley)
v.	)	Electronically filed: 12/17/2015
MYLAN PHARMACEUTICALS INC. and MYLAN INC.,	)	
Defendant.	)	

COMPLAINT

Plaintiffs Purdue Pharma L.P., Purdue Pharmaceuticals L.P., The P.F. Laboratories, Inc. (collectively, "Purdue"), and Rhodes Technologies ("Rhodes") (collectively, "Plaintiffs"), for their Complaint against Defendants Mylan Pharmaceuticals Inc. ("Mylan Pharmaceuticals") and Mylan Inc. (collectively, "Mylan" or "Defendants") aver as follows:

NATURE OF THE ACTION

1. This is an action for patent infringement arising under the patent laws of the United States, Title 35, United States Code, for infringement of United States Patent No. 9,073,933 (the ''933 patent") ("patent-in-suit"). This action relates to Abbreviated New Drug Application ("ANDA") No. 203915 ("Defendants' ANDA") submitted upon information and belief in the name of Mylan Pharmaceuticals to the United States Food and Drug Administration ("FDA").

2. Plaintiffs seek judgment that Defendants have infringed the patent-in-suit, which are 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. Defendants have infringed the patent-in-suit under 35 U.S.C.

§ 271(e)(2)(A) by filing ANDA No. 203915, submitted upon information and belief in the name of Mylan Pharmaceuticals to the FDA. Defendants' ANDA seeks approval to market a generic version of Purdue's OxyContin®, which is the subject of approved NDA No. 022272, in the 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg dosage strengths ("Defendants' ANDA Products").

THE PARTIES

3. 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, Connecticut 06901-3431. Purdue Pharma is an owner of the '933 patent, identified in paragraph 30 below. Purdue Pharma is also the holder of approved NDA No. 022272 for OxyContin®, indicated for pain severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative treatment options are inadequate. Purdue Pharma sells OxyContin® in the United States.

4. 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 '933 patent, identified in paragraph 30 below.

5. 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, Stamford, CT 06901. P.F. Labs is an owner of the '933 patent, identified in paragraph 30 below.

6. 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 '933 patent, identified in

paragraph 30 below, and is involved in the manufacture of the active pharmaceutical ingredient ("API") used in OxyContin®.

7. On information and belief, Mylan Pharmaceuticals is a corporation organized under the laws of the State of West Virginia, with its principal place of business located at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505. On information and belief, Mylan Pharmaceuticals is in the business of, *inter alia*, manufacturing and selling generic copies of branded pharmaceutical products for the U.S. market. On information and belief, Mylan Pharmaceuticals is a wholly owned subsidiary of Mylan Inc.

8. On information and belief, Mylan Inc. is a corporation organized under the laws of the Commonwealth of Pennsylvania, having its principal place of business at 1500 Corporate Drive, Canonsburg, Pennsylvania 15317. On information and belief, Mylan Inc. is in the business of, *inter alia*, marketing and selling generic copies of branded pharmaceutical products for the U.S. market, alone and/or through its wholly owned subsidiary and agent, Mylan Pharmaceuticals.

SUBJECT MATTER JURISDICTION AND VENUE

9. 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.

10. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a).

11. Venue is proper in this Court pursuant to 28 U.S.C. §§ 1391(b), 1391(c), and 1400(b).

PERSONAL JURISDICTION

12. On information and belief, this Court has personal jurisdiction over Mylan Pharmaceuticals because Mylan Pharmaceuticals has purposely availed itself of the benefits and

protections of West Virginia's laws such that it should reasonably anticipate being haled into court here. On information and belief, Mylan Pharmaceuticals has had persistent and continuous contacts with this judicial district, including, developing, manufacturing and/or selling pharmaceutical products that are sold in this judicial district.

13. On information and belief, Mylan Pharmaceuticals is incorporated under the laws of West Virginia, and has its principal place of business at 781 Chestnut Ridge Road, Morgantown, West Virginia 26505.

