

## *Mylan Labs. Ltd v. Janssen Pharmaceutica, N.V.*, 989 F.3d 1375 (Fed. Cir. 2021)

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Mylan appealed from a Patent Trial and Appeal Board (Board) discretionary denial of institution of an *inter partes* review (IPR) proceeding. The Board declined to institute Mylan's IPR under *NHK-Fintiv*, a multi-factor analysis that permits the Board to discretionarily deny institution based on the advanced status of other, parallel proceedings out of concern for efficiency. In this case, the Board denied institution based on two co-pending district court infringement actions brought by Janssen Pharmaceutica—one against Mylan Laboratories and the other against Teva Pharmaceuticals. In balancing the *NHK-Fintiv* factors to deny institution, the Board reasoned that both district court proceedings involved substantially similar invalidity contentions as Mylan's IPR petition and were set (or likely to be set) for trial prior to the mandatory deadline for Board to issue a Final Written Decision in the IPR.

Mylan sought both direct appellate review of this denial under 28 U.S.C. § 1295(a)(4)(A) and mandamus relief under 28 U.S.C. § 1651. Mylan made the same two legal assertions in its appeal and request for mandamus relief. First it argued that the Board's denial of institution based on the timing of the *Teva* litigation undermines Mylan's constitutional due process rights. Second, it argued that *NHK-Fintiv* denials are contrary to the Leahy-Smith America Invents Act (AIA). The U.S. Court of Appeals for the Federal Circuit ultimately dismissed Mylan's direct appeal for lack of jurisdiction under 35 U.S.C. § 314(d), and denied Mylan's request for mandamus on the merits.

The court first resolved the jurisdictional issue on the direct appeal. It determined that § 314(d) bars direct appellate review of *NHK-Fintiv* denials. Relying on its precedent in *St. Jude Medical, Cardiology Division, Inc. v. Volcano Corp.*, 749 F.3d 1373 (Fed. Cir. 2014), the court explained that § 314(d) limits the general appellate jurisdiction it has over Board decisions under 28 U.S.C. § 1295(a)(4)(A): both the language of § 314(d) and the surrounding structure of the law

**The U.S. Court of Appeals for the Federal Circuit's scope of review for *inter partes* review institution denials is very narrow.**

"dispel any notion" that the Federal Circuit may entertain appeals from IPR institution denials. The court explicitly rejected Mylan's argument that *Cuozzo Speed Technologies, LLC v. Lee*, 136 S. Ct. 2131 (2016), and *SAS Institute Inc. v. Iancu*, 138 S. Ct. 1348 (2018), undermined *St. Jude*. Accordingly, the court dismissed Mylan's direct appeal.

The court then turned to Mylan's request for mandamus relief. On the jurisdictional question, the court determined that § 314(d) did not bar its jurisdiction under 28 U.S.C. § 1651. Since "[a] decision denying institution prevents the Board from issuing any final decisions that falls within [the Federal Circuit's exclusive] direct appellate jurisdiction" under 28 U.S.C. § 1295(a)(4)(A), the court "must be able to protect [its] prospective jurisdiction through mandamus."

But when it came to the merits, Mylan's request for mandamus fell short. The Federal Circuit, after describing mandamus as a "drastic and extraordinary remedy," determined that the scope of the court's mandamus review for a Board decision denying institution "is very narrow" given that IPR institution decisions are committed to agency discretion. As a result, the court's review was confined to only "colorable constitutional claims." And as to Mylan's constitutional arguments, its procedural and substantive due process arguments failed because Mylan could not identify a deprivation of life, liberty, or property or a fundamental right to have the Board consider its IPR petition based only on parallel proceedings to which Mylan is party. As to Mylan's AIA challenges to *NHK-Fintiv*, the court stated that "it is difficult to imagine a mandamus petition that challenges a denial of

institution and identifies a clear and indisputable right to relief." As a result, the court found Mylan's AIA challenge unavailing.

Mylan has since filed a petition for a writ of certiorari to the U.S. Supreme Court, which remains pending. The petition asks the Court to consider the scope of § 314(d)'s direct appeal bar on decisions not to institute as well as the procedural and substantive legality of *NHK-Fintiv* under the Administrative Procedure Act and AIA, respectively.

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## RELATED CASES

- Petition for a Writ of Certiorari, *Apple Inc. v. Optis Cellular Tech., LLC*, No. 21-118 (July 2021) (asking whether the Federal Circuit may review *NHK-Fintiv* denials through direct appeal or mandamus as unlawful under the APA and AIA)
- Petition for a Writ of Certiorari, *Intel Corp. v. VLSI Technology LLC*, No. 21-888 (December 2021) (same)



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