No. 11-

IN THE

Supreme Court of the United States

GLAXOSMITHKLINE,

Petitioner,

v.

CLASSEN IMMUNOTHERAPIES, INC.,

Respondent.

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

Congress has created a statutory safe harbor from patent-infringement liability for otherwise-infringing conduct that is "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). In this case, the Federal Circuit concluded that this safe harbor "is limited to activities conducted to obtain pre-marketing approval of generic counterparts." Pet. App. 27a. The question presented is:

Whether the Federal Circuit's interpretation of § 271(e)(1), which arbitrarily restricts the safe harbor to preapproval activities, is faithful to statutory text that contains no such limitation, and decisions of this Court rejecting similar efforts to impose extra-textual limitations on the statute.

PARTIES TO THE PROCEEDING AND RULE 29.6 CORPORATE DISCLOSURE STATEMENT

Petitioner is GlaxoSmithKline LLC (GSK; incorrectly identified in Classen's complaint as "Galaxo SmithKline, Inc.").

Respondents who were defendants along with GSK, and who were appellees or cross-appellants in the Federal Circuit, are Merck & Co., Inc. (Merck) and Biogen Idec (Biogen).

Respondents who were defendants in the district court, and not party to the appeal, are Chiron Corporation, Kaiser-Permanente, Inc., Kaiser Permanente Ventures, Kaiser Permanente International, The Permanente Federation, LLC, The Permanente Company, LLC, The Permanente Foundation, The Permanente Medical Group, Inc., Kaiser Foundation Hospitals, Kaiser Foundation Added Choice Health Plan, Inc., and Kaiser Foundation Health Plan Inc.

Respondent who was the plaintiff in the district court, and appellant in the Federal Circuit, is Classen Immunotherapies, Inc.

Pursuant to Supreme Court Rule 29.6, Petitioner states as follows:

GlaxoSmithKline LLC is a Delaware corporation and wholly-owned subsidiary of GlaxoSmithKline PLC. GlaxoSmithKline PLC is a publicly traded company listed on the London and New York stock exchanges.

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PETITION FOR A WRIT OF CERTIORARI

Petitioner GSK respectfully petitions for a writ of certiorari to review the judgment of the United States Court of Appeals for the Federal Circuit in this case.

OPINIONS BELOW

The decision of the Federal Circuit is reprinted in the Petition Appendix (Pet. App.) at 1a-57a and is reported at 659 F.3d 1057. The district court issued more than one order dismissing particular claims or defendants; the decision relevant to the question presented by this Petition is reprinted at Pet. App. 58a-67a and reported at 381 F. Supp. 2d 452 (D. Md. 2005).

JURISDICTION

The Federal Circuit entered judgment on August 31, 2011, Pet. App. 1a, and denied GSK's petition for rehearing en banc on November 30, 2011, *id.* at 68a-69a. This Court has jurisdiction under 28 U.S.C. § 1254.

STATUTORY PROVISION INVOLVED

The statutory provision involved is 35 U.S.C. § 271(e)(1), which provides in relevant part as follows:

> It shall not be an act of infringement to make, use, offer to sell, or sell within 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.

STATEMENT OF THE CASE

This Court should again grant review to correct the Federal Circuit's flawed construction of the important safe-harbor provision contained in 35 U.S.C. § 271(e)(1). Twice this Court has granted review, and both times, the Court considered and rejected extra-textual limitations on the statute's plain terms. In *Eli Lilly & Co.* v. *Medtronic, Inc.*, the Court rejected a proposed limitation, based upon the legislative history's discussion of generic drugs, that would have excluded medical devices. 496 U.S. 661 (1990). More recently, in *Merck KGaA* v. *Integra Lifesciences I, Ltd.*, the Court unanimously reversed the Federal Circuit's conclusion that § 271(e)(1) excludes "uses of patented inventions in preclinical research" if "the results of [that research] are not ultimately included in a submission" to the Food and Drug Administration (FDA). 545 U.S. 193, 195 (2005). *Merck* in particular made plain that the safe-harbor provision is deliberately broad—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.* at 206; accord, *id.* at 202.

The decision below elevated legislative history over statutory text, and in so doing, it flies in the face of this Court's prior rulings. A divided panel of the Federal Circuit relied on the same legislative history that animated its unanimously reversed decision in *Merck*, and that this Court held to be of limited use in *Eli Lilly*. Having charted this erroneous course, the majority concluded that the safe harbor "is limited to activities conducted to obtain *pre-marketing approval* of *generic counterparts* of patented inventions." Pet. App. 27a (emphases added); accord, *id.* at 29a (ex-

emption does not apply because the allegedly infringing activities "are not a 'phase of research' possibly leading to marketing approval"). This was a fundamental error.

