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Federal Circuit Update (May 2023)

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This edition of Gibson Dunn's Federal Circuit Update summarizes the Supreme Court's recent decision in ***Amgen v. Sanofi*** and the current status of several other petitions pending before the Supreme Court, provides an update on a proceeding by the Judicial Council of the Federal Circuit, and summarizes recent Federal Circuit decisions concerning inventorship, attorneys' fees, obviousness, and conception and reduction to practice.

Federal Circuit News

***Supreme Court*:**

On May 18, 2023, the United States Supreme Court issued its decision in ***Amgen Inc. v. Sanofi*** (U.S. No. 21-757) and affirmed the Federal Circuit (see summary of Federal Circuit opinion from February 2021 update).

The Amgen patents at issue claimed an entire genus of antibodies that bind to specific amino acid residues on PCSK9 and block PCSK9 from binding to LDL receptors. Antibodies that inhibit PCSK9 from binding to and degrading LDL receptors are used to treat patients with high LDL cholesterol, which can lead to cardiovascular disease, heart attacks, and strokes. Amgen's patents identified 26 of these PCSK9-inhibiting antibodies and disclosed two methods to make other antibodies that perform the binding and blocking functions it described. Sanofi argued that neither of these two methods enable a person of ordinary skill in the art to generate additional antibodies reliably.

The Supreme Court agreed. While the Court acknowledged that Amgen's specification "enables the 26 exemplary antibodies it identifies," "the claims before us sweep much broader than those 26 antibodies," and Amgen's two disclosed methods failed to enable a person of skill in the art how to make the entire universe of antibodies. The first method described a step-by-step trial-and-error method that Amgen followed to identify the 26 exemplary antibodies. The second method required scientists to make substitutions to the amino acid sequences of the known antibodies to determine if they work too. The Court reasoned that this would force scientists to engage in "painstaking experimentation," which was "not enablement."

***Noteworthy Petitions for a Writ of Certiorari*:**

This month, there is a new potentially impactful petition pending before the Supreme Court:

- ***CareDx Inc. v. Natera, Inc.*** (US No. 22-1066): The petition raises the question whether a new and useful method for measuring a natural phenomenon is eligible for patent protection under 35 U.S.C. § 101. After respondent in this case waived its right to file a response, retired Federal Circuit Judge Paul R. Michel and Professor John F. Duffy filed an *amici curiae* brief in support of Petitioners. The Court thereafter requested a response, which is due on June 29, 2023.

As we summarized in our April 2023 update, there are several petitions pending before the Supreme Court. We provide an update below:

Related People

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- After requesting a response in ***Avery Dennison Corp. v. ADASA, Inc.*** (US No. 22-822) and ***Arthrex, Inc. v. Smith & Nephew, Inc.*** (US No. 22-639), the Court denied the petitions. After requesting the views of the Solicitor General, the Court also denied the petitions in ***Interactive Wearables, LLC v. Polar Electro Oy*** (US No. 21-1281) and ***Tropp v. Travel Sentry, Inc.*** (US No. 22-22), although Justice Kavanaugh would have granted both petitions.

- The Court is considering petitions in ***Nike, Inc. v. Adidas AG et al.*** (US No. 22-927) and ***Ingenio, Inc. v. Click-to-Call Technologies, LP*** (US No. 22-873), having requested a response in both cases. The response in ***Nike*** has been filed, and the response in ***Ingenio*** is due June 26, 2023.

- The Court will consider ***NST Global, LLC v. Sig Sauer Inc.*** (US No. 22-1001) during its June 15, 2023 conference.

Other Federal Circuit News:

Release of Prior Orders in Ongoing Judicial Investigation. As we summarized in our April 2023 update, the Judicial Council of the Federal Circuit released a statement confirming that a proceeding under the Judicial Conduct and Disability Act and the implementing Rules had been initiated naming Judge Pauline Newman as the subject judge. On May 16, 2023 and June 5, 2023, the Federal Circuit released public versions of all prior orders of the Special Committee and the Judicial Council, as well as Judge Newman's letter responses to date. The orders may be accessed here and here.

Upcoming Oral Argument Calendar

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

Key Case Summaries (May 2023)

HIP, Inc. v. Hormel Foods Corp., No. 22-1696 (Fed. Cir. May 2, 2023): HIP disputed the inventorship of a Hormel patent directed to methods of precooking bacon and meat pieces. Hormel had entered into a joint agreement with David Howard, an employee of HIP's predecessor company, to improve on its microwave cooking process for precooked bacon. Howard alleged that during these initial meetings, he had disclosed the infrared preheating concept at issue. Subsequent testing revealed that "preheating the bacon with a microwave oven prevented condensation from washing away the salt and flavor." Hormel then filed a patent application on this process, which was ultimately granted, but did not name Howard as an inventor. The district court concluded that Howard should have been listed as a joint inventor on the patent having contributed the preheating with an infrared oven concept in one of the independent claims.

