

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

PURDUE PHARMA L.P.,  
THE P.F. LABORATORIES, INC.,  
PURDUE PHARMACEUTICALS L.P.,  
and RHODES TECHNOLOGIES,

Plaintiffs,

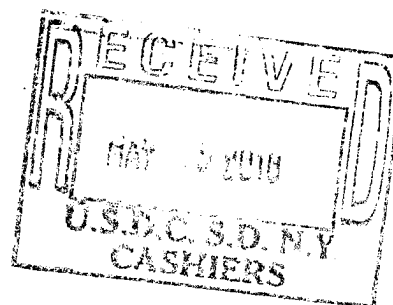
v.

RANBAXY INC.,  
RANBAXY PHARMACEUTICALS INC.,  
RANBAXY LABORATORIES LTD.,  
ACTAVIS ELIZABETH LLC,  
MYLAN PHARMACEUTICALS INC.,  
and MYLAN INC.,

Defendants.

10 CIV 3734

C.A. No. \_\_\_\_\_



**COMPLAINT**

Plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., Purdue  
Pharmaceuticals L.P., and Rhodes Technologies for their Complaint herein, 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.

**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 by assignment of the patents in suit identified in paragraphs 23-25 below, and is involved

in the sale in the United States of controlled-release oxycodone pain-relief medication under the brand name OxyContin<sup>®</sup>.

3. 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 700 Union Boulevard, Totowa, NJ 07512. P.F. Labs is an owner by assignment of the patents in suit identified in paragraphs 23-25 below, and is involved in the manufacture of controlled-release oxycodone pain-relief medication under the brand name OxyContin<sup>®</sup>.

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 by assignment of the patents in suit identified in paragraphs 23-25 below, and is involved in the manufacture of controlled-release oxycodone pain-relief medication under the brand name OxyContin<sup>®</sup>.

5. 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 by assignment of the patents in suit identified in paragraphs 23-25 below, and is involved in the manufacture of controlled-release oxycodone pain-relief medication under the brand name OxyContin<sup>®</sup>.

6. Upon information and belief, Defendant Ranbaxy Inc. (“RI”) is a corporation organized and existing under the laws of the State of Delaware, having its principal place of business at 600 College Road East, Suite 2100, Princeton, NJ 08540.

7. Upon information and belief, Defendant Ranbaxy Pharmaceuticals Inc. (“RPI”) is a corporation organized and existing under the laws of the State of Florida, having its principal place of business at 9431 Florida Mining Boulevard East, Jacksonville, FL 32257.

8. Upon information and belief, Defendant Ranbaxy Laboratories Ltd. (“RLL”) is a corporation organized under the laws of India, having its principal place of business at Plot No. 90, Sector 32, Gurgaon – 122 001 (Haryana), India.

9. Upon information and belief, RI is a wholly owned subsidiary of RLL.

10. Upon information and belief, RPI is a wholly owned subsidiary of RLL.

11. Upon information and belief, the acts of RLL complained of herein, were done at the direction of, with the authorization of, and with the cooperation, participation, and assistance of RPI and RI.

12. RI, RPI, and RLL are referred hereinafter collectively as “Ranbaxy.”

13. Upon information and belief, Defendant Actavis Elizabeth LLC (“Actavis”) is a limited liability company organized and existing under the laws of the State of Delaware, having its principal place of business at 200 Elmora Avenue, Elizabeth, NJ 07207.

14. Upon information and belief, Defendant Mylan Pharmaceuticals Inc. (“MPI”) is a corporation organized and existing under the laws of the State of West Virginia, having its principal place of business at 781 Chestnut Ridge Road, Morgantown, WV 26505.

15. Upon information and belief, Defendant Mylan Inc. (“MI”) is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having its principal place of business at 1500 Corporate Drive, Canonsburg, PA 15317.

16. Upon information and belief, MPI is a wholly owned subsidiary of MI.

17. MPI and MI are referred hereinafter collectively as “Mylan.”

## JURISDICTION AND VENUE

18. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), and 2201.