The words "pre-marketing approval" and "generic" appear nowhere in § 271(e)(1), and this Court has explained in plain terms 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." *Merck*, 545 U.S. at 202. Thus, as the dissent explained, the majority's "construction is contrary to the plain language of the statute and Supreme Court precedent." Pet. App. 53a (Moore, J., dissenting). Whatever statutory purpose was a particular focus of the legislative history, this Court already has explained—in this very context—that "'[i]t is not the law that a statute can have no effects which are not explicitly mentioned in its legislative history.'" *Eli Lilly*, 496 U.S. at 669 n.2. The majority does direct violence to these principles. Efforts to research and develop improvements to medical products commonly continue after initial drug approval, leading to changes to the approved product and its labeling. The dividing line between pre- and post-marketing-approval activities created by the majority ignores this basic reality, and is inconsistent with the FDA's mission of facilitating the development of better, safer, and more efficacious drugs. The majority's holding on an important and recurring issue warrants review by this Court. The petition for certiorari should be granted and the judgment below reversed.

I. STATUTORY BACKGROUND

a. Federal law defines certain acts to be patent infringement: "[W]hoever 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). Against this backdrop, Congress in 1984 enacted the Hatch-Waxman Act, which "was designed to respond to two unintended distortions of the 17-year patent term produced by the requirement that certain products must receive premarket regulatory approval." *Eli Lilly*, 496 U.S. at 699; see generally *id.* at 669-71 (describing this history). Relevant here, Congress amended § 271 to create a safe harbor from the general definition of infringement for certain activities related to drug development and approval; specifically, it "shall not be an act of infringement to make, use, 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." Drug Price Competition and Patent Term Restoration Act of 1984, Pub. L. No. 98-417, § 202, 98 Stat. 1585, 1603. It is "apparent from the statutory text that § 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 [Federal Food, Drug, and Cosmetic Act]." *Merck*, 545 U.S. at 202.

b. Information about the safety and efficacy of a particular drug or biological product is developed and submitted to FDA both before and after the product is originally approved or licensed for marketing. And, even once a product receives initial marketing authorization, efforts to improve the product and to refine the risk-benefit evaluation continue. Acting under the authority of multiple federal statutes, FDA has created detailed regulatory regimes that cover the full lifecycle of drugs and, relevant here, biological products such as vaccines. See Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301-399; Pub-

lic Health Service Act, 42 U.S.C. §§ 262-263 (PHS Act); 21 C.F.R. pts. 1-1271. These regulations advance FDA's core mission to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner," and to "protect the public health" by ensuring the products' safety and efficacy. 21 U.S.C. § 393(b)(1)-(2).

Thus, to market or sell a new drug or vaccine, the manufacturer typically must obtain FDA authorization. See 21 U.S.C. § 355(a) (drugs); 42 U.S.C. § 262(a) (biological products). It does so by demonstrating, among other things, the product's safety and efficacy. See 21 U.S.C. § 355(d) (drug must be safe and effective); 42 U.S.C. § 262(a)(2)(C) (biological product must be "safe, pure, and potent"). Initially, the manufacturer must submit an investigational new drug application (IND) to FDA to conduct the clinical investigations necessary to make the required showing. 21 U.S.C. § 355(i); 42 U.S.C. § 262(a)(3), (j); 21 C.F.R. pt. 312. Following the completion of these studies, the manufacturer must submit to FDA either a new drug application (NDA) or a biologics license application (BLA), both of which require extensive information about the product, including manufacturing data, proposed labeling, nonclinical pharmacology and toxicology data, human pharmacokinetic and bioavailability data, data from clinical trials, and "full reports of investigations" into the efficacy of products. 21 U.S.C. § 355(b), (i); 42 U.S.C. § 262(a)(2); 21 C.F.R. §§ 314.50, 601.2(a); see generally *Merck*, 545 U.S. at 196 (summarizing the IND and NDA processes).

FDA regulatory oversight continues after approval has been granted, as do statutory and regulatory obligations to develop and submit information to FDA. This is true, for instance, when manufacturers seek

to change or improve an already-approved drug, or seek authorization for additional uses. For example, a manufacturer wishing to change a product's FDA-approved labeling—including the schedule for administering a vaccine—must submit studies and other data that would justify the proposed change. 21 C.F.R. § 601.12(f); see also *id.* § 314.70. In other circumstances, FDA may specifically require follow-up studies. See, *e.g.*, 21 U.S.C. § 355(o)(3) (authorizing FDA to require postmarketing safety clinical studies or trials for drugs or biological products); *id.* § 355c(a)(2)(A) (permitting FDA to defer until after approval pediatric assessments for certain drugs or biological products); see also 21 C.F.R. pt. 314, subpts. H, I; *id.* pt. 601, subpts. E, H.