The Federal Circuit (Lourie, J., joined by Clevenger and Taranto, JJ.) reversed. Under Federal Circuit precedent, an inventor must make a contribution to the claimed invention that is "not insignificant in quality when the contribution is measured against the dimension of the full invention." The Court determined that Howard's alleged contribution of using an infrared oven is "insignificant in quality" to the claimed invention. In fact, preheating with an infrared oven was mentioned only once in the patent specification as an alternative to a microwave oven. In contrast, preheating with microwave ovens featured prominently throughout the specification.

Sanofi-Aventis Deutschland GmbH v. Mylan Pharmaceuticals Inc., No. 21-1981 (Fed. Cir. May 9, 2023): Mylan petitioned the Patent Trial and Appeal Board ("Board") for *inter partes* review ("IPR") of a Sanofi patent directed to a drug delivery device. The Board concluded that the challenged patent was unpatentable as obvious over prior art, including prior art reference, de Gennes. Sanofi argued that de Gennes was not analogous art, but the Board disagreed finding that de Gennes focused on a problem that was "reasonably

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pertinent" to a problem faced by an inventor of the challenged patent, in part because the problem was addressed in a second prior art reference, Burren.

The Federal Circuit (Cunningham, J., joined by Reyna and Mayer, JJ.) reversed. In determining whether a reference is analogous art, a patent challenger must compare the reference to the problem addressed by the challenged patent, not solely to the problem addressed by other prior art references. Because Mylan argued solely that de Gennes was analogous to Burren, not the challenged patent, Mylan did not meet its burden to establish de Gennes was analogous art.

OneSubsea IP UK Limited v. FMC Technologies, Inc., No. 22-1099 (Fed. Cir. May 23, 2023): OneSubsea sued FMC alleging infringement of ten OneSubsea patents related to the subsea recovering of production fluids from an oil or gas well. FMC ultimately prevailed when the district court (Judge Atlas) granted its summary judgment motion of noninfringement. FMC then filed a motion under 35 U.S.C. § 285 for attorneys' fees. After the briefing concluded, the case was reassigned to Judge Bennett following Judge Atlas's retirement. Judge Bennett denied FMC's § 285 motion.

The Federal Circuit (Moore, C.J., joined by Clevenger and Dyk, JJ.) affirmed. FMC argued that instead of applying an abuse-of-discretion standard, the Court should apply *de novo* review to the § 285 decision because Judge Bennett only briefly "lived with the case." The Court rejected this suggestion determining that appellate courts have consistently reviewed successor judges' decisions on discretionary issues for abuse of discretion.

Medtronic, Inc. v. Teleflex Innovations S.À.R.L., Nos. 21-2356, 21-2358, 21-2361, 21-2363, 21-2365 (Fed. Cir. May 24, 2023): Medtronic filed thirteen IPR petitions of five related Teleflex patents directed to guide extension catheters that use a tapered inner catheter. In five of the final written decisions, the Board found that the primary prior art reference, Itou, did not qualify as prior art because the claimed inventions were conceived prior to Itou's filing date and actually reduced to practice prior to the critical date, or diligently worked on toward constructive reduction to practice before the challenged patents' effective filing date, which requires in part, that the invention would work for its intended purpose.

The majority (Lourie, J., joined by Moore, C.J.) affirmed. While inventor testimony may serve as evidence of reduction to practice, it must be corroborated by independent evidence. The majority concluded that the Board's finding that the testing performed by Teleflex was sufficient to show that the claimed invention worked for its intended purpose. The majority also determined that the inventors' actual reduction to practice was sufficiently corroborated in the form of both documentary evidence and noninventor testimony.

Judge Dyk dissented. In his opinion, the inventors' testimony did not show that the prototypes would have worked for their intended purpose, in part because the tests were "more qualitative than quantitative," and failed to "reproduce[] the operating conditions which would be encountered in any practical use of the invention." He also found that Teleflex failed to corroborate the inventors' testimony, because "Teleflex produced essentially no internal documents corroborating any testing . . . in the critical period." Teleflex argued that this evidence likely existed at one time but had since been destroyed. Judge Dyk disagreed with the majority's concern that this would impose an "impossible standard" by requiring that "every point of reduction to practice be corroborated." In his opinion, a rule that favors retention of relevant documents does not create an "impossible standard" for inventors seeking to enforce a patent.

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 update:

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