15-1402

No. 15-

In The
Supreme Court of the United States

AMPHASTAR PHARMACEUTICALS, INC., INTERNATIONAL MEDICATION SYSTEMS, LTD., ACTAVIS, INC., AND ACTAVIS PHARMACEUTICALS, INC.,

Petitioners,

v.

MOMENTA PHARMACEUTICALS, INC. AND SANDOZ, INC.

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

PETITION FOR A WRIT OF CERTIORARI

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QUESTION PRESENTED

The Hatch-Waxman Act safe harbor provides that "[i]t shall not be an act of infringement to *** use *** a patented invention *** solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs[.]" 35 U.S.C. § 271(e)(1). The question presented is:

Whether the safe harbor protects a generic drug manufacturer's bioequivalence testing that is performed only as a condition of maintaining FDA approval and is documented in records that must be submitted to the FDA upon request.

PARTIES TO THE PROCEEDINGS

Petitioners Amphastar Pharmaceuticals, Inc., International Medication Systems, Actavis, Inc., and Actavis Pharmaceuticals, Inc. were defendants in the district court and appellees in the court of appeals. Actavis Pharmaceuticals, Inc. was formerly known as Watson Pharma, Inc.

Momenta Pharmaceuticals, Inc. and Sandoz, Inc. were plaintiffs in the district court and appellants in the court of appeals.

RULE 29.6 DISCLOSURE

Amphastar Pharmaceuticals, Inc. has no parent corporation, and no publicly held corporation owns ten percent or more of its stock. International Medication Systems, Ltd. is a wholly owned subsidiary of Amphastar Pharmaceuticals, Inc. Actavis, Inc. is a subsidiary of Actavis Capital S.a.r.l., a wholly owned subsidiary of Allergan plc. Actavis Pharmaceuticals, Inc. is a wholly owned subsidiary of Allergan plc. Teva Pharmaceuticals has announced a deal to purchase Actavis Generics from Allergan plc, but the deal has not closed.

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES:

STATUTES AND REGULATIONS:

OTHER AUTHORITIES:

BLANK PAGE

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OPINIONS BELOW

The opinion of the court of appeals (App., *infra*, 1a-38a) is reported at 809 F.3d 610. The opinion of the district court (App., *infra*, 39a-55a) is reported at 962 F. Supp. 2d 348. The prior opinion of the court of appeals (App., *infra*, 56a-128a) is reported at 686 F.3d 1348.

JURISDICTION

The court of appeals entered its judgment on November 10, 2015. Petitioners Amphastar Pharmaceuticals, Inc., International Medication

Systems, Ltd., Actavis, Inc., and Actavis Pharmaceuticals, Inc. (collectively, "Amphastar") timely filed a petition for rehearing en banc, which was denied on February 17, 2016. This Court has jurisdiction pursuant to 28 U.S.C. § 1254(1).

RELEVANT STATUTORY AND REGULATORY PROVISIONS

The Hatch-Waxman safe harbor, 35 U.S.C. § 271(e)(1), provides in relevant part:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention *** solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

INTRODUCTION

Petitioner Amphastar and Respondents Momenta Pharmaceuticals, Inc. and Sandoz, Inc. ("Momenta") are competing generic manufacturers of the unpatented drug enoxaparin. The FDA mandates that manufacturers conduct testing to ensure the bioequivalency (or sameness) of each batch of generic enoxaparin with the brand-name drug (Lovenox), as a condition of ongoing FDA approval, in conformance with the standard set forth in the United States Pharmacopeia ("USP") compendium adopted by Congress (21 U.S.C. § 351(b)). Amphastar uses the sole USP-specified testing method to satisfy the FDA's requirement.

Momenta sued Amphastar for patent infringement. Momenta alleged that Amphastar's Abbreviated New Drug Application ("ANDA") approval was conditioned on Amphastar's ongoing use of the "official" USP-specified testing method and that Momenta had patented that method. Reviewing a preliminary injunction issued by the district court against Amphastar, the Federal Circuit originally held that Amphastar's use of the USP-specified method was protected under the Hatch-Waxman safe harbor, which permits the use of a patented invention "solely for uses reasonably related to the development and submission of information under a Federal [drug] law." 35 U.S.C. § 271(e)(1). The Federal Circuit accordingly remanded with instructions to the district court to consider whether the case was "amenable to summary judgment of non-infringement in favor of Amphastar." App., *infra*, 88a.

After the district court entered summary judgment for Amphastar on remand, however, the Federal Circuit reversed course: it held that the same testing under the same authority was not protected after all. The Federal Circuit based its about-face on a purportedly new finding that Amphastar's testing was "routine," App., *infra*, 22a-23a, a word nowhere found in the statute.

