

Axinn IP Update: District Court Retains Subject Matter Jurisdiction But Grants Dismissal After Paragraph III Conversion

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Axinn Update

On June 26, 2020, in *H. Lundbeck A/S v. Apotex Inc.*, C.A. No. 18-88-LPS, 2020 WL 3507795 (D. Del. June 26, 2020), Chief Judge Leonard P. Stark denied ANDA filer Sandoz, Inc.'s ("Sandoz") motion to dismiss for lack of subject matter jurisdiction after Sandoz had converted its Paragraph IV ("PIV") certifications to Paragraph III ("PIII") certifications. *See id.* at *1. Although Judge Stark at the same time granted Sandoz's alternative motion for judgment on the pleadings under Rule 12(c) based on those PIII conversions, *see id.* at *6, the ruling on subject matter jurisdiction is instructive on the legal bases an ANDA filer should assert when seeking dismissal from litigation after converting to PIII.

In Hatch-Waxman cases, subject matter jurisdiction is established after an ANDA filer submits an ANDA with a PIV certification and "a patent owner alleges that [the ANDA submission] infringes its patent under § 271(e)(2)." *AstraZeneca Pharm. LP v. Apotex Corp.*, 669 F.3d 1370, 1377 (Fed. Cir. 2012). Previous district courts have held that jurisdiction may not always be lost simply because an ANDA filer converts to a PIII certification. Instead, some district courts have held that "it is sufficient that the case was initially certified under [PIV]." *Sanofi v. Lupin Atl. Holdings SA*, C.A. No. 15-415-RGA, 2017 WL 384062, at *1 (D. Del. Jan. 26, 2017); *see also Cephalon, Inc. v. Sandoz, Inc.*, C.A. No. 11-821-SLR, 2012 WL 682045, at *4-5 (D. Del. Mar. 1, 2012)).

Nevertheless, Sandoz argued that the "jurisdictional hook" for plaintiff's infringement claims was "eliminated" once Sandoz converted to PIII certifications. *Lundbeck*, 2020 WL 3507795, at *4. The court rejected that argument, noting that Sandoz had "expressly refused" to stipulate that it would not, at some later date, convert its PIII certifications back to PIV certifications. *See id.* As a result, the court found that the prospect of Sandoz converting back, however "hypothetical," meant that Sandoz had

failed to meet “the formidable burden of showing that it is absolutely clear the alleged wrongful behavior [that is, the filing of PIV certifications] could not reasonably be expected to recur.” *Id.* (quoting *Sanofi*, 2017 WL 384062, at *1).

Although parties can of course agree to a stipulated dismissal based on a conversion from PIV to PIII certification, see, e.g., Stipulation and Order, *Depomed, Inc. v. Impax Labs., Inc.*, C.A. No. 12-2154 (D.N.J. Dec. 17, 2012), ECF No. 82, *Lundbeck* is a reminder that a court could determine that such a conversion, standing alone, is insufficient grounds for an ANDA filer to unilaterally terminate related Hatch-Waxman litigation under Rule 12(b)(1). See also *Sanofi*, 2017 WL 384062, at *1 (denying ANDA filer’s motion to dismiss for lack of subject matter jurisdiction after PIII conversion).

Lundbeck nevertheless provides ANDA filers with guidance on best practices to obtain dismissal after conversion to a PIII certification. Filers who convert to a PIII certification should move for judgment on the pleadings under Rule 12(c) and/or to dismiss for failure to state a claim under Rule 12(b)(6). ANDA filers can also still move to dismiss for lack of subject matter jurisdiction under Rule 12(b)(1), given that the Federal Circuit has yet to address the issue and other district courts are not bound by, and in fact might disagree with, the holding on Rule 12(b)(1) in *Lundbeck*.

