No. 01-1492

In the Supreme Court of the United States

MYLAN PHARMACEUTICALS, INC., PETITIONER

v.

TOMMY G. THOMPSON, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

Whether petitioner's suit for declaratory and injunctive relief was cognizable under either the patent laws or the Hatch-Waxman Amendments of 1984, which amended the Federal Food, Drug, and Cosmetic Act.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 1a-21a) is reported at 268 F.3d 1323. The memorandum opinion of the district court (Pet. App. 24a-79a) is reported at 139 F. Supp. 2d 1.

JURISDICTION

The judgment of the court of appeals (Pet. App. 22a-23a) was entered on October 12, 2001. A petition for rehearing was denied on January 9, 2002 (Pet. App. 82a-83a). The petition for a writ of certiorari was filed on April 9, 2002. The jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. At issue in this case are provisions of the Federal Food, Drug, and Cosmetic Act (FDCA or FFDCA) that pertain to approvals of new drug applications (also known as "NDAs" or "innovator" or "pioneer" drug applications) and abbreviated new drug applications (also known as "ANDAs" or "generic" drug applications). Those provisions were added to the FDCA by the Drug Price Competition and Patent Term Restoration Act of 1984, known as the Hatch-Waxman Amendments. Pub. L. No. 98-417, 98 Stat. 1585 (21 U.S.C. 355, 360cc; 35 U.S.C. 156, 271, 282).

Title I of the Hatch-Waxman Amendments was intended "to make available more low cost generic drugs by establishing a generic drug approval procedure for pioneer drugs first approved after 1962." H.R. Rep. No. 857, 98th Cong., 2d Sess. Pt. 1, at 14 (1984). Title II was intended to provide a new incentive for research and development of pioneer drugs by "restoration of some of the time lost on patent life while the product is awaiting pre-market approval." *Id.* at 15. The statutory scheme crafted by Congress represents a delicate balancing of those two policy goals. See *Tri-Bio Labs., Inc.* v. *United States*, 836 F.2d 135, 139 (3d Cir. 1987), cert. denied, 488 U.S. 818 (1988); see also *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 676-678 (1990); *Bristol-Myers Squibb Co.* v. *Royce Labs, Inc.*, 69 F.3d 1130, 1132, 1133-1134 (Fed. Cir.), cert. denied, 516 U.S. 1026 (1995) and 516 U.S. 1067 (1996).

a. Under the FDCA, pharmaceutical companies seeking to market "pioneer" or "innovator" drugs must first obtain the approval of the Food and Drug Administration (FDA) by filing an NDA. 21 U.S.C. 355(a) and (b). In addition to submitting extensive scientific data

demonstrating the safety and effectiveness of the drug, an NDA applicant must submit specified information, including the patent number and date of expiration, on "any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. 355(b)(1).[1]

For patents covering the formulation, composition, or method of using a drug, the NDA applicant must also submit a signed declaration stating that the patent covers the formulation, composition, or use of the product described in the pending or approved application. 21 C.F.R. 314.53(c)(2). If a patent is issued after an NDA has been approved, the required patent information must be submitted to the FDA within 30 days after the issuance of the patent. 21 U.S.C. 355(c)(2); 21 C.F.R. 314.53(d)(3). FDA publishes patent information for approved drugs in a publication entitled "Approved Drug Products With Therapeutic Equivalence Evaluations," commonly referred to as the "Orange Book." See 21 U.S.C. 355(b)(1) and (c)(2); *Abbott Labs.* v. *Novopharm Ltd.*, 104 F.3d 1305, 1307 n.1 (Fed. Cir. 1997).

b. The Hatch-Waxman Amendments authorize the submission of ANDAs for approval of generic versions of approved drug products. 21 U.S.C. 355(j); see *Eli Lilly*, 496 U.S. at 676-678; *Mova Pharm. Corp.* v.

[1] "The term 'claims' has been used in patent legislation since the Patent Act of 1836 to define the invention that an applicant believes is patentable. Since that time, the term has represented that portion of the specification that defines the patent owner's property rights in the invention." *Hoechst-Roussel Pharm., Inc.* v. *Lehman*, 109 F.3d 756, 758 (Fed. Cir. 1997) (citation omitted).

