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

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

Plaintiffs,

v.

RANBAXY INC.,
RANBAXY PHARMACEUTICALS INC.,
and RANBAXY LABORATORIES LTD.,

Defendants.

C.A. No. _____

COMPLAINT

Plaintiffs Purdue Pharma L.P., The P.F. Laboratories, Inc., and Purdue Pharmaceuticals L.P. 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, Connecticut 06901-3431. Purdue Pharma is an owner by assignment of the patent in suit identified in paragraph 15 below, and is involved in the sale in the United States of controlled-release oxycodone pain-relief medication under the brand name OxyContin.®

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 patent in suit identified in paragraph 15 below, and is involved in the manufacture of controlled-release oxycodone pain-relief medication under the brand name OxyContin.®

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 patent in suit identified in paragraph 15 below, and is involved in the manufacture of controlled-release oxycodone pain-relief medication under the brand name OxyContin.®

5. 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, New Jersey 08540.

6. 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.

7. 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.

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

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

10. 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.

11. RI, RPI, and RLL are referred hereinafter, collectively as "Ranbaxy."

JURISDICTION AND VENUE

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

13. 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.

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

THE PATENT IN SUIT

15. Purdue Pharma, P.F. Labs, and Purdue Pharmaceuticals are the lawful owners of all right, title and interest in United States Patent No. 5,508,042 entitled "CONTROLLED RELEASE OXYCODONE COMPOSITIONS" ("the '042 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 OxyContin.® A copy of the '042 patent is attached hereto as Exhibit A, which was duly and legally issued on April 16, 1996, naming Benjamin Oshlack, Mark Chasin, John J. Minogue and Robert F. Kaiko as the inventors.

RANBAXY'S ANDA

16. Upon information and belief, RLL submitted Abbreviated New Drug Application No. 78-093 ("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 extended release tablets "which contain[] the equivalent of 15, 30 and 60 mg/tablet [10, 15, 20, 30, 40, 60, 80 mg/tablet] of oxycodone hydrochloride as the active ingredient" ("the Ranbaxy Tablets"), a generic version of Plaintiff's OxyContin,® before the expiration of the '042 patent.

17. 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 '042 patent, listed in the FDA's Orange Book as covering the drug OxyContin,® is "invalid, unenforceable, and/or will not be infringed by Ranbaxy's manufacture, importation, use, or sale of Ranbaxy's oxycodone hydrochloride products."

18. In a letter dated September 24, 2009 addressed to Purdue Pharma, Ranbaxy provided "notice" with respect to the Ranbaxy Tablets and the '042 patent under 21 U.S.C. § 355(j)(2)(B)(ii) ("Ranbaxy's Notice Letter").

19. Ranbaxy's submission of its ANDA was an act of infringement of the '042 patent under the United States Patent Law, 35 U.S.C. § 271(e)(2)(A).

20. Upon information and belief, the method of using the Ranbaxy Tablets are covered by one or more claims of the '042 patent.

21. 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 '042 patent.

22. Upon information and belief, Ranbaxy has been aware of the existence of the '042 patent, and has no reasonable basis for believing that the Ranbaxy Tablets will not infringe the '042 patent, thus rendering the case "exceptional," as that term is used in 35 U.S.C. § 285.

23. 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.

WHEREFORE, Plaintiffs pray for judgment:

A. Adjudging that Ranbaxy has infringed the '042 patent, and that the commercial sale, offer for sale, and/or manufacture of the Ranbaxy Tablets would infringe, induce infringement of, and/or contribute to the infringement of the '042 patent;

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 '042 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., 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 '042 patent;

D. Declaring this an exceptional case and awarding Plaintiffs their attorneys' fees, 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.

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October 20, 2009

EXHIBIT A

US005508042A

United States Patent [19]

Oshlack et al.

[11] Patent Number: 5,508,042

[45] Date of Patent: Apr. 16, 1996

[54] **CONTROLLED RELEASE OXYCODONE COMPOSITIONS**

[75] Inventors: **Benjamin Oshlack**, New York, N.Y.; **Mark Chasin**, Manalpan, N.J.; **John J. Minogue**, Mount Vernon, N.Y.; **Robert F. Kaiko**, Weston, Conn.

