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Appellate & Constitutional Law and Intellectual Property Update

July 12, 2024

Federal Circuit Update

This edition of Gibson Dunn's Federal Circuit Update for June 2024 summarizes the current status of a couple petitions pending before the Supreme Court and recent Federal Circuit decisions concerning damages, trade secret misappropriation, patent eligibility under 35 U.S.C. § 101, and induced infringement.

Federal Circuit News

Noteworthy Petitions for a Writ of Certiorari:

There was a new potentially impactful petition filed before the Supreme Court in June 2024:

- ***United Therapeutics Corp. v. Liquidia Technologies, Inc.*** (US No. 23-1298): "1. Whether the IPR statute and *SAS* require the Federal Circuit to review *de novo*, or only for an abuse of discretion, the PTO's reliance on new grounds and new printed publications—not raised in the initial petition—when deciding to cancel patent claims. 2. Whether, if § 312 is deemed ambiguous, the Court should overrule *Chevron*." The respondent waived its right to respond, the Court requested a response, which is due August 12, 2024.

We also provide an update below of the petitions pending before the Supreme Court that were summarized in our May 2024 update:

- In ***Chestek PLLC v. Vidal*** (US No. 23-1217), the response brief is due August 14, 2024. Five *amicus curiae* briefs have been filed. In ***Cellect LLC v. Vidal*** (US No. 23-1231), the response brief is due August 21, 2024, and seven *amicus curiae* briefs have been filed.

Upcoming Oral Argument Calendar

The list of upcoming arguments at the Federal Circuit is available on the court's website.

Key Case Summaries (June 2024)

EcoFactor, Inc. v. Google LLC, No. 23-1101 (Fed. Cir. June 3, 2024): EcoFactor sued Google alleging infringement of patents directed to smart thermostats in computer-networked heating and cooling systems, which adjusts the user's thermostat settings to reduce strain on the electricity grid during periods of high demand. Following a jury trial, the jury found infringement and awarded damages to EcoFactor. Google moved for a new trial on damages, which the district court denied.

The majority (Reyna, J., joined by Lourie, J.) affirmed. The majority reasoned that EcoFactor's damages expert based his royalty rate on comparable license agreements and the testimony of EcoFactor's CEO, and thus, the royalty rate was sufficiently reliable. The majority therefore concluded that the district court did not abuse its discretion in denying the motion for a new trial.

Judge Prost dissented-in-part. Judge Prost reasoned that the royalty rate from EcoFactor's damages expert "rests on EcoFactor's self-serving, unilateral recitals of its beliefs in the license agreements," which were "directly refuted" by two of the license agreements and "have no other support . . . to back them up." Judge Prost concluded that the "law does not allow damages to be so easily manufactured." Judge Prost then noted that the royalty rate suffered from another problem in that it included the value of non-asserted patents, which EcoFactor's damages expert did not properly apportion. Judge Prost therefore determined that the analysis performed by EcoFactor's damages expert was unreliable, and the district court abused its discretion by not granting a new trial on damages.

Insulet Corp. v. EOFlow, Co. Ltd., No. 24-1137 (Fed. Cir. June 17, 2024): Insulet and EOFlow manufacture insulin pump patches. Starting in the early 2000s, Insulet developed the wearable insulin pump OmniPod® followed by next generation products in 2007 and 2012. EOFlow began developing its own product in 2011, the EOPatch®, followed by its next generation product in 2017. Around that time, four former Insulet employees were hired by EOFlow, and allegedly passed confidential information to EOFlow. Insulet sued EOFlow for misappropriation of trade secrets. Insulet moved for a preliminary injunction, arguing it was likely to be irreparably harmed by the misappropriation, particularly in light of news that Medtronic would imminently acquire EOFlow, which would provide a source of capital for EOFlow and increase competition with Insulet. The district court granted the preliminary injunction.

The Federal Circuit (Lourie, J., joined by Prost and Stark, JJ.) reversed. Under the Defend Trade Secrets Act ("DTSA"), the statute of limitations to bring a trade secret misappropriation claim is three years. 18 U.S.C. § 1836(d). EOFlow had raised a statute of limitations challenge; however, the district court expressed no opinion on the matter. The Federal Circuit held that it was an abuse of discretion to ignore this argument, which was a material factor in evaluating a likelihood of success on the merits. The Court further held that, even if the statute of limitations argument had been addressed, Insulet had not established a likelihood of success on the merits because it had not alleged a trade secret with particularity, as required by the DTSA. Specifically, Insulet "advanced a hazy grouping of information that the court did not probe with particularity to determine what, if anything, was deserving of trade secret protection." Instead, the district court should have determined what "specific information" was alleged to be the trade secret, such as "particular design drawings and specifications for each physical component and subassembly." The Court also determined that the district court failed to assess whether the information was generally known or reasonably ascertainable through proper means, such as reverse engineering, particularly in light of tear-down videos and Insulet's own publications that were available on the internet. And finally, the Court determined that the district court failed to consider the disclosures in Insulet's own patents related to the OmniPod. If certain components of the OmniPod were known to the public through patent disclosures, then those components would unlikely merit trade secret protection.

