United States Court of Appeals for the Federal Circuit

AMARIN PHARMA, INC., AMARIN PHARMACEUTICALS IRELAND LTD.,
Appellants

v.

INTERNATIONAL TRADE COMMISSION,
Appellee

ROYAL DSM NV, DSM MARINE LIPIDS PERU S.A.C., DSM NUTRITIONAL PRODUCTS LLC, DSM NUTRITIONAL PRODUCTS CANADA, INC., PHARMAVITE LLC, NORDIC NATURALS, INC., NORDIC PHARMA, INC.,
Intervenors

2018-1247

Appeal from the United States International Trade Commission in Investigation No. 337-TA-3247.

IN RE: AMARIN PHARMA, INC., AMARIN PHARMACEUTICALS IRELAND LTD.,
Petitioners

2018-114

On Petition for Writ of Mandamus to the United States International Trade Commission in No. 337-TA-3247.

Decided: May 1, 2019

ASHLEY CHARLES PARRISH, King & Spalding LLP, Washington, DC, argued for appellants and petitioners. Also represented by LISA MOLOT DWYER, JESSE SNYDER, JEFFREY MARK TELEP.

HOUDA MORAD, Office of the General Counsel, United States International Trade Commission, Washington, DC, argued for appellee and respondent. Also represented by DOMINIC L. BIANCHI, WAYNE W. HERRINGTON.

MARK S. DAVIES, Orrick, Herrington & Sutcliffe LLP, Washington, DC, argued for intervenors Royal DSM NV, DSM Marine Lipids Peru S.A.C., DSM Nutritional Products LLC, DSM Nutritional Products Canada, Inc., Pharmavite LLC. Also represented by JORDAN COYLE, THOMAS KING-SUN FU; ANDREW D. SILVERMAN, New York, NY; ANNETTE LOUISE HURST, ROBERT SHWARTS, San Francisco, CA.

JOSEPH FORREST BUSA, Appellate Staff, Civil Division, United States Department of Justice, Washington, DC, argued for amicus curiae United States. Also represented by JOSEPH H. HUNT, SCOTT R. MCINTOSH.

ANDREW F. PRATT, Venable LLP, Washington, DC, for intervenors Nordic Naturals, Inc., Nordic Pharma, Inc.

DEANNA TANNER OKUN, Adduci, Mastriani & Schaumberg, LLP, Washington, DC, for amici curiae Council for Responsible Nutrition, Global Organization for EPA and

DHA Omega-3S. Also represented by ASHA ALLAM, PAUL M. BARTKOWSKI, PAULINA MARIA STAROSTKA.

Before PROST, *Chief Judge,* WALLACH and HUGHES, *Circuit Judges.*

Opinion for the court filed by *Chief Judge* PROST.

Dissenting opinion filed by *Circuit Judge* WALLACH.

PROST, *Chief Judge*.

Amarin Pharma, Inc. ("Amarin") appeals the decision of the International Trade Commission ("Commission"), which determined not to institute an investigation and, accordingly, dismissed Amarin's complaint. The Commission held that Amarin's complaint failed to allege a cognizable claim based on an unfair method of competition or unfair act under 19 U.S.C. § 1337(a)(1)(A). We affirm.

I

Amarin markets Vascepa® capsules, a prescription drug that consists of 1 gram of eicosapentaenoic acid (the omega-3 acid commonly known as "EPA") in a 1-gram capsule. The EPA in Vascepa® is in ethyl ester form and is synthetically produced from fish oil. Amarin obtained approval from the Food and Drug Administration ("FDA") to market and sell Vascepa®, which is designed to reduce triglyceride levels in adult patients with severe hypertriglyceridemia. Vascepa® is the only purified ethyl ester E-EPA product sold in the United States as an FDA-approved drug.

On August 30, 2017, Amarin filed under oath a complaint alleging violations under § 337 of the Tariff Act of 1930, as amended. J.A. 4–114 (Compl.). The complaint alleges that certain companies were falsely labeling and deceptively advertising their imported synthetically produced omega-3 products as (or for use in) "dietary

supplements," where the products are actually "new drugs" as defined in the Food, Drug, and Cosmetic Act ("FDCA") that have not been approved for sale or use in the United States. J.A. 9 ¶ 1.

Specifically, Amarin articulated two claims in its complaint: (1) that the importation and sale of the articles is an unfair act or unfair method of competition under § 337 because it violates § 43(a) of the Lanham Act, 15 U.S.C. § 1125(a), *see* J.A. 31–56 ¶¶ 53–105; and (2) that importation of the articles violates the Tariff Act "based upon the standards set forth in the FDCA," *see* J.A. 56 ¶ 106. By way of relief, Amarin's complaint seeks an order under § 337(d) that would exclude synthetically produced omega-3 products from entry into the United States, as well as a cease-and-desist order under § 337(f) to prohibit the proposed respondents from importing, using, or selling synthetically produced omega-3 products. J.A. 112–13 ¶¶ D–F.

After Amarin filed its complaint, the FDA submitted a letter urging the Commission not to institute an investigation and instead to dismiss Amarin's complaint. J.A. 627–37. In the FDA's view, the FDCA prohibits private enforcement actions, including unfair trade practice claims that seek to enforce the FDCA. J.A. 630. The FDA contended that the FDCA precludes any claim that would "require[] the Commission to directly apply, enforce, or interpret the FDCA." J.A. 631. The FDA further contended that the Commission should decline to institute an investigation based on principles of comity to the FDA. J.A. 629.

On October 27, 2017, the Commission issued its decision declining to institute an investigation and dismissing the complaint. J.A. 1–3. The Commission reasoned that Amarin's allegations are precluded by the FDCA. *Id.*; *see also POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 109 (2014) ("Private parties may not bring [FDCA] enforcement suits." (citing 21 U.S.C. § 337)).

In December 2017, Amarin filed in this court a petition for review and, separately, a petition for a writ of mandamus. We consolidated the two cases. Royal DSM NV, DSM Marine Lipids Peru S.A.C., DSM Nutritional Products LLC, and Pharmavite LLC (collectively, "DSM"); and Nordic Natural, Inc. and Nordic Pharma, Inc. (collectively, "Nordic") (both, "the Intervenors") intervened in the appeal. ECF Nos. 14, 23, 25, 49.

II

At the outset, we begin by confirming that we have jurisdiction to review the Commission's decision in this case. We then address Amarin's argument that the Commission has a mandatory, non-discretionary duty to institute an investigation when presented with a complaint under oath. Finally, we address whether the Commission correctly determined that Amarin's allegations are precluded by the FDCA.

A

Amarin contends that we have appellate jurisdiction under 28 U.S.C. § 1295(a)(6), but the Intervenors and the Commission disagree.

Our jurisdictional statute gives this court 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 of the Tariff Act of 1930 (19 U.S.C. [§] 1337)." § 1295(a)(6). "Final determinations appealable under § 1295(a)(6) are specified in § 1337(c) . . . ." *Crucible Materials Corp. v. ITC*, 127 F.3d 1057, 1060 (Fed. Cir. 1997).