[73] Assignee: **Euro-Celtigue, S.A.**, Luxembourg, Luxembourg

[21] Appl. No.: **467,584**

[22] Filed: **Jun. 6, 1995**

Related U.S. Application Data

[60] Division of Ser. No. 81,302, Jun. 18, 1993, which is a continuation-in-part of Ser. No. 800,549, Nov. 27, 1991, Pat. No. 5,266,331.

[51] **Int. Cl.**[6] **A61K 9/22**; A61K 9/26

[52] **U.S. Cl.** **424/468**; 424/469; 424/470; 424/486; 424/487; 424/488; 424/494; 424/496; 424/497; 424/498; 424/501; 424/502; 424/495

[58] **Field of Search** 424/486, 464, 424/465, 468–469, 470, 487–488, 49–98, 494

[56] **References Cited**

U.S. PATENT DOCUMENTS

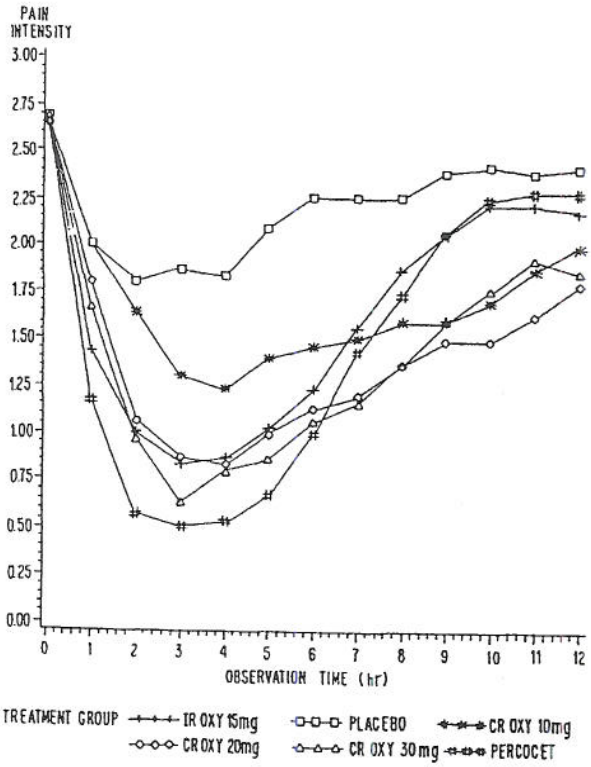
4,862,598	8/1989	Oshlack	424/470
4,990,341	2/1991	Goldie et al.	424/484
5,266,331	11/1993	Oshlack et al.	424/468

