

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,

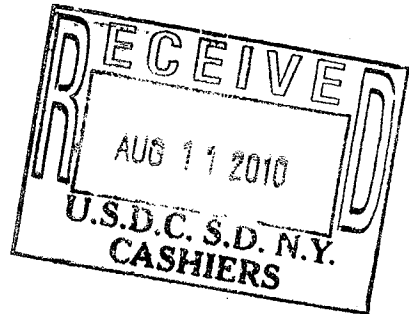
v.

VARAM, INC. and KVK-TECH, INC.

Defendants.

**10 CIV 6038**

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: PLAINTIFFS**

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 patents in suit identified in paragraphs 20-23 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 of the patents in suit identified in paragraphs 20-23 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 of the patents in suit identified in paragraphs 20-23 below, and is involved in the manufacture of controlled-release oxycodone pain-relief medication under the brand name OxyContin®.

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 of the patents in suit identified in paragraphs 21-23 below, and is involved in the manufacture of controlled-release oxycodone pain-relief medication under the brand name OxyContin®.

#### **THE PARTIES: DEFENDANTS**

6. Upon information and belief, Defendant Varam, Inc. (“Varam”) is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, having a registered address of 110 Terry Drive, Suite 200, Newtown, PA 18940.

7. On certain correspondence sent to Plaintiffs, Varam has also used as an address 5775 Lower York Road, P.O. Box 700, Lahaska, PA, 18931.

8. Upon information and belief, Defendant KVK-Tech, Inc. (“KVK”) is a corporation organized and existing under the laws of the Commonwealth of Pennsylvania with

its principal place of business at 110 Terry Drive, Suite 200, Newtown, PA 18940, the same address used by Varam.

9. Upon information and belief, Varam was incorporated by Frank A. Nekoranik on February 9, 2010. Upon information and belief, Mr. Nekoranik and the Chief Executive Officer of KVK, Frank Ripp Jr., are partners in at least one other business known as Biz-Visors, Inc.

10. Upon information and belief, on February 19, 2010, ten days after incorporating Varam, Frank Nekoranik incorporated KVK Research Inc. and KVK Bio Inc., both of which have registered offices in Bucks County, Pennsylvania that are the same as an address used by Varam: 5775 Lower York Road, P.O. Box. 700, Lahaska, PA, 18931.

11. Upon information and belief, 110 Terry Drive, Newtown, PA is the site of KVK's pharmaceutical manufacturing facility.

12. Upon information and belief, KVK manufactures generic immediate release oxycodone hydrochloride tablets at 110 Terry Drive, Newtown, PA.

13. Upon information and belief, KVK is registered as a Pharmacy Establishment in the State of New York by the New York State Department of Education, Office of the Professions. (Registration No. 028111). The Registration has an active status and is valid through August 31, 2012.

14. Upon information and belief, KVK has a License to Engage in Controlled Substance Activity, issued by the New York State Department of Health, Bureau of Narcotic Enforcement (License No. 01A0178). The License has an active status and expires April 20, 2012.

15. Upon information and belief, Varam and KVK are in the same corporate family, are sister companies, corporate affiliates, subsidiaries, child and/or parent companies, and/or agents of each other.

**JURISDICTION AND VENUE**

16. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201 and 2202.

17. This Court has personal jurisdiction over KVK because, *inter alia*, KVK has purposefully availed itself of the rights and benefits of the laws of this State and this Judicial District. Upon information and belief, KVK does business in this State and this Judicial District, has engaged in continuous and systematic contact with this State and this Judicial District, and derives substantial revenue from things used or consumed in this State and this Judicial District. Upon information and belief, KVK engages in the sale of pharmaceutical products within and directed to the United States and this Judicial District specifically. Furthermore, this Court has personal jurisdiction over KVK because KVK has a License to Engage in Controlled Substance Activity, issued by the New York State Department of Health, Bureau of Narcotic Enforcement, and is registered as a Pharmacy Establishment in the State of New York by the New York State Department of Education, Office of the Professions.

18. This Court also has personal jurisdiction over Varam because, *inter alia*, Varam, has purposefully availed itself of the rights and benefits of the laws of this State and this Judicial District. Upon information and belief, Varam, either directly or indirectly through KVK as alleged above, does business in this State and this Judicial District, has engaged in continuous and systematic contact with this State and this Judicial District, and derives substantial revenue from things used or consumed in this State and this Judicial District. In addition, upon

information and belief, KVK and Varam are in active concert preparing to make the proposed generic copies of OxyContin<sup>®</sup> that are the subject of ANDA No. 20-1523, and to use, sell and offer for sale such generic copies in this State and this Judicial District.

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

### **THE PATENTS IN SUIT**

20. 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,<sup>®</sup> which is the subject of approved New Drug Application (“NDA”) No. 20-553. 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.