The Intervenors and the Commission argue that the only "final determinations" subject to appellate review are those listed in § 1337(c). Intervenors' Br. 18–19; Commission's Br. 52–56. And these decisions, according to the Intervenors, can only be made "as a result of an investigation." Intervenors' Br. 19.

The question as to our jurisdiction in this case is resolved by our decision in *Amgen Inc. v. ITC*, 902 F.2d 1532 (Fed. Cir. 1990). In *Amgen*, the complainant alleged that a company violated § 337 by importing articles made by a patented process. *See* 19 U.S.C. § 1337(a)(1)(B)(ii). The Commission instituted an investigation. *Amgen*, 902 F.2d at 1534. Ultimately, however, the Commission dismissed the complaint because the patent at issue did not contain a process claim, which the Commission considered to be a jurisdictional prerequisite for an investigation under § 1337(a)(1)(B)(ii). *Id.* at 1535.

On appeal in *Amgen*, we first addressed our jurisdiction under 28 U.S.C. § 1295(a)(6). Interpreting 19 U.S.C. § 1337(c), we recognized that § 1337(c) "has been interpreted as requiring a 'final determination decision *on the merits*, excluding or refusing to exclude articles from entry' under section 1337(d), (e), (f) or (g)." *Id.* (quoting *Block v. ITC*, 777 F.2d 1568, 1571 (Fed. Cir. 1985)). But instead of adopting the rigid approach Intervenors argue for in this case, we concluded that the Commission's decision was "intrinsically a final determination, i.e., a determination *on the merits*," thus making it appealable under § 1295(a)(6). *Id.* (emphasis in original).

In reaching that conclusion, we carefully explained the difference between our holding there and our earlier holding in *Block*, a case in which we held that a Commission order was *not* a final determination. In *Block*, the Commission initiated an investigation on its own motion. The Commission later terminated that investigation after the patent at issue was amended during reexamination. *See id.* As we explained in *Amgen*, "nothing in the termination Order [in *Block*] prejudiced the Commission or any private party in a future proceeding." *Id.* Unlike in *Block*, however, the Commission order in *Amgen* "clearly reach[ed] the merits of [the] complaint and determinatively decide[d] [the complainant's] right to proceed in a section 1337 action." *Id.* We further explained that "any future action

brought by [the complainant] would necessarily raise the same issue, and would presumably be dismissed for the same reason." *Id.* at 1536.

As in *Amgen*, the Commission's decision not to institute in this case is "intrinsically a final determination, i.e., a determination *on the merits*." *See id.* at 1535 (emphasis in original). Here, the Commission declined to institute an investigation because the claims were precluded by the FDCA and, therefore, the complaint failed to state a cognizable claim under § 337. *See* J.A 1–3. As in *Amgen*, this decision "clearly reach[ed] the merits of [the] complaint and determinatively decide[d] [Amarin's] right to proceed in a section 1337 action." *See id.*; *see also Import Motors, Ltd., Inc. v. ITC*, 530 F.2d 940, 946–47 (CCPA 1976) (analyzing the right to appeal a Commission order by asking whether the order "has the operative effect of a 'final determination under subsection (d) or (e)'" and noting that "[s]ubstance, not form, must control"). Any future complaint brought by Amarin alleging these same facts "would necessarily raise the same issue" and "would presumably be dismissed for the same reason"—i.e., for lack of a private right of action to enforce the FDCA. *See Amgen*, 902 F.2d at 1536.[1] In other words, as discussed below, as long as

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[1] The Commission's decision to dismiss the complaint presented a pure question of law regarding FDCA preclusion. Based on that holding, Amarin was in no way free to file another complaint on the same grounds, as the dissent suggests. *See* Dissent at 12. Our recognition of the possibility that Amarin's complaint may not be precluded in the future, under a different set of facts (i.e., where FDA has provided guidance as to whether these particular articles violate the FDCA) does not make the Commission's determination "without prejudice." Indeed, that future possibility would not have existed but for our ability to

Amarin's complaint is based on proving violations of the FDCA (at least where the FDA has not provided guidance as to whether the articles violate the FDCA), Amarin's claims will be precluded. The Commission's decision is therefore intrinsically a final determination that effectively denies Amarin's request for relief under § 337(d) and (f).[2]

We are unpersuaded by the Intervenors' and the Commission's argument that a final determination can be made only after institution. *See* Intervenors' Br. 3; Commission's Br. 52. Although the decision in *Amgen* occurred after institution, the court's reasoning in that case was not based on that procedural detail. *See Amgen*, 902 F.2d at 1535. Instead, the court's analysis focused on the operative effect of the Commission decision. *See id.*; *Import Motors*, 530 F.2d at 946–47 ("Substance, not form, must control.").

The dissent makes essentially the same argument, contending that a "final determination" can exist only after

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review and narrow the Commission's even *broader* preclusion holding through this appeal.

[2] The dissent's attempt to characterize the Commission's decision in this case as an order under § 1337(b), rather than as effectively being an order under § 1337(d) or (e), cannot be reconciled with *Amgen*. *Amgen* also did not involve a formal order under § 1337(d), (e), (f), or (g). Regardless, and as the dissent recognizes, *see* Dissent at 11–12, we held in *Amgen* that the substance of the Commission's analysis meant that it "should have dismissed on the merits." 902 F.2d at 1536. But a dismissal on the merits would still not produce a formal order under § 1337(d), (e), (f), or (g). Instead, as our predecessor court emphasized in *Import Motors*, what matters is that the order "ha[s] the same operative effect, . . . as a final determination under subsections (d) and (e). Substance, not form, must control." 530 F.2d at 945–46.

institution. Dissent at 4–5, 7, 11. But this approach elevates form over substance. The dissent's approach would require the Commission to formally institute an investigation—which requires publication of notice in the Federal Register—just long enough for the Commission to issue the same dismissal order it already issued in this case. There is no indication from the statutory text or context that Congress intended such rigid formality.

Because the Commission's decision is intrinsically a final determination on the merits that has the operative effect of denying Amarin's request for relief under § 337(d) and (f), the decision is a "final determination" under § 337(c). We therefore have jurisdiction to review that decision under 28 U.S.C. § 1295(a)(6).

Having found our jurisdiction proper, we need not address Amarin's alternative argument for jurisdiction—that we have authority to compel agency action under 5 U.S.C. § 706(1).[3]

B

We next address Amarin's argument that the Commission had a mandatory duty to institute an investigation in

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[3] It is unclear whether Amarin is also arguing that we may review the decision via mandamus aside from § 706(1). Indeed, Amarin states that "[t]he judicial review provisions of the Administrative Procedure Act have effectively *displaced* the need for courts to issue writs of mandamus when asked to review agency decisions." Appellant's Br. 26 (emphasis added). Regardless, to the extent Amarin contends that some other basis for mandamus review is warranted, Amarin has failed to explain how it would satisfy the traditional mandamus requirements. *See Cheney v. U.S. Dist. Court for D.C.*, 542 U.S. 367, 380–81 (2004) (listing the three requirements that must be satisfied before a writ may issue).

this case. Amarin contends that 19 U.S.C. § 1337(b)(1) imposes a non-discretionary duty on the Commission to institute an investigation when presented with a complaint under oath. *See* § 1337(b)(1) ("The Commission shall investigate any alleged violation of this section on complaint under oath or upon its initiative.").