The Federal Circuit's (second) decision cannot be reconciled with this Court's repeated admonitions that the terms of the safe harbor must be interpreted broadly to cover the "entire statutory scheme of regulation." *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 666 (1990). And the impermissible narrowing of the safe harbor will create just the sort

of road blocks to lower-cost generic drugs that Hatch-Waxman was designed to avoid.

For that reason, as Momenta itself has acknowledged at the preliminary-injunction stage of this case, the scope of Section 271(e)(1) "is an issue of exceptional, immediate importance to the pharmaceutical industry." Petition for Certiorari at 28, *Momenta Pharms., Inc. v. Amphastar Pharms., Inc.*, No. 12-1033 (filed Feb. 15, 2013) ("Momenta Cert. Pet.") (capitalization omitted). Its significance will only grow in light of the increasing prevalence of complex biosimilar drugs, for which the FDA's bioequivalence-testing requirements are particularly salient. Hijacking one of the required bioequivalence tests, as Momenta has done, creates a roadmap for blocking generic market entry in contravention of Hatch-Waxman's purposes. Given these stakes, certiorari is warranted.

STATEMENT OF THE CASE

A. Statutory and Regulatory Framework

To facilitate consumer access to lower-priced drugs, Congress enacted special rules designed to streamline generic drug approval in the Drug Price Competition and Patent Term Restoration Act, Pub. L. No. 98-417, 98 Stat. 1585 (1984), commonly known as the Hatch-Waxman Act. *See PLIVA, Inc. v. Mensing*, 131 S. Ct. 2567, 2574 (2011). Under the Hatch-Waxman Act, "'generic drugs' can gain FDA approval simply by showing equivalence to a reference listed drug that has already been approved by the FDA." *Id.* at 2574 (citing 21 U.S.C. § 355(j)(2)(A)).

Among other reasons, because proving to the FDA that a generic drug is bioequivalent to a name-brand drug can sometimes involve the use of a patented invention, the Hatch-Waxman Act codified a new exemption to the patent infringement statute—commonly referred to as the "safe harbor" provision. The safe harbor provides:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention *** solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs[.]

35 U.S.C. § 271(e)(1) (as amended).

The Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA" or "Act") is a "Federal law which regulates the manufacture, use, or sale of drugs," within the meaning of the safe-harbor provision. *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 196 (2005) (citing 21 U.S.C. § 355(a)). The safe harbor provides a "wide berth for the use of patented [inventions] in activities related to the federal regulatory process." *Id.* at 202. It covers both pre-FDA-approval and post-FDA-approval activities. App., *infra*, 18a.

B. Factual Background

1. This case involves a patent infringement dispute between two competing manufacturers of generic enoxaparin. Enoxaparin is a complex molecule—derived from biological, rather than

chemical, sources—that treats and prevents life-threatening blood clots. App., *infra*, 5a. Until 2010, enoxaparin was available only as an expensive brand-name drug called Lovenox. *Id.* Patents no longer cover either enoxaparin or its manufacturing process.[1]

The FDA mandates that each new batch of generic enoxaparin undergoes bioequivalence testing—to show that it has the same composition as Lovenox—as a running condition of FDA approval to sell the drug. App., *infra*, 76a-77a. Demonstrating generic enoxaparin's bioequivalence to Lovenox, however, poses a "potential problem" not present with simpler drugs. *Id.* at 59a. "[U]nlike a typical small molecule drug like penicillin, enoxaparin is made up of a range of different molecules." *Id.* Heparin, a pig-intestine product from which enoxaparin is derived, contains "considerable diversity" in its molecular structure. *Id.* at 58a. The "obvious complication" with establishing bioequivalence to Lovenox is that finished enoxaparin is not made up of a single molecule but "a mixture of a number of different low molecular weight heparin molecules." *Id.* at 60a. Accordingly, the FDA determined that it would allow generic manufacturers to demonstrate bioequivalence or

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[1] In separate prior litigation, Sanofi-Aventis sued Amphastar and Teva Pharmaceuticals USA, Inc. (another producer of generic enoxaparin) for patent infringement as soon as they filed their ANDAs. But Sanofi-Aventis's patent was ultimately held unenforceable, and the door was opened to generic production of enoxaparin. *See Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334, 1349 (Fed. Cir. 2008).

"sameness" through "five criteria, or 'standards for identity,' that together provide sufficient information to conclude that generic enoxaparin has the 'same' active ingredient as Lovenox." *Id.* at 60a-61a (some internal quotation marks omitted).

One of those five standards for determining sameness is at issue in this case: "[d]etecting the presence of a 1,6 anhydro ring structure" at "the reducing ends of between 15 percent and 25 percent of its poly(oligo)saccharide chains." App., *infra*, 61a-62a. The presence of that chemical structure in the specified range indicates the drug's bioequivalence to Lovenox. *Id.* That requirement is now embodied in the USP Monograph on Enoxaparin Sodium to which all generic manufacturers, including Amphastar, must conform. *See id.* at 84a-85a.

