No. ~~12~~ 12-1033

In The
Supreme Court of the United States

MOMENTA PHARMACEUTICALS, INC.
AND SANDOZ INC., PETITIONERS

v.

AMPHASTAR PHARMACEUTICALS, INC.,
INTERNATIONAL MEDICATION SYSTEMS, LTD.,
WATSON PHARMACEUTICALS, INC.,
AND WATSON PHARMA, INC.

ON PETITION FOR 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 Drug Price Competition and Patent Term Restoration Act, also known as the Hatch-Waxman Act, created a safe harbor from liability for patent infringement. The statutory safe harbor provides that it shall not be an act of patent infringement to make or 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 safe harbor "allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval" from the Food and Drug Administration ("FDA"). *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 671 (1990). In this case, the Federal Circuit held that the safe harbor immunizes respondents' use of petitioners' patented method in the course of post-approval manufacturing of respondents' drug for commercial sale, in direct competition with petitioners, during and throughout the life of petitioners' patent.

The question presented is:

Whether the use of a patented invention in the course of post-approval manufacture of a drug for commercial sale, where the FDA requires that a record of that manufacturing activity be maintained, is exempted from liability for patent infringement under Section 271(e)(1) as "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."

PARTIES TO THE PROCEEDING

The parties are as stated in the caption.

CORPORATE DISCLOSURE STATEMENT

Momenta Pharmaceuticals, Inc. has no parent corporation, and no publicly held company owns 10% or more of its stock.

Sandoz Inc. is a subsidiary of Novartis AG. No other publicly held company owns 10% or more of the stock of Sandoz Inc.

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PETITION FOR A WRIT OF CERTIORARI

Petitioners Momenta Pharmaceuticals, Inc. and Sandoz Inc. (collectively, "Momenta") respectfully petition for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit.

OPINIONS BELOW

The opinion of the Federal Circuit (app., *infra*, 1a-64a) is reported at 686 F.3d 1348. The initial opinion of the district court (app., *infra*, 65a-94a) is unreported. The district court's subsequent opinion (app., *infra*, 97a-105a) is reported at 834 F. Supp. 2d 29.

JURISDICTION

The Federal Circuit issued its opinion on August 3, 2012. A petition for rehearing en banc was denied on November 20, 2012. App., *infra*, 108a-109a.

This Court's jurisdiction is invoked under 28 U.S.C. § 1254(1).

STATUTORY AND REGULATORY PROVISIONS INVOLVED

The Drug Price Competition and Patent Term Restoration Act ("Hatch-Waxman Act"), 35 U.S.C. § 271(e)(1), 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 (other than a

> new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) 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.

Title 35 U.S.C. § 271 is set forth in full in the appendix to the petition, along with pertinent portions of 21 U.S.C. §§ 331, 355, and 21 C.F.R. §§ 211.180, 211.186, 211.188, 211.194, 314.70, 314.97. App., *infra*, 110a-178a.

INTRODUCTION

This case concerns the scope of the safe harbor provision of the Hatch-Waxman Act, 35 U.S.C. § 271(e)(1). Once again, the Federal Circuit has misconstrued the scope of Section 271(e)(1). *See Merck KGaA v. Integra Lifesciences I, Ltd.*, 545 U.S. 193, 206-207 (2005). Section 271(e)(1) renders otherwise infringing conduct non-infringing if the conduct is "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 safe harbor was designed to allow potential competitors to engage in otherwise infringing conduct during the life of a patent, solely for the purpose of obtaining regulatory approval of proposed commercial activity. The safe

harbor allows drugs to be brought to market more quickly after the patent expires. The safe harbor does not permit competitors to use the patented invention to engage in the commercial activity itself during the life of the patent.

Eschewing the text of Section 271(e)(1), a divided Federal Circuit panel held that the safe harbor exempts from infringement any commercial activity where the Food and Drug Administration ("FDA") requires that a record of that activity be *maintained*, even if no record is "*submi[tted]*" to the FDA. As Chief Judge Rader explained in dissent, the panel majority thus read the statutory term "submission" to "mean[] not really submitting anything." App., *infra*, 43a. Based on that reading of the statute, the court of appeals held that respondents could practice Momenta's patented manufacturing method, in direct commercial competition with Momenta, throughout the patent's term. It reached this result despite the fact that Section 271(e)(1) only exempts from infringement activity "solely" related to the "development and submission" of information to the FDA. Section 271(e)(1) does not exempt respondents' commercial activity, which is not related to the "development and submission" of anything.

If not corrected, the decision below will have far-reaching consequences for the trillion-dollar pharmaceutical industry. Because records of substantially all activity related to the making and distribution of drugs is required by FDA regulation to be maintained (even though not submitted or intended to

be submitted), the Federal Circuit's reading of the statute is perilously broad. FDA regulations require drug manufacturers to maintain (but not to submit) detailed records establishing that every commercial batch of a drug is manufactured according to an approved manufacturing process. Under the Federal Circuit's novel interpretation, every step of the manufacturing process would be protected from infringement liability. As the dissent below recognized, the panel majority's "new interpretation would allow almost all activity by pharmaceutical companies to constitute 'submission' and therefore justify a free license to trespass" on patent rights. *Ibid.*