Shalala, 140 F.3d 1060, 1063-1065 (D.C. Cir. 1998); *Bristol-Myers*, 69 F.3d at 1131-1132, 1135. Under the abbreviated procedure, an ANDA applicant may rely on FDA findings of safety and effectiveness for the pioneer drug in obtaining approval of a duplicate generic product. 21 U.S.C. 355(j)(2).

An ANDA applicant must, *inter alia*, submit to FDA a certification for each patent that "claims the listed drug" or the method of the drug's use for which patent information is required to be filed. 21 U.S.C. 355(j)(2)(A)(vii). FDA has by regulation defined the term "listed drug" to mean the approved new "drug product." 21 C.F.R. 314.3(b). The certification filed by the generic manufacturer must state one of the following:

> (I) that such patent information has not been filed,
>
> (II) that such patent has expired,
>
> (III) * * * the date on which such patent will expire, or
>
> (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

21 U.S.C. 355(j)(2)(A)(vii).

"This certification is significant, in that it determines the date on which approval of an ANDA * * * can be made effective, and hence the date on which commercial marketing may commence." *Eli Lilly*, 496 U.S. at 677. If a certification is made by the generic manufacturer under paragraph I or II, indicating that patent information pertaining to the drug or its use has not been filed with FDA or that the patent has expired, the

ANDA may be approved immediately, and the generic drug may be marketed. 21 U.S.C. 355(j)(5)(B)(i). A certification under paragraph III indicates that the ANDA applicant does not intend to market the drug until after the applicable patent expires, and approval of the ANDA may be made effective on the expiration date. 21 U.S.C. 355(j)(5)(B)(ii).

If the ANDA applicant provides a certification under paragraph IV, the applicant must give notice of the filing of the ANDA to both the patent owner and the NDA holder for the listed drug. 21 U.S.C. 355(j)(2)(B). That notice "shall include a detailed statement of the factual and legal basis of the applicant's opinion that the patent is not valid or will not be infringed." 21 U.S.C. 355(j)(2)(B)(ii); see 21 C.F.R. 314.95(c)(6). An applicant whose ANDA is pending when additional patents are listed must provide the required certification with respect to the new patents, so long as the additional patents are submitted to FDA no more than 30 days after they were issued. 21 C.F.R. 314.94(a)(12)(vi). Under the Hatch-Waxman Amendments, the filing of an ANDA containing a paragraph IV certification is itself considered an act of infringement if the application is for "a drug claimed in a patent or the use of which is claimed in a patent." 35 U.S.C. 271(e)(2)(A); see *Eli Lilly*, 496 U.S. at 678 (Section 271(e)(2) creates "a highly artificial act of infringement that consists of submitting an ANDA * * * containing the fourth type of certification that is in error as to whether commercial manufacture, use, or sale of the new drug (none of which, of course, has actually occurred) violates the relevant patent.").

If the ANDA applicant provides a paragraph IV certification, and the patent holder does not commence a patent infringement action within 45 days, the FDA's

approval of the ANDA will become effective immediately. 21 U.S.C. 355(j)(5)(B)(iii). The statute also provides that "[u]ntil the expiration of forty-five days from the date the notice made under paragraph (2)(B)(i) is received, no action may be brought under section 2201 of title 28, for a declaratory judgment with respect to the patent." 21 U.S.C. 355(j)(5)(B)(iii). If the patent holder commences an infringement action within the allotted 45-day period, approval of the ANDA becomes effective 30 months from the date that the patent owner and NDA holder received notice, "or [after] such shorter or longer period as the court may order because either party to the action failed to reasonably cooperate in expediting the action." 21 U.S.C. 355(j)(5)(B)(iii). However, "if before the expiration of [the 30-month] period the court decides that such patent is invalid or not infringed, the approval shall be made effective on the date of the court decision." 21 U.S.C. 355(j)(5)(B)(iii)(I); see *Eli Lilly*, 496 U.S. at 677-678.

c. In the Orange Book, FDA publishes patent information only for the approved aspects of a drug product. 21 U.S.C. 355(b)(1) and (c)(2); 21 C.F.R. 314.53(e); see *Pfizer, Inc.* v. *FDA*, 753 F. Supp. 171, 174-178 (D. Md. 1990).[2] If a dispute arises regarding the accuracy or