The relevant statutory scheme contemplates certain scenarios in which the Commission need not institute an investigation. *See* § 1337(b)(3) (stating, for example, that the Commission "may institute" under specified circumstances); *see also* § 1330(d)(5) (stating that an investigation shall occur if "one-half of the number of commissioners voting agree that the investigation should be made"). The Commission Rules also contemplate non-institution. Rule 210.10 provides that "[t]he Commission shall determine whether the complaint is *properly filed* and whether an investigation *should be instituted* on the basis of the complaint." 19 C.F.R. § 210.10(a)(1) (emphases added). That Rule further explains that "[i]f the Commission determines not to institute an investigation on the basis of the complaint, the complaint shall be dismissed." 19 C.F.R. § 210.10(c); *see also* 19 C.F.R. § 210.9(a) ("Upon receipt of a complaint alleging violation of section 337 . . . [t]he Commission shall examine the complaint for sufficiency and compliance with the applicable sections of this chapter.").

The question remains, then, in what circumstances may the Commission decline to institute an investigation? Our precedent recognizes at least one such circumstance. *See Syntex Agribusiness, Inc. v. ITC*, 659 F.2d 1038 (CCPA 1981). In *Syntex*, our predecessor court held that the Commission was correct to dismiss a complaint without instituting an investigation where the complaint contained insufficient factual allegations to support a monopolization or conspiracy claim. *Id.* at 1044. The court framed the issue in that case as whether the complaint was a "'complaint' within the meaning of section 337." *Id.* at 1041. Noting the absence of a definition of "complaint," the court

recognized that a complaint must comply with then-Commission Rule 210.20, which set forth requirements for a complaint under § 337, including a requirement that the complaint include a statement of the facts constituting the alleged acts of monopolization and conspiracy. *Id.* at 1042.[4] The court explained that its disposition was based on the complaint's failure to comply with the requirements set forth in that Commission Rule.

Although Amarin appears to raise a broader argument regarding whether the Commission has discretion *generally* not to institute an investigation, we need not address that question here. Instead, we simply hold, consistent with *Syntex*, that the Commission may decline to institute an investigation where a complaint fails to state a cognizable claim under § 337.

The facts alleged as the basis for Amarin's complaint demonstrate that Amarin's allegations are based entirely on violations of the FDCA. As we explain below, claims based on such allegations are precluded by the FDCA, at least where the FDA has not yet provided guidance as to whether violations of the FDCA have occurred. Thus, under the facts of this case, where Amarin's complaint fails to state a cognizable claim for relief, the Commission did not err in its decision not to institute.

C

We next address the Commission's holding that Amarin's complaint "does not allege an unfair method of competition or unfair act cognizable under 19 U.S.C. § 1337(a)(1)(A), as required by the statute and the Commission's rules." J.A. 1. The Commission explained that "the Lanham Act allegations in this case are precluded by the Food, Drug and Cosmetic Act," and that "the Food and

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[4] The Commission Rule at issue in *Syntex* has since been re-codified as Commission Rule 210.12.

Drug Administration is charged with the administration of the FDCA." J.A. 1. As explained below, we agree.

As relevant here, the FDCA authorizes the FDA to regulate drugs and dietary supplements. Introducing a "new drug," 21 U.S.C. § 321(p), into interstate commerce requires FDA approval, *id.* § 355(a). Dietary supplements, however, do not require pre-market approval.

The FDCA provides the United States with "nearly exclusive enforcement authority." *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102, 109 (2014); *see also* 21 U.S.C. § 337(a) ("Except as provided in subsection (b), all such proceedings for the enforcement, or to restrain violations, of this chapter shall be by and in the name of the United States."); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349 n.4 (2001) ("The FDCA leaves no doubt that it is the Federal Government rather than private litigants who are authorized to file suit for noncompliance with the medical device provisions . . . ."). Private parties may not bring suits to enforce the FDCA. *POM Wonderful*, 573 U.S. at 109 (citing 21 U.S.C. § 337).

Given the lack of a private right to enforce the FDCA, other circuit courts have grappled with the extent to which private parties' claims under § 43(a) of the Lanham Act are limited by the FDCA. *See PhotoMedex, Inc. v. Irwin*, 601 F.3d 919 (9th Cir. 2010); *Alpharma, Inc. v. Pennfield Oil Co.*, 411 F.3d 934 (8th Cir. 2005); *cf. Sandoz Pharm. Corp. v. Richardson-Vicks, Inc.*, 902 F.2d 222 (3d Cir. 1990).

For example, in *PhotoMedex*, the Ninth Circuit affirmed a grant of summary judgment in favor of a defendant as to a Lanham Act false advertising claim based on allegations that the defendant misrepresented that its product had received FDA clearance. 601 F.3d at 922. That case involved the FDCA's 510(k) clearance process, and the court focused heavily on the details of that statutory scheme in reaching its holding. In short, the defendant had received 510(k) clearance for its earlier device, but

the plaintiff argued that based on significant changes to the device, the defendant should have made a *new* 510(k) submission to obtain market clearance for the updated product. *Id.* at 926. In reaching its conclusion, the court emphasized that "[i]t is significant that under the regulatory structure established by the FDA for the medical devices at issue in this case, clearance to market a given device did not necessarily require an affirmative statement of approval by the FDA." *Id.* Further, the court explained that even though the FDA had been aware of the alleged need for a new clearance, the FDA had never taken the position that the products had not been properly cleared. In sum, the court held that "[b]ecause the FDCA forbids private rights of action under that statute, a private action brought under the Lanham Act *may not be pursued when, as here, the claim would require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was such a violation*." *Id.* at 924 (emphasis added).[5]

The Eighth Circuit employed similar reasoning in *Alpharma*. 411 F.3d at 939–41. There, the district court granted a defendant's motion to dismiss a plaintiff's Lanham Act claim that was based on alleged misrepresentation of the uses for which a drug had been approved. *Id.* at 935–36. The Eighth Circuit reversed, reasoning that

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[5] The court limited its holding, reasoning that "we do not suggest that the Lanham Act can never support private party claims involving FDA approval or clearance of drugs or medical devices." *Id.* at 924. Giving an example, the court stated that if "it was clear that an affirmative statement of approval by the FDA was required before a given product could be marketed and that no such FDA approval had been granted, a Lanham Act claim could be pursued for injuries suffered by a competitor as a result of a false assertion that approval had been granted." *Id.* at 924–25.

because the FDA had given guidance on the precise dispute between the parties, the plaintiff's claim in this particular case did not require a "preemptive determination" of how the FDA would interpret and enforce its own regulations. *Id.* at 940; *see also PhotoMedex*, 601 F.3d at 929 (summarizing *Alpharma* and noting that, there, "FDA explicitly made clear that it had not given the defendant's product the affirmative approval required for expanding its list of permissible uses" and thus "the plaintiff could bring a Lanham Act claim based on the defendant's false statements in its advertisement that the uses had been approved").

