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Patent Cases To Watch In 2023

By **Ryan Davis**

Law360 (January 2, 2023, 12:03 PM EST) -- The Supreme Court's foray into what it takes to enable someone to make a patented invention, the patent infringement implications of labels on generic drugs and a dispute over which arguments can be in court following an inter partes review are among the patent cases attorneys will be tracking this year.

Amgen Inc. v. Sanofi

The only patent case that the U.S. Supreme Court has agreed to hear so far this term has the potential to reshape the law on the patent enablement requirement, an issue the justices have rarely delved into before.

The high court agreed in November to consider whether the Federal Circuit is correct that patents must disclose enough information to enable skilled people to "reach the full scope" of an invention or whether it's sufficient that they are simply able to "make and use" the invention, which is the wording used in the statute.

The Federal Circuit upheld a lower court ruling that wiped out a jury verdict Amgen won against Sanofi, concluding that Amgen's patents on the cholesterol-lowering drug Repatha claim a "vast" class of antibodies and that it would take "undue experimentation" to practice the claimed invention.

Amgen's cert petition argues that the appeals court's "full scope" requirement is found nowhere in the statute and is often "impossible" to meet, so "the impact on innovation is devastating."
Sanofi maintains that the Federal Circuit "merely applied well-established law" and correctly held that skilled people would not be able to make Amgen's invention.

Since the high court has infrequently opined on the patent enablement rule, the case could have significant implications, Will Milliken of Sterne Kessler Goldstein & Fox PLLC said.

"The biggest thing is that because this is not an area that the Supreme Court has a lot of jurisprudence in, whatever it says is going to be the authoritative statement of law," he said.

Whether patents meet the enablement requirement is often a key issue in biotechnology and pharmaceutical cases, so the high court's decision will be particularly influential in those areas, Irena Royzman of Kramer Levin Naftalis & Frankel LLP said.

She said she expects the justices to be wary of lowering the Federal Circuit's full scope requirement because "it's hard for me to see the Supreme Court saying that based on a limited disclosure, you can monopolize a therapeutic target."

Brian Nolan of Mayer Brown LLP noted that the requirement that patents enable someone to make and use the invention is found in the same part of the Patent Act as the rule that patents must have an adequate written description. But the justices rejected a case challenging a similar "full scope" requirement in the written description rule just days after taking the Amgen case. A rehearing petition has been filed in the written description case, and is set for consideration by the justices on Jan. 6.

"I don't know if the court has appreciated the interplay between these two issues," Nolan said. He added that if the justices undo the full scope requirement for enablement, certain patents "may get over one barrier, but they may then confront what some consider an insurmountable barrier on written description."

The case is Amgen Inc. et al. v. Sanofi et al., case number 21-757, in the Supreme Court of the United States.

Teva Pharmaceuticals USA Inc. v. GlaxoSmithKline LLC

The patent infringement risk faced by generic drugmakers when they use so-called "skinny labels" on their products is at the heart of this case, in which the Supreme Court asked for the U.S. solicitor general views in October.

The Federal Circuit held Teva liable for $235 million for infringing a GSK heart drug patent, even though Teva's product used a skinny label, which carves out uses of the drug that are patented by the name brand company.

Teva argues the finding that it induced others to infringe, despite its label not mentioning the patented use, "eviscerates" the law that inducement requires active encouragement to infringe and puts all generic drugs with skinny labels at risk. GSK counters that the decision is sound because the evidence shows Teva's marketing materials encouraged infringing uses.

Similar to the Amgen case, the Teva case is notable because induced infringement in the context of generic drugs is not an area the Supreme Court has often addressed, Milliken said.

If the justices take the case, the potential outcomes "run the gamut," he said, from a generic-friendly decision that carving out patented uses on the label effectively bars a finding of induced infringement, to a holding in favor of branded companies that even with a carveout generics makers must know that people will engage in infringing uses.

"It could have a really major impact one way or another on how quickly generic versions of branded drugs end up getting to market," Milliken said.