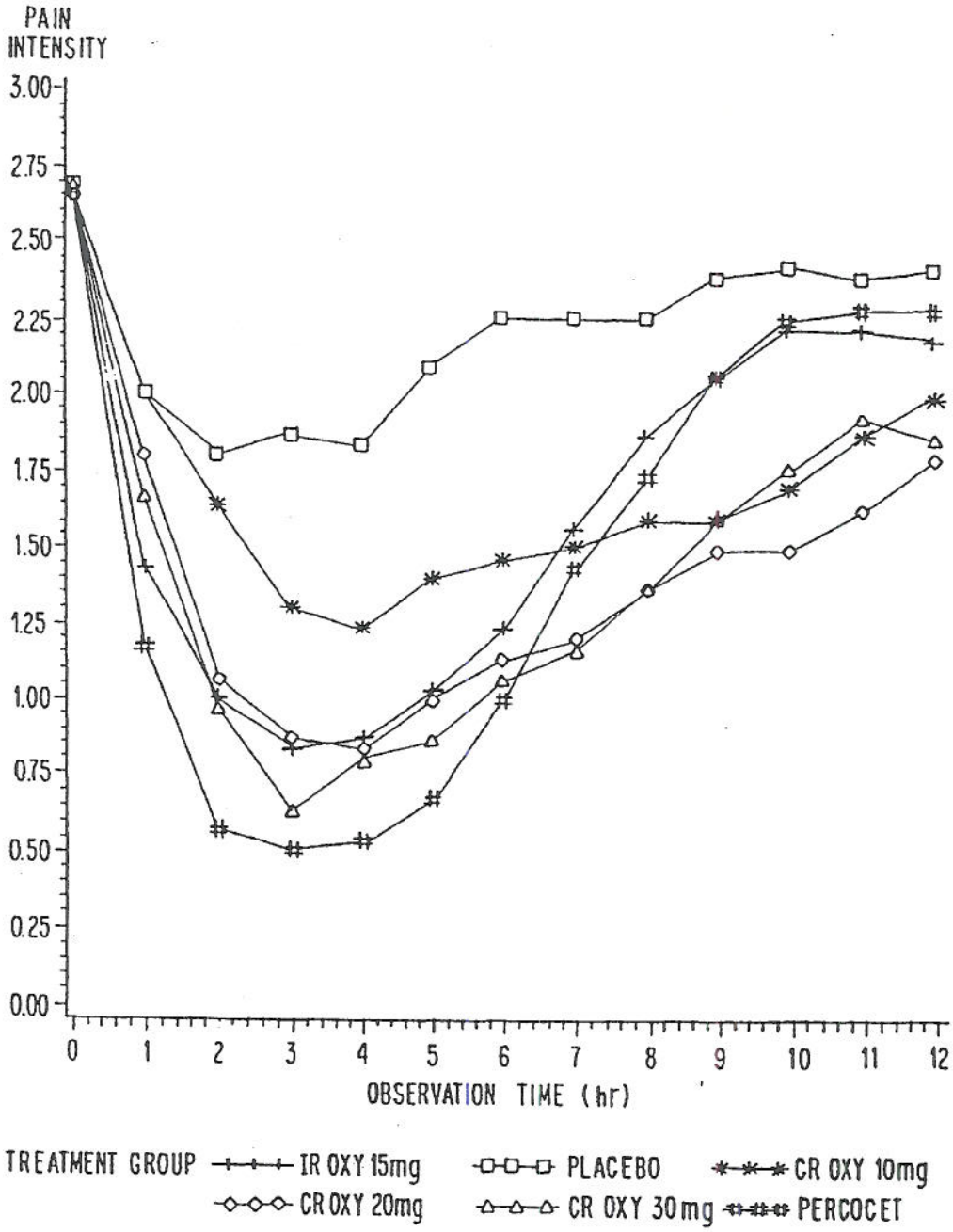
Primary Examiner—Edward J. Webman
Attorney, Agent, or Firm—Steinberg, Raskin & Davidson

[57] **ABSTRACT**

A method for substantially reducing the range in daily dosages required to control pain in approximately 90% of patients is disclosed whereby an oral solid controlled release dosage formulation having from about 10 to about 40 mg of oxycodone or a salt thereof is administered to a patient. The formulation provides a mean maximum plasma concentration of oxycodone from about 6 to about 60 ng/ml from a mean of about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration from about 3 to about 30 ng/ml from about 10 to about 14 hours after repeated "q12h" (i.e. every 12 hour) administration through steady-state conditions. Another embodiment is directed to a method for substantially reducing the range in daily dosages required to control pain in substantially all patients by administering an oral solid controlled release dosage formulation comprising up to about 160 mg of oxycodone or a salt thereof, such that a mean maximum plasma concentration of oxycodone up to about 240 ng/ml from a mean of up to about 2 to about 4.5 hours after administration, and a mean minimum plasma concentration up to about 120 ng/ml from about 10 to about 14 hours after repeated "q12h" (i.e., every 12 hour) administration through steady-state conditions are achieved. Controlled release oxycodone formulations for achieving the above are also disclosed.