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[2] There are three parts to the process by which a pioneer drug manufacturer submits patent information to FDA for listing in the Orange Book. First, when an applicant submits its NDA for approval, it files information regarding "any patent which claims the drug for which the applicant submitted the application or which claims a method of using such drug and with respect to which a claim of patent infringement could reasonably be asserted if a person not licensed by the owner engaged in the manufacture, use, or sale of the drug." 21 U.S.C. 355(b)(1). Second, an applicant sometimes will not receive approval for every aspect of the drug as described in the original NDA submission. In that circumstance,

relevance of patent information that is submitted to FDA and subsequently listed in the Orange Book, an FDA regulation provides an informal process for resolving the dispute. 21 C.F.R. 314.53(f). Under that regulation, an ANDA applicant must provide written notification of the grounds for dispute to FDA. *Ibid.* Upon receipt of the notification, FDA requests that the NDA holder confirm the correctness of the patent information and listing. *Ibid.* FDA regards its own role in the listing process as essentially ministerial, however, and will not change the patent information listed in the Orange Book unless the patent information is withdrawn or amended by the NDA holder. See *ibid.*

2. Respondent Bristol-Myers Squibb Co. (Bristol-Myers) manufactures the drug buspirone hydrochloride (buspirone) under the brand name BuSpar®. FDA approved BuSpar® in 1986. In its application for BuSpar®, Bristol-Myers included information on patent 4,182,763 (the '763 patent). Upon approval of the NDA, the '763 patent was listed in the Orange Book for BuSpar®. The patent was due to expire at 11:59 p.m. on November 21, 2000. Pet. App. 9a, 33a-34a.

In 1997, petitioner Mylan Pharmaceuticals, Inc. (Mylan) submitted an ANDA for a generic version of buspirone tablets. Mylan's ANDA contained a paragraph III certification with respect to the '763 patent under 21 U.S.C. 355(j)(2)(A)(vii)(III), stating that Mylan would not market its drug product until the expiration of Bristol-Myers' '763 patent. FDA tentatively approved

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once the NDA is approved, the applicant must amend the patent submission to list only those patents that meet the listing criteria for the approved drug product. 21 C.F.R. 314.53(c)(2)(ii). Third, if a patent is obtained after an NDA has been approved, the NDA holder must list the new patent within 30 days after the patent is issued. See 21 U.S.C. 355(c)(2).

the Mylan ANDA, making the drug eligible for final approval upon the expiration of Bristol-Myers' exclusivity period. Pet. App. 9a-10a, 34a.

On November 21, 2000, however, Bristol-Myers was issued patent 6,150,365 (the '365 patent), and it filed information with FDA on the '365 patent that same day. Pet. App. 9a-10a, 34a-35a. Bristol-Myers stated in its declaration that the patent "is a method-of-use patent covering, among other things, a method of using BuSpar® for all of its approved indications." *Id.* at 35a. As a result of FDA's receipt of the '365 patent and declaration, Mylan's buspirone product was not eligible for approval on November 22, 2000, and the agency did not give final approval to Mylan's ANDA (or to any other ANDAs filed by other applicants for generic buspirone tablets) at that time. *Id.* at 10a, 35a.

Mylan and other generic manufacturers wrote to FDA, contending that the '365 patent covers a method of use of a metabolite produced by the administration of buspirone, but not buspirone itself, and that the patent was therefore ineligible for listing in the Orange Book.[3] FDA requested clarification from Bristol-Myers as to whether the patent claimed only a metabolite of buspirone. Before FDA received a response from Bristol-Myers, Mylan filed suit, naming both FDA (and individual FDA officials) and Bristol-Myers as defendants

[3] A "metabolite" is a new molecule that is created after an existing pharmaceutical agent breaks down in the body. Pet. App. 35a n.6. The Federal Circuit's decision in *Hoechst-Roussel Pharmaceuticals, Inc.* v. *Lehman*, 109 F.3d 756 (1997), "suggested to the FDA that patents for a drug's metabolites do not 'claim' the listed drug itself" within the meaning of the FDCA. Pet. App. 37a.

and seeking "delisting" of the '365 patent. Pet. App. 10a-11a, 36a-37a.[4]

Shortly after the filing of Mylan's suit, Bristol-Myers responded to FDA's request for clarification by stating that the '365 patent does not simply claim a method of using the metabolite, but also claims a method of using buspirone itself. Based on that submission, and consistent with its long-standing administrative practice of accepting at face value the accuracy of such patent declarations, FDA continued to list the '365 patent. As a result, Mylan's ANDA for its generic version of buspirone was not approved at that time. Pet. App. 10a-11a, 38a.

