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Paper No. 13
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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 MICHAEL P. TIERNEY, LORA M. GREEN, and CHRISTOPHER G. PAULRAJ, *Administrative Patent Judges*.

GREEN, *Administrative Patent Judge*.

DECISION
Institution of *Inter Partes* Review
37 C.F.R. § 42.108

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."). Purdue Pharma L.P., The P.F. Laboratories, Inc., and Purdue Pharmaceuticals L.P. (collectively, "Patent Owner") filed a Preliminary Response to the Petition. Paper 9 ("Prelim. Resp.").

Institution of an *inter partes* review is authorized by statute when "the information presented in the petition . . . and any response . . . shows that there is a reasonable likelihood that the petitioner would prevail with respect to at least 1 of the claims challenged in the petition." 35 U.S.C. § 314; *see* 37 C.F.R. §§ 42.4, 42.108. Upon considering the Petition and the Preliminary Response, we determine that Petitioner has demonstrated a reasonable likelihood that it would prevail in showing the unpatentability of claim 1. Accordingly, we institute an *inter partes* review of that claim.

A. Related Proceedings

Petitioner states that the '976 patent is asserted against it "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.

Petitioner states further that 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 it, 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]." Pet. 1–2.

Finally, Petitioner notes that it filed a second Petition challenging the validity of claim 1 of the '976 patent, IPR2016-01028. *Id.* at 2. 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 notes that opioid analgesics may sometimes be subject to abuse. *Id.* at 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 gellike 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 gelling agent may be present in a ratio to the opioid agonist of from about 1:15 to about 15:1, preferably in a ratio of from about 1:8 to about 8:1, and more preferably from about 1:3 to about 3:1 by weight of the opioid agonist.

Id. at 7:12–20.

The '976 patent teaches:

> The opioid analgesic formulation in combination with one or more aversive agents can be formulated as an immediate release formulation or controlled release oral formulation in any suitable tablet, coated tablet or multiparticulate formulation known to those skilled in the art. The controlled release dosage form may include a controlled release material which is incorporated into a matrix along with the opioid analgesic. In addition, the aversive agent may be separate from the matrix, or incorporated into the matrix.

Id. at 12:29–37.

C. District Court Proceeding Involving the '888 patent

According to the district court in the SDNY Litigation, the '888 patent relates to "a controlled release oral dosage form containing oxycodone that forms a gel when dissolved in an aqueous liquid," wherein the "gelling properties . . . enable it to resist abuse by injection, snorting, and oral ingestion." Ex. 1003, 1. Claim 1 of the '888 patent is reproduced below:

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