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The Federal Circuit finds jurisdiction over the ITC's decision not to institute an investigation under Section 337 and explains when claims are precluded by the FDCA

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On May 1, 2019, a three-judge panel of the Court of Appeals for the Federal Circuit issued its long-awaited decision in *Amarin Pharmaceuticals, Inc. v. ITC*, No. 2018-1247, 2019 WL 1925649 (Fed. Cir. May 1, 2019).

In that decision, the Federal Circuit affirmed the ITC's determination not to institute an investigation and to dismiss the complaint filed by Amarin Pharmaceuticals, Inc. ("Amarin"), holding that the complaint failed to present a cognizable claim under Section 337.

On August 30, 2017, Amarin filed a complaint at the ITC under Section 337, alleging that the named respondents falsely labeled and deceptively advertised their imported, synthetically-produced omega-3 products as "dietary supplements." Amarin asserted the products at issue were actually "new drugs" as defined in the FDCA and had not been approved for sale or use in the United States.

In its complaint, Amarin asserted two claims: (1) the respondents' importation and sale of the products was an unfair act or unfair method of competition under Section 337 because it violated § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a); and (2) the importation and sale of the products violated Section 337 based on the respondents' alleged violations of the standards and requirements for "new drugs" set forth in the FDCA.

On October 27, 2017, the ITC determined not to institute an investigation and dismissed Amarin's complaint on the basis that the allegations in the complaint were precluded by the FDCA. The ITC found that the FDA is charged with the exclusive administration of the FDCA.

On December 1, 2017, Amarin filed both a petition for review and a petition for a writ of mandamus to the Federal Circuit, arguing that the ITC has a statutory mandate to institute an investigation for all complaints filed under oath.

Among other arguments, Amarin contended that Section 337(b) imposed a nondiscretionary duty on the ITC to institute an investigation when presented with complaint, based on the statutory text stating "[t]he [ITC] shall investigate any alleged violation of this section on complaint under oath or upon its initiative."

MAJORITY OPINION

Chief Judge Prost, writing for the panel majority, first confirmed that the Federal Circuit had jurisdiction to review the ITC's decision in the case. The Federal Circuit then addressed Amarin's argument that the ITC had a mandatory duty to institute an investigation when presented with a complaint under oath.

> The Federal Circuit noted that the United States government has "nearly exclusive enforcement authority" under the FDCA such that "private parties may not bring suits to enforce the FDCA."

Lastly, the Federal Circuit held that the ITC correctly determined that Amarin's allegations were precluded by the FDCA.

The Federal Circuit has appellate jurisdiction over the ITC's decision not to institute an investigation

Amarin argued that the Federal Circuit has appellate jurisdiction to review the ITC's decision not to institute an investigation under 28 U.S.C. § 1295(a)(6), which grants the court with exclusive jurisdiction "to review the final determinations of the [ITC] relating to unfair practices in import trade, made under [S]ection 337 []."

In response, the ITC and the respondents (as intervenors in the appeal) argued that the Federal Circuit only has jurisdiction over final determinations made in instituted investigations and does not have jurisdiction over the ITC's decision to institute or not institute an investigation.

The Federal Circuit held that its decision in *Amgen Inc. v. ITC*, 902 F.2d 1532 (Fed. Cir. 1990), was controlling on this issue.

In *Amgen*, the ITC declined to institute an investigation where the patent at issue did not contain a process claim, which the ITC found to be a jurisdictional prerequisite to institute an investigation under Section 337(a)(1)(B)(ii).

In addition, the Federal Circuit in *Amgen* acknowledged that Section 337(c) had "been interpreted as requiring a 'final determination decision *on the merits*,'" but held that the ITC's decision not to institute an investigation was "intrinsically a final determination" because it "clearly reach[ed] the merits of [the] complaint and determinatively decide[d] [the complainant's] right to proceed in a [Section 337] action."

The Federal Circuit further explained in *Amgen* that "any future action brought by [the complainant] would necessarily raise the same issue, and would presumably be dismissed for the same reason."

In view of the fact that the FDA had not provided guidance as to whether the products at issue in Amarin should be considered "new drugs" that require approval, the Federal Circuit affirmed the ITC's decision not to institute an investigation under Section 337 based on the allegations in Amarin's complaint.

In view of the *Amgen* precedent, the Federal Circuit held that the ITC's decision not to institute an investigation based on Amarin's complaint was "intrinsically a final determination, i.e., a determination *on the merits*" like in *Amgen* because the ITC's determination "clearly reached the merits of the complaint and determinatively decided Amarin's right to proceed in a [Section 337] action."

Accordingly, "as long as Amarin's complaint is based on proving violations of the FDCA … Amarin's claims will be precluded." Finding appellate jurisdiction to be proper, the Federal Circuit did not substantively address Amarin's petition for a writ of mandamus.