3. The district court granted Mylan's motion for a preliminary injunction. Pet. App. 24a-79a.

a. The district court first held that it had subject-matter jurisdiction over Mylan's complaint. Pet. App. 41a-52a. The court found that Mylan's request for a judicial order directing Bristol and FDA to "delist" the '365 patent was not properly characterized as an effort to enforce the FDCA. *Id.* at 42a. Rather, the court concluded, Mylan's suit was an independent action with respect to a patent that was properly brought pursuant to 28 U.S.C. 1338(a), which provides district courts with subject-matter jurisdiction of civil actions arising under any Act of Congress relating to patents. Pet. App. 42a-52a.

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[4] Danbury Pharmacal, Inc. filed suit in the District of Maryland, naming then-FDA Commissioner Henney as the sole defendant. See Pet. App. 39a-41a. Danbury also sought preliminary injunctive relief to prevent the listing of the '365 patent and to require FDA to immediately approve its application to market a generic version of buspirone. Ultimately, Danbury and Bristol-Myers entered into a settlement, and Danbury's generic product is now on the market.

b. On the merits, the district court found that Mylan had demonstrated a likelihood that Bristol-Myers' '365 patent did not claim the buspirone product for which Bristol-Myers had earlier obtained FDA approval and that no claim of patent infringement could reasonably be asserted by Bristol-Myers against Mylan. Pet. App. 54a-72a. Specifically, the court found that the '365 patent does not claim a method of using BuSpar® (*id.* at 56a-61a); that the '365 patent expressly disclaims coverage of the administration of buspirone in the manner currently approved (*id.* at 62a-68a); and that, during the prosecution of the '365 patent, Bristol-Myers had surrendered the coverage of the administration of buspirone at issue in Mylan's ANDA (*id.* at 68a-72a).

The district court found that Mylan had failed to establish that it would suffer irreparable injury (Pet. App. 72a-75a), but that the balance of harms to the parties tilted in favor of Mylan (*id.* at 75a-76a), and that the public interest weighed in favor of granting a preliminary injunction (*id.* at 76a-77a). Based on its consideration of the relevant factors, the court granted Mylan's request for a preliminary injunction. *Id.* at 77a-78a. The preliminary injunction ordered Bristol-Myers to request "delisting" of the '365 patent from the Orange Book and directed FDA to approve Mylan's ANDA. *Id.* at 78a. In accordance with the order, Bristol-Myers requested the "delisting" of the '365 patent, and FDA then removed the patent from the Orange Book and approved Mylan's ANDA, thereby permitting Mylan to begin marketing its generic version of buspirone.

4. Bristol-Myers appealed, and the federal defendants moved to be realigned with Mylan as appellees. Pet. 9; see Pet. App. 12a. The government argued that Mylan's complaint stated a cognizable cause of action

under the patent laws and that the district court had properly exercised subject-matter jurisdiction over the case. The government took no position as to the correctness of the district court's holding on the merits. The court of appeals reversed. *Id.* at 1a-21a.

a. The thrust of the government's argument was that, as this Court recognized in *Eli Lilly*, a patent infringement suit under 35 U.S.C. 271(e)(2) is "highly artificial" (496 U.S. at 678) because Section 271(e)(2) defines the mere filing of an ANDA with a paragraph IV certification (rather than the manufacture, use, or sale of the generic drug) as the actionable act of infringement. See p. 5, *supra*. But a paragraph IV certification is required, the government argued, only if the NDA holder has timely submitted to FDA for listing, and FDA has listed, a patent that "claims" the drug product previously approved by FDA. The government's brief explained that only patents that "claim" the approved drug product may be listed, see Gov't C.A. Br. 9 (citing *Pfizer, Inc.* v. *FDA*, *supra*), and therefore only such patents can trigger the requirement to file an ANDA with a paragraph IV certification. The paragraph IV certification requirement, in turn, allows the NDA holder or patent owner to file the "highly artificial" (*Eli Lilly*, 496 U.S. at 678) patent infringement action under 35 U.S.C. 271(e)(2)(A). The government argued that a declaratory judgment action filed by a generic manufacturer seeking the "delisting" of a patent on the ground that the patent was improperly listed—*e.g.*, because it did not claim the approved drug product—was cognizable under the patent laws under the "well-pleaded" complaint rule. See Gov't