In addition, USP publishes an "official" companion test—known as the General Chapter <207> Test for 1,6-Anhydro Derivative for Enoxaparin Sodium ("USP Method <207>")—for establishing that a batch of enoxaparin meets the 15-25% standard. App., *infra*, 86a. "Only those results obtained by the methods and procedures given in the compendium are conclusive."[2]

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[2] USP General Notices and Requirements § 6.30, *available at* http://www.usp.org/sites/default/files/usp_pdf/EN/USPNF/USP34-NF29General%20Notices.pdf. Although the USP allows a manufacturer to use an alternative to the official test if it "provide[s] advantages in terms of accuracy, sensitivity, precision, selectivity, or adaptability," any "[s]uch alternative procedures and methods shall be validated" first in accordance with USP procedures and also "must be shown to give equivalent or better results." *Id.*

Because the FDCA prohibits the sale of drugs that fail to meet the standard set forth in the relevant USP Monograph, *see* 21 U.S.C. §§ 321(j), 331(a), 351(b), generic manufacturers must maintain bioequivalence between enoxaparin and Lovenox on a batch-by-batch basis as an ongoing "condition for [FDA] approval and release." 21 C.F.R. § 211.165(d); *see id.* § 211.165(a) ("For each batch of drug product, there shall be appropriate laboratory determination of satisfactory conformance to final specifications for the drug product *** prior to release."). Any batch of enoxaparin that is not successfully tested in accordance with the "established specifications and standards" in "the current revision of the [USP]," 21 C.F.R. § 211.194(a)(1)-(2), "shall be rejected" and its approval for marketing withdrawn, *id.* § 211.165(f); *see* 21 U.S.C. §§ 321(j), 331(a), 351(b). Manufacturers like Amphastar are obligated to provide documentation of their bioequivalence testing to the FDA upon request. *See* 21 U.S.C. § 374(a)(4)(A) ("Any records or other information that the Secretary may inspect under this section *** shall, upon the request of the Secretary, be provided to the Secretary *** in advance of or in lieu of an inspection[.]"); 21 C.F.R. § 211.180(c) (records "shall be readily available for authorized inspection" by the FDA at any time).

2. Amphastar was the first company to file an ANDA with the FDA for generic enoxaparin. App., *infra*, 62a. In accordance with FDA requirements, Amphastar tests samples of enoxaparin using the "official" USP Method <207> to ensure bioequivalence. *Id.* at 85a-86a. Indeed, before approving the ANDA, the FDA "expressly require[d]"

Amphastar to conduct testing to prove conformance with the USP standard. C.A. Supp. App. A15276-A15277, No. 14-1276 (Fed. Cir. July 24, 2015) ("[T]he above FDA documentation shows that Amphastar was 'required' by the FDA to test *** during and after ANDA approval."); *see also id.* at A15368 (Mar. 22, 2007 FDA letter); Amphastar C.A. Supp. Br. 4, No. 14-1276 (Fed. Cir. Sept. 9, 2015). Amphastar would not conduct such testing but for FDA's demand. *See* C.A. Supp. App. A15277 ("It is possible to make enoxaparin and sell it without conducting [the relevant] testing. *** Amphastar has no need to conduct [such] testing other than to satisfy the FDA's requirement for such tests.").

Although Momenta was the third generic manufacturer to file,[3] the FDA approved Momenta's generic version of enoxaparin first. App., *infra*, 62a. During the approximately one-year period it was the lone supplier of generic enoxaparin on the market, Momenta enjoyed profits on more than one billion dollars in sales. *Id.*

Momenta is the assignee of U.S. Patent No. 7,575,886 ("the '886 patent"), which claims "[a] method for analyzing an enoxaparin sample." C.A. App. 102; *see also* App., *infra*, 63a. Momenta alleges that the '886 patent covers USP Method <207>.

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[3] Momenta also sued another competitor, Teva Pharmaceuticals (the second filer), for infringement. Teva is a foreign manufacturer and therefore subject to liability only if its enoxaparin is "made by a process patented in the United States." 35 U.S.C. § 271(g). Because enoxaparin is not "made by" Momenta's patent, the Federal Circuit affirmed judgment for Teva in Momenta's infringement suit. App., *infra*, 16a.

App., *infra*, 86a. Despite USP's policy of developing publicly available standards and discouraging adoption of patented tests,[4] Momenta (a participant in the relevant USP committee) never disclosed to USP its then-pending patent application. The patent ultimately issued after adoption of USP Method <207> as the official companion test for the USP Monograph.

