GIBSON DUNN

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FEDERAL CIRCUIT UPDATE

To Our Clients and Friends:

This edition of Gibson Dunn's Federal Circuit Update summarizes the Supreme Court's on-sale bar decision as well as key filings for certiorari or en banc review. The Update lists the Federal Circuit's new guidelines to address scheduling conflicts. We also summarize recent Federal Circuit decisions confirming the scope of required IPR review, deciding the impact of term changes on obvious-type double patenting, and reflecting differences in how infringement letters can give rise to personal jurisdiction for declaratory judgment claims.

Federal Circuit News

Supreme Court:

Helsinn Healthcare S.A. v. Teva Pharm. USA, Inc. **(No. 17-1229):** On January 22, 2019, the Supreme Court unanimously affirmed the Federal Circuit's decision that a commercial sale to a third party may trigger the "on-sale bar" under 35 U.S.C. § 102(a), even if that third party is required to keep the sale confidential. The Supreme Court explained that its pre-AIA precedent did not require a sale to be public for purposes of the bar. Writing for the Court, Justice Thomas explained: "we presume that when Congress reenacted the same language in the AIA, it adopted the earlier judicial construction of that phrase." The AIA's addition of the phrase "or otherwise available to the public" was insufficient to support a different conclusion.

Helsinn stands to particularly impact companies where inventors need to raise capital before an invention, although sufficiently complete for a patent application, is ready to be commercialized. Biotechnology and life sciences firms, for example, may need to consider earlier filings at the research and development stage or strategically review how capital acquisition is structured. A summary of the decision from our Appellate and Constitutional Law Practice can be found here.

There is one additional patent case from the Federal Circuit scheduled to be heard in 2019, and one trademark case for which certiorari was granted.

Case	Status	Issue	Amicus Briefs Filed
Return Mail Inc. v. United States Postal Service, No. 17-1594	Argument scheduled February 19, 2019.	Whether the government is a "person" who may petition to institute review proceedings under the Leahy-Smith America Invents Act	9
Iancu v. Brunetti, No. 18-302	Certiorari granted January 4, 2019.	Whether Section 2(a) of the Lanham Act's prohibition on registration of "immoral" or "scandalous" marks is facially invalid under the free speech clause of the First Amendment	–

Noteworthy Petitions for a Writ of Certiorari:

***HP Inc. v. Berkheimer* (No. 18-415):** On September 28, 2018, HP filed for certiorari, presenting the question of "whether patent eligibility is a question of law for the court based on the scope of the claims or a question of fact for the jury based on the state of the art at the time of the patent." HP argued that, based on Supreme Court precedent, including *Alice Corp. Pty. Ltd. v. CLS Bank Int'l*, 134 S. Ct. 2347 (2014), patent eligibility is a question of law for the court.

As we earlier reported, the Federal Circuit (Moore, Taranto, Stoll, JJ.) held that step two of the *Alice*patent-eligibility analysis—whether claims involve well-known, routine, or conventional activities—presents a question of fact. Accordingly, the panel vacated in part and remanded a grant of summary judgment under Section 101, holding that a genuine issue of material fact existed. HP petitioned for rehearing en banc, which the Federal Circuit denied. Judge Reyna dissented from that denial, arguing that the decision is a "change in" the Federal Circuit's law and "counter to guidance from the Supreme Court" in *Alice*. As a practical matter, the decision limits accused infringers ability to obtain a dismissal on subject matter grounds before trial.

Several amici have filed to support HP's petition, including the Electronic Frontier Foundation, T-Mobile USA, Inc. and Sprint Spectrum L.P. On January 7, 2019, the Supreme Court invited the Solicitor General to file a brief expressing the views of the United States on this issue.

Mark Perry of Gibson Dunn serves as co-counsel for HP in this matter. Mark, as well as Gibson Dunn attorneys Helgi Walker, Brian Buroker, and Alex Harris, also successfully represented CLS Bank in the Supreme Court *Alice* case.

***Hikma Pharmaceuticals USA Inc. v. Vanda Pharmaceuticals Inc.* (No. 18-817):** On December 27, 2018, Hikma filed for certiorari, seeking review of "whether patents that claim a method of medically treating a patient automatically satisfy Section 101 … even if they apply a natural law using only routine

and conventional steps." Hikma argues that the Federal Circuit's decision "sharply breaks" from and "effectively overrules" Supreme Court precedent in *Alice* and *Mayo*.