Paul Ragusa of Baker Botts LLP said if the justices take the case, they may be skeptical of the Federal Circuit's holding that generics makers may need to alter skinny labels, which are approved by the U.S. Food and Drug Administration, to avoid infringement liability.

"That's where this conflict comes into play — doing something that's contrary to what the FDA has already told you that you can do," he said.

The case is Teva Pharmaceuticals USA Inc. v. GlaxoSmithKline LLC et al., case number 22-37, in the Supreme Court of the United States.

Apple Inc. v. California Institute of Technology

The Supreme Court is weighing an appeal by Apple in this case involving which invalidity arguments companies that challenge a patent at the Patent Trial and Appeal Board can later make in court if it survives. The outcome could have a significant impact on the willingness of companies to challenge patents at the board.

Apple succeeded in getting the Federal Circuit to vacate a $1.1 billion verdict against it and Broadcom in a suit by Caltech, but in the process, the appeals court overruled precedent regarding the estoppel provision in inter partes reviews.

Previously, the court had held that patent challengers could not later raise in court any invalidity argument the PTAB addresses in its final decision. But it reversed course in the Apple case and held that the bar applies to any argument the challenger raised, or reasonably could have raised, at the board.

Apple says that change "essentially rewrites the statute" and has "far-reaching consequences for the patent system." Caltech has responded that the Federal Circuit's ruling was a "clear and proper application of the statutory language" and that Apple's reading of the statute is "unnatural and illogical."

Eliot Williams of Baker Botts LLP said if the justices take the case "it would be huge. It could have a significant effect on PTAB filings." A decision reversing the Federal Circuit and letting patent challengers withhold invalidity arguments in PTAB petitions, then later raise them in court, would make inter partes reviews "much more attractive to many accused infringers," he said.

While IPRs have become a key part of patent litigation, Williams said there are still many defendants who are very concerned about being left with no invalidity arguments if they lose an IPR and thus forgo challenging patents at the PTAB.

"Taking some of that sting away would make it more popular than it even is today," he said.

The case is Apple Inc. et al. v. California Institute of Technology, case number 22-203, in the Supreme Court of the United States.

In re Grand Jury

It doesn't involve patents, but this case about attorney-client privilege set for argument at the Supreme Court on Jan. 9 could be especially important in intellectual property litigation, with one IP group urging the justices to undo a decision they say will hinder the ability to advise clients in patent litigation.

The Ninth Circuit ordered an unnamed tax law firm to turn over documents the court said were not privileged because their primary purpose was business, rather than legal advice.

The New York Intellectual Property Law Association told the justices last month that IP attorneys often provide both business and legal advice, and a holding that such communications are not privileged will discourage their ability to have frank communications with clients.

NYIPLA President-Elect Robert Rando of Greenspoon Marder LLP said in an interview that the issues with legal and business components that patent attorneys frequently discuss with clients include the strength of a patent, technology investment and licensing.

If clients are concerned that those discussions could be produced in court, they "might be wary about disclosing everything that they might otherwise feel comfortable disclosing" to their attorney, he said.

The case is In re Grand Jury, case number 21-1397, in the Supreme Court of the United States.

University of California v. the Broad Institute Inc.

This Federal Circuit appeal of a PTAB decision over which scientists were the first to invent the breakthrough gene-editing technology CRISPR will impact what it means to have conceived of an invention, said Royzman of Kramer Levin.

The PTAB found that the Broad Institute and the Massachusetts Institute of Technology invented the use of CRISPR in plants and animals before scientists at the University of California and University of Vienna — who won the Nobel Prize for it — based in part on lab notes and emails from members of the latter group that they weren't sure the invention would work.

Prominent scientists have weighed in and maintained that using such comments against inventors "basically chills normal scientific communications, and I think that's actually very interesting," Royzman said. The appeals court has not yet scheduled arguments.

The case is the Regents of the University of California v. the Broad Institute Inc., case number 22-1594, in the U.S. Court of Appeals for the Federal Circuit.

--Editing by Gemma Horowitz.