Manufacturers face serious consequences for failing to comply with FDA obligations, including civil or criminal penalties, 21 U.S.C. §§ 332-334; or a determination that their product is misbranded, *id.* §§ 352(z), 355(p)(2), 355c(d)(1), which could stop all sales of the drug and subject the company to criminal prosecution or an action to seize the drugs, *id.* §§ 355(o)(1), 331(a), (d).

II. BACKGROUND OF THE CASE

GSK is one of the world's leading biopharmaceutical manufacturers. Among other products, GSK markets a hepatitis B vaccine under the name ENGERIX-B. FDA initially approved ENGERIX-B, including the schedule for administering the vaccine, in 1989. See Pl.'s Mot. for Partial Recons. (Dkt. 79) at 3, *Classen Immunotherapies, Inc.* v. *Biogen Idec*, No. 04-2607 (D. Md. Aug. 1, 2005)[1]; GlaxoSmithKline, *High-*

[1] All "Dkt." entries refer to materials filed in the district court that are available through the District of Maryland's PACER system for electronic records access.

lights of Prescribing Information, http://us.gsk.com /products/assets/us_engerixb.pdf (approved labeling for ENGERIX-B); see also 21 C.F.R. § 201.57(c)(3) (drug and biological product labeling must include dosage and administration information). The administration schedule for ENGERIX-B has not changed since the vaccine originally was approved in 1989,[2] prior to the issuance of the Classen patents at issue here.

A. Dr. Classen And His Patents

Classen Immunotherapies, Inc. holds several patents that are based on the theories of its CEO, Dr. John Barthelow Classen. Classen believes that he has "uncovered a serious risk associated with the administration of vaccines."[3] Thus, he has theorized "that the schedule of infant immunization for infectious diseases can affect the later occurrence of chronic immune-mediated disorders such as diabetes, asthma, hay fever, cancer, multiple sclerosis, and schizophrenia, and that immunization should be conducted on the schedule that presents the lowest risk with respect to such disorders." Pet. App. 4a. He has obtained various patents embodying his theories of vaccine risk, including the patents at issue here, which cover methods "for evaluating the safety of

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[2] *See generally* FDA, *Vaccines, Blood & Biologics*, http://www.fda.gov/BiologicsBloodVaccines/Vaccines/ApprovedProducts/ucm110102.htm (last updated Aug. 18, 2011) (containing links to Engerix-B-related documentation).

[3] Pl.'s Mem. in Opp. to Merck's Mot. for Summ. J. (Dkt. 66), Ex. C ¶ 7; Federal Circuit Joint Appendix at 1019, *Classen Immunotherapies, Inc.* v. *Biogen Idec*, Nos. 2006-1634, -1649 (Fed. Cir. May 4, 2007) (CAFC JA) (printout from Classen's web site, vaccines.net: "Classen Immunotherapies discovered that common vaccines are one of the most important causes of diabetes in children and in highly immunized adults.").

vaccine administration schedules by comparing or identifying the adverse events associated with various vaccine schedules." *Id.* at 59a.

Three of Classen's patents are principally at issue.[4] Claim 1 of U.S. Patent No. 5,723,283 (the '283 patent), which was designated as a representative claim of that patent, discloses a method for screening immunization schedules by "reviewing and comparing published information on the effects of immunization schedules" as they concern "the occurrence of immune-mediated disorders." Pet. App. 7a. Simply put, it claims "the idea of comparing known immunization results that are, according to the patent, found in the scientific literature." *Id.* at 19a; *id.* at 43a (Moore, J.) ("In the '283 patent, Classen claims the scientific method as applied to the field of immunization."). Classen makes the sweeping contention that this claim is infringed, among other ways, whenever a "person reviews relevant information" about immunization schedules, "whether the person is a producer of vaccines, a health care provider, or a concerned parent." *Id.* at 7a.[5]

The two other patents—U.S. Patent Nos. 6,638,739 (the '739 patent) and 6,420,139 (the '139 patent)—have been handled in tandem. Claim 1 of the '739 patent, which was treated as representative of both patents, claims the same method of "collecting and com-

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[4] Classen voluntarily dismissed claims related to a fourth patent, U.S. Patent No. 5,728,385 (the '385 patent). *See* Pl.'s Voluntary Dismissal of Count III (Dkt. 92).