The Federal Circuit panel majority (Lourie, Hughes, JJ.) held that a method of treating schizophrenia with iloperidone, with dosage based on a patient's genotype, is patent-eligible. According to the ruling, the method "makes iloperidone safer" and requires a doctor to administer the drug in set amounts based on testing. The claims are thus "directed to a specific method . . . using a specific compound at specific doses to achieve a specific outcome."

Chief Judge Prost dissented, arguing the claims were no more than an "optimization" of an existing treatment and that the specific dosage required added "nothing inventive . . . beyond [a] natural law." Adding to Judge Prost's criticism, Hikma argues that, so long as claims are now drafted as methods of treatment, the Federal Circuit's ruling no longer requires claims directed to natural laws to contain other inventive elements as *Mayo* dictates, with the PTO now using the challenged ruling to instruct examiners that "it is not necessary for 'method of treatment' claims that practically apply natural relationships to include nonroutine or unconventional steps."

Noteworthy Petitions for En Banc Review:

Eli Lilly has petitioned for en banc review from the decision in *Erfindergemeinschaft UroPep Gb v. Eli Lilly and Co.* (No. 17-2603). The petition asks as one of its two questions:

Does a single-step therapeutic method claim violate the "written description" and "enablement" requirements of 35 U.S.C. § 112 under longstanding precedent of this Court and the Supreme Court where:

a) the sole limitation in the claim's single step that potentially imparts patentability to the claim merely recites a function to be performed,

b) the claim preempts all future ways that might be discovered to perform the function recited in the claim, and

c) the specification fails to identify which, if any, of the embodiments disclosed in the specification actually perform the function to which the claim is directed.

This petition could allow the Federal Circuit to clarify written description and enablement requirements for methods of medical treatment, particularly in light of decisions such as *Mayo* and *Alice.* Coupled with the certiorari petition from *Hikma*, it also reflects further challenge to the Federal Circuit's upholding method of treatment claims, albeit in the context of Section 112. The Washington Legal Foundation and Eisai Co. have filed amicus briefs in support of Eli Lilly.

Federal Circuit Practice Update

Revision to Process for Advising of Scheduling Conflicts:

On December 10, 2018, the Federal Circuit revised its process for advising it of scheduling conflicts:

1. The court will only consider scheduling conflicts by arguing counsel; non-arguing counsel and client conflicts will no longer be considered when scheduling argument.

2. Arguing counsel must provide an explanation, including a showing of good cause, for any submitted scheduling conflict.

3. Arguing counsel will be limited to submitting only ten total days of unavailability during the six consecutive court weeks identified in the Notice to Advise of Scheduling Conflicts.

The Federal Circuit also stated that "[c]onflicts submitted without a sufficient showing of good cause will not be considered by the court when scheduling argument." The Federal Circuit's notice can be found here.

Key Case Summaries (December 2018 – January 2019)

***AC Technologies S.A. v. Amazon.com Inc.*, No. 18-1433 (Fed. Cir. Jan. 9, 2019):** If the Board institutes an IPR, it must address all grounds of unpatentability raised by the petitioner.

Amazon petitioned for review of one of AC's patents relating to a data management system. Although Amazon only identified one piece of prior art, it asserted three grounds depending on how a key term was construed. The Board instituted the IPR on the basis of one construction. Later, the Board construed the claim differently, finding that Amazon had failed to show invalidity on two of its three grounds. Amazon moved for reconsideration, noting that the Board did not address its third ground. The patentee argued that the third ground had never been instituted, but the Board evaluated it and invalidated the challenged claims on that basis.

The Federal Circuit (Stoll, J.) affirmed, rejecting the patentee's argument that the Board erred by addressing a ground of invalidity that was not expressly part of its institution decision. The panel explained that the Board either institutes review, or does not, and it must render a final decision addressing all challenged claims. Likewise, "if the Board institutes an IPR, it must similarly address all *grounds* of unpatentability raised by the petitioner" (emphasis added).

***Novartis AG v. Ezra Ventures LLC*, No. 2017-2284 (Fed. Cir. Dec. 7, 2018) and *Novartis Pharms. Corp. v. Breckenridge Pharm. Inc.*, Nos. 2017-2173, -2175, -2176, -2178, -2179, -2180, -2182, -2183, -2184 (Fed. Cir. Dec. 7, 2018):** Term extensions do not give rise to obviousness-type double patenting (Novartis represented successfully by Gibson Dunn in *Ezra*).