C. Procedural History

1. Two days after Amphastar obtained FDA approval to market its less-expensive version of enoxaparin, Momenta sued Amphastar for allegedly infringing Momenta's '886 patent. The premise of Momenta's complaint is that the '886 patent covers USP Method <207> and that, "in order for the FDA to have approved Defendants' manufacture of generic enoxaparin," Amphastar must be performing that bioequivalence test on each batch of enoxaparin. Am. Compl. ¶ 27, C.A. App. 963. Momenta has repeatedly acknowledged "[t]he FDA requires manufacturers of generic enoxaparin" to perform the USP-specified testing. Momenta C.A. Br. 41, No. 12-1062 (Fed. Cir. Dec. 13, 2011); *see* Am. Compl. ¶¶ 22, 24, C.A. App. 962-963 ("FDA requires" testing); *see also* App., *infra*, 64a, 66a, 81a.

Crediting these allegations, the district court granted Momenta a preliminary injunction that

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[4] *See* USP Guideline for Submitting Requests for Revision to *USP-NF*: General Information for All Submissions (Apr. 2016), *available at* http://www.usp.org/sites/default/files/usp_pdf/EN/USPNF/general-information-for-all-submissions.pdf.

categorically barred Amphastar from advertising, offering for sale, or selling its enoxaparin. App., *infra*, 129a-161a.

2. In its first decision, the Federal Circuit vacated the preliminary injunction. It held that Amphastar's USP-compliant bioequivalence testing, which "generates information for submission pursuant to the [FDCA]," "falls squarely within the scope of the safe harbor" provision of the Hatch-Waxman Act, 35 U.S.C. § 271(e)(1). App., *infra*, 86a. The Federal Circuit emphasized Momenta's own "allegations and concessions" that the allegedly infringing activity was "necessary because the 'FDA requires a generic manufacture[r]'" to undertake such testing. *Id.* at 64a, 67a.

Focusing on the statutory text, the Federal Circuit determined that Amphastar's compliance with the FDA mandate is "solely" for purposes "reasonably related to *** [the] submission of information" to the FDA, as the safe harbor requires, for two reasons. 35 U.S.C. § 271(e)(1). First, the testing is "reasonably related" to the development and submission of information to the FDA, even if not ultimately submitted, given the "requirement to maintain records for FDA inspection." App., *infra*, 77a. Second, because "the information here is not generated voluntarily by the manufacturer but is generated by FDA requirements the manufacturer is obligated under penalty of law to follow," the court concluded, the information is "gathered solely for submission to the FDA." *Id.* at 80a. The court of appeals found that the testing at issue was "anything but 'routine'" because it implicated Amphastar's very ability to maintain its FDA approval and to continue

manufacturing and marketing its enoxaparin under the ANDA. *Id.* The court rejected as inconsistent with its precedent the dissent's argument that Amphastar's testing was not "solely" for protected activity because it also served a commercial end. *Id.* at 84a (citing *Abtox Inc. v. Exitro Corp.*, 122 F.3d 1019, 1030 (Fed. Cir. 1997)).

The Federal Circuit noted that its decision applying the safe harbor to post-marketing-approval testing was consistent with two decisions of this Court. First, this Court's decision in *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 666 (1990), held that the safe harbor applies to the FDA's "entire statutory scheme of regulation." App., *infra*, 73a-74a (emphasis omitted). Second, this Court's decision in *Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005), held that "'[t]here is simply no room in the statute for excluding certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included.'" App., *infra*, 75a (alteration in original) (emphasis omitted). In other words, Section 271(e)(1) did not "create an exemption applicable only to the research relevant to filing an ANDA." *Id.* at 77a-78a (quoting *Merck*, 545 U.S. at 206). The Federal Circuit thus remanded for the district court to consider entering "summary judgment of non-infringement in favor of Amphastar." *Id.* at 88a.

3. Momenta filed a petition for rehearing *en banc* in the Federal Circuit and a petition for a writ of certiorari to this Court, both of which were denied. Order, No. 12-1062 (Fed. Cir. Nov. 20, 2012); Order, No. 12-1033 (U.S. June 24, 2013).

4. On remand, applying the Federal Circuit's decision, the district court entered summary judgment of non-infringement of the '886 patent in favor of Amphastar on the ground that Amphastar's testing "activities are *** protected by the safe harbor" of 35 U.S.C. § 271(e)(1). App., *infra*, 7a.

5. Momenta filed an appeal, and—after soliciting the views of the (non-party) Attorney General on the interpretation of Section 271(e)(1)—the Federal Circuit reversed the district court as well as its own prior decision.