[5] *See also* Pet. App. 19a ("Classen states, for example, that Merck induces direct infringement by parents when Merck provides and physicians distribute the book 'What Every Parent Should Know About Vaccines,' because the book advises parents to understand vaccines and vaccination schedules. Classen Br. 18.").

paring known information" as the '283 patent, Pet. App. 19a, and adds the further step of administering a vaccine according to the schedule determined to have a lower risk. *Id.* at 5a. That is, these patents "state the method whereby information on immunization schedules and the occurrence of chronic disease is 'screened' and 'compared,' the lower risk schedule is 'identified,' and the vaccine is 'administered' on that schedule." *Id.* Classen contends that these patents are infringed, among other times, whenever "a health care provider reads the relevant literature and selects and uses an immunization schedule that is of lower risk for development of a chronic immune-mediated disorder." *Id.* at 6a. This is true regardless of whether the provider's review of the literature actually causes him or her to make "any change in the immunization schedule." *Id.*[6]

B. Proceedings Below

1. Classen filed suit against GSK and other pharmaceutical companies (as well as various Kaiser Permanente entities), alleging that they infringed the '283, '139, and '739 patents. The complaint rests on allegations that the defendants "'collectively license, manufacture, use, market, distribute and sell vaccines for human use,'" and that their "'products have participated in studies on the effects of the timing of administration of these vaccines and incidence of chronic immune mediated disorders.'" Pet. App. 59a (quoting Am. Compl. ¶ 6). The complaint alleges that

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[6] *See also* Pet. App. 43a-44a (Moore, J., dissenting) ("These claims cover any kind of comparison between any two schedules, using any drugs and comparing the incidence of any chronic immune disease. After the user performs this completely abstract mental comparison, then the user should immunize the subject with the drug they choose on the schedule they deem lower risk.").

defendants infringed the patents through direct infringement (i.e., performing each step in the claimed method themselves); joint infringement (which occurs when multiple defendants each perform at least one step in the method); and also that they allegedly contributed to or induced infringement by others.[7]

The focus of the infringement allegations, as the district court explained, was a study published in the journal *Pediatrics* in 2001 by Dr. Frank DeStefano, a medical epidemiologist at the Immunization Safety Office of the Centers for Disease Control and Prevention (CDC). See CAFC JA 220-25 (DeStefano study), 1099 (DeStefano declaration). According to Classen, defendants infringed the patents when they allegedly "'participated in, facilitated and/or otherwise conducted [DeStefano's] study." Pet. App. 61a-62a (quoting Am. Compl. ¶ 7). This study, sponsored by CDC, see CAFC JA 1099, evaluated Classen's claim of an association between the administration schedules for childhood hepatitis B or influenza vaccinations and the later development of type 1 diabetes,[8] *and concluded that there was no such association*. *Id.* at 221. According to Classen, GSK and others have used DeStefano's study results to determine the proper schedule for administering hepatitis B vaccines (even if only to conclude that the schedules previously approved by FDA were appropriate). Pet. App. 61a-62a (quoting Am. Compl. ¶ 7); *id.* at 25a. Simply put,

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[7] *See* CAFC JA 72, 73 (complaint); *see generally Muniauction, Inc.* v. *Thomson Corp.*, 532 F.3d 1318, 1329-30 (Fed. Cir. 2008) (describing joint infringement); *Global-Tech Appliances, Inc.* v. *SEB S.A.*, 131 S. Ct. 2060, 2067-68 (2011) (discussing contributory and induced infringement under 35 U.S.C. § 271(b), (c)).

[8] CAFC JA 222, 225 nn.8-9 (DeStefano study citing Classen's "hypothesi[s]"); *id.* at 1037 (fact sheet from CDC web site concerning Classen's claims).

Classen believes that GSK and others are liable for infringement because they supported testing that proved his theories wrong, and then made no change to their vaccine administration protocols.

Confirming the breadth of Classen's extravagant infringement theories, he also has asserted that other infringers of his patents, although not named as defendants in this case, include the United States government (particularly CDC and the Department of Defense), Children's Hospital, the University of Pennsylvania, the American Academy of Pediatrics, the Members of the National Partnership of Immunization, the Medical College of Ohio, the University of Illinois, University of Maryland School of Medicine, and Harvard University. See Decl. of John B. Classen in Support of Pl.'s Reply in Support of it's Mot. for Partial Recons. of Summ. J. (Dkt. 135-1) ¶¶ 2, 8, 10, 12-13. Classen contends that these entities, like the named defendants, have infringed merely by referencing studies that compare the adverse events associated with the timing of vaccine administration, and then administering vaccines on the lower-risk schedule.

GSK and Biogen moved to dismiss, citing the safe-harbor provision contained in 35 U.S.C. § 271(e)(1). Pet. App. 63a. The district court granted the motion because GSK and Biogen's "alleged participation in a study evaluating risks associated with various vaccination schedules was reasonably related to the development and submission of information required under the Federal Food, Drug, and Cosmetic Act." *Id.* at 63a-64a. The court rejected Classen's argument that § 271(e)(1) "applies only to drugs which have not yet been approved by the FDA" as contrary to the plain statutory language. *Id.* at 63a.

The district court also granted separate summary judgment motions filed by Merck. The court agreed with Merck that Classen's inventions are not patentable subject matter under 35 U.S.C. § 101. They claim "'thinking about' the risks of vaccination," which is "a mental process" and "an abstract idea and therefore not eligible for patenting." Pet. App. 10a. The court also granted Merck's motion for summary judgment of non-infringement, agreeing that the "'only specific act of infringement alleged in Classen's amended complaint was Merck's participation in or facilitation of the 2001 study'" conducted by Dr. DeStefano and that "'Merck offered uncontroverted evidence that it had no involvement in the DeStefano study.'" *Id.* at 24a-25a.