Even worse, before issuance of the decision in this case, a divided panel of the Federal Circuit provided a fundamentally conflicting, but equally atextual, interpretation of Section 271(e)(1) in another case. *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d 1057 (Fed. Cir. 2011), *cert. denied sub nom. GlaxoSmithKline v. Classen Immunotherapies, Inc.*, 184 L. Ed. 2d 749 (2013). The panel majority in *Classen* held that the safe harbor is "limited to activities conducted to obtain pre-marketing approval of generic counterparts of patented inventions." *Id.* at 1070. But the panel majority in this case (authored by the *Classen* dissenter) declined to follow *Classen*. And while Momenta would have prevailed under *Classen*'s reading of the statute, that decision is no more faithful to the statutory text than the ruling below. It elevated legislative history—which was "replete with statements that the legislation concerns premarketing approval of generic drugs"—over statutory text so as

to exclude categorically all post-FDA approval activity from the safe harbor. *Id.* at 1071.

These two interpretations of Section 271(e)(1) are irreconcilable, and yet both are fundamentally wrong. Both *Classen* and the ruling below give the wrong scope to the safe harbor provision and together they leave its meaning in an intolerable state of uncertainty. The Federal Circuit has shown no willingness to correct its interpretation or to provide the needed certainty. In the absence of guidance from this Court, future panels will have two purportedly binding precedents from which to choose. District courts are left adrift with two conflicting compasses, each purporting to be definitive. Companies attempting to chart their own courses have no idea whether they are free to use patented inventions or whether such use will subject them to infringement liability. The pharmaceutical industry cannot wait for the Federal Circuit to get it right (or wrong) a third or fourth time.

Absent review, the ruling below will undermine pharmaceutical industry investment in life-saving and life-enhancing innovations. Each drug the pharmaceutical industry brings to market requires enormous investment. That investment is predicated on the protection provided by the patent laws: protection for innovators, during a patent's term, from unlicensed, commercial competition from their own invention. The court of appeals' sweeping interpretation of Section 271(e)(1) calls into question the value of a great many pharmaceutical patents.

This Court's immediate review is imperative to clarify the scope of the Hatch-Waxman safe harbor.

STATEMENT OF THE CASE

A. Statutory And Regulatory Framework

1. The patent laws provide that, in general, "whoever without authority makes, uses, offers to sell, or sells any patented invention * * * during the term of the patent therefor, infringes the patent." 35 U.S.C. § 271(a). In the Hatch-Waxman Act, Congress created a safe harbor from patent-infringement liability for certain activities related to drug development and approval. Pub. L. No. 98-417, § 202, 98 Stat. 1585 (1984). The exemption provides that it "shall not be an act of infringement to make, use, offer to sell, or sell * * * 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).

Congress enacted this safe harbor to eliminate an "unintended distortion[ ]" of the patent term for patents in the context of pharmaceutical drugs, which cannot be marketed without regulatory approval. *Eli Lilly & Co. v. Medtronic, Inc.*, 496 U.S. 661, 669 (1990). Before enactment of Section 271(e)(1), a drug manufacturer infringed a patented invention even though the infringing conduct was solely related to the development of the information needed to apply for FDA approval of a competing product. *Id.* at 670. Because manufacturers could not market their

competing drug without FDA approval and could not even begin the process of developing the drug until after the relevant patent expired (due to the threat of patent infringement), patentees received a de facto extension of their patent terms. *Ibid.* Patentees were protected from competition both during the term of the patent and after patent expiration while a potential competitor went through the lengthy process of obtaining FDA approval of the sale of its product.

Section 271(e)(1) addressed this unintended distortion of the patent term by "allow[ing] competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval." *Id.* at 671. To fall within the scope of the exemption, the otherwise infringing activity must be conducted "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 protection afforded by Section 271(e)(1) applies equally to both brand and generic pharmaceutical companies—so long as their use of a patented invention falls within the scope of the safe harbor provision. *See Merck*, 545 U.S. at 206 ("Congress did not * * * create an exemption applicable only to the research relevant to filing * * * for approval of a generic drug.").

2. The Federal Food, Drug, and Cosmetic Act ("FDCA"), ch. 675, 52 Stat. 1040 (1938), codified as

amended at 21 U.S.C. § 301 *et seq.*, is a federal law that regulates the manufacture, use, or sale of drugs. *Merck*, 545 U.S. at 196.

The FDCA expressly distinguishes between information that must be "submitted" to the FDA and records that must be "maintained" by a drug manufacturer. The FDCA requires drug companies desiring to market a new drug to "submit" to the FDA a new drug application ("NDA"), and it requires companies desiring to market a generic version of an already-approved drug (also called a "listed" drug) to submit an abbreviated new drug application ("ANDA"). 21 U.S.C. § 355(b)(1), (j). An ANDA must demonstrate that the proposed generic drug has the same active ingredients, route of administration, dosage form, strength, and proposed labeling as the listed drug and that the proposed drug and listed drug are bioequivalent. *Id.* § 355(j)(2)(A)(ii)-(v). Both an NDA and an ANDA must detail the manufacturing methods proposed to make the drug to be marketed. 21 C.F.R. §§ 314.50(d)(1), 314.94(a)(9)(i).