The ITC does not have a mandatory duty to institute an investigation

Next, Amarin argued that Section 337(b) imposes a mandatory duty on the ITC to institute an investigation when presented with a complaint under oath. However, the Federal Circuit rejected this argument, noting that both the statute and the ITC Rules "contemplate certain scenarios in which the [ITC] need not institute an investigation."

Moreover, the Federal Circuit noted that it previously recognized the ITC's decision to decline to institute an investigation in *Syntex Agribusiness, Inc., v. ITC*, 659 F.2d 1038 (C.C.P.A. 1981). In *Syntex*, the predecessor court to the Federal Circuit held that the ITC had the ability to dismiss a complaint without instituting an investigation where the complaint contained insufficient factual allegations to support a monopolization or conspiracy claim and therefore failed to comply with the ITC Rules.

Consistent with *Syntex*, the Federal Circuit held that the ITC can decline to institute an investigation where a complaint fails to state a cognizable claim under Section 337.

Amarin's complaint did not allege a cognizable claim under Section 337

The Federal Circuit next addressed whether Amarin's complaint stated a cognizable claim under Section 337. As noted, Amarin's complaint alleged that Section 337 jurisdiction existed due to violations of both: (1) § 43(a) of the Lanham Act; and (2) the FDCA.

The Federal Circuit determined that both of Amarin's claims were based on the same factual allegations, that the respondents' products do not meet the definition of "dietary supplement" in the FDCA and should be considered unapproved "new drugs" under the FDCA.

The Federal Circuit also noted that the United States government has "nearly exclusive enforcement authority" under the FDCA such that "private parties may not bring suits to enforce the FDCA." On this basis, the Federal Circuit held that a "complainant fails to state a cognizable claim under [Section] 337 where that claim is based on proving violations of the FDCA and where the FDA has not taken the position that the articles at issue do, indeed, violate the FDCA" because "[s]uch claims are precluded by the FDCA."

In view of the fact that the FDA had not provided guidance as to whether the products at issue in *Amarin* should be considered "new drugs" that require approval, the Federal Circuit affirmed the ITC's decision not to institute an investigation under Section 337 based on the allegations in Amarin's complaint.

JUDGE WALLACH'S DISSENT

Judge Evan J. Wallach issued a dissent, agreeing with the majority that "the ITC did not err in declining to institute an investigation" but disagreeing with the majority's approach to determining appellate jurisdiction of the ITC's decision.

Judge Wallach argued that the Federal Circuit lacked appellate jurisdiction, and should have instead exercised mandamus jurisdiction to find that Amarin "[had] not demonstrated that the 'extraordinary remedy' of issuing a writ of mandamus [was] appropriate."

In analyzing appellate jurisdiction, Judge Wallach stated that the ITC's decision not to institute an investigation based on Amarin's complaint "is not an appealable final determination" under Section 337. Judge Wallach stated that the ITC's authority to institute an investigation is found in Section 337(b), and ITC determinations under Section 337(b), including the ITC's decision in this case, were non-appealable.

Specifically, Judge Wallach would have found that appealable final determinations of the ITC can be made only for determinations made "under subsection (d), (e), (f), or (g) [of Section 337]" as enumerated in Section 337(c), where "[e]ach subsection contemplates determinations made by the ITC post-initiation of an investigation," and not under section 337(b), which Congress excluded from the text of Section 337(c).

Here, Judge Wallach noted that the ITC declined to institute the investigation under Section 337(b) and did not decline to institute an investigation based on any of the subsections listed in Section 337(c). In view of the statutory context and legislative history, Judge Wallach therefore found "no support for the proposition that Congress intended a non-institution decision [under Section 337(b)] to be an appealable final determination."

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Key points

- ☑ The International Trade Commission (ITC) can decline to institute an investigation when a complaint fails to state a cognizable claim under Section 337 of the Tariff Act, 19 U.S.C. § 1337 ("Section 337").
- ☑ A decision by the ITC not to institute an investigation is a final determination on the merits of the complaint for purposes of appellate review and jurisdiction.
- ☑ A complainant fails to state a cognizable claim under Section 337 where the complaint is based on violations of the Food, Drug and Cosmetic Act (FDCA) and where the Food and Drug Administration (FDA) has not provided guidance on whether the articles at issue violate the FDCA.
- ☑ The dissent agreed with the majority that the ITC correctly determined not to institute an investigation, but disagreed that appellate jurisdiction was proper based on the text of Section 337 and the legislative history.

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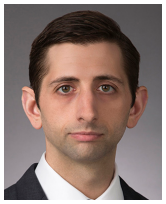


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