

Patent Cases To Watch In 2021

By **Ryan Davis**

Law360 (January 3, 2021, 12:02 PM EST) -- A constitutional challenge to the Patent Trial and Appeal Board and a call for the U.S. Supreme Court to clarify patent eligibility after a bitter Federal Circuit split are among the high-profile patent cases on the docket this year. Here's a look at those and others to watch.

U.S. v. Arthrex Inc.

No case looms larger on the 2021 patent landscape than the U.S. Supreme Court's review of a Federal Circuit ruling that Patent Trial and Appeal Board judges are unconstitutionally appointed, which has the potential to shake up patent law.

"Arthrex is the 800-pound gorilla in the Supreme Court because of the potential ramifications that it can have, depending on how the court decides the case," said John O'Quinn of Kirkland & Ellis LLP.

The appeals court held in 2019 that PTAB judges did not have adequate oversight from the director of the U.S. Patent and Trademark Office. It stripped them of employment protections so they can be more easily fired, saying that solved the problem, which spurred all three parties in the case to appeal to the high court.

The USPTO and Smith & Nephew Inc., which successfully challenged Arthrex's suture patent, told the justices the appeals court was wrong and the judges were properly appointed. Arthrex maintains the Federal Circuit's fix didn't go far enough and that the entire inter partes review system must be struck down so Congress can pass a new law.

The Supreme Court will hear arguments later this year, and a decision siding with Arthrex could turn the patent world upside down by eliminating, possibly for an extended period, a tool that has become a key part of most patent cases.

"We have a very, very wide spectrum of what potentially could happen," said Ashley Moore of McKool Smith PC. "That's why I'm definitely keeping an eye on it, as it seems like at least there's an option for there to be a big change in IPRs."

If the justices find no constitutional problem, or that the Federal Circuit's fix was appropriate, the case will have minimal impact. But if they find a flaw, the most important thing will be what they identify as

the remedy, "because that will be the driver of whether or not the system in its current form can continue, or whether it will require a legislative fix," O'Quinn said.

The court might accept the Federal Circuit's solution, come up with another that could cause limited disruption, or kick it Congress.

If the Supreme Court finds a constitutional problem and disagrees with the Federal Circuit's approach, "it could be more aggressive or it could be less aggressive. There's a lot of options on the table," said Steven Horowitz of Sidley Austin LLP.

The outcome might impact hundreds or even thousands of inter partes review decisions, so "it can have some far-reaching effects with regards to IPRs, if the Federal Circuit's solution wasn't sufficient to fix the problem," said Ha Kung Wong of Venable LLP.

American Axle & Manufacturing Inc. v. Neapco Holdings LLC

This patent eligibility case bitterly divided the full Federal Circuit, which voted 6-6 in July not to hear it en banc, setting the stage for a U.S. Supreme Court appeal that once again asks the justices to wade into the contentious issue of what type of inventions are eligible for patenting under Section 101 of the Patent Act.

Half the Federal Circuit judges backed a panel ruling that American Axle's driveshaft technology can't be patented because it claims only a natural law regarding vibrations, while the other half maintained it is a patent eligible mechanical invention, not simply a natural law. One dissenting judge said the ruling will "lead to insanity."

After a series of patent eligibility rulings like *Alice v. CLS Bank* several years ago, the justices have rejected dozens of other petitions on the issue. American Axle's attorney, Jay Nuttall of Steptoe & Johnson LLP, said the sharp Federal Circuit split and the nature of the invention means that "this is something the Supreme Court would likely be interested in."

"There's obviously been a lot of 101 petitions that have been denied, and we're well aware of those, but we do think that this case is different," he said. The company filed its cert petition in late December.

Jeff Nichols of Brinks Gilson & Lione said the case "may buck the trend" of the Supreme Court refusing to address patent eligibility again. While other cases on the issue have involved business methods, software and life sciences, American Axle stands out because it involves a traditional mechanical invention, he said.

"Many have argued that the Federal Circuit's decision in *American Axle* will open the floodgates to Section 101 challenges to mechanical inventions, well beyond what was intended by Section 101 or the Supreme Court's *Alice* decision," he said.