19. This Court has personal jurisdiction over Ranbaxy because, *inter alia*, Ranbaxy has purposefully availed itself of the rights and benefits of the laws of this State and this Judicial District. Upon information and belief, Ranbaxy engages in the manufacture and sale of a range of pharmaceutical products within and directed to the United States and this Judicial District specifically. Upon information and belief, Ranbaxy has previously consented to personal jurisdiction in this Judicial District.

20. This Court has personal jurisdiction over Actavis because, *inter alia*, Actavis has purposefully availed itself of the rights and benefits of the laws of this State and this Judicial District. Upon information and belief, Actavis engages in the manufacture and sale of a range of pharmaceutical products within and directed to the United States and this Judicial District specifically. Upon information and belief, Actavis has previously consented to personal jurisdiction in this Judicial District.

21. This Court has personal jurisdiction over Mylan because, *inter alia*, Mylan has purposefully availed itself of the rights and benefits of the laws of this State and this Judicial District. Upon information and belief, Mylan engages in the manufacture and sale of a range of pharmaceutical products within and directed to the United States and this Judicial District specifically. Upon information and belief, Mylan Inc. operates offices at 405 Lexington Avenue, New York, NY 10174. Upon information and belief, Mylan has previously consented to personal jurisdiction in this Judicial District.

22. Venue is proper in this Judicial District under 28 U.S.C. §§ 1391(b) and (c) and § 1400(b).

**THE PATENTS IN SUIT**

23. Purdue Pharma, P.F. Labs, Purdue Pharmaceuticals, and Rhodes are the lawful owners of all right, title and interest in United States Patent No. 7,674,799 entitled “OXYCODONE HYDROCHLORIDE HAVING LESS THAN 25 PPM 14-HYDROXYCODEINONE” (“the ’799 patent”), including all right to sue and to recover for past infringement thereof, which patent is listed in the U.S. Food and Drug Administration’s (“FDA”) “Orange Book” (*Approved Drug Products With Therapeutic Equivalence Evaluation*) as covering the drug OxyContin<sup>®</sup>, which is the subject of approved New Drug Application (“NDA”) No. 20-553. A copy of the ’799 patent is attached hereto as Exhibit A, which was duly and legally issued on March 9, 2010, naming Robert Chapman, Lon S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

24. Purdue Pharma, P.F. Labs, Purdue Pharmaceuticals, and Rhodes are the lawful owners of all right, title and interest in United States Patent No. 7,674,800 entitled “OXYCODONE HYDROCHLORIDE HAVING LESS THAN 25 PPM 14-HYDROXYCODEINONE” (“the ’800 patent”), 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<sup>®</sup>, which is the subject of approved NDA No. 20-553. A copy of the ’800 patent is attached hereto as Exhibit B, which was duly and legally issued on March 9, 2010, naming Robert Chapman, Lon S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

25. Purdue Pharma, P.F. Labs, Purdue Pharmaceuticals, and Rhodes are the lawful owners of all right, title and interest in United States Patent No. 7,683,072 entitled

“OXYCODONE HYDROCHLORIDE HAVING LESS THAN 25 PPM 14-HYDROXYCODEINONE” (“the ’072 patent”), 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<sup>®</sup>, which is the subject of approved NDA No. 20-553. A copy of the ’072 patent is attached hereto as Exhibit C, which was duly and legally issued on March 23, 2010, naming Robert Chapman, Lon S. Rider, Qi Hong, Donald Kyle, and Robert Kupper as the inventors.

### **RANBAXY’S ANDA**

26. Upon information and belief, in 2009, RLL submitted Abbreviated New Drug Application No. 78-093 (“Ranbaxy’s ANDA”) to the FDA, 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, offer for sale or sale of generic oxycodone hydrochloride extended release tablets “which contain[] the equivalent of 10, 20, 40, and 80 mg/tablet of oxycodone hydrochloride as the active ingredient” (“the Ranbaxy Tablets”), based on the Reference Listed Drug (“RLD”) OxyContin<sup>®</sup> which is the subject of approved NDA No. 20-553.

27. The ’799, ’800, and ’072 patents subsequently issued and were listed in the FDA’s Orange Book as covering the drug OxyContin<sup>®</sup>, which is the subject of approved NDA No. 20-553.