21. 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 FDA’s Orange Book 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 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.

22. 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 C, 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.

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. 7,683,072 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 D, 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.

#### **DEFENDANTS' ANDA**

24. Upon information and belief, Varam submitted Abbreviated New Drug Application No. 20-1523 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, sale, offer for sale or importation of generic oxycodone hydrochloride extended release tablets based

on the Reference Listed Drug (“RLD”) OxyContin<sup>®</sup>, which is the subject of approved NDA No. 20-553, (“proposed generic copies of OxyContin<sup>®</sup>”) before the expiration of the ’042, ’799, ’800, and ’072 patents.

25. Upon information and belief, Varam and KVK were actively involved in the preparation and are actively involved in the prosecution before the U.S. Food and Drug Administration of ANDA No. 20-1523.

26. Upon information and belief, Varam and KVK are actively involved in the planning to manufacture, market, sell and/or distribute the proposed generic copies of OxyContin<sup>®</sup> if ANDA No. 20-1523 is approved by the FDA.

27. Upon information and belief, ANDA No. 20-1523 contains a “Paragraph IV” certification under 21 U.S.C. § 355(j)(2)(A)(vii)(IV) alleging that the ’042, ’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 the manufacture, use, sale, offer for sale or importation of [the proposed generic copies of OxyContin<sup>®</sup>].”

28. In a letter dated June 28, 2010 addressed to Plaintiffs, Varam provided “notice” with respect to its proposed generic copies of OxyContin<sup>®</sup> and the ’042, ’799, ’800, and ’072 patents under 21 U.S.C. § 355(j)(2)(B) (“Notice Letter”).

29. Varam did not include with its Notice Letter an Offer of Confidential Access pursuant to 21 U.S.C. § 355(j)(5)(C)(i)(III).

30. In a letter dated July 9, 2010, Plaintiffs requested that Varam provide Plaintiffs with material on a confidential basis to assist Plaintiffs in evaluating whether to bring a patent infringement suit against Varam. Plaintiffs included a proposed Confidential Disclosure

Agreement because Varam did not include an Offer of Confidential Access with its Notice Letter.

31. On August 2, 2010, having had no response from Varam regarding Plaintiffs' July 9, 2010 letter, Plaintiffs telephoned Varam to inquire whether the letter had been received. On August 3, 2010, Frank Nekoranik telephoned Plaintiffs stating that Varam had received Plaintiffs' letter and would respond. To date, Varam has not responded to Plaintiffs' letter.

32. Varam's submission of ANDA No. 20-1523, with active assistance and involvement by KVK, is an act of infringement of the '042, '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 proposed generic copies of OxyContin<sup>®</sup> are covered by one or more claims of the '042, '799, '800, and '072 patents.

34. Upon information and belief, commercial sale, offer for sale, use, and/or manufacture of the proposed generic copies of OxyContin<sup>®</sup> would infringe, contribute to the infringement of, and/or induce the infringement of one or more claims of the '042, '799, '800, and '072 patents.

35. Upon information and belief, Varam and KVK have been aware of the existence of the '042, '799, '800, and '072 patents, and have no reasonable basis for believing that the commercial sale, offer for sale, use, and/or manufacture of the proposed generic copies of OxyContin<sup>®</sup> will not infringe, contribute to the infringement of, and/or induce the infringement of the '042, '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 Varam and KVK 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 Varam and KVK have infringed the '042, '799, '800, and '072 patents, and that the commercial sale, offer for sale, use, and/or manufacture of the proposed generic copies of OxyContin<sup>®</sup> described in ANDA No. 20-1523 would infringe, induce infringement of, and/or contribute to the infringement of the '042, '799, '800, and '072 patents;

B. Adjudging, pursuant to 35 U.S.C. § 271(e)(4)(A), the effective date of any approval of ANDA No. 20-1523, 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, '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., Varam and KVK, 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 infringes the '042, '799, '800, and '072 patents;

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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ROPES & GRAY LLP



Pablo D. Hendler  
Sona De  
1211 Avenue of the Americas  
New York, NY 10036  
(212) 596-9000  
[pablo.hendler@ropesgray.com](mailto:pablo.hendler@ropesgray.com)  
[sona.de@ropesgray.com](mailto:sona.de@ropesgray.com)

Robert J. Goldman  
Sasha G. Rao  
1900 University Avenue, 6th Floor  
East Palo Alto, CA 94303  
(650) 617-4000  
[robert.goldman@ropesgray.com](mailto:robert.goldman@ropesgray.com)  
[sasha.rao@ropesgray.com](mailto:sasha.rao@ropesgray.com)

*Attorneys for Plaintiffs  
Purdue Pharma L.P.,  
The P.F. Laboratories, Inc.,  
Purdue Pharmaceuticals L.P.,  
and Rhodes Technologies*