If the justices hear the case, they could use it to clarify the standard for patent eligibility, which Nuttall said would be welcome because "there is a lot of ambiguity and confusion and contradictory opinions on what the law is, even amongst the judges that are supposed to be experts in this area."

Apple Inc. v. Iancu

It's Silicon Valley versus the USPTO in this high-profile case, where Apple, Google, Intel and Cisco are asking a Northern District of California judge to block PTAB rules that allow the board to refuse to review patents when an infringement trial is looming in court.

The tech titans claim in their suit, filed in August, that the practice undermines the America Invents Act and has "dramatically reduced the availability" of inter partes reviews. The patent office moved to dismiss in November, saying the companies have no standing to challenge agency policies.

Groups representing inventors have sought to intervene and asked the court to halt all AIA reviews until the PTAB codifies its current practice in formal rules.

If the tech companies prevail, "the impact will likely be significant," and will aid companies that challenge patents, Nichols said.

"More IPR petitions will likely be granted, resulting in more instances of simultaneous parallel litigation at the patent office and the district court," he said.

The USPTO's rules have made it harder to get inter partes reviews instituted, so the case "is an interesting and potentially important issue," O'Quinn said. However, he noted that the policy's future depends not just on the litigation, but also on the upcoming change in the White House.

While the USPTO has put out a request for comments on whether the policy should be enshrined in formal rules, that process is unlikely to be complete by Jan. 20, and President-elect Joe Biden's administration might not be inclined to keep pursuing it, he noted.

"Query whether there will be an interest in making it easier to institute IPRs and reducing some of the burdens vis-a-vis IPR proceedings," O'Quinn said. "So I think that's something to keep your eye on."

Idenix Pharmaceuticals LLC v. Gilead Sciences Inc.

Billions of dollars are on the line in this Supreme Court appeal, in which Merck & Co. unit Idenix is fighting to revive the largest patent verdict in U.S. history and asking the justices to reconsider key validity requirements for patents.

In a petition filed in September, Idenix said the Federal Circuit wrongly upheld a Delaware judge's ruling that a patent for a hepatitis C treatment, which a jury ordered Merck to pay \$2.54 billion for infringing, was invalid.

The court found the patent did not enable a skilled person to make and use the invention, as required by patent law, because it described thousands of compounds and each would have to be screened.

Idenix argues the Federal Circuit was wrong in determining that genus claims, those that describe a collection of related pharmaceutical compounds, do not meet the enablement requirement as a matter of law if they contain a large number of compounds. It also maintains there is no separate requirement that patents must have an adequate written description, as the Federal Circuit has held.

"If they do take this case up, it will be one of most significant pure substantive patent law issues that the court has addressed in a long time," Horowitz said. The court will decide within months whether to hear the case.

A decision backing Idenix would mean that "it would be much clearer how the patentee could satisfy the enablement requirement," making it easier for pharmaceutical companies to claim large sets of compounds in a patent, he said.

If the court were to discard the written description requirement, he added, "that would have a very significant impact on patent litigation, because one of the handful of standard defenses in patent cases would go away."

Others To Watch

Minerva Surgical Inc. v. Hologic Inc.: Both sides in this case have asked the Supreme Court to review the doctrine of assignor estoppel, which bars inventors who sell their patent rights from challenging the patent's validity. Minerva maintains the doctrine should be abolished entirely, while Hologic says it should apply both in court and the PTAB, not just in court, as the Federal Circuit has ruled.

"It's a really interesting case because there is a clear acknowledgment from both sides that the Federal Circuit has inconsistent results," said Greg Corbett of Wolf Greenfield & Sacks PC. "Hopefully, the Supreme Court will resolve that."

California v. Texas: This case is about the constitutionality of the Affordable Care Act, but it contains a lurking patent law issue: If the health care law is struck down, the regulatory pathway it created for biosimilar drugs could fall as well.

Venue fights: 2020 saw an unusual number of mandamus rulings by the Federal Circuit about whether complaints were properly filed in the patent hotbeds of the Eastern District and Western District of Texas. Given the volume of cases filed in those courts, more disputes are likely to arise this year that could potentially clarify when venue is proper there.

--Editing by Philip Shea.