The Federal Circuit first identified the purpose of the safe-harbor provision as "facilitat[ing] market entry upon patent expiration." App., *infra*, 17a (quoting *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057, 1072 (Fed. Cir. 2011)). The Federal Circuit highlighted a U.S. House of Representatives Committee report statement focusing on the need to permit "experimentation with a patented drug product, when the purpose is to prepare for commercial activity which will begin after a valid patent expires." *Id.* at 17a-18a (quoting H.R. REP. NO. 98-857(I), at 45 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2647, 2648) (emphasis omitted). The Federal Circuit acknowledged that the safe harbor is not restricted to pre-approval activities, but stated that the safe harbor does not apply to information "that may be routinely reported to the FDA, long after marketing approval has been obtained." *Id.* at 19a (quoting *Classen*, 659 F.3d at 1070).

The Federal Circuit then turned to the question whether "Amphastar's submissions are appropriately characterized as 'routine.'" App., *infra*, 21a. The

court held that they were because Amphastar tested and developed information demonstrating bioequivalence for "each batch" of enoxaparin. *Id.* at 22a. The court contrasted this testing with "non-routine submissions that may occur both pre- and post-approval," which are covered by the safe harbor. *Id.* The court held that "routine quality control testing of each batch" is not "reasonably related to the development and submission of information" to the FDA. *Id.* at 22a-23a.

The Federal Circuit denied rehearing en banc. App., *infra*, 162a-163a.

REASONS FOR GRANTING THE WRIT

The Court should grant review to correct once again the Federal Circuit's overly narrow interpretation—cabined by its view of the legislative history—of the Hatch-Waxman safe harbor, and to construe instead the words Congress enacted. This Court has examined the safe harbor twice since 1990; each time it has rejected the Federal Circuit's attempts to impose atextual restrictions on the safe harbor's scope based on congressional "purpose" supposedly revealed in legislative history. The Federal Circuit nevertheless again eschewed the statutory language in favor of a new restriction, excluding so-called "routine" uses, that the court made no attempt to locate in the safe harbor's text—which, after all, is the best evidence of Congress's *actual* purpose.

Both sides agree that "the proper scope of the safe harbor is a critical issue for the pharmaceutical industry." Now that the Federal Circuit has definitively resolved the scope of the safe harbor with

respect to FDA-mandated bioequivalence testing, it is time for this Court to step in and give effect to the terms that Congress wrote.

I. THE FEDERAL CIRCUIT'S CATEGORICAL EXCLUSION OF "ROUTINE" USES FROM THE HATCH-WAXMAN SAFE HARBOR CONFLICTS WITH THIS COURT'S PRECEDENTS AND THE STATUTE

A. Limiting The Safe Harbor's Scope Based On A General Purpose Divined From Legislative History Conflicts With *Eli Lilly* And *Merck*

1. This Court's precedents establish that the safe harbor cannot be narrowed by reference to legislative history

The safe harbor protects from infringement certain acts so long as they are "solely for uses reasonably related to the development and submission of information under" the FDCA and its implementing regulations. 35 U.S.C. § 271(e)(1). Acknowledging the "breadth" of that language, this Court has held "[t]here is simply no room in the statute for excluding certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included." *Merck*, 545 U.S. at 202.

On two occasions, this Court has analyzed and rejected judicially crafted restrictions in favor of the safe harbor's broad terms. First, in *Eli Lilly*, the Court flatly rejected an attempt to qualify Section 271(e)(1)'s plain text based on limitations pulled from the legislative history. 496 U.S. at 669. At issue in

Eli Lilly was whether the safe harbor—which indisputably protects the use of patented inventions in pursuit of new *drug* approval—also protects the use of patented inventions in pursuit of *medical device* approval. *Id.* at 665. This Court held that the best reading of the relevant text ("a Federal law which regulates the manufacture, use, or sale of drugs") applies to the "entire statutory scheme of regulation," not just to the drug-approval process. *Id.* at 665, 666. Thus, even though the legislative history "mentions only drugs," the Court refused to exclude from the safe harbor's unqualified and broad language the use of patented inventions for the purpose of obtaining approval of medical devices. *See id.* at 669 & n.2. The actual terms of the safe harbor apply to the FDCA's "entire" statutory scheme—not just to particular uses disclosed in the legislative history. *Id.* at 666.

More recently, in *Merck,* this Court rejected another judicially fashioned limitation on the safe harbor's scope. Relying on the Act's ostensible goal of protecting "clinical testing" on the road to new drug approval, the Federal Circuit had determined that certain research fell outside the safe harbor because it was merely "general biomedical research to identify new pharmaceutical compounds," rather than "clinical testing to supply information to the FDA." *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860, 866 (Fed. Cir. 2003).

