UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE PATENT TRIAL AND APPEAL BOARD

AMNEAL PHARMACEUTICALS, LLC
Petitioner

v.

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

Cases IPR2016-01027 and IPR2016-01028[1]
U.S. Patent No. 9,060,976

(Exhibit 2097)

DECLARATION OF BENJAMIN OSHLACK

[1] The word-for-word identical paper is filed in each proceeding identified in the heading.

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I, Benjamin Oshlack, hereby declare:

I. INTRODUCTION

1. I make this declaration in support of Patent Owners Purdue Pharma L.P., The P.F. Laboratories, Inc., and Purdue Pharmaceuticals L.P.'s Response, and specifically, to attest to facts relating to the conception and reduction to practice of the invention claimed in U.S. Patent No. 9,060,976 (the "'976 patent").

2. I received a Bachelor of Pharmacy degree from Victorian College of Pharmacy in Melbourne, Australia, in 1972. For several years thereafter, I worked in retail pharmacy, including some time in Great Britain.

3. In 1976, I joined Dagra, N.V., a small pharmaceutical company in the Netherlands that was associated with Purdue Frederick Company. At Dagra, I was the head of the Pharmaceutical Research and Development department and was responsible for the development, scale-up, and manufacturing of new formulations. My work at Dagra primarily focused on immediate-release solid oral dosage forms, although it also included development of suspensions, creams, and extended-release products.

4. In 1980, I was transferred to the company now known as Purdue Pharma L.P. ("Purdue"), at its Yonkers, New York site, which later moved to Ardsley, New York. For my first several years at Purdue, I was a scientist responsible for the development of solid dosage forms in the Pharmaceutical

Development department. This involved many of the same development, scale-up, and manufacturing activities I was involved with at Dagra. At Purdue, however, I began to develop a specialization in extended-release delivery systems, particularly for oral administration. Shortly after I arrived at Purdue, I was temporarily sent to an associated company in Scotland, Napp Pharmaceuticals, to train with them in the development of extended-release dosage forms. When I returned to the United States, I brought this expertise back to Purdue's formulation development team and began to focus on extended-release dosage forms.

5. In 1984, I was promoted to Director of the Pharmaceutical Development Solid Dosage Forms group at Purdue. Between 1986 and 1998, I was promoted several times, becoming the Director of the entire Pharmaceutical Development group, and ultimately being named the Executive Director of the group. During this time, I became responsible for all aspects of the development of all of Purdue's new pharmaceutical dosage forms.

6. It was also during this time that I and my team developed the original OxyContin® formulation. The original OxyContin® formulation was a 12-hour, extended-release formulation, and is described in Examples 3 and 4 of U.S. Patent No. 5,508,042. (Ex. 2100.) I am a named inventor on this patent and on other patents covering the original OxyContin® product. (*Id.*; Ex. 2101; Ex. 2102; Ex. 2103.) The original formulation was prepared by the following procedure: (1)

Eudragit® RS 30D and Triacetin® are combined and mixed at low shear to prepare a suspension; (2) oxycodone hydrochloride, lactose, and povidone are placed in a fluid bed granulator, and the suspension prepared in (1) is sprayed onto the powder in the fluid bed to prepare a granulation, which is then dried; (3) stearyl alcohol is heated to approximately 70 °C and then mixed with the warm granulation to wax-coat the granules; (4) after the waxed granulation is cooled, it is lubricated by blending with talc and magnesium stearate for approximately 3 minutes; and (5) the lubricated granulate is then compressed in a tableting machine. (Ex. 2100 at Examples 3, 4; *see also id.* at Tables 5, 7.) According to this manufacturing procedure, the oxycodone hydrochloride is contained inside the wax-coated granules, whereas the magnesium stearate and talc are on the outside as lubricant.

7. The original OxyContin® product was approved by the FDA in December 1995 and entered the market in 1996. The original OxyContin® formulation was considered a significant advance at the time. In contrast to other oxycodone formulations that required administration every several hours to avoid break-through pain, OxyContin®'s formulation permitted patients to take a tablet only twice daily.

8. It was also during this period, in 1991, that I received my Master of Science degree in Industrial Pharmacy from Long Island University in Brooklyn, New York. As part of my master's program, I prepared a thesis based on research

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