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Arthrex takes patent fight to United States Supreme Court, awaits crucial decision

12-15 minutes

Arthrex has taken a contentious patent fight all the way to the Supreme Court.

The local medical device manufacturer has argued its points and awaits a decision from the high court.

On March 1, the Supreme Court <u>heard oral arguments in the case</u>, which involves how administrative patent judges are appointed. A decision on the case is expected by the end of June.

In its challenge, North Naples-based Arthrex contends the system for choosing U.S. patent judges is not only flawed, but unconstitutional.

The Supreme Court case arose out of a patent dispute between Arthrex and Smith & Nephew, a British-based competitor. It led to an unfavorable decision by the Patent Trial and Appeal Board against Arthrex.

The board found the challenged patent claims "unpatentable."

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If successful in its arguments, Arthrex could get that decision overturned, or invalidated.

Since its creation nearly 10 years ago, the patent board has canceled thousands of claims, leading critics to dub it a patent "death squad."

Lisa Gardiner, a spokeswoman for Arthrex, declined to discuss the situation saying: "We are not able to comment or speak on matters of pending litigation."

The Supreme Court's decision will not only affect Arthrex.

The ruling could have bearing on 100 or so other cases involving appeals of patent judges' decisions based on what has become known as the Arthrex case. Those other cases now sit in limbo, awaiting an outcome from the high court.

The case also puts into question the future of the more than 250 administrative judges who hear patent disputes.

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A rivalry

Pioneers in arthroscopic, or minimally invasive, surgical technology, used for the repair of knees, shoulders, hips and other joints, Arthrex and Smith & Nephew have been involved in costly and drawn-out patent disputes with one another for nearly 20 years.

Naples resident and CEO Reinhold Schmieding founded Arthrex in 1981. The company has seen rapid and steady growth, and Forbes estimates the company's annual revenue at \$2.6 billion.

The company has developed thousands of products, with more than 1,500 patents or patents pending.

Court battles between Arthrex and Smith & Nephew have resulted in multimillion-dollar awards and settlements on both sides over the years — as well as multiple appeals, ending in a few reversals.

In 2018, Smith & Nephew challenged the validity of various claims in a <u>patent</u> owned by Arthrex for knotless sutures used to reattach tissue to bone, asking for a review by a three-judge panel of the Patent Trial and Appeal Board.

The challenge came after the two settled a lawsuit Arthrex brought over the same patent.

After a review, the patent board found Arthrex's claims unpatentable, determining they were anticipated or obvious, based on art published before the company applied for protection.

After the panel ruled in Smith & Nephew's favor, Arthrex sought relief from the Federal Circuit of the U.S. Court of Appeals, with national jurisdiction, claiming the judges had been unconstitutionally appointed, so they had no power to render a final decision on its patent claims.

Ultimately, the appeals court agreed with Arthrex, but offered a remedy the company didn't like or see as a cure — eliminating the judges' tenure protections, making them removable at will by their bosses, without cause. Arthrex has argued the court decision does nothing to solve the real

issue the company has raised — a lack of a higher authority to review and overturn the administrative patent judges' decisions.

Neither side in the legal spat liked the outcome from the Federal Circuit. After that court denied a rehearing, both sides appealed to the Supreme Court.

The Supreme Court granted a review in October, consolidating the appeals into a single case. The case involves two questions: Was there a constitutional violation and if so, did the Federal Circuit properly resolve it?

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The arguments

Smith & Nephew and the U.S. government, which joined the case on its side, argue the system for choosing the patent judges is constitutional and makes sense because the judges carry out, but don't make policy.

Arthrex, however, sees a need to upend the appointment process, which it views as unbalanced.

The company's arguments center around whether the patent judges should be classified as "principal," rather than "inferior" officers as they are today.

Arthrex contends the judges must be viewed as principal officers because they have so much power, with limited oversight, supervision or review over their decisions. As a result, the company argues the patent board's current structure violates the Appointments Clause of the U.S. Constitution because its judges aren't chosen by the President and confirmed by the Senate, like other principal officers, such as department heads, federal judges and ambassadors.



Instead, the Secretary of Commerce chooses the patent judges, in concert with the <u>United States</u> Patent and Trademark Office director.

"Administrative patent judges do one thing: decide cases. Their decisions are the executive's final word resolving billion-dollar disputes affecting the innovation landscape. They can even overturn earlier decisions by their own agency head to grant a patent," said Jeffrey Lamken, Arthrex's attorney, in his opening statements before the Supreme Court.

Without a superior in the executive branch to review or overturn the judges' decisions, "accountability suffers," he added.

"If a principal officer has review authority but refuses to exercise it and overrules subordinates, the President and the public can hold him accountable for that choice," Lamken said.

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A possible fix?

How to fix the situation, is for Congress, not the courts, to decide, Lamken told the justices.

"This court can't pencil in those solutions," he said. "It's more respectful of Congress to allow Congress to choose how to structure the agency."