28. Upon information and belief, Ranbaxy has amended ANDA No. 78-093 or otherwise has made a request to the FDA to seek approval to engage in the commercial manufacture, use, offer for sale or sale of Ranbaxy Tablets before the expiration of the ’799, ’800, and ’072 patents.

29. Upon information and belief, Ranbaxy’s ANDA contains a “Paragraph IV” certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the ’799, ’800, and ’072

patents, listed in the FDA's Orange Book as covering the drug OxyContin<sup>®</sup>, which is the subject of approved NDA No. 20-553, are "invalid, unenforceable, and/or will not be infringed by Ranbaxy's manufacture, importation, use, or sale of Ranbaxy's oxycodone hydrochloride products."

30. In a letter dated March 24, 2010 addressed to Purdue Pharma, Ranbaxy provided "notice" with respect to the Ranbaxy Tablets and the '799 and '800 patents under 21 U.S.C. § 355(j)(2)(B)(ii).

31. In a letter dated April 8, 2010 addressed to Purdue Pharma, Ranbaxy provided "notice" with respect to the Ranbaxy Tablets and the '072 patent under 21 U.S.C. § 355(j)(2)(B)(ii).

32. Ranbaxy's submission of its ANDA was an act of infringement of the '799, '800, and '072 patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

33. Upon information and belief, the Ranbaxy Tablets are covered by one or more claims of the '799, '800, and '072 patents.

34. Upon information and belief, Ranbaxy's commercial manufacture, use, sale, and/or offer for sale of the Ranbaxy Tablets would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '799, '800, and '072 patents.

35. Upon information and belief, Ranbaxy has been aware of the existence of the '799, '800, and '072 patents, and has no reasonable basis for believing that the Ranbaxy Tablets will not infringe the '799, '800, and '072 patents, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

36. The acts of infringement by Ranbaxy set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

### ACTAVIS'S ANDA

37. Upon information and belief, Actavis submitted Abbreviated New Drug Application No. 200455 (“Actavis’s ANDA”) to the FDA, 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, offer for sale or sale of Oxycodone Hydrochloride ER Tablets 10 mg, 20 mg, 40 mg, and 80 mg (“the Actavis Tablets”), based on the Reference Listed Drug (“RLD”) OxyContin<sup>®</sup> which is the subject of approved NDA No. 20-553, before the expiration of the ’799, ’800, and ’072 patents.

38. Upon information and belief, Actavis’s ANDA contains a “Paragraph IV” certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the ’799, ’800, and ’072 patents, listed in the FDA’s Orange Book as covering the drug OxyContin<sup>®</sup>, which is the subject of approved NDA No. 20-553, are “invalid, unenforceable or will not be infringed by the commercial manufacture, use, importation, offer for sale or sale of the [Actavis Tablets].”

39. In a letter dated April 8, 2010 addressed to Purdue Pharma, Actavis provided “notice” with respect to the Actavis Tablets and the ’799, ’800, and ’072 patents under 21 U.S.C. § 355(j)(2)(B)(ii).

40. Actavis’s submission of its ANDA was an act of infringement of the ’799, ’800, and ’072 patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

41. Upon information and belief, the Actavis Tablets are covered by one or more claims of the ’799, ’800, and ’072 patents.



42. Upon information and belief, Actavis's commercial manufacture, use, sale, and/or offer for sale of the Actavis Tablets would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '799, '800, and '072 patents.

43. Upon information and belief, Actavis has been aware of the existence of the '799, '800, and '072 patents, and has no reasonable basis for believing that the Actavis Tablets will not infringe the '799, '800, and '072 patents, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

44. The acts of infringement by Actavis set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

#### **MYLAN'S ANDA**

45. Upon information and belief, MPI submitted Abbreviated New Drug Application No. 200692 ("Mylan's ANDA") to the FDA, 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, offer for sale or sale of oxycodone hydrochloride 10 mg, 15 mg, 20 mg, 30 mg, 40 mg, 60 mg and 80 mg extended-release oral tablets ("the Mylan Tablets"), based on the Reference Listed Drug ("RLD") OxyContin<sup>®</sup> which is the subject of approved NDA No. 20-553, before the expiration of the '799, '800, and '072 patents.

