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IP News

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Federal Circuit: PTAB Did Not Err In Finding That It Retained Authority to Issue Final Written Decision After Deadline Passed

On Nov. 21, 2023, a Federal Circuit panel of Judges Dyk, Hughes, and Stoll issued a unanimous opinion, authored by Judge Dyk, in *Purdue Pharma L.P. v. Collegium Pharmaceutical, Inc.*, Case No. 2022-1482. The panel affirmed the Patent Trial and Appeal Board's (the Board) decision denying Purdue Pharma L.P. and Purdue Pharmaceuticals L.P.'s (collectively Purdue) motion to terminate Post Grant Review (PGR) proceedings and finding that claims 1–17 of Purdue's U.S. Patent No. 9,693,961 ('961 patent) are invalid for lack of written description and anticipation. Slip Op. at 1.

The '961 patent is directed to a method for preparing an abuse deterrent for use with opioid analgesics. *Id*. at 2–3. Purdue sued Collegium Pharmaceutical, Inc. (Collegium) for infringement of the '961 patent in September 2017, and Collegium thereafter petitioned the Board for PGR of claims 1–17 on grounds that they lacked a sufficient written description. *Id*. at 3. The district court infringement case proceeded in parallel to the PGR. *Id*. The Board had one year to issue a Final Written Decision (FWD), subject to a six-month extension by the Chief Administrative Patent Judge for good cause. *Id* at 4.

In September 2019, Purdue filed a Notice of Bankruptcy Filing and Imposition of Automatic Stay, after which the Board stayed the PGR proceeding, and the district court similarly stayed the infringement case. *Id*. Before the one-year deadline had passed for the Board to issue a Final Written Decision (FWD) in the PGR proceeding, the Chief Administrative Patent Judge granted a six-month extension for the Board to issue a FWD so that the bankruptcy court could determine whether the automatic stay applied to the PGR proceeding. *Id*. The Board advised both parties to seek a determination from the bankruptcy court on the issue, but neither did so, and the deadline passed. *Id*. The bankruptcy court, on motions by both parties, eventually lifted the stay. *Id*. Purdue, however, filed a motion with the Board to terminate the PGR proceeding on grounds that the Board no longer had the authority to issue a FWD after the 18-month deadline had passed. *Id*. at 4–5. The Board denied the motion and issued a decision that claims 1–17 are unpatentable for lack of written description and anticipation. *Id*. at 5.

As a matter of first impression, the Federal Circuit first addressed whether the Board maintains authority to issue a FWD in a PGR proceeding after the statutory deadline lapses. The Federal Circuit identified Supreme Court precedent establishing that when a statute does not specify a consequence for non-compliance with statutory timing provisions, federal courts will not ordinarily impose coercive sanctions. *Id*. at 7. Since the statute at issue did not provide such consequences, the Federal Circuit reviewed the statutory language, context, and legislative history, ultimately rejecting Purdue's arguments that the statutory language deprived the Board of authority. *Id.* at 8–10. Specifically, the Federal Circuit recognized that 35 U.S.C. § 328(a) mandates that the Board issue a FWD and that other provisions of the America Invents Act (AIA) use "quite different language" to bar action after deadlines pass. *Id*. at 10. The Federal Circuit also rejected arguments that the structure of the statute supported a loss of the Board's authority. *Id*. at 11. Congress created PGR proceedings through the AIA to create an expeditious alternative to costly litigation. *Id*. Preventing the Board from issuing a FWD after the lapse of a statutory deadline would force parties to litigate in federal court, contrary to the purpose of the AIA. *Id*. Finally, the Federal Circuit rejected Purdue's argument that the Board's interpretation allowed the Board to ignore statutory deadlines. *Id*. The Federal Circuit commented that Purdue could have petitioned the court for a writ of mandamus when the deadline had passed, but Purdue opted not to do so. *Id*. at 12. Because Purdue's failure to seek relief by mandamus did not extinguish the Board's authority to act, the Federal Circuit affirmed the Board's denial of Purdue's motion to terminate. *Id*.

The Federal Circuit also briefly considered whether substantial evidence supported the Board's conclusion that claims 1–17 of the '961 patent lack an adequate written description. At issue was whether the '961 patent's specification adequately discloses the claimed polyglycolyzed glycerides (PGGs) as an aversive agent. *Id*. at 13–14. The '961 patent defines "aversive agent" as "a bittering agent, an irritant, a gelling agent, or a combination thereof," but it does not clarify that PGGs are gelling agents. *Id*. at 14. As a result, the Federal Circuit found that substantial evidence suggests that the disclosure does not reasonably convey to persons of ordinary skill in the art that the inventor had possession of the claimed drug formula containing PGGs as an aversive agent. *Id*. at 14–15. Accordingly, the Federal Circuit panel affirmed the Board's finding that the claims are unpatentable. *Id*. at 15.

