

# CAFC Affirms Invalidation of Oxycodone Patent for Lack of Written Description

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On April 19th, 2019 the Court of Appeals of the Federal Circuit (CAFC) affirmed the decision reached at the Patent Trial and Appeal Board (PTAB) in the case of Purdue Pharma L.P., P.F. Laboratories, Inc. and Purdue Pharmaceuticals L.P. (“Purdue”) v. Andrei Iancu (“Iancu”). The case first began when an inter partes review (IPR) at the PTAB against Purdue’s patent 9,034,376 (‘376) titled “Pharmaceutical Formulation Containing Gelling Agent” was filed. The ‘376 patent describes an abuse deterrent extended release version of oxycodone. Oxycodone is a semi-synthetic opioid with agonist activity on mu, kappa, and delta receptors. The principal therapeutic action of oxycodone is analgesia. Oxycodone can be an addictive substance, that is crushed and either snorted or injected, producing a high. The abuse deterrent extended release version of oxycodone prevents the tablet from being used in this fashion.

The ‘376 patent describes two gelling agents that deter potential opioid abuse by making it unsuitable for parenteral and nasal administration when exposed to an aqueous solution. Amneal Pharmaceuticals LLC (“Amneal”) filed two petitions for IPR of claims 1-13 and 16-19 of the ‘376 patent. Amneal asserted the ‘376 patent was not valid on grounds of obviousness. One of the references asserted by Amneal, as support for obviousness, was Patent US 2002/0187192 A1 (“Joshi”), which was published on December 12, 2002 based on an application filed April 30th, 2001. Amneal asserted that Joshi was valid prior art under [35](#) 102(e).

During the IPR, Purdue argued that Joshi was not prior art under [35](#) 102(e) because the ‘376 was entitled to an earlier priority date than Joshi’s priority date, which claimed priority to a provisional application filed April 30, 2001. However, the PTAB failed to allow Purdue’s arguments as to the Joshi patent being prior art to be relitigated, because of a district court case involving Purdue, that derived from the same provisional application as the ‘376 patent which was subsequently invalidated using Joshi. The PTAB reasoned that based on the legal doctrine of collateral estoppel, Purdue was estopped from challenging Joshi’s status as prior art. Further, the PTAB recognized that Purdue had never previously argued that Joshi did not qualify as prior art and collateral estoppel applies “to issues that were or could have been raised.”

In addition, the PTAB held that even if collateral estoppel did not apply, Joshi qualifies as prior art under 35 U.S.C. 102(e) because Purdue failed to show that the '376 patent was entitled to a filing date that predated Joshi's priority date. The earliest filing date the '376 patent could claim priority to was August 6, 2002, which was after Joshi, as Joshi had a priority date of April 30, 2001. Further, the PTAB held that the '376 patent did not have support in an earlier draft or in the provisional application disclosing the exact formulation as described in the '376 patent. The PTAB reasoned that the earlier draft and the provisional included a "laundry list" of possible gelling agents and neither document "specifically named or mentioned the combination in any manner."

On appeal to the CAFC, Purdue challenged the Board's conclusion that Joshi qualifies as prior art, arguing that the PTAB improperly invoked collateral estoppel. The CAFC dismissed Purdue's argument, reasoning that the doctrine of collateral estoppel was properly applied.

Further, in regards to the issues regarding the lack of support in the provisional patent that the '376 patent claimed priority to, the CAFC affirmed that ruling of the PTAB as well. The CAFC reasoned that "simply describing a large genus of compounds is not sufficient to satisfy the written description requirement as to particular species or sub-genuses." Further, the CAFC reasoned that such "laundry list" disclosures do not provide support as to written description requirements necessary to Purdue's claim of priority. Based on this, the CAFC affirmed that claims 1-13 and 16-19 of the '376 patent were unpatentable for obviousness.

In conclusion, this case highlights the importance of well drafted provisional patent applications that explicitly described the claimed invention with adequate specificity. Absence of such explicit details contained within a provisional patent may cause a subsequent nonprovisional application to lose the ability to claim priority to the provisional patent filing date. Further, the nonprovisional patent can become susceptible to invalidation based on lack of written description and obviousness challenges in later filed post grant proceedings.