On the other side of the legal fence, Malcolm Stewart, deputy solicitor general for the Department of Justice, who represents the U.S. government in the case, said the director of the Patent and Trademark Office can exercise control over the judges through guidance, opinions and other internal mechanisms, including halting a review, if necessary.

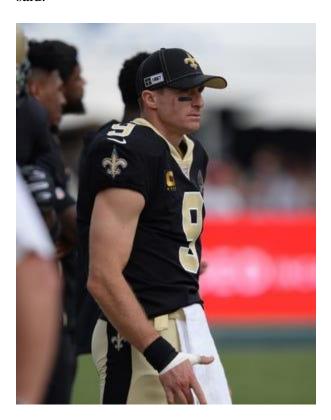
Therefore, the judges should be deemed inferior officers, as they are now, with no need to change the status quo, Stewart told the Supreme Court.

"Arthrex focuses primarily on the purported absence of any mechanism by which the director can review a panel's final written decision. But the board can grant rehearing of any such decision, and the director is a member of the board and is authorized to decide which members will sit on any panel," he said.

In his arguments before the Supreme Court, Mark Perry, the attorney for Smith & Nephew, said the director of the Patent and Trademark Office "can and does give substantive guidance" to the patent judges.

He emphasized the director can order a review of any of the patent board's decisions.

"Moreover, only the director takes final actions by confirming or canceling patent claims," Perry said.



To further his argument, he pointed out the patent involved in the Arthrex case is still valid.

"The board has declared it to be unpatentable, but the director has not canceled it. So, to this day, three years later, nothing has happened," he said.

He didn't discuss why the director never canceled the patent.

Asked about possible remedies if Arthrex prevails in the case, Perry suggested one solution may be to allow the director to unilaterally review patent board decisions, but he stated that's not the kind of outcome Arthrex seeks. Rather, he said, the company wants to "take down this whole system."

"You know, they don't actually want presidential confirmation," he said. "They don't actually want director review. What they want is for the court to — to blow up the whole thing because of a structural problem that ... we think doesn't exist."

The Obama Administration created the Patent Trial and Appeal Board in 2012 under the America Invents Act. At the time, then-president Obama described the act as "long overdue reform," saying it was "vital to our ongoing efforts to modernize America's patent laws," keeping them current with the rest of the world.

The legislation was designed to curtail patent infringement litigation, giving the board the power to review questionable patents and revoke them. The board's powers and decisions have proved controversial.

Supreme Court justices have scrutinized the tribunal six times since its creation, including Arthrex's constitutional challenge.

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"Enormous power"

During the <u>Supreme Court hearing</u> on the Arthrex case, several justices commented about the unusualness of the patent board's structure, describing it as a "rare bird," a "significant departure from general historical practice" and a "hybrid" model that appears to "give enormous power to inferior officers."

In response, Perry, Smith & Nephew's attorney agreed it's unusual, but noted it's also "well and historically founded" and unchallenged until now.

He said there's no question, these types of patent interferences have been decided by inferior, or non-principal, officers since as early as 1793.

"That's what has been carried forward into the modern tradition," Perry said.

In their deliberations, Supreme Court justices appeared conflicted about the issues Arthrex has raised and what if anything they should do about the legal challenge.

Based on their comments, some justices seemed more concerned about the deeply-rooted tradition of dealing with patent disputes than others.

During the hearing, justices discussed several of the hypothetical ways they might address Arthrex's constitutional concerns if the company should prevail in the case, including elevating the patent judges to true principal officers, appointed by the President, or making the patent office's director the final decision maker, with the ability to overturn the patent judges' decisions.

Arthrex's attorney reiterated that any permanent fix should come from Congress — and that what Arthrex seeks from the Supreme Court is relief from the patent board's unfavorable decision on its patent claims.

"Ultimately, it's more deferential, it's more respectful of Congress to give Congress the ultimate authority and give Congress the choice of what it believes is the right answer for the structure for an agency responsible for technological innovation and important property rights," Lamken said.

Justice Neil Gorsuch suggested waiting on Congress to do something could "take a long time."

Naples patent attorney Bryan Loeffler said the Arthrex case is an interesting and unusual one.

"What Arthrex is saying definitely has merit. These judges are taking away a very valuable property right," he said.

Obtaining patents is costly and time-consuming in the first place, so it shouldn't be too easy to challenge or overturn protective claims, Loeffler said.

"It's not a rubber stamp process to obtain a patent," he said. "I don't think it's right for the patent office to provide such an easy pathway for competitors to invalidate a patent."

Especially, he said, when there isn't a review process in place for board decisions.

Academic opinions on the Arthrex challenge vary, illustrated by a <u>panel discussion</u> of the legal arguments organized by Duke University's law school before the Supreme Court heard the case.

During the discussion, Melissa Wasserman, a professor at the University of Texas Law School, said case law and the supervision over the judges are "enough to make them inferior officers."

However, she said, if the Supreme Court finds otherwise, she would prefer to see Congress give the patent agency's head the final decision-making power over third-party challenges of granted claims in approved patents.

"I think that's the best way forward," Wasserman said.