C.A. Br. 26-31 (citing, *inter alia*, *Speedco, Inc.* v. *Estes*, 853 F.2d 909, 912 (Fed. Cir. 1988)).[5]

b. The court of appeals reversed the district court's grant of a preliminary injunction. The court first held that Mylan's challenge to Bristol-Myers' listing of the '365 patent in the Orange Book could not be raised as a defense to an action for infringement under 21 U.S.C. 271(e)(2)(A). Pet. App. 14a-16a. The court explained that "[d]efenses to allegations of patent infringement fall into two broad groups: statutory and equitable." *Id.* at 15a-16a. In the court's view, Mylan's contention that the '365 patent had been improperly listed in the Orange Book does not fall within either of those two recognized categories of defenses to patent infringement actions. *Id.* at 16a. The court further held that the Hatch-Waxman Amendments do not create additional defenses to a claim of patent infringement. *Id.* at 16a-18a. The court of appeals concluded on that basis

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[5] As the Federal Circuit explained in *Speedco*, a court "determine[s] whether federal court jurisdiction exists in a case seeking a declaratory judgment by applying the well-pleaded complaint rule not to the declaratory judgment complaint, but to the action that the declaratory defendant would have brought." 853 F.2d at 912. In the present case, the government's brief in the court of appeals explained that if Mylan had submitted a paragraph IV certification regarding the '365 patent, Bristol-Myers could then have filed an infringement action under 35 U.S.C. 271(e)(2)(A). Gov't C.A. Br. 28. The government observed that "[t]he threshold inquiry" in such a suit would be "whether the ANDA pertains to a drug 'claimed in a patent' or to a use that is 'claimed in a patent.'" *Id.* at 28-29. The government contended that Mylan's declaratory judgment action—which alleges that the '365 patent does *not* "claim" buspirone and therefore was not properly listed in the Orange Book—is therefore properly regarded as arising under Section 271(e)(2)(A) (a provision of the patent laws) rather than under the FDCA. *Id.* at 29-31.

that "Mylan's action here against Bristol is in essence an attempt to assert a private right of action for 'delisting' under the FFDCA" (*id.* at 18a), and that the suit was therefore foreclosed by "the long line of cases precluding private rights of action under the FFDCA" (*id.* at 19a).

5. During the pendency of the instant suit, Bristol-Myers filed a separate action under 35 U.S.C. 271(e)(2), alleging that Mylan's submission of an ANDA for its generic product infringed the '365 patent. See *In re Buspirone Patent Litig.*, 185 F. Supp. 2d 340, 350-351 (S.D. N.Y. 2002). The district court ruled in Mylan's favor, holding that the '365 patent does not cover FDA-approved uses of buspirone and that the patent would be invalid if construed to cover the approved uses. *Id.* at 351-363. Bristol-Myers has filed a notice of appeal from that judgment. Bristol-Myers Br. in Opp. 6 n.2.

ARGUMENT

Mylan seeks review of the court of appeals' holding that the district court lacked subject-matter jurisdiction over its declaratory judgment action. Mylan contends, *inter alia*, that the court of appeals' decision will enable pioneer drug manufacturers to delay the marketing and sale of generic equivalents by submitting new patents for listing in the Orange Book and then initiating infringement actions against generic drug manufacturers that have filed an ANDA, which would then postpone the effective date of FDA's approval of the ANDA for up to 30 months. See Pet. 11-17. In the court of appeals, the government argued that Mylan's declaratory judgment action arose under the patent laws and that the district court had subject-matter jurisdiction over the suit. See pp. 10-12, *supra*. Despite the court of appeals' contrary holding, the jurisdictional

question does not warrant this Court's review, at least in the context of the present suit.

1. This Court's resolution of the question presented would have no immediate practical impact on the parties to this case. At the time that Mylan filed suit, no generic version of buspirone was on the market because Bristol-Myers' listing of the '365 patent had blocked FDA's approval of all generic equivalents. That is no longer the case. Mylan's generic product is now on the market, and so are versions produced by Danbury Pharmacal, see note 4, *supra*, and other ANDA holders.