Once a drug is approved for commercial sale, the FDCA provides that the manufacturer must "maintain" extensive records concerning the commercial manufacture of each batch of drugs. *See, e.g.*, 21 U.S.C. § 355(e), (i), (k). The manufacturer must use the methods described in its NDA or ANDA, or accepted equivalent methods, as a condition of the FDA's continued approval. 21 C.F.R. §§ 314.70(a)(1)(i), 314.97. And the manufacturer must maintain records detailing the manufacturing process used to make the

drug, including quality-control testing performed on the batches produced. Companies must maintain "master production and control records," which include the "[c]omplete manufacturing and control instructions" and the "sampling and testing procedures" used to make the drug. *Id.* § 211.186(a), (b)(9). The manufacturer must create "[b]atch production and control records," which include "[a]n accurate reproduction of the appropriate master production or control record" and detailed "[d]ocumentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished." *Id.* § 211.188. Additionally, companies must maintain "[l]aboratory records," which "include complete data derived from all tests necessary to assure compliance with established specifications and standards." *Id.* § 211.194(a).

None of these batch records is submitted to the FDA, intended to be submitted, or likely to lead to a submission. Rather, the records must be "retained for at least 1 year after the expiration date of the batch." *Id.* § 211.180(a). The records must be "readily available for authorized inspection during the retention period at the establishment where the activities described in such records occurred." *Id.* § 211.180(c).

B. Factual Background

This case involves a dispute between Momenta and respondents Amphastar Pharmaceuticals, Inc., International Medication Systems, Ltd., Watson Pharmaceuticals, Inc., and Watson Pharma, Inc.

(collectively, "Amphastar"). Momenta and Amphastar directly compete in the manufacture and sale of generic versions of enoxaparin, an anticoagulant sold by Sanofi-Aventis under the brand name Lovenox®. App., *infra*, 2a-3a, 6a.

Momenta is the assignee of U.S. Patent No. 7,575,886 ("'886 patent"). The '886 patent claims a multi-step method for analyzing enoxaparin to determine the presence of a particular, unique structural feature of the drug as part of quality control during manufacture of the drug. *Id.* at 7a. In July 2010, the FDA approved the sale by Sandoz of Momenta's generic version of enoxaparin. *Id.* at 6a. Momenta was the first to obtain FDA approval to market a generic version of enoxaparin. *Ibid.* Momenta's product proved extremely successful, generating over $1 billion in revenue in its first year of sales. *Id.* at 6a-7a.

In September 2011, Amphastar also obtained FDA approval to market its own generic version of enoxaparin. *Id.* at 6a. Momenta immediately sued Amphastar, alleging, *inter alia*, that Amphastar's commercial manufacturing process infringes Momenta's '886 patent. *Id.* at 7a-8a.

Amphastar practices Momenta's patent when it performs a quality-control procedure in the course of manufacturing each batch of its enoxaparin for commercial sale. *Id.* at 8a. But Amphastar does not submit the results of the patented procedure to the FDA. *See id.* at 19a-20a. Instead, as required by the

FDA's retention requirements under 21 C.F.R. § 211.180(a), Amphastar merely retains records of that procedure, as well as all other procedures and materials related to the manufacture and distribution of enoxaparin. *See ibid.*

C. Proceedings Below

1. Momenta moved for a preliminary injunction to enjoin Amphastar from selling its generic version of enoxaparin. After multiple hearings, the district court found that Momenta likely would succeed on the merits of its claim of patent infringement, that Amphastar failed to raise a substantial question as to the validity of Momenta's patent, and that Amphastar's conduct would cause irreparable harm to Momenta if that conduct were not enjoined. App., *infra*, 81a-85a, 88a. The court granted the injunction and later denied two emergency motions seeking dissolution of or relief from the injunction. *Id.* at 65a-107a.

The district court held that Amphastar's commercial manufacture of enoxaparin was not protected by Section 271(e)(1). Expressly relying on the Federal Circuit's decision in *Classen*, the court explained that "although the safe harbor provision permits otherwise infringing activity that is conducted to obtain regulatory approval of a product," it does not permit continuation of that infringing activity after obtaining that approval. *Id.* at 86a-87a. Quoting *Classen*, the district court explained that Section 271(e)(1) does not allow a commercial manufacturer

"'to market the patented drug during the life of the patent.'" *Id.* at 87a (quoting *Classen*, 659 F.3d at 1071). Section 271(e)(1) allows the competing manufacturer only to "'test the drug for purposes of submitting data to the FDA for approval.'" *Ibid.* (quoting *Classen*, 659 F.3d at 1071).

2. A divided panel of the Federal Circuit vacated the injunction, holding that Section 271(e)(1) exempts from infringement Amphastar's use of Momenta's patented method, even though Amphastar's use occurred in the course of routine, post-approval, commercial activity.

The panel majority decision, written by Judge Moore (who had authored the dissent in *Classen*), identified certain regulatory requirements that Amphastar conduct quality-control testing of commercial batches of its product. App., *infra*, 22a (citing 21 U.S.C. § 351(b); 21 C.F.R. § 211.165(a)). The panel majority further observed that "FDA regulations require that all records associated with a produced batch of drugs, including * * * batch records, 'be retained for at least 1 year after the expiration date of the batch.'" *Id.* at 19a (quoting 21 C.F.R. § 211.180(a)); *see also id.* at 22a-23a (noting other records that must be maintained during post-approval, commercial manufacturing of a drug under 21 C.F.R. §§ 211.186, 211.188, 211.194). The panel recognized "that the FDA does not in most cases actually inspect the records" and that the records only need "'be readily available for authorized inspection' by the FDA at any time." *Id.* at 20a (quoting 21 C.F.R. § 211.180(c)).