2. Classen appealed to the Federal Circuit, which summarily affirmed under § 101, relying on its prior decision in *In re Bilski*, 545 F.3d 943 (Fed. Cir. 2008) (en banc). Pet. App. 10a. After this Court issued its decision in *Bilski* v. *Kappos*, 130 S. Ct. 3218 (2010), it vacated *Classen* in light of *Bilski* and remanded for further consideration. Pet. App. 2a & n.1, 10a.

3. On remand from this Court, a sharply divided panel of the Federal Circuit affirmed in part, vacated in part, and remanded.

a. Writing for herself and Chief Judge Rader, Judge Newman first addressed § 101, and concluded that the '283 patent failed the threshold test of patentability—it merely claims an "'abstract idea,'" as it is directed to a method for obtaining knowledge about the effects of immunization, much like "the first step of the scientific method." Pet. App. 20a-21a. The majority upheld the '139 and '739 patents against the § 101 challenge, however, on the theory that those patents "require the further act of immunization in accordance with a lower-risk schedule, thus moving

from abstract scientific principle to specific application." *Id.* at 21a.

Second, the panel affirmed summary judgment of non-infringement for Merck. It saw no basis to disturb the district court's conclusions that the only specific act of alleged infringement was participation in the DeStefano study, and that Merck did not participate in that study. This aspect of the decision was unanimous. Pet. App. 25a-26a; *id.* at 57a (Moore, J.).

Finally, and relevant here, the majority vacated the district court's dismissal of claims against GSK and Biogen under § 271(e)(1). Pet. App. 33a. They agreed with Classen that § 271(e)(1) only provides "an exception to the law of infringement in order to expedite development of information for regulatory approval of generic counterparts of patented products." *Id.* at 27a; *id.* ("there is no issue in this case of submissions for regulatory approval of generic products, or like policy considerations"); *id.* at 29a (no exemption because the "activities charged with infringement are not related to producing information for an IND or NDA, and are not a 'phase of research' possibly leading to marketing approval"). In reaching this conclusion, the majority focused principally on the statute's legislative history. *Id.* at 27a-28a. Quoting a House Report, the majority concluded that "'the only activity which will be permitted by the bill is a limited amount of testing so that generic manufacturers can establish the bioequivalency of a generic substitute'"; the alleged activities of GSK and Biogen "cannot be stretched into this role." *Id.* at 28a.

b. Judge Moore dissented. First, she would have affirmed the district court's judgment that all of the asserted patents, not just the '283 patent, are unpatentable under § 101. According to Judge Moore, the patents claim "a fundamental scientific principle so

basic and abstract as to be unpatentable subject matter .... Classen claimed a monopoly over the scientific method itself." Pet. App. 38a; *id.* at 40a-50a.

Judge Moore also dissented from the panel's "construction of the safe harbor provision under § 271(e)(1)." Pet. App. 39a. "The majority's construction," she explained, "is contrary to the plain language of the statute and Supreme Court precedent." *Id.* at 53a. "Nowhere does the statute limit the safe harbor to pre-approval uses." *Id.* On the contrary, Judge Moore reasoned, this Court made clear that the text of § 271(e)(1) "'provides a wide berth for the use of patented drugs in activities related to the federal regulatory process.'" *Id.* at 54a (quoting *Merck*, 545 U.S. at 202). The statute "'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.* (quoting *Merck*, 545 U.S. at 206). And, Judge Moore further explained, the legislative history is of limited assistance: Everyone agrees that § 271(e)(1) applies to pre-approval activities; the question is "whether the enacted legislation covers *more* than just preapproval activity," and on that question the statute "is plain on its face." *Id.* at 55a. In application, Judge Moore concluded that "the alleged participation by GSK and Biogen in studies evaluating risks associated with different vaccination schedules is reasonably related to their requirement to review and report adverse information to the FDA," and therefore is exempt under § 271(e)(1), but that the alleged performance of "post-approval vaccinations in order to generate data" is not. *Id.* at 55a-56a.

The following ipse dixit was the entirety of the majority's response:

> Our colleague in dissent strays from statute and precedent, in arguing that any activity by any entity concerning any adversely patented product or method is exempted from infringement by § 271(e)(1), provided only that the information obtained is "reasonably related to submitting *any* information under the FDCA," "including information regarding post-approval uses." Such a massive enlargement of the statutory exemption is incorrect.

Pet. App. 30a n.4 (internal citations omitted).