In unanimously reversing, this Court held that "[t]hough the contours of [the safe harbor] provision are not exact in every respect, the statutory text makes clear that it provides a wide berth for the use of patented drugs in activities related to the federal

regulatory process." *Merck*, 545 U.S. at 202. The terms of the statute made "apparent" that "Section 271(e)(1)'s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA." *Id.* Congress neither limited Section 271(e)(1)'s safe harbor "to the development of information for inclusion in a submission to the FDA; nor did it create an exemption applicable only to the research relevant to filing an ANDA for approval of a generic drug." *Id.* at 206. "Rather," Congress "exempted from infringement *all* uses of patented compounds 'reasonably related' to the process of developing information for submission under *any* federal law regulating the manufacture, use, or distribution of drugs." *Id.* (citing *Eli Lilly*, 496 U.S. at 674).

The upshot of these cases is clear: courts are to respect the "wide berth" that Congress gave the users of patented inventions "in activities related to the federal regulatory process"; they are not to impose artificial limitations grounded in the statute's perceived purposes drawn from statements in its legislative history. *Merck*, 545 U.S. at 202. "There is simply no room in the statute" to confine its protections to particular types of submissions to the FDA or the particular stage of the regulatory process. *Id.*

2. The Federal Circuit has engrafted an atextual limitation on the safe harbor in conflict with this Court's cases

The Federal Circuit lost sight of the rules articulated by this Court when it once again relied on

the safe harbor's legislative history, instead of its text, to cabin its reach. Indeed, the Federal Circuit could hardly have been more explicit about what it was doing: it opened its analysis by noting that, as the "legislative history makes *** clear," the "purpose" of the statute was "to facilitate market entry upon patent expiration." App., *infra*, 17a (quoting *Classen*, 659 F.3d at 1072). Relying on that inquiry rather than the provision's text, the Federal Circuit held that the safe harbor could not protect "information that may be routinely reported to the FDA, long after marketing approval has been obtained." *Id.* at 18a-19a (quoting *Classen*, 659 F.3d at 1070). And because the court thought (incorrectly, as explained *infra*) that Amphastar "makes no claim that its accused, post-approval use of the patented method is related to obtaining FDA approval," it "conclude[d] [that] Amphastar's submissions are appropriately characterized as 'routine'"—and thus that the safe harbor did not apply. *Id.* at 21a, 23a.

That analysis conflicts with this Court's precedents. The decision below relied on legislative history in holding that the statute's purpose is limited to "obtaining FDA approval," App., *infra*, 23a, without any "anchor[] in the text of the statute," *Shannon v. United States*, 512 U.S. 573, 583 (1994). As discussed, *Eli Lilly* already rejected a similar reliance on legislative history in the context of this very safe harbor. *See Eli Lilly*, 496 U.S. at 669 n.2 ("It is not the law that a statute can have no effects which are not explicitly mentioned in its legislative history.") (quoting *Pittston Coal Group v. Sebben*, 488 U.S. 105, 115 (1988)). In *Merck*, too, this Court reversed a Federal Circuit opinion that had relied

extensively (and erroneously) on the legislative history to narrow Section 271(e)(1)'s scope. *See, e.g., Merck KGaA*, 331 F.3d at 865 (relying on House Committee report suggesting that safe harbor is restricted to allowing "'a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute'"), *rev'd* 545 U.S. 193.

The Federal Circuit has made the same mistake again. Its focus on obtaining initial "FDA approval" to the exclusion of other later submissions hearkens back to the artificial distinction between pre- and post-approval uses that was rightly rejected by the Federal Circuit at the preliminary-injunction stage of the case, and which even Momenta has since condemned. *See* Momenta Cert. Pet. 4-5 (arguing that earlier Federal Circuit decision erred in "elevat[ing] legislative history *** over statutory text") (citing *Classen*, 659 F.3d at 1071); *see also* U.S. Amicus Br. at 20, *GlaxoSmithKline v. Classen Immunotherapies, Inc.*, No. 11-1078 (U.S. Dec. 13, 2012) ("U.S. Classen Br.") (similar). And that focus ignores the fact that FDA requires the bioequivalence testing at issue to first *obtain* and then to *maintain* FDA approval. *See* p. 9, *supra*.

