Amneal Pharmaceuticals, LLC. (“Amneal”) filed two petitions for inter partes review of claims 1–13 and 16–19 of U.S. Patent No. 9,034,376 (the ’376 patent) of Purdue Pharma L.P., P.F. Laboratories, Inc. and Purdue Pharmaceuticals L.P. ("Purdue"). In the petitions, Amneal argued that claims 1–13 and 16–19 were unpatentable for obviousness over the combinations of multiple prior art references including US 2002/0187192 A1 ("Joshi"). The Patent Trial and Appeal Board ("the Board") granted the petitions on all grounds and found claims 1–13 and 16–19 of the ’376 patent unpatentable as being obvious. Purdue appealed from the decisions of the Board. In the non-precedential decision in Perdue Pharma L.P. v. Iancu, the Federal Circuit ("the Court") agreed with the Board.

The ’376 patent, entitled "Pharmaceutical Formulation Containing Gelling Agent," is directed to abuse-deterrent, extended release formulations of oxycodone. The ’376 patent claims priority to provisional application No. 60/310,534 ("the ’534 application"), filed on August 6, 2001. The Court had addressed several issues in its decision including the priority.

The ’376 patent contemplates using two gelling agents, polyethylene oxide ("PEO") and hydroxypropylmethylcellulose ("HPMC") in an oxycodone formulation. When the oxycodone formulation is exposed to an aqueous liquid, those gelling agents impart a viscosity to the formulation that makes it unsuitable for parenteral and nasal administration.

Claim 1 of the 376 patent reads:

1. A controlled release oral solid dosage form comprising:
   a controlled release matrix comprising a mixture of
   (i) from 2.5 mg to 320 mg oxycodone or a pharmaceutically acceptable salt thereof; and
   (ii) a gelling agent comprising [PEO] and [HPMC], the gelling agent in an effective amount to
   impart a viscosity of at least 10 cP when the dosage form is subjected to tampering by
dissolution in from 0.5 to 10 ml of an aqueous liquid;
the controlled release matrix providing a therapeutic effect for at least 12 hours when orally
administered to a human patient.

Prior to reaching the merits in both proceedings, the Board addressed Joshi’s status as prior art. Joshi was published on December 12, 2002, based on an application filed on August 30, 2001. It claims priority to a provisional application filed on April 30, 2001. In the petitions for inter partes review, Amneal asserted that Joshi qualifies as prior art under 35 U.S.C. § 102(e). Purdue responded that Joshi did not qualify as 102(e) prior art for two reasons: (1) the ’376 patent is entitled to an earlier filing date based on the ’534 application, filed on August 6, 2001, whereas Joshi is not entitled to its provisional filing date of April 30, 2001, and (2) even if Joshi is entitled to priority based on its provisional filing date of April 30, 2001, the ’376 patent has an earlier invention date.

The Board held that Joshi qualified as prior art under section 102(e) and explained that the claims of the ’376 patent did not have written description support in the ’534 provisional or a draft of the patent application dated April 25, 2001. According to the Board, "both the ’534 provisional and the draft application merely include ‘laundry list’ disclosures of possible gelling agents, in which [HPMC] . . . [PEO] . . . and mixtures thereof are among a large number of other possible gelling agents.” The Board pointed out that documents relied upon by Purdue did not "specifically named or mentioned the combination in any manner." Additionally, the Board found that "the inventors of the ’376 patent had not conceived of or reduced to practice the claimed formulation prior to Joshi’s August 30, 2001 filing date.”
therefore held that the ’376 patent was unpatentable for obviousness on all instituted grounds.

In addressing the issue of whether the ’376 patent is entitled to priority to the filing date of its provisional application, the Court reiterated that “[f]or a patent to claim priority from the filing date of its provisional application, it must satisfy 35 U.S.C. § 119(e)(1) (2006)” citing in support its decision in Dynamic Drinkware. Relying further on its decisions in New Railhead Manufacturing and Dynamic Drinkware, the Court reminded that under section 119(e)(1), the specification of the provisional must "contain a written description of the invention and the manner and process of making and using it, in such full, clear, concise, and exact terms," 35 U.S.C. § 112 ¶ 1, to enable an ordinarily skilled artisan to practice the invention claimed in the non-provisional application.

Purdue argued that the ’534 provisional application satisfied the written description requirement as to the ’376 claims and pointed to the following disclosure in the ’534 provisional as supporting the claimed dosage forms:

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 carboxymethyl cellulose, methylcellulose, ethyl cellulose, hydroxyethyl cellulose, hydroxypropyl cellulose, and [HPMC], attapulgites, bentonites, dextrans, alginates, carrageenan, gum tragacanth, gum acacia, guar gum, xanthan gum, pectin, gelatin, kaolin, lecithin, magnesium aluminum silicate, the carbersoms and carbopol, polyvinylpyrrolidone, poly-ethylene glycol, [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.

Purdue also highlighted other portions of the ’534 application that discuss HPMC and PEO as components in preferred embodiments of the invention, though never in combination.

However, the Court explained that "simply describing a large genus of compounds is not sufficient to satisfy the written description requirement as to particular species or subgeneruses," relying in support on Fujikawa v. Wattanasin, 93 F.3d 1559, 1571 (Fed. Cir. 1996) and In re Ruschig, 379 F.2d 990, 994–95 (CCPA 1967). The Court pointed out that in the ’534 application disclosure, PEO and HPMC were merely two of many undifferentiated compounds that fall within the genus of gelling agents. "Such 'laundry list' disclosures do not provide adequate specificity to constitute written description support for Purdue's claim of priority. To be sure, the language 'mixtures thereof' suggests the possibility of combining two or more of the listed gelling agents. Without more, however, that language fails to highlight any preference for how many and which gelling agents to combine.

The Court further pointed out that additional references to PEO and HPMC in the provisional did not constitute "blaze marks" that indicate that the claimed specific combination should be selected from many other possible combinations. The Court agreed with the Board’s conclusion that the claims of the ’376 patent do not have written description support in the ’534 provisional application and affirmed the Board’s determination that claims 1–13 and 16–19 of the ’376 patent were unpatentable for obviousness.

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Applicants and attorneys must be careful what they describe even in a seemingly thoroughly drafted provisional application, as the provisional description may not be sufficient if it does not include "blaze marks" that highlight the claimed invention of a non-provisional application, claiming priority to the provisional, with adequate specificity. In the absence of "blaze marks", claims of the non-provisional may become vulnerable to a lack of written description challenge and assertion of intervening prior art in an IPR.