4. Following remand from the Federal Circuit, and during the time to petition this Court for certiorari, Classen filed a second amended complaint. See Second Am. Compl. for Patent Infringement (Dkt. 172-1). It contains the same allegations of infringement that were at issue in the prior complaint and which formed the basis for the lower courts' decisions concerning § 271(e)(1). *Id.* ¶¶ 6, 10. It also makes additional infringement allegations that depend on studies that were reflected in the "package insert[s]" for vaccines,[9] or submitted for consideration at FDA meetings. *Id.* ¶¶ 12, 15, 16-18.

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[9] The "package insert"—the information inserted into a medical product's packaging—contains the FDA-approved labeling. *See* 21 C.F.R. §§ 201.56, 201.57, 201.100.

REASONS FOR GRANTING THE PETITION

CERTIORARI IS WARRANTED BECAUSE THE FEDERAL CIRCUIT HAS ERRONEOUSLY LIMITED § 271(E)(1) TO PREAPPROVAL ACTIVITIES, CONTRARY TO THIS COURT'S PRECEDENTS AND THE STATUTORY TEXT.

The Court should grant certiorari to reaffirm what it already has made clear—that 35 U.S.C. § 271(e)(1) should be read according to its plain terms, and not limited to just those effects that are "'explicitly mentioned in its legislative history.'" *Eli Lilly*, 496 U.S. at 669 n.2. Nothing in the statutory text limits § 271(e)(1) to premarket approval of generic drugs, and the limitation created by the panel majority is utterly at odds with the reality of the FDA approval process. And, most fundamentally, this Court twice has refused to read limitations into the statute that Congress did not include in the text. As Judge Moore properly explained in dissent, the panel's "construction [of § 271(e)(1)] is contrary to the plain language of the statute and Supreme Court precedent." Pet. App. 53a. That is a quintessential basis for this Court's review, see Sup. Ct. R. 10(c), which is appropriate now and in this case.

A. The Federal Circuit's Categorical Limitation On § 271(e)(1) Conflicts With The Plain Language Of This Provision And This Court's Precedents Interpreting That Language.

The plain language of § 271(e)(1) protects specified acts—without regard to *when* they occurred—so long as they are "solely for uses reasonably related to the development and submission of information under" certain federal laws. 35 U.S.C. § 271(e)(1). Thus, subject to this latter, explicit limitation, the statute

sweeps broadly. The Court has confirmed that § 271(e)(1) means what it says: the provision extends to "*all* uses of patented [inventions] 'reasonably related' to the process of developing information for submission under *any* federal law regulating the manufacture, use, or distribution of drugs." *Merck*, 545 U.S. at 206; *id.* at 202 (exemption "extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA").

On two separate occasions, the Court has rejected proposed limitations on the statute—like the one adopted by the Federal Circuit here—that appear nowhere in the statutory text. In *Eli Lilly*, it was argued that medical devices are unprotected by § 271(e)(1) because Congress was concerned only with the federal drug-approval process when it enacted this provision. The Court rejected that argument, reasoning that the most natural reading of the relevant statutory text—"'a Federal law which regulates the manufacture, use, or sale of drugs'"—is a "statutory scheme of regulation" that regulates drugs at least in part. 496 U.S. at 665-67. Accordingly, because the FDCA—the "statutory scheme" at issue there—regulates both drugs and devices, the use of a patented invention for the purpose of submitting information to FDA concerning medical devices fell within the exemption. *Id.* at 664-67, 679.

In *Merck*, the Court again rejected a proposed limitation on the statutory safe harbor that was not rooted in the provision's text. The Federal Circuit had focused on the statute's supposed purpose to shield generic drug manufacturers, and concluded that § 271(e)(1) excludes "uses of patented inventions in preclinical research" if the results of that research "are not ultimately included in a submission to" FDA.

545 U.S. at 195. On the contrary, this Court explained, "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." *Id.* at 202. Thus, there "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." *Id.*; accord, *id.* (it is "apparent from the statutory text that § 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" relevant statutes). Merck, an innovator in developing pharmaceuticals, therefore was not excluded from seeking the protection of § 271, contrary to the Federal Circuit's reading of the legislative history.

In the decision below, the Federal Circuit again imposed limitations on § 271(e)(1), doing serious violence to both this Court's teachings and the statutory language that Congress enacted. The panel majority held that this provision cannot protect activities occurring after FDA has granted marketing approval of a drug; instead, according to the panel majority, this provision "provides an exception to the law of infringement in order to expedite development of information for regulatory approval of generic counterparts of patented products." Pet. App. 27a; *id.* (agreeing with Classen that the safe harbor "is limited to activities conducted to obtain pre-marketing approval of generic counterparts"); *id.* at 28a ("§ 271(e)(1) is directed to premarketing approval of generic counterparts before patent expiration").

As Judge Moore recognized, however, "[n]owhere does the statute limit the safe harbor to pre-approval uses," nor restrict its scope to generic drugs. Pet. App.

