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ALERT

IP Litigation

October 31, 2017

ITC Defers to FDA, Declining to Institute Section 337 Investigation

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In what represents a departure from typical U.S. International Trade Commission (ITC) practice, the ITC on October 27, 2017 declined to institute a Section 337 investigation based on a complaint brought by Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. ("Amarin"). The Commission's non-institution decision (as well as a brief concurring memorandum from Commissioner Broadbent) provides incremental insight into the question of the ITC's jurisdiction and deference to sister government agencies.

Background

Amarin filed its complaint with the ITC on August 30, alleging that certain synthetically produced omega-3 products—specifically, synthetically produced eicosapentaenoic acid (EPA) omega-3 products in ethyl ester or re-esterified triglyceride form—were unlawfully labeled and marketed as "dietary supplements" in violation of Section 337, the Lanham Act, and the Food, Drug, and Cosmetic Act (FDCA). Amarin alleged that, based on the standards and definitions in the FDCA, these products are not "dietary supplements," but instead are actually unapproved "new drugs" that require approval from the Food & Drug Administration (FDA) (as well as pre-approval testing) and cannot lawfully be marketed and sold as dietary supplements. Amarin named a variety of domestic and foreign entities as proposed Respondents, and requested that the ITC institute a Section 337 investigation and issue a general exclusion order barring the importation into the United States by any entity of synthetically produced omega-3 products.

Amarin's complaint drew significant interest from the proposed Respondents and other members of the public, as well as from industry press. In addition to proposed Respondents DSM Nutritional Products, Pharmavite, and Nordic Naturals, several other entities initially submitted comments to the ITC requesting that the ITC decline to institute the investigation on public interest grounds, including:

- The Council for Responsible Nutrition
- The Global Organization for EPA and DHA Omega
- The Consumer Healthcare Products Association
- Hale Oswick Family and Friends

Amarin and several of the proposed Respondents engaged in an unusual exchange of pre-institution briefing on the issue of whether the ITC appropriately had jurisdiction over Amarin's claims—with the proposed Respondents arguing that the FDA, not the ITC, should be the agency to determine the propriety of complained-of conduct. The proposed Respondents argued in part that Amarin's claims were improper because the FDA is exclusively tasked with administration of the FDCA and has not made a determination as to whether the accused products are properly labeled as drugs or dietary supplements. Many of the proposed Respondents and third parties relied on the ITC's 2012 decision not to institute a complaint brought by K-V Pharmaceutical in *Certain Hydroxyprogesterone Caproate and Products Containing the Same*, Docket No. 2919, where the ITC declined to investigate claims brought under the FDCA.

On October 6, the FDA itself weighed in, filing its own request asking the ITC not to institute an investigation into Amarin's complaint. The FDA claimed that Amarin was attempting an unlawful private FDCA enforcement action, and that the FDCA precludes claims that would require any entity other than the FDA to interpret provisions of the FDCA. The FDA echoed the proposed Respondent's arguments, stating that it had not yet made a decision on whether the synthetically produced omega-3 products were "dietary supplements" or "new drugs" under the FDCA, and that it was in the process of drafting guidance for the industry. As such, the FDA requested that the ITC decline to institute under principles of inter-agency comity.

Given the voluminous submissions from the parties and the public and the unique issues posed by Amarin's complaint, the ITC twice delayed its decision on whether to institute the complaint, deliberating for nearly an additional month before finally issuing its decision on October 27.

The ITC's Non-Institution Decision

The ITC's governing statute, 19 U.S.C. § 1337, provides in part that the ITC "*shall* investigate any alleged violation of this section on complaint under oath." 19 U.S.C.§ 1337(b). Nonetheless, the ITC here found that "Amarin's complaint does not allege an unfair method of competition or an unfair act" as required by the statute and the Commission's rules. Specifically, the ITC determined that the Lanham Act allegations in this case were precluded by the FDCA, and noted that the FDA is the entity charged with the administration of the FDCA. As such, the ITC declined to institute an investigation and dismissed the complaint.

Commissioner Broadbent issued a brief memorandum concurring with the ITC's non-institution decision, agreeing that Amarin's complaint failed to properly allege an unfair method of competition or an unfair act under Section 337. However, she left the door open for future complaints, stating that she did *not* reach the issue of whether properly pleaded claims based on the FDCA may be cognizable under Section 337. (It is worth noting Commissioner Broadbent, along with then-Commissioner Pinkert, issued a similar concurring memorandum in *Certain Hydroxyprogesterone*.)

What's Next?

In the short term, Amarin could potentially petition the Commission to reconsider its dismissal of the complaint. Furthermore, given that the ITC's governing statute directs that the ITC "shall investigate" alleged violations of Section 337, it's possible that Amarin might seek to challenge that ITC's non-institution as an arbitrary and capricious act in violation of the Administrative Procedures Act ("APA")—either in an appeal to the Federal Circuit or in a collateral district court action. (In fact, Amarin hinted in some of its briefing that it would consider a denial of institution to be a potential APA violation.)

In the long term, and for those who have been watching this case with interest, the ITC's decision provides incremental guidance regarding the types of non-patent claims that may (or may not) give rise to a Section 337 investigation, especially in the FDCA context. The ITC's position here and in *Certain Hydroxyprogesterone* seems to be one of deference to the FDA on issues that are unique to the FDA's enforcement authority—*i.e.*, where a theory of a violation of Section 337 would require the ITC to interpret the FDCA in an area where the FDA has not yet provided guidance, the ITC will likely decline to institute. It remains to be seen whether it is possible to bring a cognizable Section 337 claim based at least in part on the FDCA—at least one Commissioner may be open to the assertion of such claims.

If you would like to discuss the foregoing or any potential ITC litigation matter, please contact the Ropes & Gray attorney with whom you regularly work or any attorney in our IP litigation practice.