14. On information and belief, Mylan Pharmaceuticals is registered to do business in West Virginia, and has thereby consented to suit in West Virginia.

15. On information and belief, Mylan Pharmaceuticals has appointed the West Virginia Secretary of State as its registered agent for the receipt of service of process.

16. On information and belief, Mylan Pharmaceuticals has also appointed Corporation Service Company, 209 West Washington Street, Charleston, West Virginia 25302 as its registered agent for the receipt of service of process.

17. On information and belief, Mylan Pharmaceuticals is registered with the West Virginia Board of Pharmacy as "Manufacturer," "Wholesale Distributor," and "Medical Examiner."

18. On information and belief, Mylan Pharmaceuticals derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this judicial district.

19. On information and belief, Mylan Pharmaceuticals, itself or through one of its agents, has authorized distributors in the State of West Virginia to distribute Mylan's generic pharmaceutical products throughout the State of West Virginia.

20. On information and belief, this Court has personal jurisdiction over Mylan Inc. because Mylan Inc. has purposely availed itself of the benefits and protections of West Virginia's laws such that it should reasonably anticipate being haled into court here. On information and belief, Mylan Inc. has had persistent and continuous contacts with this judicial district, including, developing, marketing and/or selling generic pharmaceutical products that are sold in this judicial district.

21. On information and belief, Mylan Inc., directly and/or through Mylan Pharmaceuticals, markets, distributes and sells generic pharmaceutical products throughout the United States, including in this judicial district.

22. On information and belief, Mylan Inc. derives substantial revenue from selling generic pharmaceutical products throughout the United States, including in this judicial district.

23. On information and belief, Mylan Inc. is registered to do business in West Virginia, and has therefore consented to suit in West Virginia.

24. On information and belief, Mylan Inc. has appointed the West Virginia Secretary of State as its registered agent for the receipt of service of process.

25. On information and belief, Mylan Inc. has also appointed Corporation Service Company, 209 West Washington Street, Charleston, West Virginia 25302 as its registered agent for the receipt of service of process.

26. On information and belief, Mylan Inc., itself or through one of its agents, has authorized distributors in this judicial district to distribute Mylan's generic pharmaceutical products throughout this judicial district.

27. On information and belief, Mylan Pharmaceuticals acts as the agent of

Mylan Inc. and has submitted regulatory filings for generic pharmaceutical products to the FDA on behalf of Mylan Inc.

28. On information and belief, Mylan Inc. and Mylan Pharmaceuticals operate and act in concert as an integrated, unitary business.

29. On information and belief, Mylan Pharmaceuticals and Mylan Inc. have previously invoked this Court's jurisdiction, or have stipulated and/or consented to personal jurisdiction in this district in prior cases under the Hatch-Waxman Act. *See e.g. Novartis Pharmaceuticals Co. et al v. Mylan Pharmaceuticals Inc. et al*, No. 1:11-cv-00015-IMK (N. D. W. Va.); *Shire LLC et al v. Mylan Pharmaceuticals Inc. et al*, No. 1:11-cv-0055-IMK-JSK (N. D. W. Va.); *Alza Corporation et al v. Mylan Pharmaceuticals Inc. et al*, No. 1:14-cv-00086- IMK-JSK (N. D. W. Va.); *Acorda Therapeutics, Inc. et al v. Mylan Pharmaceuticals Inc. et al*, No. 1:14-cv-00139-IMK (N. D. W. Va.); *Teva Pharmaceuticals USA, Inc. et al v. Mylan Pharmaceuticals Inc. et al*, No. 1:14-cv-00167-IMK (N. D. W. Va.); *Pfizer Inc. et al v. MylanInc. et al*, No. 1:15-cv-00004-IMK (N. D. W. Va.); *Noven Pharmaceuticals, Inc. et al v. Mylan Technologies, Inc. et al*, No. 1:15-cv-00069-IMK-JSK (N. D. W. Va.).