In its complaint, Amarin includes two separate bases for its § 337 claims. First, Amarin alleges that respondents' labeling or advertisements about the articles is false or misleading, in violation of § 43(a) of the Lanham Act, such that importation of those articles is an "unfair act" under § 337 of the Tariff Act. *See* J.A. 31–56 ¶¶ 53–105 (Compl.). This claim is based on the allegation that labeling the products as "dietary supplements" is literally false because the products "cannot meet the definition of 'dietary supplement' in Section 201(ff) of the FDCA." J.A. 33 ¶ 60 (Compl.). And, the claim is further based on the allegation that the products "are actually unapproved 'new drugs' under the FDCA." J.A. 47 (Compl.). Amarin's complaint relies on these alleged FDCA violations to support key elements of its Lanham Act false-advertising claim. *See* J.A. 55 ¶¶ 102–03 (applying these allegations to the elements of a false advertising claim). In other words, proving the Lanham Act claim in this case requires proving violations of the FDCA.

The second claim in Amarin's complaint alleges that the respondents' importation and sale of the products constitute unfair acts or unfair methods of competition under § 337 based on the standards set forth in the FDCA. J.A. 56 ¶ 106; *see* J.A. 56–59 (Compl.). For example, Amarin alleges that the products are "misbranded drugs in violation of the standards set forth in Section 502 of the

FDCA, [21 U.S.C.] § 352, and adulterated drugs, in violation of Section 501 of the FDCA, *id.* § 351." J.A. 57 ¶ 107. Every allegation supporting this claim rests on an alleged violation of the FDCA.

In sum, Amarin's two § 337 claims are based on the same factual allegations—that respondents' products do not meet the definition of "dietary supplement" in the FDCA, *see* 21 U.S.C. § 321(ff), and are instead unapproved "new drugs" under the FDCA. *E.g.*, J.A. 33–34 ¶¶ 60–61; J.A. 47–49 ¶¶ 84–87; J.A. 56 ¶ 106.

The case before us bears much resemblance to *PhotoMedex*, and we consider the Ninth Circuit's reasoning in that case persuasive. In our case, the alleged violations of § 337 are based entirely on—and could not exist without—the FDCA. Because private parties are prohibited from enforcing the FDCA, the same concerns expressed in *PhotoMedex* apply here. *See PhotoMedex*, 601 F.3d at 924. We note, however, that a major concern of the court in *PhotoMedex* was that proceeding with the Lanham Act claim would "require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was such a violation." *Id.* The court in *PhotoMedex* appears to have been concerned with adjudicating FDCA violations for the first time via a Lanham Act claim, rather than via the FDA. *See id.*; *id.* at 928 (noting that the court's decision was consistent with other decisions "refusing to allow private actions under the Lanham Act premised on enforcement determinations *that the FDA and other regulatory agencies did not themselves make*" (emphasis added)); *see also Alpharma*, 411 F.3d at 935–37; *Sandoz*, 902 F.2d at 231 (noting that what the FDCA "do[es] not create directly, the Lanham Act does not create indirectly, at least not in cases requiring original interpretation of these Acts or their accompanying regulations").

As in *PhotoMedex* (and unlike in *Alpharma*), affirmative FDA approval is not required in the dietary supplement context. Instead, manufacturers self-police. And as in *PhotoMedex* (and unlike in *Alpharma*), the FDA has not provided guidance as to whether the products at issue in this case should be considered "new drugs" that require approval. Given this lack of guidance, we see no need to go further than the court in *PhotoMedex* did. We therefore hold 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. Such claims are precluded by the FDCA.

We note that this limited holding is consistent with the Commission's arguments in its briefing, which indicated that Amarin's claims are precluded *at least* until the FDA has provided guidance as to whether the products at issue are dietary supplements. *See, e.g.*, Commission's Br. 58 (suggesting that "Amarin is free to file a new complaint once the FDA issues sufficient guidance with respect to the accused products such that the Commission is not required to interpret the FDCA in the first instance and Amarin's claims are otherwise no longer precluded by the FDCA"). We also note that the United States, as amicus, appears to seek a broader ruling—that all such claims are precluded *regardless* of whether the FDA has provided guidance. As explained above, we need not address that broader question here, as the FDA has not provided guidance as to whether the products at issue properly qualify as "dietary supplements."

Despite Amarin's heavy reliance on *POM Wonderful LLC v. Coca-Cola Co.*, 573 U.S. 102 (2014), that recent decision does not alter our analysis. There, the plaintiff sued a competitor under § 43 of the Lanham Act, alleging that the label on one of the defendant's products was deceptive and misleading. *Id.* at 106. The product at issue was a juice blend sold with a label featuring the words

"pomegranate blueberry" more prominently than the words "flavored blend of 5 juices." *Id.* at 106, 110. Despite the prominence of the names of those two juices, the product actually contained just 0.3% pomegranate juice and 0.2% blueberry juice. *Id.* at 110. The plaintiff alleged that this labeling (and other features) mislead consumers into thinking that the juice blend contained primarily pomegranate and blueberry juices. *Id.* The issue in the case was whether a private party could bring a Lanham Act claim challenging a food label as misleading, where that food label was regulated by the FDCA. The Ninth Circuit held that the plaintiff's Lanham Act claim was precluded by the FDCA, which forbids misbranding of food, including by misleading labeling. *Id.* The Supreme Court reversed, holding instead that the Lanham Act claim in that case was not precluded.

Amarin views *POM Wonderful* as rejecting the view that the FDCA precludes Lanham Act claims. But this reads *POM Wonderful* too broadly. Although *POM Wonderful* held that the FDCA does not categorically preclude a Lanham Act claim based on a product (e.g., a label) that is regulated by the FDCA, the court did not open the door to Lanham Act claims that are based on proving FDCA violations. The allegations underlying the Lanham Act claim in *POM Wonderful* did not require proving a violation of the FDCA itself. *See id.* at 117 ("But POM seeks to enforce the Lanham Act, not the FDCA or its regulations."). This stands in stark contrast to the allegations in our case, which are based solely on alleged violations of the FDCA's requirements.

Amarin also relies on this court's decision in *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350 (Fed. Cir. 2013). But *Allergan* was a pre-emption case—not a preclusion case. As the Supreme Court explained in *POM Wonderful*, "[i]n pre-emption cases, the question is whether state law is pre-empted by a federal statute, or in some instances, a federal agency action." *POM Wonderful*, 573

U.S. at 111. Meanwhile, in cases where a cause of action under one federal statute is alleged to be precluded by the provisions of another federal statute, "the state-federal balance does not frame the inquiry," and the "'presumption against pre-emption' has no force." *Id.* (internal citation omitted). In *Allergan*, we simply held that the FDCA did not preempt certain state law claims based on violations of state law requirements that paralleled FDCA requirements. *Allergan*, 738 F.3d at 1354–56. That analysis has no bearing on this case.

