

Hirshfeld's Arthrex Clearance Empowers Interim Leaders

By **Dani Kass**

Law360 (May 27, 2022, 12:38 PM EDT) -- The Federal Circuit on Friday held that Patent Commissioner Drew Hirshfeld had the authority to conduct U.S. Patent and Trademark Office director reviews mandated by the U.S. Supreme Court in *Arthrex*, adding clarity to the powers of interim agency directors.

The Supreme Court ruled in June 2021's *U.S. v. Arthrex* that a Senate-approved officer must be able to overturn Patent Trial and Appeal Board decisions that the USPTO disagrees with, since the PTAB judges themselves are not Senate-confirmed.

Hirshfeld — who is not Senate-confirmed but was leading the agency as a temporary director between former Director Andrei Iancu's January 2021 resignation and Director Kathi Vidal's April 2022 swearing in — set up a review process, and medical device company Arthrex Inc. challenged his authority to do so.

The Federal Circuit's precedential opinion Friday said Hirshfeld was within his rights to perform the reviews, as he was in a temporary role performing the director's duties while under a standing order issued by a director. The panel's analysis turned on a 1898 Supreme Court decision in *United States v. Eaton*, which confirms the president can set up a temporary official when a congressionally approved official is not available.

"In sum, Arthrex's appointments clause challenge runs headlong into *Eaton* and the Supreme Court's prior decision in this case," the opinion written by Chief Judge Kimberly Moore states. "We therefore conclude that the commissioner's exercise of the director's authority while that office was vacant did not violate the appointments clause."

If Arthrex had gotten its way, the case would have been remanded to the USPTO for Vidal to see whether she wants to rehear a PTAB decision invalidating one of Arthrex's patents. Baker Botts LLP partner Eliot Williams said, "practically," the decision Friday was "sort of inevitable" given the complications of an agency head not being allowed to make certain decisions.

"The other result would lead to paralysis at the Patent Office until a new director was appointed," Williams said.

Much of the opinion's tension comes from whether the Federal Vacancies Reform Act applies to the litigation. The FVRA focuses on duties that cannot be delegated, and at oral argument, the government

had stated that all USPTO director duties are delegable, including deciding rehearing requests. That didn't sit right with the panel.

"We find it disquieting that the government views the FVRA as impacting such a 'very small subset of duties' and not impacting the PTO at all," the opinion states. "That does not, however, justify departing from the plain language of the statute."

As such, the Federal Circuit agreed with the government that the FVRA doesn't apply, holding that because there is no language that "the director and only the director" can conduct the reviews, the director may delegate the duty.

Sterne Kessler Goldstein & Fox PLLC director William H. Milliken said part of the frustration is that the director rehearing isn't written in any statute, but was instead a mandate of the Supreme Court.

"[It's] something the Supreme Court imposed on the statute as a remedy for the constitutional violation," Milliken said. "It created this weird circumstance where the Federal Circuit has to interpret the statute to figure out if duties are delegable when the duty it's looking at isn't in the statute. It's this very weird, complicated exercise that the Federal Circuit was forced to go through."

Arthrex had also argued that allowing Hirshfeld to perform director duties violates the separation of powers based on how difficult it would be for the president to remove him, an argument the Federal Circuit said had "no merit." The court concluded that the president cannot remove Hirschfeld from his commissioner role without merit, but he has "unfettered power" to take the director's duties away.

Arthrex will have the ability to appeal based on arguments under the appointments clause, FVRA or separation of powers, if it's so inclined, Milliken said.

"The question is does the Supreme Court have an appetite to weigh back in after having resolved it once," Milliken said. "It's not unprecedented to look at a case twice at different stages, but we'll just have to wait and see whether Arthrex wants to pursue it further."

The justices may be attracted to how to construe an administrative law, which Baker Botts' Williams said makes the case have "higher than average odds" of getting taken up by the justices. But in all, "the odds are this is probably the end of [Arthrex]," he said.

Friday's ruling came down in a case where Smith & Nephew Inc. had successfully challenged Arthrex's suture patent at the PTAB. At the Federal Circuit, the case got sidetracked when Arthrex persuaded a panel that PTAB judges were not constitutionally appointed and couldn't make final decisions. That ultimately led to the Supreme Court's June decision giving the board more oversight.

On remand, Hirshfeld had denied Arthrex's review petition, meaning the PTAB's invalidation stood. The Federal Circuit affirmed that invalidation Friday.

As part of that analysis, the Federal Circuit addressed Arthrex's argument that the PTAB wrongfully delved into written description under Section 112 of the Patent Act when inter partes reviews are only allowed to raise Section 102 anticipation and Section 103 obviousness grounds.

The Patent Act requires the grounds of invalidation to be 102 or 103, but does not bar other sections from being reviewed, the panel said. In this case, written description was used by the PTAB to determine

whether a particular publication counted as prior art.

A USPTO spokesperson on Friday said the agency "welcomes the court's decision."

An attorney for Smith & Nephew declined to comment. Counsel for Arthrex didn't immediately respond to a request for comment.

The patent-in-suit is U.S. Patent No. 9,179,907.

Arthrex is represented by Anthony P. Cho, David Gaskey, Jessica Fleetham and David L. Atallah of Carlson Gaskey & Olds PC, and Jeffrey A. Lamken, Robert K. Kry and Jordan A. Rice of MoloLamken LLP.

Smith & Nephew is represented by Charles T. Steenburg, Richard F. Giunta, Nathan R. Speed, Turhan F. Sarwar and Michael N. Rader of Wolf Greenfield & Sacks PC, and in-house by Mark J. Gorman.

The case is Arthrex Inc. v. Smith & Nephew Inc. et al., case number 18-2140, in the U.S. Court of Appeals for the Federal Circuit.

--Editing by Robert Rudinger.