During the pendency of the instant suit, Bristol-Myers' patent infringement action proceeded to judgment in the district court. See *In re Buspirone Patent Litig.*, *supra*. The district court ruled in Mylan's favor, holding that the '365 patent does not cover FDA-approved uses of buspirone and that the patent would be invalid if construed to cover the approved uses. 185 F. Supp. 2d at 351-363. Bristol-Myers has filed a notice of appeal from that judgment. Bristol-Myers Br. in Opp. 6 n.2. If the district court's judgment in the patent infringement suit is affirmed by the court of appeals, the decision in the instant case will pose no threat to Mylan's continued manufacture and sale of buspirone. In any event, as a result of the district court's ruling in the infringement case, Mylan currently enjoys the right to market its generic product pending a final judicial determination whether such marketing will infringe Bristol-Myers' '365 patent.

As the court of appeals observed, moreover, "Congress has considered legislation to amend the FFDCA to loosen the restrictions on generic ANDA applicants under 21 U.S.C. § 355(j)(5)." Pet. App. 20a. Now that the Federal Circuit has construed the existing statutory scheme, it is appropriate that Congress be given

an opportunity to consider the possible need for legislation to clarify its intent regarding the propriety of declaratory judgment actions such as the one at issue here. If Congress does not address the question and the Federal Circuit continues to abide by its current ruling, the Court may have occasion to consider in a future case whether review is warranted. In the meantime, of course, the alternative mechanism invoked in this case for resolving the underlying patent controversy—the commencement of an infringement action by the patent holder within 45 days after the filing of the paragraph IV certification—will remain available in comparable situations. In this case, that alternative mechanism resulted in a district court judgment in petitioner's favor in less than 15 months, far less than the 30-month period during which FDA approval of an ANDA is presumptively postponed upon commencement of such a suit.

2. The FDCA provides, with an exception for state enforcement not relevant here, that "all such proceedings for the enforcement, or to restrain violations, of this chapter [*i.e.*, the FDCA] shall be by and in the name of the United States." 21 U.S.C. 337(a). Mylan contends (Pet. 22-25) that, even if its suit is found to arise under the FDCA rather than under the patent laws, its private cause of action against Bristol-Myers for "delisting" is not barred by Section 337(a). Mylan argues (Pet. 23) that the word "such" in Section 337(a) "limits the proceedings whose enforcement is reserved to the United States to those enumerated in the [preceding] sections of Subchapter III, 21 U.S.C. §§ 331-336." That argument lacks merit.

Every court of appeals that has addressed the scope of Section 337(a) has held that private enforcement of the FDCA is categorically precluded. See *In re*

Orthopedic Bone Screw Prods. Liab. Litig., 193 F.3d 781, 788 (3d Cir. 1999) ("It is well settled * * * that the FDCA creates no private right of action."); *PDK Labs, Inc.* v. *Friedlander*, 103 F.3d 1105, 1113 (2d Cir. 1997) (plaintiff's suit "represents an 'impermissible attempt to enforce the FDCA through a private action'"); *Bailey* v. *Johnson*, 48 F.3d 965, 966-968 (6th Cir. 1995) (same); *Mylan Laboratories, Inc.* v. *Matkari*, 7 F.3d 1130, 1139 (4th Cir. 1993) (same), cert. denied, 510 U.S. 1197 (1994); see also *Eli Lilly & Co.* v. *Roussel Corp.*, 23 F. Supp. 2d 460, 476 (D.N.J. 1998) ("Every federal court that has addressed the issue has held that the FDCA does not create a private right of action to enforce or restrain violations of its provisions and accompanying regulations."); *National Women's Health Network, Inc.* v. *A.H. Robins Co.*, 545 F. Supp. 1177, 1179 (D. Mass. 1982) (rejecting an argument that the phrase "such proceedings" was meant to limit the scope of Section 337(a) to the proceedings specifically addressed in preceding provisions, and stating that "the section must be construed to refer to the enforcement power generally, rather than some limited aspect of that power"). Mylan identifies no contrary authority. In the absence of a circuit conflict, the question whether private enforcement of the FDCA is permissible in this context does not warrant this Court's review, particularly since the court of appeals' decision has no effect on Mylan's present ability to market its generic product.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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