In short, although Amarin presents its claims as violations of the Tariff Act, in reality those claims constitute an attempt to enforce requirements of the FDCA through the remedies provided under the Tariff Act. Because private parties have no such enforcement authority, Amarin's allegations fail to state a cognizable claim for relief.[6]

III

For the foregoing reasons, we hold that we have appellate jurisdiction to review the Commission's decision not to institute an investigation in this case. Exercising that jurisdiction, we hold that the Commission correctly held that Amarin's complaint fails to present a cognizable claim under § 337. The decision is therefore affirmed and the petition for mandamus is denied as moot.

AFFIRMED

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[6] Although the Intervenors argue that the Commission should receive *Chevron* deference for its interpretation of § 337 with respect to the preclusion issue in this case, *see* Intervenors' Br. 54–68, the Commission does not. The United States, as amicus, also does not argue in favor of *Chevron* deference.

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On Petition for Writ of Mandamus to the United States International Trade Commission in No. 337-TA-3247.

WALLACH, *Circuit Judge*, dissenting.

It is axiomatic that "the power which [C]ongress possess[es] to create [c]ourts of inferior jurisdiction, necessarily implies the power to limit the jurisdiction of those [c]ourts to particular objects." *United States v. Hudson*, 11 U.S. (7 Cranch) 32, 33 (1812); *see Lockerty v. Phillips*, 319 U.S. 182, 187 (1943) (explaining that Congress may "withhold[] jurisdiction from [lower courts] in the *exact degrees and character* which to Congress may seem proper for the public good" (emphasis added) (internal quotation marks and citations omitted)). The statute is clear: Congress limited our subject-matter jurisdiction "to review the *final determinations* of the United States International Trade Commission [('ITC')] . . . made under [19 U.S.C. § 1337 (2012)[1]]," 28 U.S.C. § 1295(a)(6) (2012) (emphasis added), by defining an ITC "final determination" as a determination made "*under subsection (d), (e), (f), or (g)* of [§ 1337]," 19 U.S.C. § 1337(c) (emphasis added).

Although I agree with the majority's conclusion that the ITC did not err in declining to institute an investigation into the complaint under § 1337 brought by Appellants-Petitioners Amarin Pharma, Inc. and Amarin Pharmaceuticals Ireland Ltd. (together, "Amarin"), *see* J.A. 4–114 (Complaint), I disagree with the majority's approach, for it

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[1] Section 1337 addresses, inter alia, "[u]nfair methods of competition and unfair acts in the importation of articles . . . into the United States." 19 U.S.C. § 1337(a)(1)(A). Section 1337 is part of the Tariff Act of 1930 ("Tariff Act"). *See* Pub. L. No. 71-361, § 337, 46 Stat. 590, 703–04 (codified at 19 U.S.C. §§ 1304 et seq.).

fails to give due respect to Congress's choice to limit our appellate jurisdiction. As the ITC's decision not to institute was made pursuant to § 1337(b), I believe that we lack appellate jurisdiction; however, I would instead exercise mandamus jurisdiction and conclude that Amarin has not demonstrated that the "extraordinary remedy" of issuing a writ of mandamus is appropriate. *Gulfstream Aerospace Corp. v. Mayacamas Corp.*, 485 U.S. 271, 289 (1988). Because I would dismiss Amarin's appeal and deny its petition for a writ of mandamus, I respectfully dissent.

DISCUSSION

I. Congress Limited Our Appellate Jurisdiction

Congress conferred upon us exclusive jurisdiction "to review the final determinations of the [ITC] relating to unfair practices in import trade, made under [§ 1337]." 28 U.S.C. § 1295(a)(6). Relevant here, § 1337(c) employs the term "final determination" and states that "[a]ny person adversely affected by a final determination of the [ITC] under subsection (d), (e), (f), or (g) of [§ 1337] may appeal such determination . . . to the United States Court of Appeals for the Federal Circuit." In interpreting these statutes, we have said that "[f]inal determinations appealable under § 1295(a)(6) are specified in § 1337(c)." *Crucible Materials Corp. v. U.S. Int'l Trade Comm'n*, 127 F.3d 1057, 1060 (Fed. Cir. 1997).

II. We Lack Appellate Jurisdiction to Review the ITC's Decision Not to Institute an Investigation

Amarin filed its Complaint, which alleges, inter alia, that Royal DSM NV et al. ("Intervenors") have "falsely labeled[] and/or promoted for use" synthetically produced omega-3 products ("the Accused Products"), labelled "as dietary supplements," even though they "are actually unapproved new drugs under the Federal Food, Drug and Cosmetic Act ('FDCA')," 21 U.S.C. §§ 301 et seq. (2012), thereby violating "Section 43(a) of the Lanham Act, 15

U.S.C. § 1125(a) [(2012)], and the standards established by the FDCA," J.A. 9 (internal quotation marks omitted). The Commissioners of the ITC voted not to institute an investigation, *see* J.A. 681, and sent a letter to Amarin's counsel notifying it of that decision, J.A. 1–2; *see* 19 C.F.R. § 210.10(c) (2018) ("If the [ITC] determines not to institute an investigation on the basis of the complaint, the complaint shall be dismissed, and the complainant and all proposed respondents will receive written notice of the [ITC]'s action and the reason(s) therefor."). The ITC stated it "has determined not to institute an investigation based on the [C]omplaint . . . and has dismissed the [C]omplaint." J.A. 1. According to the ITC, the "[C]omplaint does not allege an unfair method of competition or an unfair act cognizable under . . . § 1337(a)(1)(A), as required by the statute and the [ITC]'s rules." J.A. 1. The ITC reasoned "that the Lanham Act allegations in this case are precluded by the [FDCA]," and that "the Food and Drug Administration [('FDA')] is charged with the administration of the FDCA." J.A. 1.

The ITC's Decision Not to Institute is not an appealable final determination. An appealable final determination is an ITC determination made "under subsection (d), (e), (f), or (g) of [§ 1337]." 19 U.S.C. § 1337(c). Subsections (d)–(g) pertain to determinations on exclusion orders, *see id.* § 1337(d)–(e), (g), and cease-and-desist orders, *see id.* § 1337(f)–(g).[2] Amarin contends that the ITC's Decision Not to Institute is a final determination under either § 1337(d) or (f). *See* Appellants' Br. 20; *see* Oral Arg. at 1:37–55, http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2018-1247.mp3 (disclaiming reliance on § 1337(e)

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[2] Section 1337(g) governs determinations rendered pursuant to a default and thereby relates to both exclusion and cease-and-desist orders. *See* 19 U.S.C. § 1337(g)(1)–(2).

or (g)). Each subsection contemplates determinations made by the ITC *post-initiation* of an investigation. Subsection (d) explicitly provides that the ITC's determination to exclude articles will be made "as a result of an investigation." 19 U.S.C. § 1337(d)(1) (emphasis added); *see id.* § 1337(c) (directing that a "determination under subsection (d) or (e) . . . shall be made on the record after notice and opportunity for a hearing"). Subsection (f) sets forth that the ITC's determination to issue a cease-and-desist order is "[i]n addition to, or in lieu of, taking action" pursuant to other statutory provisions that involve an initiated investigation, i.e., taking action "under subsection (d)," which involves a completed investigation, "or [subsection] (e)," *id.* § 1337(f)(1), which covers the ITC's determination to exclude articles made "during the course of an investigation," *id.* § 1337(e)(1).

