GIBSON DUNN

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FEDERAL CIRCUIT UPDATE

To Our Clients and Friends:

This edition of Gibson Dunn's Federal Circuit Update summarizes key filings for *certiorari* or *en banc* review, as well as additional new Federal Circuit processes to address scheduling conflicts, for the period February through April 2019. We also summarize recent Federal Circuit decisions concerning the patent eligibility of method of treatment claims, the impact of an inventor's subjective views on the on-sale and prior use bars, and the constitutional and statutory standing requirements to appeal IPR decisions.

Federal Circuit News

Supreme Court:

Decisions are pending from the Supreme Court for one patent case and one trademark case from the Federal Circuit. In March, the Supreme Court also granted *certiorari* over an additional patent case from the Federal Circuit.

Case	Status	Issue	Amicus Briefs Filed
Return Mail Inc. v. United States Postal Service, No. 17-1594	Argued on February 20, 2019.	Whether the government is a "person" who may petition to institute review proceedings under the Leahy-Smith America Invents Act.	11
Iancu v. Brunetti, No. 18-302	Argued on April 15, 2019.	Whether Section 2(a) of the Lanham Act's prohibition on the federal registration of "immoral" or "scandalous" marks is facially invalid under the free speech clause of the First Amendment.	10
Iancu v. NantKwest Inc., No. 18-801	Petition for *certiorari* granted on March 4, 2019.	Whether the phrase "[a]ll the expenses of the proceedings" in 35 U.S.C. § 145 encompasses the personnel expenses the PTO incurs when its employees, including attorneys, defend the agency in Section 145 litigation.	–

Noteworthy Petitions for a Writ of Certiorari:

***Acorda Therapeutics, Inc. v. Roxane Labs., Inc.* (No. 18-1280):** Question presented: "whether objective indicia of nonobviousness may be partially or entirely discounted where the development of the invention was allegedly 'blocked' by the existence of a prior patent, and, if so, whether an 'implicit finding' that an invention was 'blocked,' without a finding of *actual* blocking, is sufficient to conclude that an infringer has met its burden of proof." Acorda is represented by Ted Olson, Thomas Hungar, Amir Tayrani, and Jessica Wagner of Gibson Dunn.

***Ariosa Diagnostics Inc. v. Illumina Inc.* (No. 18-109):** Question presented: "Do unclaimed disclosures in a published patent application and an earlier application it relies on for priority enter the public domain and thus become prior art as of the earlier application's filing date, or, as the Federal Circuit held, does the prior art date of the disclosures depend on whether the published application also claims subject matter from the earlier application?"

***RPX Corp. v. ChanBond LLC* (No. 17-1686):** Question presented: "Can the Federal Circuit refuse to hear an appeal by a petitioner from an adverse final decision in a Patent Office inter partes review on the basis of lack of a patent-inflicted injury in fact when Congress has (i) statutorily created the right to have the Director of the Patent Office cancel patent claims when the petitioner has met its burden to show unpatentability of those claims, (ii) statutorily created the right for parties dissatisfied with a final decision of the Patent Office to appeal to the Federal Circuit, and (iii) statutorily created an estoppel prohibiting the petitioner from again challenging the patent claims?"

***HP Inc. v. Berkheimer* (No. 18-415):** Question presented: "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." On January 7, 2019, the Supreme Court invited the U.S. Solicitor General to file a brief expressing the views of the United States. Mark Perry of Gibson Dunn continues to serve as co-counsel for HP in this matter.

***Hikma Pharmaceuticals USA Inc. v. Vanda Pharmaceuticals Inc.* (No. 18-817):** Question presented: "whether patents that claim a method of medically treating a patient automatically satisfy Section 101 of the Patent Act, even if they apply a natural law using only routine and conventional steps." On March 18, 2019, the Supreme Court invited the U.S. Solicitor General to express the views of the United States.

Other Federal Circuit News

On March 22, 2019, the New York Intellectual Property Law Association held the 97th Annual Dinner in Honor of the Federal Judiciary. The Honorable Kathleen O'Malley of the Federal Circuit was honored with the 17th Annual Outstanding Public Service Award.