Obviousness-type double patenting (ODP) is a judicial doctrine that prevents patentees from obtaining sequential patents on the same invention, or obvious variants, that extend exclusivity beyond the original patent term. In the two *Novartis* cases, the Federal Circuit addressed how to apply ODP if an earlier-filed patent obtains a *later* expiration than a later-filed patent due to a term extension or due to the term change in the 1995 Uruguay Round Agreements Act (URAA).

In ***Ezra***, the Federal Circuit considered ODP in the context of Section 156, which can extend term up to five years when an invention could not be commercialized without approval from a regulatory agency, such as the FDA. Novartis's first patent was to expire in 2014, and a second, related patent to expire in 2017. But, based on an extension, the first patent's term was extended to 2019—after expiration of the second, later-filed patent. Ezra argued that the first patent was invalid or should be at least terminally disclaimed to the expiration of the later-filed patent.

The Federal Circuit (Chen, J.) rejected Ezra's positions. According to the panel, Section 156 allows a patentee to choose one patent to extend, and "[a]s long as the requirements for a patent term extension recited in § 156(a) are met, the Director of the Patent and Trademark Office 'shall' grant a [patent term extension] on the patent of the patentee's choice." ODP does not invalidate a patent with a validly-obtained patent term extension because holding otherwise "would mean a judge-made doctrine would cut off a statutorily-authorized time extension."

Breckenridge considered ODP in light of the 1995 change in patent term from 17 years after issuance to 20 years from the earliest effective filing date. Novartis had two patents that both claimed the same priority date. Because of the URAA's change in term, the first, earlier-filed patent, a pre-URAA patent, was to expire later than the second post-URAA patent.

The Federal Circuit (Chen, J.) held that the URAA change did not give rise to ODP. Novartis had not tried to extend its patent term. Rather, the difference was created by the URAA—indeed, it "truncated" the term of Novartis's second-filed patent. The panel held that a change in law "should not truncate the term statutorily assigned" to the first patent, and that holding otherwise "would abrogate Novartis's right to enjoy one full patent term on its invention."

***Jack Henry & Assoc., Inc. v. Plano Encryption Techs. LLC*, No. 16-2700 (Fed. Cir. Dec. 7, 2018):** Infringement letters can establish personal jurisdiction and venue in a declaratory action.

Jack Henry brought a declaratory action against Plano in the Northern District of Texas. Plano had sent enforcement letters to Jack Henry (which did business in the district) identifying Plano's patents, stating its belief that infringement was occurring, and offering a license. Thus, minimum contacts were met—the issue was whether exercising jurisdiction would be reasonable and fair. The district court held that Plano's contacts should not subject it to jurisdiction.

The Federal Circuit (Newman, J., joined by Wallach and Stoll, JJ.) reversed, rejecting the view that infringement letters alone cannot provide a basis for personal jurisdiction in a declaratory action. The panel noted that Plano did not contend that jurisdiction in the district would be inconvenient. Plano was also subject to general jurisdiction in Texas and was registered to do business throughout the state. Under these facts, personal jurisdiction and venue were satisfied.

***Maxchief Investments v. Wok & Pan, Indus.*, No. 18-1121 (Fed. Cir. Nov. 29, 2018)**: Infringement letters do not establish jurisdiction just because they are directed to the forum.

Maxchief brought a declaratory judgment action against Wok & Pan in the Eastern District of Tennessee. Wok & Pan had sent infringement notices to Maxchief's attorney in the district, although Maxchief itself was a Kansas company that did not operate in Tennessee. Maxchief also argued that a separate suit by Wok in California, which sought a broad injunction impacting Maxchief's products, would have "effects" in Tennessee as one of its distributors operated there. But the district court dismissed the suit, holding Maxchief failed to allege the minimum contacts.

The Federal Circuit (Dyk, J., joined by Reyna, J., and Hughes, J.) affirmed, holding that personal jurisdiction based on enforcement activity requires intentional conduct "directed at the forum." "[I]t is not enough that Wok's lawsuit might have 'effects' in Tennessee." As to infringement letters, the panel deemed the contact to be with Maxfield in Kansas, notwithstanding that the letter was sent to a lawyer in Tennessee. Taken with *Jack Henry* above, this illustrates the fact-dependent nature of the personal jurisdiction inquiry for declaratory judgment actions.

Upcoming Oral Argument Calendar

For a list of upcoming arguments at the Federal Circuit, please click here.

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 or the authors of this alert:

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