

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

KASHIV PHARMA, LLC,
Petitioner

v.

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

Case IPR2018-00625
Case IPR2018-00717
U.S. Patent No. 9,492,392
U.S. Patent No. 9,492,393

(Exhibit 2029)

**DECLARATION OF STEPHEN BYRN, Ph.D. IN SUPPORT OF
PATENT OWNERS' PRELIMINARY RESPONSE
TO PETITION FOR INTER PARTES REVIEW**

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I, Stephen Byrn, hereby declare:

I. INTRODUCTION

1. I am a U.S. citizen and a resident of Indiana.
2. I am the Charles B. Jordan Professor of Medicinal Chemistry in the Department of Industrial and Physical Pharmacy at Purdue University.
3. I am also a consultant with an independent organization, Improved Pharma LLC, which is a pharmaceutical research and information company that my wife and I founded to provide pharmaceutical research and information, including analyzing drug substances and drug products, formulating drug products, and consulting on dosage forms and regulatory issues, as well as consulting for pharmaceutical litigation.
4. Improved Pharma and I have been retained in this proceeding by Jones Day, counsel for patent owners Purdue Pharma L.P., The P.F. Laboratories, Inc., and Purdue Pharmaceuticals L.P. (collectively, “Purdue Pharma”), to consider Kashiv Pharma, LLC’s (“Kashiv”) Petition for Inter Partes Review of U.S. Patent No. 9,492,392 (IPR2018-00625) (“IPR625 Petition”) and U.S. Patent No. 9,492,393 (IPR2018-00717) (“IPR717 Petition”), including the Declaration of Dr. Omidian (“Dr. Omidian’s Declaration”). I make this declaration in support of Purdue Pharma’s Preliminary Response to the IPR625 Petition IPR717 Petition and in response to Dr. Omidian’s Declaration.

5. The 1000-series exhibit cites in this declaration are to the exhibits to the Petition. The 2000-series exhibits cites are to the exhibits to the Preliminary Response.

6. Improved Pharma LLC is being compensated at the usual rate of \$650 per hour for my time of which I receive \$650 per hour. My compensation does not depend in any way on the substance of my testimony or on the outcome of this or any other proceeding.

A. Background, Experience, and Qualifications

7. I received a Ph.D. in Chemistry from the University of Illinois in 1970 and was a post-doctoral fellow at UCLA from 1970 to 1972. In 1972, I became a Professor of Pharmacy at Purdue University. I was Head of the Department of Medicinal Chemistry and Pharmacognosy at Purdue University in the School of Pharmacy and Pharmaceutical Sciences from 1988 to 1994. I was the Director of the Center for AIDS Research at Purdue University from 1988 until 1998, and since 1994, I have been the Head of the Department of Industrial and Physical Pharmacy. I became the Charles B. Jordan Professor of Medicinal Chemistry in 1992.

8. I am an author of over 180 peer-reviewed publications in technical journals on topics relating to solid-state chemistry, formulation, X-ray crystallography, stability, medicinal chemistry, chemistry, among other things. I

am also co-author of the leading book in the field of solid-state chemistry of pharmaceuticals, "Solid Chemistry of Drugs." I have organized and taught numerous courses in solid-state chemistry, manufacturing, analysis and related areas. I have also taught at the federal Food and Drug Administration, and I have also given over 270 invited lectures and symposium talks and presentations on solid-state chemistry, polymorphs, and similar topics, as well as abuse deterrence.

9. My current research focuses on formulation and solid-state chemistry, specifically related to abuse-deterrent products; amorphous formulations of anticancer drugs; formulation of antiviral drugs; and formulation of drugs for rare diseases, including tuberculosis, leprosy, worms, and other diseases prominent in Africa. I am also doing extensive work at Argonne National Laboratories, where I utilize synchrotron x-rays to analyze amorphous and liquid-crystal drugs. In the past, I have done extensive work on the solid-state chemistry of drugs and related areas as outlined in my publications and teaching activities in my curriculum vitae (Exhibit 1.)

10. Under my supervision, over 50 students and post-doctoral associates have published numerous papers and theses on many different compounds and formulations. I currently have two Ph.D. students, one senior scientist, one master's student, and two Pharm. D. and undergraduate students working in my laboratory on a range of projects including, abuse-deterrent formulations,

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