Here, the ITC neither initiated an investigation, decided whether a violation of § 1337 occurred, nor determined whether to issue an exclusion or cease-and-desist order. *See* J.A. 1–2. In *Block v. United States International Trade Commission*, we held that the "ITC's decision to terminate its investigation as 'abated' [was not] an appealable 'final determination.'" 777 F.2d 1568, 1570 (Fed. Cir. 1985); *see id.* at 1571. The ITC terminated the investigation because, following the U.S. Patent and Trademark Office's reexamination relating to an allegedly-infringed patent, the reexamined claims were substantively changed. *Id.* at 1570. There, the ITC's termination decision "did not rule on the merits," so its "action could not intrinsically be a final determination within the meaning of . . . § 1337(c) because it was not a decision *to exclude or refuse to exclude* articles from entry under . . . § 1337(d), (e), or (f)." *Id.* at 1571 (emphasis added). Similarly, the Decision Not to Institute did not render a decision on whether to exclude the allegedly mislabeled products or issue a cease-and-desist order. *See* J.A. 1–2. The ITC refused institution of an investigation and dismissed the

Complaint, without reaching the requested relief. *See* J.A. 1–2.

Rather than placing the ITC's authority to investigate in subsections (d), (e), (f), or (g), of § 1337, Congress located that authority in subsection (b). Section 1337(b) authorizes the ITC to "investigate any alleged violation of [§ 1337] on complaint under oath or upon its initiative," 19 U.S.C. § 1337(b)(1), and contemplates instances where the ITC "shall terminate, *or not institute*, any investigation" or "suspend its investigation," *id.* § 1337(b)(3) (emphasis added); *see VastFame Camera, Ltd. v. Int'l Trade Comm'n*, 386 F.3d 1108, 1112, 1113 (Fed. Cir. 2004) (explaining that § 1337(b) "gives the [ITC] general authority to investigate violations of the statute"). Congress indicated its intent to make § 1337(b) determinations, such as the Decision Not to Institute, non-appealable through its exclusion of subsection (b) from the list of final determinations in § 1337(c). *See Marx v. Gen. Revenue Corp.*, 568 U.S. 371, 392 (2013) ("[T]he *expressio unius, exclusio alterius* canon, . . . instructs that when Congress includes one possibility in a statute, it excludes another by implication."); *cf. United States v. Erika*, 456 U.S. 201, 207 (1982) ("In the context of the statute's *precisely drawn provisions*, this omission provides persuasive evidence that Congress deliberately intended to foreclose further review of such claims." (emphasis added)).[3] Had Congress intended to make non-

[3] Case law, while not expressly deciding the issue, supports this conclusion. *See BASR P'ship v. United States*, 795 F.3d 1338, 1342 (Fed. Cir. 2015) (consulting case law to construe a statute). In *Syntex Agribusiness, Inc. v. United States International Trade Commission*, the ITC decided not to institute an investigation pursuant to § 1337 and accordingly dismissed a complaint. *See* 659 F.2d 1038, 1040 (CCPA 1981). The complainant first petitioned our predecessor court for a writ of mandamus based

institution decisions appealable, it merely needed to include them in its list of determinations that would be considered final in § 1337(c). Given that Congress decided not to adopt this "obvious alternative," "the natural implication is that [it] did not intend" for such decisions under § 1337(b) to be appealable. *Lozano v. Montoya Alvarez*, 572 U.S. 1, 16 (2014). "We cannot revisit that choice." *Id.*

The statutory context further reveals that Congress did not contemplate appealability of an ITC non-institution decision. *See Digital Realty Tr., Inc. v. Somers*, 138 S. Ct. 767, 777 (2018) (acknowledging that courts may rely upon a statute's "purpose and design" to "corroborate" their understanding of the statutory text); *Block v. Cmty. Nutrition Inst.*, 467 U.S. 340, 349 (1984) ("[T]he presumption favoring judicial review of administrative action may be overcome by inferences of intent drawn from the statutory scheme as a whole."). In fact, § 1337(b)(1) covers the procedures for commencing and conducting an investigation, and details that, "[u]pon commencing any such investigation, the [ITC] shall publish notice thereof in the Federal Register." Moreover, "the [ITC] shall, within 45 days *after an investigation is initiated*, establish a target date for its *final determination*." 19 U.S.C. § 1337(b)(1) (emphases added). Through this language, Congress established two separate types of ITC determinations—a decision whether to institute an investigation and, separately, a final determination, i.e., those made under subsections (d), (e), (f), or (g)—and clarified that a final determination is rendered *after* an institution decision. *See id.*

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on the ITC's refusal to investigate and later filed an appeal from the ITC's decision. *Id.* at 1041. Our predecessor court, by separate order, "dismissed [the complainant's] . . . *appeal* on the ground that there had been *no final determination* by [the] ITC, which is essential for jurisdiction of the court." *Id.* (emphases added).

Similarly, § 1337(j) provides that, when the ITC "determines that there is a violation of [§ 1337] . . . or . . . [ha]s reason to believe that there is such a violation," it shall, inter alia, "transmit to the President a copy of such determination and the action taken under subsection (d), (e), (f), (g), or (i)[4] of [§ 1337]." *Id.* § 1337(j)(1), (j)(1)(B). The President then has the option "for policy reasons" to "disapprove[of] such determination" within sixty days, *id.* § 1337(j)(2), and, if not disapproved or if approved, the "determination *shall become final*," *id.* § 1337(j)(4) (emphasis added). Such determinations that are submitted to the President become final well after an investigation is complete. *See id.* § 1337(b), (j). Tellingly, Congress has conferred jurisdiction explicitly over certain administrative decisions not to institute an investigation, elsewhere in the Tariff Act. Congress explained that "an interested party . . . may commence an action in the United States Court of International Trade [('CIT')]" challenging "a determination by [the U.S. Department of Commerce] . . . *not to initiate an investigation*" related to antidumping and countervailing duty proceedings. 19 U.S.C. § 1516a(a)(1), (a)(1)(A) (emphasis added); *see* 28 U.S.C. § 1581(c) (conferring the CIT with "exclusive jurisdiction" over actions commenced pursuant to § 1516a). Congress did not confer such jurisdiction in § 1337.