Nevertheless, the panel majority held that "the requirement to maintain records for FDA inspection satisfies the requirement that the uses be reasonably related to the development and submission of information to the FDA." *Ibid.*

In a 29-page dissent, Chief Judge Rader (who had joined the majority in *Classen*) explained that "allow[ing] *continuous, commercial* infringing sales during any portion of the life of the patent" could not be squared with the text or purpose of Section 271(e)(1)—or with the Federal Circuit's earlier decision in *Classen*. *Id.* at 41a (emphasis in original). He observed that the majority opinion "rewrites the law to allow Amphastar to infringe Momenta's patent throughout *the entire life of Momenta's patent* and for the purpose of obtaining profits on *commercial sales* of a product that *competes with the patentee*." *Ibid.* (emphasis in original).

As Chief Judge Rader explained, the majority, in so concluding, erroneously "discount[ed] the word 'solely'" in the statute's text. *Id.* at 42a. In addition, the panel's conclusion that "the mere retention of records can satisfy the 'submission' requirement in § 271(e)(1)" finds no support in the text of the statute. *Id.* at 43a. "Maintaining or keeping a document has the exact opposite meaning of submitting a document." *Ibid.* The majority's conclusion "that 'submission' can mean not really submitting * * * reads this requirement out of the statute." *Ibid.* That interpretation "allow[s] almost all activity by pharmaceutical companies to constitute 'submission' and therefore

justif[ies] a free license to trespass" on patent rights. *Ibid.* The "drug manufacturer need only make a record, which could potentially be inspected by the FDA, and then any activity could satisfy this new meaning of 'submission.'" *Id.* at 43a-44a.

The Federal Circuit denied Momenta's petition for rehearing en banc, *id.* at 108a, and remanded to the district court.

REASONS FOR GRANTING THE PETITION

THE FEDERAL CIRCUIT HAS ISSUED IRRECONCILABLE DECISIONS ON THE SCOPE OF THE SAFE HARBOR, AND BOTH DECISIONS ARE FUNDAMENTALLY WRONG

A. The Ruling Below And *Classen* Cannot Be Reconciled

The Federal Circuit has provided two fundamentally conflicting interpretations of Section 271(e)(1)'s scope, and it has declined to review those interpretations en banc. Absent this Court's immediate review, the pharmaceutical industry has no certainty as to whether, and to what extent, post-approval commercial use of a patented invention constitutes infringement.

1. In *Classen*, a divided panel of the Federal Circuit held that the exemption from infringement provided by Section 271(e)(1) "is limited to activities conducted to obtain pre-marketing approval of generic counterparts of patented inventions, before patent expiration." *Classen*, 659 F.3d at 1070. The

panel majority, which included Chief Judge Rader, held that "§ 271(e)(1) provides an exception to the law of infringement in order to expedite development of information for regulatory approval of generic counterparts of patented products." *Ibid.*

Dissenting in *Classen*, Judge Moore defined the question at issue as "whether the enacted legislation covers *more* than just preapproval activity." *Id.* at 1083. Judge Moore described the majority as construing Section 271(e)(1) to be "limited to preapproval activities." *Ibid.*

2. By contrast, in the ruling below, a divided panel of the Federal Circuit adopted the very interpretation that had been rejected in *Classen*. The majority opinion—this time authored by Judge Moore—expressly holds "that post-approval studies * * * fall within the scope of the § 271(e)(1) safe harbor." App., *infra*, 24a. The court held that the "scope of the Hatch-Waxman safe harbor does not stop at activities reasonably related to development of information submitted in an ANDA" but extends to post-approval, commercial conduct. *Id.* at 16a.

As Chief Judge Rader's dissent recognized, the ruling below "cannot be genuinely reconciled with *Classen*." *Id.* at 48a. Although the panel majority here attempted to explain away the conflict between the two decisions, Judge Moore's dissent in *Classen* expressly identified as the holding of *Classen* that "§ 271(e)(1) is limited to pre-approval activities." *Classen*, 659 F.3d at 1083 (describing that holding as

the basis for reversal of the district court). Had *Classen* been applied in this case, Amphastar's use of Momenta's patented invention would not have been exempted from infringement. Amphastar uses Momenta's patented method in the course of routine post-approval, commercial manufacturing of its drug, not "to obtain pre-marketing approval." *Id.* at 1070. "[P]ost-approval, continuous, commercial use is the exact opposite of the *Classen* rule." App., *infra*, 47a (Rader, C.J., dissenting).

3. There now are two diametrically opposing views of Section 271(e)(1) in the Federal Circuit. Both are seemingly definitive. The court of appeals has shown no inclination to resolve this conflict, having denied rehearing en banc in this case. This division within the Federal Circuit on an important question of patent law justifies this Court's review. *See, e.g.*, *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, 23-24 (1997).