Beteiro, LLC v. DraftKings Inc., No. 22-2275 (Fed. Cir. June 21, 2024): Beteiro owns four patents directed to methods that enable users to participate in online gambling using a user communication device by first determining whether the user is physically located in a state that allows gambling by using the GPS on the mobile device. DraftKings filed a motion to dismiss under Rule 12(b)(6) on the grounds that the patents were directed to patent-ineligible subject matter under 35 U.S.C. § 101, and the district court granted the motion.

The Federal Circuit (Stark, J., joined by Dyk and Prost, JJ.) affirmed. At step one, the Court stated that the claims are directed to the abstract idea of "exchanging information concerning a bet and allowing or disallowing the bet based on where the user is located." In doing so, the Court specifically found that Beteiro's patent claims "exhibit several features that are well-settled indicators of abstractness," such as detecting information, generating and sending notifications, receiving messages (bets), determining legality (GPS location), and processing information (allowing/disallowing bets). The Court also determined that the claims were drafted in a result-oriented, functional manner, using language that described the desired outcomes without explaining how to achieve them. The Court further determined that the claims did not recite any improvement in the way computers operate, and thus, the claims were directed to an abstract idea. As to step two, the Court determined that the use of GPS on a mobile phone was conventional, contrary to Beteiro's contentions.

Amarin Pharma, Inc. v. Hikma Pharmaceuticals USA Inc., No. 23-1169 (Fed. Cir. June 25, 2024): Amarin sells icosapent ethyl (an omega-3 fatty acid commonly found in fish oils) under the brand name Vascepa® for the treatment of patients with high triglyceride levels. In 2012, Amarin received FDA approval for treatment of severe hypertriglyceridemia, a condition where a patient's blood triglyceride is at least 500 mg/dL ("the SH indication"), and later in 2019, for treatment to reduce cardiovascular risk in patients having blood triglyceride levels of at least 150 mg/dL ("the CV indication"). Hikma submitted an Abbreviated New Drug Application ("ANDA") for approval of

its generic icosapent ethyl in 2016 when Vascepa® was only approved for the SH indication, and in 2019, opted to carve out the additional CV indication by seeking FDA approval only for uses not covered by Amarin's newly listed CV indication patents. However, around the same time, Hikma also removed the CV limitation of use from its product label, which had originally been included when it initially filed its ANDA. Hikma then issued several press releases advertising its product as a generic version of Vascepa®, referencing Vascepa®'s $1.1 billion in sales, which included sales for *all* uses of Vascepa® including the CV indication that made up 75% of the sales.

Amarin sued Hikma for inducing infringement of two of its patents directed to uses of icosapent ethyl based on (1) Hikma's public statements in press releases and on its website, and (2) the product label for its generic icosapent ethyl product. Hikma moved to dismiss under Rule 12(b)(6), and the district court granted the motion. The district court found that the removal of the CV limitation of use from the product label would not be understood by physicians as suggesting that Hikma's product had been approved for the CV indication. The district court also found that while Hikma's press releases and website were relevant to an intent to induce, it did not rise to the level of encouraging, recommending, or promoting Hikma's generic for the CV indication.

The Federal Circuit (Lourie, J., joined by Moore, C.J., and Albright, J. (sitting by designation)) reversed, holding that the district court had to examine the label and public statements in its totality to determine what they "would communicate to physicians and the marketplace." In so holding, the Court noted that while the underlying case was a traditional Hatch-Waxman case, the issue on appeal was nothing more than "a run-of-the-mill induced infringement case." The Court concluded that while the label alone would not recommend, encourage, or promote infringement, a physician would read Hikma's press releases as an instruction or encouragement to prescribe Hikma's product for any FDA-approved use, which included the CV indication that Hikma carved out from its ANDA. The Court concluded that these allegations, taken together, plausibly stated a claim for induced infringement.

The following Gibson Dunn lawyers assisted in preparing this update: Blaine Evanson, Audrey Yang, Al Suarez, Evan Kratzer, and Julia Tabat.

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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