Indeed, the Federal Circuit's scant analysis of Section 271(e)(1) barely cites the text at all, and nowhere locates the exclusion of "routine" submissions within it. There are ample textual anchors for determining the safe harbor's scope, including the terms "solely," "reasonably related," and "submission." Indeed, the Federal Circuit took the unusual step of seeking the Attorney General's views on "the meaning of the *** 'submission' and

'solely' language." Order, No. 14-1276, at 2 (Fed. Cir. May 7, 2015). Yet the Federal Circuit cast all of that text aside, in favor of a word—"routine"—that is nowhere to be found in the statute. It even went so far as to quote *dictionary definitions* of that word, as if that term were Congress's rather than the Federal Circuit's own invention. App., *infra*, 21a (citing definitions of the term "routine" from Webster's and the American Heritage Dictionary as meaning "of a commonplace or repetitious character" and "[h]abitual; regular") (alteration in original).[5]

But the safe harbor's actual text—as distinct from its perceived (or committee-reported) "purpose"—in no way excludes supposedly "routine" uses. On the contrary, Congress's choice of the phrase "related to"—particularly when preceded by the term "reasonably"—is *broadening* language meant to impart expansive, not restrictive, scope. *See Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 383 (1992) (The "ordinary meaning" of "relating to" "is a broad one—'to stand in some relation; to have bearing or concern; to pertain; refer; to bring into association with or connection with.'") (quoting Black's Law Dictionary 1158 (5th ed. 1979)). That is presumably why this Court has emphasized that the safe harbor provides a "wide berth for the use of patented [inventions] in activities *related to the*

[5] The word "routine" is drawn from vague dicta in the Federal Circuit's since-narrowed decision in *Classen*, 659 F.3d at 1070—a decision that, as the Solicitor General told this Court, "appeared seriously to misconstrue Section 271(e)(1)" by adopting an atextual construction of the statute. U.S. Classen Br. 20.

federal regulatory process," *Merck*, 545 U.S. at 202 (emphasis added)—not just, as the court of appeals would have it, for experimentation in pursuit of "obtaining FDA approval," App., *infra*, 23a. The Federal Circuit's elevation of legislative-history-derived purpose over text flatly contradicts the teachings of *Merck* and *Eli Lilly*.

B. The Federal Circuit Erred In Excluding From The Safe Harbor Testing Required For Ongoing FDA Approval

When the safe harbor's text is examined, it demonstrates the error in the Federal Circuit's decision. The safe harbor protects uses that are "solely" for purposes "reasonably related" to the "development and submission of information" to the FDA. That language plainly encompasses FDA-mandated post-approval testing (which is necessarily designed to "develop[] *** information" for the FDA), notwithstanding its habitual nature. At the same time, it comfortably excludes ordinary manufacturing methods (which generate such information only incidentally, if at all).

Amphastar's testing falls firmly on the protected side of the line. Amphastar conducts the FDA-mandated bioequivalence testing "solely" to "develop[]" the resulting information for "submission" to FDA upon request, as the law requires—not as a manufacturing quality-control step that it would otherwise perform. App., *infra*, 79a-80a; *see* pp. 7-9, *supra*. Indeed, Amphastar is accused of infringing a patented "method for *analyzing* an enoxaparin sample," C.A. App. 102 (emphasis added)—*i.e.*, a

method for *developing information* for the FDA, not for manufacturing.

Moreover, Amphastar uses the USP-specified testing method only because the FDA specifically required Amphastar (as a condition of ANDA approval) to conduct 1,6-anhydro ring structure batch-release testing to produce bioequivalence information. *See* App., *infra*, 80a ("[T]he information here is not generated voluntarily by the manufacturer but is generated by FDA requirements the manufacturer is obligated under penalty of law to follow."); *see* pp. 7-9, *supra*. Conducting that testing and documenting it for FDA submission was a condition to receiving and maintaining FDA approval—and thereby not only "reasonably related" but directly related to safe-harbor protected uses.

The United States agreed that Amphastar satisfies the "solely" and "submission" limitations, because the testing records Amphastar generates may be part of a "submission" to the FDA, U.S. Amicus Br., No. 14-1276, at 15-16 (Fed. Cir. July 17, 2015), and because Amphastar makes "only a single relevant 'use'" of the required testing method, *id.* at 23-24. It took the view, however, that Amphastar's commercial activity does not involve the "development" of information and the testing is not "reasonably related" to the submission of information to the FDA. *Id.* at 2-3, 12.

The latter conclusion fundamentally misunderstands how the FDA-specified bioequivalence testing relates to the safe harbor. Amphastar "develops" new information through the testing; it does not simply collect information that is incidentally generated through the manufacturing

process. It performs the testing for the specific purpose of creating the "information *** necessary both to the continued approval of the ANDA and to the ability to market the generic drug." App., *infra*, 79a. And the use of the USP-specified testing method is not only "reasonably related" to developing information to submit to the FDA; that is its *raison d'etre*. Amphastar would not otherwise conduct such testing. Amphastar's testing therefore bears a "substantial, proximate relationship" to developing and submitting information to the FDA. U.S. Amicus Br. at 18. At the very least, it is "reasonably related" to that goal.