The legislative history does not support the majority's conclusion. *See Thunder Basin Coal Co. v. Reich*, 510 U.S. 200, 207, 209–12 (1994) (consulting legislative history for statutory interpretation). Although the original version of § 1337 did not define an ITC final determination by

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[4] Section 1337(i) authorizes the ITC, "[i]n addition to taking action under subsection (d)," to "issue an order providing that any article imported in violation of the provisions of [§ 1337] be seized and forfeited to the United States" in certain situations.

reference to specific subsections, *see* Tariff Act § 337, 46 Stat. at 703–04, Congress amended § 1337(c) and added that "[a]ny person adversely affected by a final determination of the [ITC] under subsection (d) or (e) may appeal such determination," Trade Act of 1974, Pub. L. No. 93-618, § 341(a), 88 Stat. 1978, 2054.[5] When Congress inserted this language, the Senate Finance Committee recognized it was "extend[ing] the right to judicial review of final [ITC] determinations." S. Rep. No. 93-1298, at 197 (1974) (Conf. Rep.). It provided that "[b]y *final determination*, as used in this section, *the Committee means a*[*n ITC*] *determination which has been referred to the President under* [*the predecessor to current § 1337(j)*], and has been approved by the President or has not been disapproved . . . after referral of the determination." *Id.* (emphases added). This appears to be the only time in the legislative history Congress expounded its understanding of the term final determination in § 1337. Nowhere does Congress equate a non-institution decision to a final determination. *See id.*

While this court has acknowledged that § 1337 "provides for judicial review of both positive and negative determinations," we should be careful not to expand the scope of the term final determination to include determinations beyond those contemplated by Congress. *Amgen, Inc. v. U.S. Int'l Trade Comm'n*, 902 F.2d 1532, 1535 (Fed. Cir. 1990) (footnote omitted); *see Imp. Motors, Ltd. v. U.S. Int'l Trade Comm'n*, 530 F.2d 940, 945 (CCPA 1976) (explaining that § 1337(c) "indicate[s] an intent to provide appeal of such an unfavorable decision"). I find no support for the proposition that Congress intended a non-institution

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[5] Congress later amended this language to include additional subsections under the definition of an ITC final determination. *See, e.g.*, Trade Agreements Act of 1979, Pub. L. No. 96-39, § 1105(c), 93 Stat. 144, 311 (adding subsection (f)).

decision to be an appealable final determination. Accordingly, I do not believe that the ITC's Decision Not to Institute is a final determination under § 1337(c).

Apparently recognizing that it is not a final determination as defined by § 1337(c), the majority sweeps the ITC's Decision Not to Institute under our jurisdiction by holding that it is *intrinsically* a final determination, based on *Amgen*. *See* Maj. Op. 6–9. In *Amgen*, the ITC dismissed a complaint for lack of subject-matter jurisdiction because the patent-at-issue did "not contain any process patent claims," which the ITC considered "a jurisdictional prerequisite." 902 F.2d at 1535. We exercised appellate jurisdiction and vacated and remanded the ITC's dismissal, determining that the dismissal "should have been phrased as a dismissal on the merits." *Id.* at 1537.[6] There, the ITC's determination that the patent's claims "do not, in fact, cover a process [as required by statute] . . . clearly

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[6] *Amgen*'s statement that "when a decision is intrinsically a final determination, i.e., a determination on the merits, then that decision is appealable under [§] 1337(c)," traces back to our predecessor court's decision in *Import Motors*. *Amgen*, 902 F.2d at 1535 (emphasis omitted) (citing, inter alia, 530 F.2d at 944). Even under this interpretation of "final determination," the ITC's determination must be made "under subsection (d), (e), (f), or (g)" because the statutory language cabins the *types* of final determinations that are appealable. 19 U.S.C. § 1337(c); *see Import Motors*, 530 F.2d at 944 (recounting that an earlier version of § 1337, "[s]trictly interpreted[,] . . . refers to a final administrative decision on the merits, excluding or refusing to exclude articles from entry under subsection (d) or (e)"). *Amgen* does not expand our jurisdiction to determinations made under different subsections of § 1337, nor could it. *See Lozano*, 572 U.S. at 16 (recognizing that we are bound by Congress's choice).

reache[d] the merits of [the] complaint and determinatively decide[d the complainant's] right to proceed in a [§] 1337 action." *Id*. at 1535. The court recognized that "the jurisdictional requirements of [§] 1337 mesh with the factual requirements necessary to prevail on the merits," and explained that "the fact that [the complainant] was later unable to sustain these allegations [regarding whether its patent covered a process] is not material to the issue of *jurisdiction*." *Id.* at 1536.

The majority's reliance on *Amgen* is misplaced. *Amgen* did not involve a determination made pursuant to § 1337(b); instead, the ITC in that case "conduct[ed] a full investigation" before dismissing the complaint. *Id.* at 1534. The majority dismisses this fact by stating "the court's reasoning in [*Amgen*] was not based on that procedural detail" but "focused on the operative effect of the [ITC] decision." Maj. Op. 8. That is hardly a procedural detail; this fact, coupled with § 1337(c)'s precise definition of a final determination, fundamentally limits *Amgen*'s holding. *See* 19 U.S.C. § 1337(c). The majority criticizes "this approach [as] elevat[ing] form over substance." Maj. Op. 9. There is a "general principle that agencies with statutory enforcement responsibilities enjoy broad discretion in allocating investigative and enforcement resources." *Torrington Co. v. United States*, 68 F.3d 1347, 1351 (Fed. Cir. 1995). The majority fails to give due respect to Congress's choice, thereby placing "this court in the position of routinely second-guessing the [ITC]'s decisions [on non-institution] . . . , a role for which [we] are ill-suited and one that could be quite disruptive of [the ITC]'s effort to establish enforcement priorities." *Id.*

In addition, *Amgen* determined that the ITC improperly characterized its dismissal as jurisdictional on the process patent claim issue, but we explained that the substance of its analysis meant it "should have dismissed on the merits." 902 F.2d at 1536 (footnote omitted). By contrast, the ITC's two-page Decision Not to Institute,

which dismissed on jurisdictional grounds, does not purport to, nor in fact does, reach the merits of Amarin's Complaint; rather, it recognizes that the FDCA vests the FDA with primacy over such claims. *See* J.A. 1–2. Amarin is not barred from seeking relief; for instance, the ITC did not find that Amarin failed to "pro[ve] . . . an element of the cause of action," such as finding the Intervenors did not falsely label their accused products and therefore did not commit an unfair act under § 1337(a). *Engage Learning, Inc. v. Salazar*, 660 F.3d 1346, 1354 (Fed. Cir. 2011) (citation omitted); *see Block*, 777 F.2d at 1571 (dismissing for lack of appellate jurisdiction where the ITC did not make a "finding as to whether . . . § 1337 was violated"); J.A. 1–2. As in *Block*, the ITC's Decision Not to Institute is not "the equivalent of a final determination," as it was "without prejudice," because it did not make findings on the merits, and Amarin is "free to" file another complaint. 777 F.2d at 1571; *see id.* (rejecting the argument that the ITC's "order . . . involved the denial of substantive rights"); *Amgen*, 902 F.2d at 1535 (distinguishing *Block* and recognizing there that the court "found the *lack of any findings* by the [ITC] to be critical; nothing in the termination [o]rder prejudiced the [ITC] or any private party in a future proceeding" (emphasis added) (citation omitted)). Indeed, the ITC represents, on appeal, that its dismissal is "without prejudice." Appellee's Br. 57. The ITC notes that "Amarin is free to file a new complaint once the FDA issues sufficient guidance with respect to the [A]ccused [P]roducts such that the [ITC] is not required to interpret the FDCA in the first instance and Amarin's claims are otherwise no longer precluded by the FDCA." *Id.* at 58 (footnote omitted); *see Imp. Motors*, 530 F.2d at 947 & n.13 (relying on an ITC representation made on appeal regarding whether a party could participate in the second stage of a § 1337 investigation). The majority implicitly recognizes that Amarin may eventually re-file. *See* Maj. Op. 7–8 ("[A]s long as Amarin's [C]omplaint is based on proving violations of the FDCA (*at least where the FDA has not provided guidance as to*

whether the articles violate the FDCA), Amarin's claims will be precluded." (emphasis added)).[7] Accordingly, I conclude that the ITC's Decision Not to Institute is not an appealable final determination within the meaning of § 1337(c).