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Federal Circuit: District Court Did Not Err In Finding That an Abbreviated New Drug Application Is Limited to the Uses Described Therein

On Dec. 7, 2023, a Federal Circuit panel of Judges Dyk, Prost, and Hughes issued a unanimous opinion, authored by Judge Dyk, in *Lundbeck v. Lupin Ltd.*, Case Nos. 2022-1194, 2022-1208, and 2022-1246. The panel affirmed the U.S. District Court for the District of Delaware's decision that appellee's Abbreviated New Drug Application (ANDA) did not infringe appellant's U.S. Patent Nos. 9,278,096 ('096 patent) or 9,125,910 ('910 patent) but did infringe appellant's U.S. Patent No. 9,101,626 ('626 patent). Slip Op. at 4.

H. Lundbeck A/S, Takeda Pharmaceutical Company Ltd., Takeda Pharmaceuticals U.S.A., Inc., Takeda Pharmaceuticals International AG, and Takeda Pharmaceuticals America, Inc. (collectively Lundbeck) own the '096, '910, and '626 patents. *Id*. at 3–4. The '096 patent is directed to the use of the drug vortioxetine — sold under the brand name "Trintellix" — in patients who had previously taken certain other antidepressant medications and had to cease or reduce use due to sexually related adverse events. *Id*. at 3. The '910 patent is directed to the use of vortioxetine in patients with Major Depressive Disorder (MDD) who experience cognitive impairment. *Id*. Both the '096 and '910 patents are listed in the U.S. Food and Drug Administration's Approved Drug Products with Therapeutic Equivalence Evaluations ("the Orange Book") for Trintellix. *Id*. at 6. Additionally, Lundbeck's '626 patent is directed to a process for manufacturing vortioxetine. *Id*. at 4.

Defendants Lupin Ltd., Lupin Pharmaceuticals, Inc., Macleods Pharma USA, Inc., Macleods Pharmaceuticals Ltd., Sandoz Inc., Sigmapharm Laboratories, LLC, Zydus Pharmaceuticals (USA) Inc., Alembic Global Holding S.A., Alembic Pharmaceuticals Inc., Alembic Pharmaceuticals, Ltd., Cadila Healthcare Ltd., and Lek Pharmaceuticals, d.d. (collectively "Lupin"), sought to market a generic version of Trintellix for the treatment of MDD in adults and filed ANDAs to become effective after expiration of Lundbeck's patents on the compound vortioxetine. *Id*. Lundbeck argued that approval of the ANDA would infringe the '096, '910, and '626 patents. *Id*. at 9–10.

The Federal Circuit began with a review of Section 271(e)(2)(A) of the Hatch-Waxman Act to determine whether the ANDA infringed the '096 and '910 patents. *Id*. at 10. Although the drug labels associated with the ANDA did not explicitly prohibit doctors from prescribing a generic vortioxetine for the uses covered by the '096 and '910 patents, the Federal Circuit declined to find infringement. *Id*. at 11. Specifically, the Federal Circuit recognized that to find infringement, the use claimed in a patent under section 271(e)(2)(A) "must be the use for which an applicant is seeking marketing approval." *Id*. Because Lupin's ANDA did not seek approval for the uses covered by Lundbeck's '096 and '910 patents, the court accordingly affirmed the district court's finding that the ANDA does not infringe those patents. *Id*. at 13.

The Federal Circuit then turned to the district court's findings that the ANDA does not induce infringement or constitute contributory infringement of the '096 and '910 patents. *Id*. at 13, 19. Again, the Federal Circuit declined to find infringement on either theory. *Id*. Lundbeck's argument that the ANDA induces infringement rested on the fact that the drug label associated with the ANDA includes commentary about potential "adverse reactions" to the drug. *Id*. at 15. However, the Federal Circuit recognized that this section of the label is required by the Food and Drug Administration for approval to market the drug. *Id*. Further, Lundbeck failed to offer any evidence that Lupin has advertising or promotional material that encourages infringement. *Id*. at 14. The Federal Circuit accordingly affirmed the district court's finding that the ANDA does not induce infringement. *Id*. at 19. Similarly, the Federal Circuit affirmed the district court's ruling that the ANDA does not constitute contributory infringement because the record established substantial noninfringing uses of the drug. *Id*. at 20–21.

Finally, the Federal Circuit considered whether the district court erred in construing "reacting" in the '626 patent to mean "the changing of a reactant(s) to product(s)" and finding infringement under that construction. *Id*. at 21. Lupin argued that "reacting" has a meaning limited to the chemicals specified in

claim 1 of the ‘626 patent, which Lupin does not use as starting material to produce vortioxetine. *Id*. The Federal Circuit disagreed with Lupin’s interpretation. *Id*. The Federal Circuit found no evidence in the prosecution history that Lundbeck limited the scope of “reacting.” *Id*. at 22. Further, the Federal Circuit identified that dependent claim 3 of the ‘626 patent recites the process in claim 1 but with different compounds. *Id*. at 22–23. The Federal Circuit therefore declined to find that “reacting” is limited to the chemical compounds listed in claim 1 of the ‘626 patent and affirmed the district court’s decision that the ANDA infringes the ‘626 patent. *Id*. at 23.

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