This Court long has recognized the importance of the scope of Section 271(e)(1), having reviewed the Federal Circuit's construction of this provision in *Eli Lilly* and *Merck*. Indeed, even before the Federal Circuit issued its conflicting decision in this case, this Court invited the views of the Solicitor General as to whether certiorari should be granted in *Classen*. *GlaxoSmithKline v. Classen Immunotherapies, Inc.*, 133 S. Ct. 50 (2012). Although the decision below had issued by the time the Solicitor General recommended that this Court deny review in *Classen*, there were issues particular to *Classen* (and not present in this

case) that led the Solicitor General to believe that *Classen* did not present a suitable context in which to address the scope of Section 271(e)(1). Brief for United States as Amicus Curiae at 10, 20-23, *GlaxoSmithKline v. Classen Immunotherapies, Inc.*, No. 11-1078 (U.S. Dec. 13, 2012).

Moreover, the Solicitor General's recommendation was based on the fundamental misconception that the panel majority in this case could somehow overrule or limit *Classen*. *Id.* at 20. That simply is not so: under Federal Circuit law, a panel opinion "remains binding precedent until it is over-turned by the Supreme Court or by [the court of appeals] *en banc*." *Masias v. Secretary of Health & Human Servs.*, 634 F.3d 1283, 1288 (Fed. Cir. 2011). "Where there is direct conflict [between two decisions of the Federal Circuit], the precedential decision is the first." *Newell Cos. v. Kenney Mfg. Co.*, 864 F.2d 757, 765 (Fed. Cir. 1988).

Significantly, the Solicitor General neither defended the holding of *Classen* nor endorsed the breadth of the Federal Circuit's holding in this case. As to *Classen*, he opined that the scope of the safe harbor is not confined categorically to pre-approval activities. Brief for United States, *supra*, at 11-18. As to the decision here, the Solicitor General explicitly expressed no view as to the "correctness" of the Federal Circuit's conclusion that "information may be deemed 'submitted' to FDA if it is preserved in records that FDA regulations require a drug manufacturer to make available for inspection by FDA on request." *Id.* at 20 n.4.

Until this Court steps in, the outcome of Section 271(e)(1) disputes will turn on which purportedly binding decision a district court decides to follow, and then on which judges happen to be on the reviewing Federal Circuit panel. This unpredictability (and arbitrariness) flies in the face of the very purpose of the Federal Circuit—to ensure national uniformity in patent law. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370, 390 (1996). Companies will have no idea whether they are free to use patented inventions or whether such use will subject them to infringement liability, whether they should invest in various types of new technology, or what value, if any, their own patents have.

B. Both *Classen* And The Decision Below Are Inconsistent With The Statutory Text And This Court's Precedents

Not only has the Federal Circuit issued two fundamentally conflicting decisions, both decisions are fundamentally wrong. Neither *Classen* nor *Momenta* can be squared with the statutory text or this Court's decisions. As a result, both give the wrong scope to the safe harbor provision. This Court twice has rejected such atextual readings of the safe harbor. It should again grant review to do so here.

1. This Court has instructed that the scope of Section 271(e)(1) must be interpreted faithfully to the statutory text. In *Eli Lilly*, the Court rejected an extratextual limitation on the safe harbor that would have excluded medical devices. 496 U.S. at 665-666,

679. The petitioner there argued that "a Federal law which regulates the manufacture, use, or sale of drugs" in Section 271(e)(1) referred only to those individual provisions of federal law that regulate drugs, rather than to the entirety of any Act of which at least some portion regulates drugs. *Id.* at 665. This Court rejected that argument, explaining that "a Federal law" refers "to an entire Act," *e.g.*, the entire FDCA. *Id.* at 666.

Subsequently, in *Merck*, the Court unanimously rejected the Federal Circuit's conclusion that Section 271(e)(1) does not protect "uses of patented inventions in preclinical research" where the results "are not ultimately included in a submission" to the FDA. 545 U.S. at 195. The Court explained that the text of the safe harbor protects not only actual submissions to the FDA but any "uses of patented compounds 'reasonably related' to the process of developing information for submission." *Id.* at 206. That includes "uses [of] the compound in research that, if successful, would be appropriate to include in a submission to the FDA." *Id.* at 207.

Despite this Court's repeated insistence that the text of the safe harbor provision governs, the conclusions reached by the panel majorities in both *Classen* and in this case are unmoored from the statutory text. *See, e.g.*, *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670, 1680 (2012) (relying on "statutory text and context" to reverse Federal Circuit's interpretation of Hatch-Waxman Act).

2. In *Classen*, the Federal Circuit ignored Section 271(e)(1)'s text and, instead, rested its interpretation almost exclusively on the legislative history. The panel majority emphasized that the legislative history is "replete with statements that the legislation concerns premarketing approval of generic drugs." *Classen*, 659 F.3d at 1071; *see also ibid.* (quoting H.R. Rep. No. 98-857, pt. 1, at 15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2648 (explaining that the safe harbor protects uses "in preparation for seeking FDA approval")). Based on this undue preference for legislative history over statutory text, the court of appeals concluded that the safe harbor is "limited to activities conducted to obtain premarketing approval." *Id.* at 1070.

That was error. *See* Brief for United States, *supra*, at 11-12. As this Court repeatedly has explained, "it is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed." *Oncale v. Sundowner Offshore Servs., Inc.*, 523 U.S. 75, 79 (1998). Like the Federal Circuit's mistake in *Merck*, nothing in Section 271(e)(1)'s text makes the availability of the safe harbor categorically contingent on whether the activity at issue takes place before or after FDA approval. *See Merck*, 545 U.S. at 206.

