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Paper No. 48
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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 Owner.

Case IPR2016-01027
Patent 9,060,976 B2

Before LORA M. GREEN, CHRISTOPHER G. PAULRAJ, and JACQUELINE T. HARLOW, *Administrative Patent Judges*.

PAULRAJ, *Administrative Patent Judge*.

FINAL WRITTEN DECISION
Determining That Claim 1 Has Been Shown To Be Unpatentable
35 U.S.C. § 318(a) and 37 C.F.R. § 42.73

I. INTRODUCTION

Amneal Pharmaceuticals LLC ("Petitioner") filed a Petition requesting an *inter partes* review of claim 1 of U.S. Patent No. 9,060,976 B2 (Ex. 1001, "the '976 patent"). Paper 2 ("Pet."). The P.F. Laboratories, Inc., Purdue Pharma L.P., and Purdue Pharmaceuticals L.P. (collectively, "Patent Owner") filed a Preliminary Response to the Petition. Paper 9 ("Prelim. Resp."). We determined that the information presented in the Petition demonstrated that there was a reasonable likelihood that Petitioner would prevail in challenging claim 1 as unpatentable under 35 U.S.C. § 103(a). Pursuant to 35 U.S.C. § 314, the Board instituted trial on November 9, 2016, as to that claim of the '976 patent. Paper 13 ("Institution Decision" or "Inst. Dec.").

Following our institution, Patent Owner filed a Response to the Petition (Paper 17, "PO Resp.") and Petitioner filed a Reply to Patent Owner's Response (Paper 20, "Reply"). Pursuant to our authorization, Patent Owner also filed a Sur-Reply (Paper 40, "PO Sur-Reply"). An oral hearing was held on August 2, 2017. The transcript of the hearing has been entered into the record. Paper 47 ("Tr.").

We have jurisdiction under 35 U.S.C. § 6. This Final Written Decision is issued pursuant to 35 U.S.C. § 318(a) and 37 C.F.R. § 42.73. Based on the record before us, we conclude that Petitioner has demonstrated by a preponderance of the evidence that claim 1 of the '976 patent is unpatentable as obvious.

A. Related Proceedings

The '976 patent is asserted against Petitioner in two civil actions pending in the United States District Court for the District of Delaware

captioned *Purdue Pharma L.P. et al. v. Amneal Pharmaceuticals LLC*, 15-cv-831, filed September 17, 2015 (Ex. 1007), and *Purdue Pharma L.P. et al. v. Amneal Pharmaceuticals LLC*, 15-cv-1152, filed December 15, 2015 (Ex. 1008). Pet. 1.

Furthermore, the claims of U.S. Patent No. 8,337,888 B2 (Ex. 1002, the '888 patent), of which the '976 patent is a continuation (Ex. 1001), were also asserted against Petitioner, and were held invalid in a district court proceeding in the Southern District of New York captioned *Purdue Pharma L.P. et al. v. Amneal Pharmaceuticals LLC*, No. 13-cv-3372 ("the SDNY Litigation"). The Federal Circuit upheld the invalidity of those claims on April 8, 2016. Ex. 1004.

Additionally, Petitioner filed a second Petition challenging the validity of claim 1 of the '976 patent. *See* Case IPR2016-01028, Paper 1. IPR2016-01028 is being decided concurrently with the instant proceeding.

B. The '976 Patent (Ex. 1001)

The '976 patent issued on June 23, 2015, with Curtis Wright, Benjamin Oshlack, and Christopher Breder as the listed co-inventors. Ex. 1001. The '976 patent is a continuation of application number 13/349,449, which issued as the '888 patent. *Id.* The '976 patent claims priority to a non-provisional application (No. 10/214,412) filed August 6, 2002 and a provisional application (No. 60/310.534) filed August 6, 2001. *Id.*

The '976 patent relates generally to a controlled release formulation of oxycodone, which has been marketed by Patent Owner under the tradename "OxyContin." *Id.* at 1:46–48. As noted in the SDNY Litigation, OxyContin, which was originally approved in 1995, has been at the center of

the current national opioid abuse epidemic, and Patent Owner stopped selling the original formulation in 2010 because it was susceptible to tampering and abuse. Ex. 1003, 28–29. The invention claimed in the '976 patent stems from Patent Owner's efforts to develop an abuse-deterrent alternative to the original formulation.