2 Claims, 5 Drawing Sheets

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2.50
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2.00
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1.50
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1.00
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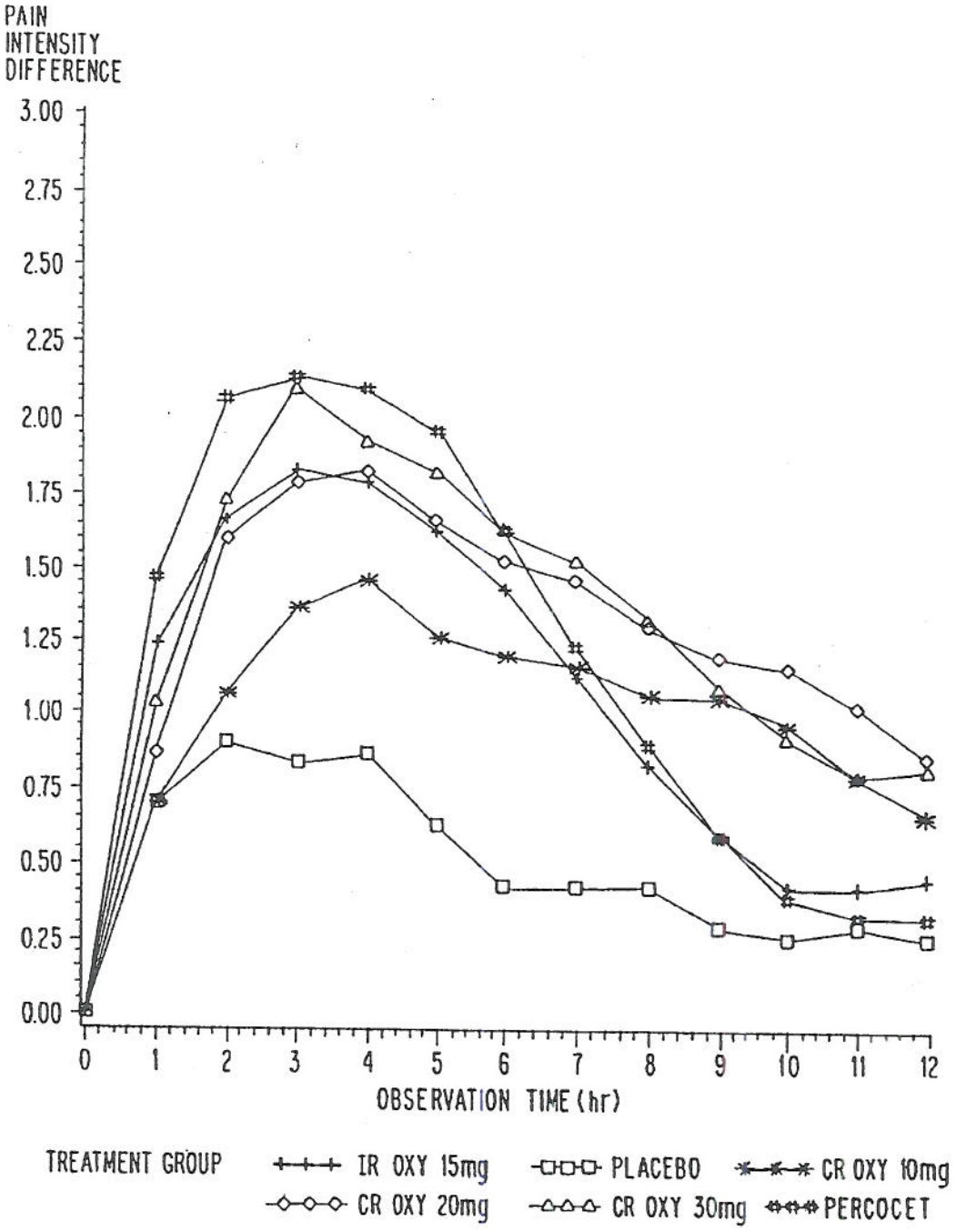
0.50
0.25
0.00
0
1
2
3
4
5
6
7
8
9
10
11
12
OBSERVATION TIME (hr)
TREATMENT GROUP
IR OXY 15mg
PLACEBO
CR OXY 10mg
CR OXY 20mg
CR OXY 30mg
PERCOCET

FIG. 1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11
12
OBSERVATION TIME (hr)
TREATMENT GROUP
IR OXY 15mg
PLACEBO
CR OXY 10mg
CR OXY 20mg
CR OXY 30mg
PERCOCET

FIG.2