To the contrary, the FDCA contemplates that drug manufacturers may develop and submit information to the FDA after approval. The FDA may require the manufacturer to conduct post-approval studies and to submit the results to the FDA. Brief

for United States, *supra*, at 12-15. For example, the FDA may designate certain new drugs for "fast track" review and accelerated approval—which may result in FDA approval contingent on the applicant "conduct[ing] appropriate postapproval studies." 21 U.S.C. § 356(c)(2)(A). And the FDA may require a manufacturer to perform a post-approval study to investigate unexpected safety-related issues with its product and to submit periodic status reports describing the progress of its investigation. *Id.* § 355(o)(3). Moreover, after receiving FDA approval to market a drug, a drug manufacturer may submit new information to the FDA to obtain authorization for a new use of that drug. *See* 21 U.S.C. §§ 321(p), 355(a), (b); 21 C.F.R. § 310.3(h). Contrary to *Classen*'s holding, nothing in the statutory text suggests that such post-approval conduct is categorically excluded from the safe harbor.

3. The decision below is no more faithful to the text of Section 271(e)(1) than *Classen*.

a. In this case, the panel majority read the safe harbor to encompass any use of a patented invention where federal law requires that a record of that activity merely be *maintained*, even though not (and never intended to be) *submitted* to the FDA or any other agency under any federal law. Although the panel majority purported to apply the plain language of Section 271(e)(1) (app., *infra*, 14a-16a), its decision turns the meaning of the statutory term "submission" on its head. As the dissent explained, "[m]aintaining

or keeping a document has the exact opposite meaning of submitting a document." App., *infra*, 43a.

The panel majority's interpretation ignores that the text of the FDCA expressly distinguishes between two types of activity: "submitting" information to the FDA and "maintaining" records for possible FDA inspection. Specifically, the sections of the FDCA regulating new drug, generic, and other efforts to obtain regulatory approvals use the word "submit," "submitted," or "submission." 21 U.S.C. § 355(b)(1) ("Such person shall submit to the Secretary as a part of the application * * * "), (b)(2) ("An application submitted * * * "), (b)(3)(D)(i) ("an application that contains bioavailability or bioequivalence studies has been submitted"), (i)(1)(A) ("the submission to the Secretary, before any clinical testing of a new drug is undertaken, of reports * * * of preclinical tests * * * of such drug adequate to justify the proposed clinical testing"), (j)(2)(B)(iv)(I) ("an [ANDA] application * * * has been submitted"), (j)(2)(C) ("If a person wants to submit an abbreviated application for a new drug which has a different active ingredient or whose route of administration, dosage form, or strength differ from that of a listed drug, such person shall submit a petition to the Secretary * * * ."), (j)(4)(F), (G), (H) ("information submitted in the application").

In stark contrast, the FDCA uses the word "maintain" to describe the obligation to keep records related to the ordinary course of commercial activities, including manufacturing an already-approved

drug (such as the batch records at issue here). *See, e.g.*, 21 U.S.C. § 355(e)(5) ("The Secretary may also * * * withdraw the approval of an application submitted under subsection (b) or (j) of this section with respect to any drug under this section if the Secretary finds (1) that the applicant has failed to establish a system for maintaining required records, or has repeatedly or deliberately failed to maintain such records * * * ."), (k)(1) ("In the case of any drug for which an approval of an application filed under subsection (b) or (j) of this section is in effect, the applicant shall establish and maintain such records * * * as the Secretary may * * * prescribe * * * ."), (k)(2) ("Every person required under this section to maintain records * * * shall, upon request of an officer or employee designated by the Secretary, permit such officer or employee at all reasonable times to have access to and copy and verify such records."); *see also* 21 C.F.R. § 211.180. The FDA regulations provide that these batch records are to be "retained" by the manufacturer, "at the establishment where the activities described in such records occurred." 21 C.F.R. § 211.180(a), (c). The FDA may come inspect the maintained records at that location, *id.* § 211.180(c), and the manufacturer is required to "permit access" to the records, 21 U.S.C. § 331(e).

Notably, this textual distinction between submission and maintenance is not just semantic. It reflects the purpose animating the safe harbor provision. The statutory scheme, including Section 271(e)(1), uses the term "submit" with respect to information that

has been developed to obtain regulatory approval. This includes NDAs, ANDAs, and research studies, including both pre- and post-approval studies and clinical trials that are submitted (or are intended to be submitted) to the FDA. *See* Brief for United States, *supra*, at 12-15. Activity related to these submissions is precisely the type of conduct the safe harbor was intended to exempt. *Eli Lilly*, 496 U.S. at 671; see pp. 26-28, *infra*. In ignoring this textual and contextual distinction, the panel majority disregarded this Court's admonition that the safe harbor must be construed in light of the "entire statutory scheme of regulation." *Eli Lilly*, 496 U.S. at 666.