In this respect, the '976 patent notes that "[o]pioid analgesics are sometimes the subject of abuse." Ex. 1001, 1:17. According to the '976 patent, the opioid analgesic may be more potent when injected after mixing with a suitable vehicle, or when crushed and administered orally or nasally. *Id.* at 1:18–29. The '976 patent discloses that "[o]pioid antagonists have been combined with certain opioid agonists in order to deter the parenteral abuse of opioid agonists," but states that there is still a need of opioid dosage forms that are less subject to abuse *Id.* at 1:32–34, 2:9–11.

Thus, the '976 patent discloses "oral dosage forms . . . comprising an opioid analgesic; and an aversive agent or agents as a component(s) of the dosage form helps to prevent injection, inhalation, and/or oral abuse by decreasing the 'attractiveness' of the dosage form to a potential abuser." *Id.* at 2:42–47. The '976 patent defines "aversive agent" as "a bittering agent, an irritant, a gelling agent, or combinations thereof." *Id.* at 4:12–14.

According to the '976 patent:

> In certain embodiments of the present invention, the dosage form comprises an aversive agent such as a gelling agent to discourage an abuser from tampering with the dosage form and thereafter inhaling, injecting, and/or swallowing the tampered dosage form. Preferably, the gelling agent is released when the dosage form is tampered with and provides a gel-like quality to the tampered dosage form which slows the absorption of the opioid analgesic such that an abuser is less likely to obtain a rapid "high". In certain preferred embodiments, when the

> dosage form is tampered with and exposed to a small amount (e.g., less than about 10 ml) of an aqueous liquid (e.g., water), the dosage form will be unsuitable for injection and/or inhalation. Upon the addition of the aqueous liquid, the tampered dosage form preferably becomes thick and viscous, rendering it unsuitable for injection.

Id. at 2:64–3:11. Moreover, upon contact with the mucous membranes of the nasal passages the gelling agent may also become a gel, which sticks to the nasal passage, minimizing absorption of the opioid. *Id.* at 3:25–30.

The '976 teaches as to the gelling agent:

> In certain embodiments of the present invention wherein the dosage form includes an aversive agent comprising a gelling agent, various gelling agents can be employed including, for example and without limitation, sugars or sugar derived alcohols, such as mannitol, sorbitol, and the like, starch and starch derivatives, cellulose derivatives, such as microcrystalline cellulose, sodium cahoxymethyl cellulose, methylcellulose, ethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, and hydroxypropyl methylcellulose, attapulgites, bentonites, dextrins, alginates, carrageenan, gum tragacanth, gum acacia, guar gum, xanthan gum, pectin, gelatin, kaolin, lecithin, magnesium aluminum silicate, the carbomers and carbopols, polyvinylpyrrolidone, polyethylene glycol [PEG], *polyethylene oxide* [PEO], polyvinyl alcohol, silicon dioxide, surfactants, mixed surfactant/wetting agent systems, emulsifiers, other polymeric materials, and mixtures thereof, etc. In certain preferred embodiments, the gelling agent is xanthan gum. In other preferred embodiments, the gelling agent of the present invention is pectin.

Id. at 6:45–63 (emphasis added).

The '976 patent teaches further:

> A gelling agent may be added to the formulation in a ratio of gelling agent to opioid agonist of from about 1:40 to about 40:1 by weight, preferably from about 1:1 to about 30:1 by weight, and more preferably from about 2:1 to about 10:1 by weight of the opioid agonist. In certain alternative embodiments, the

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