53a. The statutory language connotes breadth both in the range of conduct that is exempted—making, using, offering to sell or selling a patented invention—and in the federal laws that qualify for the exemption—those that "regulate[ ] the manufacture, use, or sale of drugs." None of those verbs supports a distinction between pre- and post-marketing conduct. On the contrary, as noted above (at 4-6) and discussed in greater detail below (at 23-25), such a distinction ignores the reality of the FDA regulatory regime. Although the statute is not without limits—the conduct must be "solely for uses reasonably related to the development and submission of information under" a relevant federal law, 35 U.S.C. § 271(e)(1); see *Merck*, 545 U.S. at 202, 206—the exemption created by the majority is made of whole cloth.

The decision below is irreconcilable with this Court's precedents in at least two fundamental ways. *First*, the majority's apparent limitation of § 271(e)(1) to activities undertaken by manufacturers of generic products—and seemingly generic *drugs*—cannot coexist with *Eli Lilly* and *Merck*. See Pet. App. 27a (concluding that § 271(e)(1) is limited to "pre-marketing approval of generic counterparts"); *id.* (the House "Report is replete with statements that the legislation concerns premarketing approval of generic drugs"); *id.* at 28a ("premarketing approval of generic counterparts"). Such a rule would have compelled an opposite result in both *Merck* and *Eli Lilly*, neither of which concerned manufacturers seeking approval of generic drug counterparts. *Merck* concerned an investigational new drug application (IND) that was not submitted by a generic manufacturer. 545 U.S. at 199; *id.* at 196 & n.1. And *Eli Lilly* held that § 271(e)(1) could exempt activities related to the submission of information for medical devices. 496

U.S. at 664-67, 679. There are, however, no "generic" versions of medical devices, see 21 U.S.C. § 360c, and there is no application process for devices under the FDCA similar to the one for "generic" drugs. See *Telectronics Pacing Sys., Inc.* v. *Ventritex, Inc.*, 982 F.2d 1520, 1525 (Fed. Cir. 1992).

Second, the panel majority relied overwhelmingly on legislative history to limit the plain text of § 271(e)(1) in the very fashion this Court has already rejected. After quoting the statutory text at the outset, see Pet. App. 26a, the majority subsequently ignored it. Instead, its decision turned on the conclusion that the legislative history is "replete with statements that the legislation concerns premarketing approval of generic drugs." *Id.* at 27a. In *Eli Lilly*, however, this Court specifically rejected an argument that § 271(e)(1) is limited to the purposes that were a focus of its legislative history. The petitioner had argued that § 271(e)(1) could not extend to medical devices because the legislative history only mentioned drugs. Judge Newman reasoned likewise in her dissent from denial of rehearing en banc. *Eli Lilly & Co.* v. *Medtronic, Inc.*, 879 F.2d 849, 849-50 (Fed. Cir. 1989). This Court has already rejected that argument, explaining that "'[i]t is not the law that a statute can have no effects which are not explicitly mentioned in its legislative history.'" *Eli Lilly*, 496 U.S. at 669 & n.2 (quoting *Pittston Coal Grp.* v. *Sebben*, 488 U.S. 105, 115 (1988)).

In *Merck*, likewise, Judge Rader's opinion for the Federal Circuit relied heavily on legislative history to limit § 271(e)(1). See, *e.g.*, *Integra LifeSciences I, Ltd.* v. *Merck KGaA*, 331 F.3d 860, 865 (Fed. Cir. 2003) ("The House Committee that initiated this provision expressly described the pre-market approval activity as 'a limited amount of testing so that generic manu-

facturers can establish the bioequivalency of a generic substitute.'"); *id.* at 867 ("the 1984 Act enacted § 271(e)(1) to create a safe harbor for those pre-expiration tests necessary to satisfy FDA requirements"). This Court held otherwise. *Merck*, 545 U.S. at 202, 206.

These decisions follow the long-established rule that the otherwise plain text of a statute cannot "be added to or subtracted from by … reports accompanying their introduction." *Caminetti* v. *United States*, 242 U.S. 470, 490 (1917). "Reports to Congress," as the Court has explained, may of course "aid the courts in reaching the true meaning of the legislature in cases of doubtful interpretation." *Id.* But the use of that legislative history must be "anchored in the text of the statute." *Shannon* v. *United States*, 512 U.S. 573, 583 (1994). This is because "'courts have no authority to enforce [a] principl[e] gleaned solely from legislative history that has no statutory reference point.'" *Id.* at 584 (quoting *Int'l Bhd. of Elec. Workers, Local Union No. 474, AFL-CIO* v. *NLRB*, 814 F.2d 697, 712 (D.C. Cir. 1987)); see also *Oncale* v. *Sundowner Offshore Servs., Inc.*, 523 U.S. 75, 79 (1998) ("it is ultimately the provisions of our laws rather than the principal concerns of our legislators by which we are governed"); *NOW* v. *Scheidler*, 510 U.S. 249, 262 (1994) ("The fact that RICO has been applied in situations not expressly anticipated by Congress does not demonstrate ambiguity. It demonstrates breadth." (alterations and internal quotation marks omitted)).

