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Federal Circuit Affirms ITC's Non-Institution Decision, Offering Guidance for Future FDCA-Related Section 337 Claims

In its long-awaited [decision in *Amarin Pharma. v. ITC*](#), the Federal Circuit provided guidance on the U.S. International Trade Commission's discretion to decline to institute an investigation under section 337 of the Tariff Act (19 U.S.C. § 1337) and the interplay between section 337 claims and the Food, Drug, and Cosmetics Act (FDCA) – an increasingly common issue at the ITC. The opinion also addressed the Federal Circuit's appellate jurisdiction to review the ITC's non-institution decisions. Companies that litigate at the ITC, particularly those that manufacture, distribute, or import FDA-regulated products, should be aware of the implications of this decision.

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Background

As explained in a previous [Ropes & Gray Alert](#), Amarin had filed a complaint under section 337, alleging that the importation and sale of certain synthetically produced omega-3 products was an unfair method of competition because these products were unlawfully labeled and marketed as “dietary supplements,” when they were instead actually unapproved “new drugs” that require approval from the Food & Drug Administration (FDA). The ITC declined to institute an investigation, finding Amarin's complaint failed to allege a claim based on an unfair method of competition or unfair act under section 337(a)(1)(A). More specifically, the ITC found that the section 337 claims here were precluded by the FDCA, as they necessarily required a determination of whether the products at issue violated the FDCA, a statute that the FDA is charged with administering.

The Federal Circuit's Decision

Amarin appealed the ITC's non-institution decision, both in a direct appeal and in a petition for a writ of mandamus. After hearing oral argument in June 2018, the court waited 11 months before issuing its decision on May 1, 2019. Chief Judge Prost's majority opinion first addressed the jurisdictional issue, finding that the ITC's non-institution decision is reviewable by the Federal Circuit on a direct appeal. The court reasoned that under 28 U.S.C. § 1295(a)(6), it has exclusive jurisdiction “to review the final determinations of the United States International Trade Commission relating to unfair practices in import trade, made under section 337.” While the Commission did not style its non-institution decision as a “final determination,” the Federal Circuit held that it was effectively a final determination on the merits, as it “determinatively decided Amarin's right to proceed in a section 1337 action” both in this case and “[a]ny future complaint...alleging these same facts.” In coming to this conclusion, the court stressed that it should not elevate “form over substance” when deciding whether it had appellate jurisdiction over an ITC determination.

Next, the court addressed the ITC's discretion to institute a section 337 investigation. Amarin had argued “that the Commission had a mandatory duty to institute an investigation,” relying on the language of section 337(b)(1) that the Commission “shall investigate any alleged violation of this section on complaint under oath.” But the Federal Circuit disagreed. Relying on its prior decision in *Syntex Agribusiness, Inc. v. ITC*, 659 F.2d 1038 (CCPA 1981), the court held “that the Commission may decline to institute an investigation where a complaint fails to state a cognizable claim under § 337.” Because the ITC determined that Amarin's complaint required the ITC to weigh in on violations of the FDCA and the ITC is therefore precluded from addressing such issues, the Federal Circuit found that the ITC had discretion to decline to institute. (However, as noted above, this non-institution was then appealable to the Federal Circuit.)

Finally, the Federal Circuit analyzed the merits of the appeal – whether the FDA's role as the sole enforcer of the FDCA precluded Amarin's section 337 claims. The Federal Circuit found that the two claims raised by Amarin – the claim that the omega-3 products were being unlawfully sold in violation of the FDCA, as well as its Lanham Act-based false advertising claims – *each* requires proving a violation of the FDCA itself. And because the FDCA does not include a private right of action and the FDA had not ruled on the legality of sales of the omega-3 products, the court found

Amarin's section 337 claims to be precluded. Specifically, the Federal Circuit held "that a complainant fails to state a cognizable claim under § 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." Although Amarin attempted to rely on the Supreme Court's 2014 decision in *POM Wonderful v. Coca-Cola* – where the Supreme Court found that a Lanham Act claim related to labeling was not pre-empted by the FDCA's misbranding rules – the Federal Circuit distinguished *POM Wonderful*, finding that the false advertising claim at issue there did not rely on an underlying violation of the FDCA.

Despite the United States' argument (in an amicus brief) that *all* claims depending on FDCA violations should be precluded – whether or not the FDA has previously ruled on the legality of the practice at issue – the Federal Circuit declined to address the broader question of whether a section 337 claim may be brought in a situation where the FDA has already provided "guidance" on the merits of the alleged FDCA violation.

Takeaways

[Non-patent section 337 claims are on the rise](#), both in overall numbers and types of claims complainants have raised. The Federal Circuit's determination that it has jurisdiction to review at least some non-institution decisions may embolden creative litigants to raise section 337 claims for less common "unfair acts," knowing that even if a complaint is not instituted, the non-institution decision would likely be reviewable by the Federal Circuit.

Additionally, for litigants raising FDCA-related section 337 claims, this decision mandates careful drafting such that the claims do not rely on an alleged violation of the FDCA that the FDA has not yet ruled upon. But because the Federal Circuit's decision arguably leaves the door open to claims based on actions that the FDA *has* identified as violations of the FDCA, even if the FDA has not yet taken enforcement action itself, we likely have not seen the last of FDCA-related section 337 claims at the ITC.