The annual Federal Circuit Bench and Bar Conference will take place June 12–15, 2019, at the Broadmoor in Colorado Springs, CO.

Federal Circuit Practice Update

New Process for Notifying Counsel of Accepted Scheduling Conflicts:

On December 10, 2019, the Federal Circuit announced revisions to its process for advising it of scheduling conflicts. Those changes were summarized in our January 2019 newsletter.

The Federal Circuit has now issued a follow-up announcement, discussing the new process for notifying counsel of accepted scheduling conflicts:

1. The Federal Circuit will continue to review Responses to Notice to Advise of Scheduling Conflicts to determine whether conflicts are accepted.

2. Only accepted conflict dates will be indicated on the public docket. Submitted conflict dates that are not accepted will not be listed on the public docket.

3. The non-acceptance of a submitted conflict date does not mean that oral argument necessarily will be scheduled on that date.

The Federal Circuit's notice can be found here.

Key Case Summaries (February 2019–April 2019)

***Natural Alternatives Int'l, Inc. v. Creative Compounds, LLC*, No. 18-1295 (Fed. Cir. Mar. 15, 2019):** Claims to treatment methods using existing products in new ways are patent eligible.

Natural Alternatives' patents relate to the use of the amino acid beta-alanine as a supplement to increase muscle capacity. The district court granted judgment on the pleadings that the claims are ineligible as directed to the natural law that ingesting beta-alanine (a natural substance) will increase the carnosine concentration in human tissue and thereby increase muscle capacity.

The Federal Circuit (Moore, J., joined by Wallach, J.; Reyna, J., dissenting in part) reversed. The majority reasoned that the claims not only "embody" the "discovery" that administering certain quantities of beta-alanine alters a human's natural state, but also require that an infringer actually administer the dosage claimed in the manner claimed to provide the described benefits. Citing *Vanda Pharms. Inc. v. West-Ward Pharms. Int'l Ltd.* (Fed. Cir. 2018)—addressed in our January 2019 Update and pending petition for writ of *certiorari*—the majority reasoned that, because the claims specify a compound and dosages, they go "far beyond merely stating a law of nature, and instead set[] forth a particular method of treatment," rendering them patent eligible at step one of the *Alice* inquiry. The decision thus continues the Federal Circuit's recent practice of distinguishing claims written as "methods of treatment" (held patent eligible) from those worded in "diagnostic" terms (held ineligible in *Mayo*). The majority also ruled that "factual impediments" exist in analyzing step two of the *Alice* inquiry, such that disputed questions of eligibility "may not be made on a motion for judgment on the

pleadings." This is challenged in the pending *HP Inc. v. Berkheimer certiorari* petition prepared by Gibson Dunn (see above).

***Endo Pharmaceuticals Inc. v. Teva Pharmaceuticals USA, Inc.*, Nos. 2017-1240, 1455-1887 (Fed. Cir. Mar. 28, 2019)**: Claims to treatments relying on natural laws can be patent eligible.

Two weeks after *Natural Alternatives* was decided, another Federal Circuit panel (Wallach, Clevenger, and Stoll, JJ.) continued the Court's view that "methods of treatment" can avoid ineligibility under *Mayo* and *Alice*. In *Endo*, the claims relied on the relationship between the body's rate of clearing the metabolite creatine and the rate for clearing opioids. The method required measuring a patient's creatine clearance rate and then administering an opioid based on that rate. Citing *Vanda Pharmaceuticals*, the panel reversed the district court's finding of ineligibility. As the panel reasoned, method of treatment claims like in *Endo* and *Vanda* can be distinguished from *Mayo* in that, while the claims in *Mayo* merely required "giving [a] drug to a patent with a certain disorder," the claims in *Endo* and *Vanda* require giving a specific dose of the drug based on specific testing. According to the panel, such claims are eligible because they are "directed to a specific method of treatment for specific patients using a specific compound at specific doses to achieve a specific outcome" whether or not steps are governed by natural laws.