Nor is the panel's conclusion justified by the fact that any activity "reasonably related" to the submission of information to the FDA is protected. "[O]rdinary commercial exploitation of a patented invention is not 'reasonably related to the development and submission of information' for the FDA." Brief for United States, *supra*, at 18. As this Court explained in *Merck*, "reasonably related" would not include research "performed without the intent to develop a particular drug or a reasonable belief that the compound will cause the sort of * * * effect the researcher intends to induce." 545 U.S. at 205-206. That is, the statutory terms "reasonably related" do not allow uses that may not reasonably be expected to lead to an actual submission.

b. The ruling below's expansive reading of the safe harbor also cannot be squared with Section 271(e)(1)'s express limitation to uses "solely" related to the "development and submission" of information to the FDA.

The word "solely" in the statute makes clear that even if the patented invention is used for a purpose reasonably related to the development and submission of information to the FDA, other uses of the invention are not protected under the safe harbor. For example, a drug manufacturer may use a patented invention both to sell a drug commercially and to conduct a post-approval clinical trial. The clinical trial is protected under the plain terms of the safe harbor. But use of the patented invention for commercial manufacturing and sale of the drug is not exempted from infringement liability because such use is not reasonably related to the development and submission of information to the FDA. *See* Brief for United States, *supra*, at 17-18 (providing examples of protected and unprotected use).

Here, Amphastar's "infringing activity is *not solely* for developing and submitting information to the FDA. Instead, Amphastar uses this method for the purpose of manufacturing a product to sell on the market in commerce." App., *infra*, 42a-43a (Rader, C.J., dissenting) (italics substituted for bold font). In holding that such previously approved, ordinary commercial activity is exempt from infringement,

the Federal Circuit robbed the term "solely" of any meaning. The majority's decision extends Section 271(e)(1)'s safe harbor to (1) post-approval conduct, (2) for a commercial purpose, (3) during the term of a patent, and (4) in direct competition with the patent holder.

Moreover, the term "development" "implies more than merely the collection of information incidental to commercial transactions." Brief for United States, *supra*, at 18. The ordinary meaning of that term connotes a generative process. By contrast, Amphastar uses Momenta's patented method merely for routine quality-control testing as part of their manufacturing process for commercial sale. That is not a use "solely" related to the "development" of information for submission to the FDA. *See* H.R. Rep. No. 98-857, *supra*, pt. 1, at 45 ("The information which can be developed under this provision is the type which is required to obtain approval of the drug.").

c. Finally, the panel majority's interpretation of Section 271(e)(1) is inconsistent with the purpose of the safe harbor.

This statutory provision reversed a Federal Circuit decision holding that the "use" of a patented invention was infringement "even if it was for the sole purpose of conducting tests and developing information necessary to apply for regulatory approval."

Eli Lilly, 496 U.S. at 670. That earlier Federal Circuit ruling resulted in a de facto extension of the patent term, because a would-be competitor had to wait until after expiration of a rival's patent to seek regulatory approval. *Ibid.* The Hatch-Waxman Act was designed to remedy this. *Id.* at 671; *see* H.R. Rep. No. 98-857, *supra*, pt. 1, at 45 ("The purpose of section[ ] 271(e)(1) * * * is to establish that experimentation with a patented drug product, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement."). Section 271(e)(1) thus "allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval" of prospective commercial activity, not the commercial activity itself. *Eli Lilly*, 496 U.S. at 671.

The panel majority's interpretation does not serve this purpose. Instead of enabling Amphastar to prepare to compete with Momenta immediately upon the expiration of Momenta's patent, the decision below "allow[s] Amphastar to infringe Momenta's patent throughout *the entire life of Momenta's patent* and for the purpose of obtaining profits on *commercial sales* of a product that *competes with the patentee.*" App., *infra*, 41a (Rader, C.J., dissenting, emphasis in original).

In short, while the text of the statute sweeps more broadly than the categorical "pre-approval" line drawn by *Classen*, nothing in the text or purpose of Section 271(e)(1) supports the wholesale expansion

given the safe harbor by the panel majority in this case.

C. The Scope Of Section 271(e)(1) Is An Issue Of Exceptional, Immediate Importance To The Pharmaceutical Industry

1. The proper scope of the safe harbor is a critical issue for the pharmaceutical industry. Those who develop and market drugs need to know which activities are exempt from infringement under the safe harbor and which are not. The Federal Circuit's diametrically opposed interpretations of Section 271(e)(1) have created immense uncertainty in a trillion-dollar industry that develops life-saving and life-enhancing drugs. Unless this Court reviews and reverses the ruling below, research necessary for innovation in the development of pharmaceutical products, procedures, and methods will be threatened.

The ruling below sweeps into the safe harbor post-approval, commercial manufacturing activity that long has been understood to enjoy patent protection. That patent protection is necessary to warrant the immense research and development costs associated with drug development—which, for new drugs, average $1.3 billion to bring to market. Tufts Center for the Study of Drug Development, *Outlook 2010* at 3;[1] Matthew Herper, *The Truly Staggering Cost of*

[1] Available at http://csdd.tufts.edu/_documents/www/Outlook2010.pdf.

Inventing New Drugs, Forbes.com (Feb. 10, 2012).[2] Yet the Federal Circuit's ruling in this case could shield from infringement any approved activity by a pharmaceutical company for which the company must maintain a record for possible future FDA inspection. App., *infra*, 20a ("the requirement to maintain records for FDA inspection satisfies the requirement that the uses be reasonably related to the development and submission of information to the FDA"). This could render numerous method, composition, and packaging patents completely worthless.