THE PATENT-IN-SUIT

30. Purdue and Rhodes are the lawful owners of all right, title and interest in the ’933 patent, titled “OXYCODONE HYDROCHLORIDE HAVING LESS THAN 25 PPM 14-HYDROXYCODEINONE,” including the right to sue and to recover for past infringement thereof. The ’933 patent is listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272. A copy of the ’933 patent is attached hereto as Exhibit A, which was duly and legally issued on July 7, 2015, naming Robert Chapman, Lonn S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

DEFENDANTS' ANDA

31. On information and belief, on or before November 2, 2015, Defendants filed Defendants' ANDA under § 505(j) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 355(j)), seeking approval to engage in the commercial manufacture, use, sale, offer for sale, or importation of Defendants' ANDA Products, generic products based on the Reference Listed Drug OxyContin®, which is the subject of approved NDA No. 022272. On information and belief, Defendants' ANDA contained a "Paragraph IV" certification under 21 U.S.C. § 355(U)(2)(A)(vii)(IV) alleging that the '933 patent, listed in the Orange Book as covering OxyContin®, which is the subject of approved NDA No. 022272, is "invalid, unenforceable, and/or not infringed by the commercial manufacture, use or sale of" the drug products described in Defendants' ANDA.

32. In a letter dated November 2, 2015, addressed to Plaintiffs and received by Purdue Pharma on or about November 3, 2015, Defendants provided what purports to be a "Notice of Paragraph IV Certification" with respect to Defendants' ANDA and Defendants' ANDA Products, and the patent-in-suit, under § 505(j)(2)(B)(iv) of the Federal Food, Drug, and Cosmetic Act ("Notice Letter").

33. Plaintiffs commenced this action within the 45 day period after receiving the Notice Letter as described in 21 U.S.C. § 355(j)(5)(B)(iii).

FIRST CLAIM FOR RELIEF
(PATENT INFRINGEMENT OF U.S. PATENT NO. 9,073,933)

34. Purdue and Rhodes incorporate by reference and reallege paragraphs 1 through 33 above as though fully restated herein.

35. Pursuant to 35 U.S.C. § 271(e)(2), Defendants' submission of ANDA No. 203915 to the FDA seeking approval of Defendants' ANDA Products was an act of infringement

of the ’933 patent by Defendants.

36. Defendants’ ANDA Products, or the use or manufacture thereof, are covered by one or more claims of the ’933 patent, including but not limited to independent claims 1 and 16, 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 various claims dependent therefrom.

37. If approved by the FDA, Defendants’ commercial manufacture, use, importation, sale, and/or offer for sale of Defendants’ ANDA Products will infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the ’933 patent under 35 U.S.C. § 271(a)-(c).

38. Defendants’ ANDA Products constitute a material part of the inventions covered by the claims of the ’933 patent.

39. Upon information and belief, Defendants have been aware of the existence of the ’933 patent, and has no reasonable basis for believing that Defendants’ ANDA Products will not infringe the ’933 patent, thus rendering the case “exceptional,” as that term is used in 35 U.S.C. § 285.

40. Unless Defendants are enjoined by the Court, Purdue and Rhodes will be substantially and irreparably harmed by Defendants’ infringement of the ’933 patent. Purdue and Rhodes do not have an adequate remedy at law.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for judgment as follows:

A. Adjudging that Defendants have infringed one or more claims of the ’933 patent, and that the commercial sale, offer for sale, use, importation, and/or manufacture of

Defendants' ANDA Products would infringe, induce infringement of, and/or contribute to the infringement of one or more claims of each of the '933 patent;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No 203915 and Defendants' ANDA Products, under § 505(j) of the Federal Food, Drug and Cosmetic Act (21 U.S.C. § 355(j)), to be a date not earlier than the date of expiration of the '933 patent, plus any additional periods of extension or exclusivity attached thereto;

C. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., Defendants, their 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 ANDA No. 203915, including Defendants' ANDA Products or any other drug product that infringes the '933 patent;

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

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

Date: December 17, 2015

/s/ Carrie Goodwin Fenwick
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