III. We Should Exercise Mandamus Jurisdiction and Deny Amarin's Petition

Intervenors argue that we lack mandamus jurisdiction to review Amarin's Petition, *see* Intervenors' Br. 34–37, because we may not "use mandamus to obtain jurisdiction over agency decisions otherwise beyond [our] reach," *id.* at 36. Amarin and the ITC contend that we have mandamus jurisdiction. *See* Appellants' Br. 25–27; Appellee's Br. 51–52. I agree with Amarin and the ITC.

Pursuant to the All Writs Act, we "may issue all writs necessary or appropriate in aid of" our jurisdiction. 28 U.S.C. § 1651(a). Therefore, our "authority to issue writs of mandamus is restricted by statute to those cases in which the writ is in aid of [appellate] jurisdiction." *Roche v. Evaporated Milk Ass'n*, 319 U.S. 21, 25 (1943). "The authority is not limited to issuance of the writ where the court already had jurisdiction on appeal; rather, the authority extends to those cases which are within its appellate jurisdiction although no appeal has been perfected." *In re Princo Corp.*, 478 F.3d 1345, 1351 (Fed. Cir. 2007) (internal quotation marks and citation omitted).

I believe we have jurisdiction to consider Amarin's Petition, which seeks mandamus relief. Section 1295(a) gives us "exclusive jurisdiction . . . (6) to review the final determinations of the [ITC] . . . made under [§ 1337]." *See* 19

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[7] Because the dismissal is without prejudice and Amarin can re-file, the majority need not be concerned that the ITC would unnecessarily be required "to formally institute . . . just long enough . . . to issue the same dismissal order it already issued in this case." Maj. Op. 9.

U.S.C. § 1337(c) (defining "a final determination"). If the ITC were to erroneously refuse to initiate an investigation, we might consequently be divested of appellate jurisdiction over a matter which we should have had jurisdiction following ITC's institution and final determination. *See id.*; 28 U.S.C. § 1295(a)(6). Review over such matters is necessary as an exercise of "limited judicial power to preserve th[is] court's jurisdiction." *FTC v. Dean Foods Co.,* 384 U.S. 597, 604 (1966). Amarin's Petition asks whether the ITC is required to initiate an investigation under the governing statute. *See, e.g.*, Appellants' Br. 38 ("The Tariff Act imposes a non-discretionary duty on the [ITC] to institute investigations into alleged unfair trade practices and methods of competition."); *see id.* at 39 (relying on § 1337(b)). Accordingly, we retain mandamus jurisdiction, which, under these circumstances, is "necessary to protect [our] prospective jurisdiction." *Telecomms. Research & Action Ctr. v. FCC*, 750 F.2d 70, 76 (D.C. Cir. 1984); *see, e.g., Syntex*, 659 F.2d at 1041 (considering, but ultimately denying, a petition for writ of mandamus where petitioner sought "to compel [the] ITC to institute an investigation"); *cf. In re Cypress Semiconductor Corp.*, 321 F. App'x 964, 965 (Fed. Cir. 2009) (exercising jurisdiction over, but ultimately denying, a petition for writ of mandamus seeking to compel the ITC "to halt its investigation").

Heckler v. Chaney does not require a different result. *See* 470 U.S. 821 (1985); *see also* Intervenors' Br. 26–27, 35 (citing *Heckler* to argue the ITC's Decision Not to Institute is immune from judicial review). Although *Heckler* held that "an agency's decision not to take enforcement action should be presumed immune from judicial review," 470 U.S. at 832, the Supreme Court did not address "a refusal by the agency to institute proceedings based solely on the belief that it lacks jurisdiction," *id.* at 833 n.4, or a "decision [that] is predicated solely on the agency's interpretation of a statute," *Int'l Union, United Auto., Aerospace & Agric. Implement Workers of Am. v. Brock*, 783 F.2d 237, 245 n.10

(D.C. Cir. 1986). However, as discussed above, the Petition challenges the ITC's interpretation of § 1337 and the FDCA, *see* Appellants' Br. 38–39, 50, and the ITC refused to institute because it lacked jurisdiction over Amarin's Complaint, *see* J.A. 1. Thus, I would exercise mandamus jurisdiction over Amarin's Petition, but agree with the majority's conclusion that Amarin has failed to demonstrate that it is entitled to the extraordinary relief of mandamus. *See* Maj. Op. 9 n.3, 9–18.[8]

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[8] To the extent there remains a question about whether we have mandamus jurisdiction, the ITC's failure to institute an investigation would not evade judicial review. Instead, the Administrative Procedure Act ("APA"), 60 Stat. 237 (1946) (codified in scattered sections of 5 U.S.C. (2012)), provides that "[a] person . . . adversely affected" by "final agency action[s] for which there is no other adequate remedy in a court" may seek review of that action, 5 U.S.C. §§ 702, 704. Under this type of action, a reviewing court may "compel agency action unlawfully withheld," *id.* § 706(1), for example the ITC's failure to institute an investigation. Therefore, if appellate and mandamus jurisdiction are lacking in this court, Amarin may be able to raise an APA challenge in district court. *See Norton v. S. Utah Wilderness All.*, 542 U.S. 55, 64 (2004) (holding "a claim under § 706(1) can proceed only where a plaintiff asserts that an agency failed to take a *discrete* agency action that it is *required to take*"). It is useful to note that § 1337(c) expressly contemplates APA review of certain types of determinations. *See* 19 U.S.C. § 1337(c) (stating that ITC "determinations under subsections (d), (e), (f), and (g) . . . with respect to its findings on the public health and welfare, competitive conditions in the United States economy, the production of like or directly competitive articles in the United States, and United States consumers, the amount and nature of bond, or the appropriate

CONCLUSION

Through § 1337(c), Congress expressly defined a final determination of the ITC and thereby precisely drew the limits of our appellate jurisdiction. The majority disregards the text of the statute and Congress's intent by holding that a § 1337(b) non-institution determination is appealable, even though Congress expressly defined a final determination as one made under § 1337(d)–(g). Because I believe we must follow Congress's directive, I respectfully dissent.

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remedy shall be reviewable in accordance with [§] 706" and "[d]eterminations . . . under subsections (e), (f), and (j) . . . with respect to forfeiture of bonds and under subsection (h) . . . with respect to the imposition of sanctions for abuse of discovery or abuse of process shall also be reviewable in accordance with [§] 706").