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GIBSON DUNN

Appellate & Constitutional Law and
Intellectual Property Update

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Federal Circuit Update

This edition of Gibson Dunn's Federal Circuit Update for April 2024 summarizes the current status of several petitions pending before the Supreme Court, and recent Federal Circuit decisions concerning patent eligibility under 35 U.S.C. § 101, obviousness, and unenforceability due to inequitable conduct and unclean hands.

Federal Circuit News

Noteworthy Petitions for a Writ of Certiorari:

There were no new potentially impactful petitions filed before the Supreme Court in April 2024. We provide an update below of the petitions pending before the Supreme Court that were summarized in our [March 2024 update](#):

- The petitions in ***Vanda Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.*** (US No. 23-768) and ***Ficep Corp. v. Peddinghaus Corp.*** (US No. 23-796) were denied.

Upcoming Oral Argument Calendar

The list of upcoming arguments at the Federal Circuit is available on the court's [website](#).

Key Case Summaries (April 2024)

AI Visualize, Inc. v. Nuance Communications, Inc., No. 22-2109 (Fed. Cir. Apr. 4, 2024): AI Visualize asserted four related patents in the field of visualization of medical scans. Specifically, the patents disclose using two-dimensional MRI scans to present three-dimensional views that can lead to better diagnosis and prognosis. The district court granted a motion to dismiss under Rule 12(b)(6), determining that the asserted claims were directed to patent-ineligible subject matter under 35 U.S.C. § 101.

The Federal Circuit (Reyna, J., joined by Moore, C.J., and Hughes, J.) [affirmed](#), holding that the claims were directed to patent-ineligible subject matter. At step one, “the asserted claims are directed to converting data and using computers to collect, manipulate, and display the data” and “the steps of obtaining, manipulating, and displaying data, particularly when claimed at a high level of generality, are abstract concepts.” At step two, the Court agreed with the district court that “the asserted claims involved nothing more than the abstract idea itself” and conventional computer technology. AI argued that creation of virtual views significantly transforms the claims into patent-eligible subject matter; however, the Court determined that the specification conceded that this was known in the art, which AI also acknowledged at oral argument.

Salix Pharmaceuticals, Ltd. v. Norwich Pharmaceuticals Inc., No. 22-2153 (Fed. Cir. Apr. 11, 2024): Norwich filed an ANDA seeking to market 550 mg tablets of a generic version of rifaximin to treat hepatic encephalopathy (“HE”) and irritable bowel syndrome with diarrhea (“IBS-D”). Salix, which sells rifaximin under the name Xifaxan® for the treatment of HE and IBS-D, sued Norwich for infringement. The district court held that (1) Norwich infringed Salix’s patents directed to the use of rifaximin for treating HE, and (2) Norwich infringed Salix’s patents directed to the use of rifaximin for treating IBS-D, but that those claims would have been obvious over certain prior art. Norwich then amended its ANDA to remove the infringing HE indication, and moved to modify the judgment under Rule 60(b) asserting that the amendment negated any possible infringement, but the district court denied this motion.

The majority (Lourie, J., joined by Chen, J.) [affirmed](#). The majority first affirmed the district court’s holding that the asserted claims of the IBS-D patents were invalid as obvious. Salix’s patents are directed to treating IBS-D with 550 mg of rifaximin three times a day. One prior art reference had a study evaluating 550 mg doses twice a day, and a second prior art reference teaches administering 400 mg three times a day and further states that “[r]ecent data suggest that the optimal dosage of rifaximin may, in fact, be higher.” Based on the combination of these references, the majority determined that there was no clear error in the conclusion that a skilled artisan would have had a reasonable expectation of success in the claimed dosage. A skilled artisan would have discerned from the combination that the optimal dosage for treating patients suffering from IBS-D may be higher than 400 mg three times a day, and the next higher dosage unit from the clinical trial was 550 mg. The majority also concluded that the district court did not abuse its discretion in refusing to modify the judgment under Rule 60(b), because considering the amended ANDA, which removed the infringing HE indication, would “essentially be a second litigation.”

Judge Cunningham dissented-in-part, writing that she would have instead vacated the district court's conclusion that the asserted claims of the IBS-D patents are invalid as obvious. Specifically, she concluded that the prior art references' lack of discussion of the claimed dosage would mean that a skilled artisan would not have had a reasonable expectation of success for the claimed dosage. In particular, Judge Cunningham disagreed with the majority's reliance on the prior art reference's statement that "[r]ecent data suggest that the optimal dosage of rifaximin may, in fact, be higher" because that statement does not discuss an actual optimal dosage and uses the word "may."

Luv N' Care, Ltd. v. Laurain, Nos. 22-1905, 22-1970 (Fed. Cir. Apr. 12, 2024): Laurain (the inventor) and Eazy-PZ ("EZPZ") alleged that Luv n' care, Ltd. ("LNC") infringed EZPZ's patent directed to toddler dining mats. LNC asserted defenses of inequitable conduct and unclean hands. The district court concluded that LNC had failed to prove that the patent was unenforceable due to inequitable conduct. Although Laurain and patent prosecution counsel had made a misrepresentation to the Patent and Trademark Office ("PTO"), the district court found the misrepresentation was not but-for material to the patentability of the asserted patent. The district court, however, concluded EZPZ's litigation conduct did amount to unclean hands, including by failing to disclose certain patent applications during discovery and attempting repeatedly to block LNC from obtaining Laurain's prior art searches.

The Federal Circuit (Stark, J., joined by Reyna and Hughes, JJ.) [affirmed-in-part, vacated-in-part, and remanded](#). The Court affirmed the ruling of unclean hands finding the district court did not clearly err in its determination that EZPZ's litigation conduct, including its failure to disclose related patent applications amounted to unclean hands. For inequitable conduct, which requires showing the patentee (1) withheld information from the PTO, and (2) did so with specific intent to deceive the PTO, the Court vacated the district court's judgment and found that the district court failed to make separate findings as to materiality and deceptive intent. Additionally, regarding materiality, the Court remanded for the district court to determine whether Laurain's misrepresentation to the PTO amounted to "affirmative egregious misconduct" that would establish *per se* materiality. Regarding deceptive intent, the Court determined that the district court erred in considering the "individual acts of misconduct in isolation and failed to address the collective weight of the evidence regarding each person's misconduct as a whole." The Court remanded for the district court to reevaluate Laurain's deceptive intent based on her misconduct in the aggregate and to do the same for prosecution counsel.

The following Gibson Dunn lawyers assisted in preparing this update: Blaine Evanson, Jaysen Chung, Audrey Yang, Al Suarez, Evan Kratzer, and Michelle Zhu.

Gibson Dunn's lawyers are available to assist in addressing any questions you may have regarding developments at the Federal Circuit. Please contact the Gibson Dunn lawyer with whom you usually work, any leader or member of the firm's [Appellate and Constitutional Law](#) or [Intellectual Property](#) practice groups, or the following authors:

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