

## **See Here: No Standing Based on Vague Future Plans or Adverse Priority Findings**

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The US Court of Appeals for the Federal Circuit dismissed an appeal from a final written decision in an inter partes review (IPR) proceeding, finding that the petitioner lacked standing because it suffered no injury in fact. *Allgenesis Biotherapeutics Inc. v. Cloudbreak Therapeutics, LLC*, Case No. 22-1706 (Fed. Cir. Nov. 7, 2023) (Moore, Stoll, Cunningham, JJ.)

Allgenesis Biotherapeutics filed an IPR petition challenging a patent owned by Cloudbreak Therapeutics. The challenged patent discloses compositions and methods for treating the eye condition pterygium. During the IPR proceeding, Cloudbreak disclaimed all but two of the claims. The Patent Trial & Appeal Board issued a final written decision finding that Allgenesis failed to show that the remaining two claims were unpatentable. As part of its decision, the Board made a priority decision that a Patent Cooperation Treaty (PCT) application belonging to Allgenesis was not prior art to Cloudbreak's patent. Allgenesis appealed.

Article III of the US Constitution limits the Federal Circuit's jurisdiction to adjudication of "cases" or "controversies," which means the appellant must have (1) suffered an injury in fact (2) that is fairly traceable to the challenged conduct of the defendant and (3) likely to be redressed by a favorable judicial decision.

Allgenesis attempted to establish Article III standing based on two separate arguments. First, Allgenesis argued that it had standing based on potential infringement liability. To support that argument, Allgenesis offered a declaration by its vice president of finance that included information about a Phase II trial completed three years prior and a related 2020 publication. That declaration, however, did not identify any specific plan to conduct a Phase III trial or to seek US Food and Drug Administration (FDA) approval, and instead only contained generic statements that the project was not abandoned. While Allgenesis's briefing and oral argument included statements that it planned to engage in a Phase III trial, the Federal Circuit determined that there was no record support for this claim. The Court found that the evidence before it did not constitute the necessary concrete plans to convey standing to appeal the final written decision. Allgenesis also attempted to rely on its own failed attempts at seeking a settlement from Cloudbreak, but the Court concluded that this was insufficient to show a substantial risk of infringement.

Allgenesis's second argument was that the Board's priority decision created an injury in fact.

Allgenesis argued that the Board's determination about the priority date of Cloudbreak's patent affected Allgenesis's patent rights because it would have a preclusive effect on Allgenesis's pending applications. The Federal Circuit was unpersuaded and explained that collateral estoppel does not attach to a non-appeal priority decision from an IPR decision. To the extent that an examiner did reach the same conclusion as the Board, Allgenesis would be free to appeal that decision.

**Practice Note:** For Board petitioners seeking to establish standing to appeal unfavorable final written decisions, it is necessary to develop sufficient support to show standing in fact. For life sciences companies working in drug development, declarations should contain specific information about ongoing clinical trials and concrete timelines for future events, such as Phase III clinical trials or target dates for FDA submission. If a company either cannot provide such information or declines to do so for business purposes, the risks of not having Article III jurisdiction for appeal should be a consideration early in the IPR decision-making process.

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