These concerns are real. Pharmaceutical companies are required by law to use the methods described in their applications, or accepted equivalent methods, as a condition of the FDA's continued approval, 21 C.F.R. §§ 314.70(a)(1)(i), 314.97, and to maintain records memorializing that they have done so, 21 C.F.R. §§ 211.180 *et seq.* The "batch records" regulations relied on by the panel majority require pharmaceutical companies to maintain a huge swath of records relating to the manufacture of an already-approved product for commercial sale. *See* App., *infra* 22a ("such batch records" include, for example, "master production and control records," "batch production and control records," and "laboratory records") (citing, *e.g.*, 21 C.F.R. §§ 211.180, 211.186, 211.188, 211.194).

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[2] Available at http://www.forbes.com/sites/matthewherper/2012/02/10/the-truly-staggering-cost-of-inventing-new-drugs/.

These batch records must show the manufacturing instructions that were followed, the quality-control tests that were performed, the formulating methods and packaging methods that were used, and the results of each of these steps. 21 C.F.R. §§ 211.186, 211.188, 211.194. The records, which justified the panel majority's ruling, must include "[d]ocumentation that each significant step in the manufacture, processing, packing, or holding of the batch was accomplished," *id.* § 211.188(b), and "complete data derived from all tests necessary to assure compliance with established specifications and standards," *id.* § 211.194(a). All of these records must be maintained for possible FDA inspection. *Id.* § 211.180.

Because the Federal Circuit held that "submission of information" includes "maintenance of information," no principled distinction would preclude the safe harbor from encompassing the commercial use of *any* patented method to produce a batch of drugs for commercial sale. This would include the manufacturing, testing, and processing methods of the batches of drugs themselves. As Chief Judge Rader explained, the panel majority's interpretation "would essentially render manufacturing method patents worthless." App., *infra*, 49a. It "allow[s] almost all activity by pharmaceutical companies to constitute 'submission' and therefore justify a free license to trespass" on patent rights. *Id.* at 43a.

For the same reasons, the panel's rationale could extend safe harbor protection beyond method patents.

Composition patents are infringed by making or using the composition. The FDA likewise requires records of the components of the manufacturing process and the actual formulation to be maintained. 21 C.F.R. §§ 211.180 *et seq.* Thus, under the panel majority's interpretation, the safe harbor could immunize the use of patents on biologic media and media components; on formulation and formulation components; on syringes, pens, and other delivery devices; and on packaging technology.

2. The scope of Section 271(e)(1) is far too important for this Court to let it percolate. The consequences of the ruling below are reverberating through the industry, and are influencing how pharmaceutical companies are planning their businesses.[3] Commentators have noted the conflict within the Federal Circuit and the resulting confusion over the scope of the safe harbor.[4] If not corrected now, the uncertainty

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[3] *See, e.g.*, Kevin Murphy & Andrew Nason, *Patents and Postapproval Batch Testing: Can Postapproval FDA Filings Immunize Pharma Companies from Patent Lawsuits?*, Biopharm Int'l, Dec. 2012, at 55; Christine Norris, *The Federal Circuit's Recent "Safe Harbor" Ruling Could Impact Biosimilars Drug Development*, Mondaq Business Briefing, Sept. 25, 2012.

[4] *See, e.g.*, Sarah Karlin, *High Court Likely to Keep 'Safe Harbor' Broad, Boosting Generics, Biosimilars*, Generic Line, Sept. 12, 2012 (suggesting, contrary to Federal Circuit law, that *Momenta* might trump *Classen* "because it's the latest case to be decided"); Melanie Rupert, *Limitation on Future Patent Protection for Biosimilars?*, Mondaq Business Briefing, Aug. 13, 2012 (positing that decision's reasoning could shield other manufacturing activities); Aaron Barkoff, *Federal Circuit Continues to be*

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the Federal Circuit has created will be felt by the industry for a decade, as it takes over seven years to research and develop a new drug. Tufts, *Outlook 2010*, *supra*, at 3.

Nor can this Court expect the Federal Circuit to reconcile its own division or to correct its erroneous interpretations. The court of appeals had an opportunity to do so by taking the issue en banc, but it declined. No better vehicle to resolve this issue of paramount importance is on the horizon.

3. Finally, the current procedural posture of this case provides no basis to defer review. Although the Federal Circuit's ruling arises in the context of a preliminary injunction, the court of appeals definitively determined the scope of Section 271(e)(1). The ruling below rests on an error of law. In similar circumstances, this Court recently and repeatedly has reviewed issues of law decided in preliminary injunction appeals. *See, e.g.*, *National Meat Ass'n v. Harris*, 132 S. Ct. 965 (2012); *National Aeronautics & Space Admin. v. Nelson*, 131 S. Ct. 746 (2011); *Pleasant Grove City, Utah v. Summum*, 555 U.S. 460 (2009). In each of those cases respondents argued that the interlocutory posture of the case—including a need for further factual development—counseled against

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Split Over Scope of 271(e)(1) Safe Harbor, Orange Book Blog (Aug. 8, 2012), http://orangebookblog.com/2012/08/internal-federal-circuit-struggle-over-scope-of-271e1-safe-harbor-continues.html (discussing intracircuit split).

this Court's review. The Court nevertheless granted review and reversed the court of appeals. The Court should do the same here.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be granted.

Respectfully submitted,

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