Under the Federal Circuit's decision, however, future applications of the safe harbor will not turn on any of these factors—whether a particular activity is "solely" for uses "reasonably related" to the "development and submission" of information to the FDA, as Section 271(e)(1) provides. Instead, the Federal Circuit's test turns on whether a particular use can be considered "routine." Unsurprisingly, the statute's plain language better reflects Congress's balancing of "the need to stimulate innovation" against the significant "public interest" in low-cost generic drugs. App., *infra*, 69a (quoting H.R. REP. NO. 98–857(II), at 30 (1984), *as reprinted in* 1984 U.S.C.C.A.N. 2686, 2714).

Even assuming an atextual "routine testing" exception, the Federal Circuit erred when it reversed its earlier conclusion that Amphastar's FDA-required testing is "anything but 'routine.'" App., *infra*, 80a. That conclusion had nothing to do with how "habitually" the tests were performed, *id.* at 22a, and everything to do with the fact that "the information

here is not generated voluntarily by [Amphastar] but is generated by FDA requirements the manufacturer is obligated under penalty of law to follow," *id.* at 80a. After all, Momenta sued Amphastar based on an allegation that Amphastar must have been using the USP-specified testing method for FDA-required bioequivalence testing on which continuing ANDA approval was conditioned (and over which Momenta claims a patent). *Id.* at 81a-82a. Testing *required* to maintain ANDA authorization is not "routine"; it is fundamental to the ability to secure ongoing approval from the FDA. It therefore falls squarely within the safe harbor's protection of activities "reasonably related to the development and submission of information" to the FDA. 35 U.S.C. § 271(e)(1). The Federal Circuit erred in concluding otherwise.

II. WHETHER HATCH-WAXMAN PROTECTS TESTING REQUIRED FOR CONTINUED FDA APPROVAL IS AN EXCEPTIONALLY IMPORTANT QUESTION

The Federal Circuit's decision puts at risk the ability of generic manufacturers to conduct FDA-required post-approval testing necessary to maintain approval of an unpatented drug. Put another way, the Federal Circuit's decision may enable Momenta, and other companies that seize on this strategy, to monopolize the generic market for a drug—or, worse yet, in the case of a brand-name manufacturer, to extend its monopoly to block generic entry altogether—even if (like here) the drug itself and manufacturing process are unpatented. Allowing competitors to sue for complying with FDA directives to use particular bioequivalence or "sameness" testing methods is not only perverse, but would

undermine the objectives of the Hatch-Waxman Act and its safe harbor.

As Momenta has recognized, and as reinforced by the Federal Circuit's *sua sponte* call for the Attorney General's views, "[t]he proper scope of the safe harbor is a critical issue for the pharmaceutical industry." Momenta Cert. Pet. at 28. The application of the safe harbor to FDA-required testing is of ever-growing importance given the increasing prevalence of biologics, and hence biosimilar generics, which require bioequivalence testing on an ongoing basis as a condition first to obtain and then to maintain FDA approval.[6] Unlike small-molecule drugs, and due to their complex molecular characteristics, biologics "usually require complex bioassays for batch release and stability assessment."[7] A neutered safe harbor could therefore enable companies holding patents on FDA-approved testing methods to stymie generic competition via patent-infringement lawsuits—long after the patents on the drug and its manufacturing method have expired.

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[6] E.g., D. Meininger, IP Policy Forum: The Increasing Importance of Biologics-Based Drugs in Pharmaceutical Pipelines, 18 MARQ. INTELL. PROP. L. REV. 19, 20 (2014) ("biologics projected to comprise an ever greater component of the biopharmaceutical product mix"), http://scholarship.law.marquette.edu/cgi/viewcontent.cgi?article=1251&context=iplr.

[7] Thomas Morrow & Linda Hull Felcone, *Defining the Difference: What Makes Biologics Unique*, NIH BIOTECHNOLOGY HEALTHCARE J. (Sept. 2004), at 24-26, http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3564302/.

At stake, therefore, is whether the safe harbor protects a generic manufacturer's use of USP-specified bioequivalence testing methods to obtain and maintain FDA approval, or instead whether competitors can block market entry despite the lack of any product or manufacturing patent. The Federal Circuit chose the latter, thereby impeding Hatch-Waxman's goal of "getting safe and effective generic substitutes on the market as quickly as possible." H.R. REP. NO. 98-857(II), at 9, *as reprinted in* 1984 U.S.C.C.A.N. at 2686, 2693.

The Federal Circuit's decision, including its vague exclusion of "routine" uses from the safe harbor, will have far-reaching consequences for the pharmaceutical industry. Without a clear line that protects generic manufacturers when they engage in FDA-mandated testing, generic manufacturers will be at perpetual risk of infringement liability, stifling the marketing of competitively priced generic drugs that Hatch-Waxman was designed to encourage. This question of "exceptional, immediate importance" to the industry, Momenta Cert. Pet. at 28, requires the Court's intervention.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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