46. Upon information and belief, Mylan's ANDA contains a "Paragraph IV" certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that "[n]o valid claim of the ['799, '800, and '072 patents, listed in the FDA's Orange Book as covering the drug OxyContin<sup>®</sup> which is the subject of approved NDA No. 20-553,] will be infringed by the manufacture, use, sale or importation of [the Mylan Tablets]."

47. In a letter dated April 1, 2010 addressed to Purdue Pharma, Mylan provided “notice” with respect to the 40 mg Mylan Tablet and the ’799 and ’800 patents under 21 U.S.C. § 355(j)(2)(B)(ii).

48. In a letter dated April 7, 2010 addressed to Purdue Pharma, Mylan provided “notice” with respect to the 40 mg Mylan Tablet and the ’072 patent under 21 U.S.C. § 355(j)(2)(B)(ii).

49. In a letter dated April 9, 2010 addressed to Purdue Pharma, Mylan provided “notice” with respect to the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg and 80 mg Mylan Tablets and the ’799 and ’800 patents under 21 U.S.C. § 355(j)(2)(B)(ii).

50. In a letter dated April 9, 2010 addressed to Purdue Pharma, Mylan provided “notice” with respect to the 10 mg, 15 mg, 20 mg, 30 mg, 60 mg and 80 mg Mylan Tablets and the ’072 patent under 21 U.S.C. § 355(j)(2)(B)(ii).

51. Mylan’s submission of its ANDA was an act of infringement of the ’799, ’800, and ’072 patents under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

52. Upon information and belief, the Mylan Tablets are covered by one or more claims of the ’799, ’800, and ’072 patents.

53. Upon information and belief, Mylan’s commercial manufacture, use, sale, and/or offer for sale of the Mylan Tablets would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the ’799, ’800, and ’072 patents.

54. Upon information and belief, Mylan has been aware of the existence of the ’799, ’800, and ’072 patents, and has no reasonable basis for believing that the Mylan Tablets will not infringe the ’799, ’800, and ’072 patents, thus rendering the case “exceptional,” as that term is used in 35 U.S.C. § 285.

55. The acts of infringement by Mylan set forth above will cause Plaintiffs irreparable harm for which they have no adequate remedy at law, and will continue unless enjoined by this Court.

WHEREFORE, Plaintiffs pray for judgment:

A. Adjudging that Ranbaxy has infringed the '799, '800, and '072 patents, and that the commercial sale, offer for sale, use, and/or manufacture of the Ranbaxy Tablets would infringe, induce infringement of, and/or contribute to the infringement of the '799, '800, and '072 patents;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Ranbaxy's ANDA No. 78-093, 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 '799, '800, and '072 patents 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., Ranbaxy, its officers, 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 '799, '800, and '072 patents;

D. Adjudging that Actavis has infringed the '799, '800, and '072 patents, and that the commercial sale, offer for sale, use, and/or manufacture of the Actavis Tablets would infringe, induce infringement of, and/or contribute to the infringement of the '799, '800, and '072 patents;

E. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Actavis's ANDA No. 200455, 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 '799, '800, and '072 patents plus any additional periods of exclusivity;

F. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., Actavis, its officers, 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 '799, '800, and '072 patents;

G. Adjudging that Mylan has infringed the '799, '800, and '072 patents, and that the commercial sale, offer for sale, use, and/or manufacture of the Mylan Tablets would infringe, induce infringement of, and/or contribute to the infringement of the '799, '800, and '072 patents;

H. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of Mylan's ANDA No. 200692, 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 '799, '800, and '072 patents plus any additional periods of exclusivity;

I. Preliminarily and permanently enjoining, pursuant to 35 U.S.C. §§ 271(e)(4)(B) and 283 and Rule 65, Fed. R. Civ. P., Mylan, its officers, 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

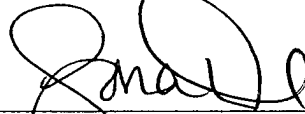
and assigns, from any commercial manufacture, use, offer to sell, or sale within the United States, or importation into the United States, of any drug product that infringes the '799, '800, and '072 patents;

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

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

May 5, 2010

ROPES & GRAY LLP



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