***Barry v. Medtronic, Inc.*, No. 2017-2463 (Fed. Cir. Jan. 24, 2019):** An inventor's subjective and unclaimed "intended purpose" for an invention can determine public use and on-sale bars.

More than a year before filing, Dr. Barry successfully used his claimed surgical method on three patients. He then saw each patient for follow-up appointments that he deemed necessary to determine if his method worked, with two of the appointments also falling outside the pre-AIA Section 102(b) grace period. It was only after the third of these appointments, which was within the Section 102(b) grace period, that Dr. Barry felt confident that his invention functioned for its intended purpose. Accordingly, the district court held that his earlier actions did not constitute invalidating public use or sales (i.e., that the invention was not "ready for patenting" earlier).

The Federal Circuit majority (Taranto, J., joined by Moore, J.) affirmed that the invention was not "ready for patenting" before the critical date and that the surgeries fell in the experimental-use exception to "on sale" and "public use" bars. The majority concluded that Dr. Barry did not reduce his invention to practice until the final postoperative follow-up because that follow up was "reasonably needed" to determine if the invention worked for its "intended purpose."

In dissent, Chief Judge Prost argued that the "ready for patenting" requirement that defines the statutory bars is distinct from "reduction to practice" and meant to answer whether the inventor could have obtained a patent. According to the dissent, Dr. Barry's method was ready to patent after the first two surgeries and follow-ups, if not after the first. Dr. Barry charged his usual fee for the surgeries, and the patients were not told that the surgery was experimental. The early surgeries worked, and no multiple surgery or follow up requirement or "purpose" was claimed.

On April 29, 2019, Medtronic's petition for panel rehearing and rehearing *en banc* was denied, leaving stand the panel majority decision that gives strong weight in determining Section 102 bars to the inventor's subjective view of whether an invention works for its "intended purpose."

***Mylan Pharms. Inc. v. Research Corp. Techs., Inc.*, Nos. 2017-2088, -2089, -2091 (Fed. Cir. Feb. 1, 2019):** Joined parties can appeal adverse IPR decision without initial petitioner.

An initial Petitioner timely filed an IPR, but had not been threatened with infringement and thus lacked Article III standing to appeal. Three days after the Board instituted the initial petition, three other companies filed for joinder under 35 U.S.C. § 315(c). Each joining company had been sued for infringement more than a year earlier, and thus, absent joinder, their petitions were otherwise time barred. After an adverse decision from the Board, the initial petitioner did not appeal, leaving only the joined parties to appeal. The patentee objected that, absent the initial petitioner, the joined parties lacked standing and did not "fall within the zone of interests of 35 U.S.C. § 319"—i.e., absent the initial petitioner, their own petitions were allegedly time barred.

The Federal Circuit (Lourie, Bryson, and Wallach, JJ.) disagreed. As the panel explained, Section 315 allows entities to be joined "as a party" and Section 319 gives a "party" a right to appeal. Thus, even absent the initial petitioner, the joined parties fell "within the zone of interests of § 319 and are not barred from appellate review."

***Momenta Pharma v. Bristol-Myers Squibb Co.*, No. 2017-1694 (Fed. Cir. Feb. 7, 2019)**: IPR petitioner lacked standing for appeal after it suspended plans for a competing product.

Momenta petitioned for IPR of a patent covering the immunosuppressant Orencia. At the time, Momenta was planning a biosimilar, which it had in clinical trials. But by the time of appeal, Momenta had suspended its development plans after its competing product failed Phase 1 trials. The Federal Circuit (Newman, Dyk, and Chen, JJ.) held that Momenta thus lacked the present "concrete and particularized" interest required for Article III standing. The panel rejected the argument that the patent could impact future development, finding a generalized threat of harm fell short of an "impending" injury: "[T]he cessation of potential infringement means that Momenta no longer has the potential for injury, thereby mooting the inquiry." Taken with *Mylan* above, *Momenta* illustrates that, while statutory standing may be durable, constitutional standing for Article III courts must be preserved up to and through appeal.

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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