The panel majority committed this cardinal interpretive sin. It gave dispositive "effect to ... legislative history" by "abandon[ing] altogether the text of the statute as a guide in the interpretative process." *Shannon*, 512 U.S. at 583. The panel majority never

identified any ambiguity in the text of § 271(e)(1) about whether the statute applies to activities occurring after a vaccine has been approved by FDA. Instead, it derived its limitation on the otherwise plain language of § 271(e)(1) solely from the provision's legislative history. That approach directly contradicts this Court's decisions. The panel majority may have believed as a matter of policy that § 271(e)(1) is too sweeping, but that "is no reason why the court[ ] should refuse to enforce it according to its terms." *Caminetti*, 242 U.S. at 490; see *Conn. Nat'l Bank* v. *Germain*, 503 U.S. 249, 254 (1992) ("'It would be dangerous in the extreme to infer ... that a case for which the words of an instrument expressly provide, shall be exempted from its operation.'").

The Federal Circuit's construction of § 271(e)(1), and its mode of doing so, contradict the statutory text and are inconsistent with this Court's decisions. Certiorari is warranted to correct the Federal Circuit's erroneous and artificial limitation on this important safe harbor.

B. The Federal Circuit's Categorical Limitation On § 271(e)(1) To Preapproval Activities Ignores The Reality Of FDA Regulation, And Threatens Uncertainty For Innovators.

This Court's review is warranted not only because the decision below is wrong and conflicts directly with this Court's decisions, but also because the line it purports to draw—at the point of marketing authorization—ignores or misapprehends the functioning of the FDA process. In so doing, it threatens to sow confusion, to create unwarranted infringement liability for activities in service of the public health, and to compromise the public's interest in the availability of new and improved products.

The panel majority erred when it assumed, without explanation, that there is a clear division between pre- and post-marketing activities in this context, and on that basis erroneously excluded certain activities from the safe harbor "on the basis of the phase of research in which [they are] developed." *Merck*, 545 U.S. at 202. Drug development is not a binary process in which all that matters is a one-time decision whether to grant a product marketing authorization. Quite the contrary, it is an iterative process both for manufacturers (who seek to develop additional or improved uses for already-approved products) and for regulators (who review information about safety and efficacy on an ongoing basis, and whose tolerance for risk and assessment of benefit may change over time as new therapeutic options become available). The "preapproval" line drawn by the decision below therefore creates considerable uncertainty about whether a variety of such socially important activities will fall within the statutory safe harbor.

For instance, holders of an approved NDA or BLA commonly will develop and submit information concerning improvements on, or new uses of, already-approved drugs, or new drug combinations including an already-approved drug. See 21 U.S.C. §§ 355(a), (b)(2), 321(p); 21 C.F.R. § 310.3(h). Activities directed to improving a product by researching new uses, new formulations, new dosing regimens or combination therapies will occur both prior to the initial drug authorization and afterwards. Researching possible new combinations is particularly common in cancer treatment, for instance; developing new combination regimens and new fixed-dose combination formulations commonly is undertaken, even after initial marketing authorization. In many cases, moreover, clinical studies directed to approval of multiple indi-

cations will be started prior to approval and conclude after approval of a first indication. Such efforts to refine, improve, and expand upon the uses of existing drugs are efficient; they benefit the public health; and Congress in the Hatch-Waxman Act itself affirmatively encouraged these activities. See 21 U.S.C. §§ 355(c)(3)(E)(iv), 355(j)(5)(F)(iv). But, when innovators work to improve a drug or its administration, they do not know in advance whether or in what form the information they "develop" will be "submitted" to FDA. There is no principled basis to distinguish these studies based upon the phase of research underway at the time an initial approval is obtained, and nothing in § 271(e)(1) requires this result.

In addition, there exist numerous provisions authorizing FDA to require that information be submitted to it following marketing approval, either in general or for a particular product. For instance, manufacturers must submit to FDA all information necessary to justify virtually any labeling change, including (directly relevant here) studies relevant to a change in the schedule for administering a vaccine. 21 C.F.R. § 601.12(f)(1), (f)(2)(ii) (regulating supplemental BLAs); see *id.* § 201.57(c)(3) (requirement of submitting dosage information). The same is true for drugs. 21 C.F.R. § 314.70 (regulatory requirements for supplemental NDAs). Yet, under the panel's reasoning, this very same information that would be protected if submitted as part of an NDA before original marketing authorization, apparently would be excluded from protection if submitted in a supplemental NDA.[10]

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[10] There are also other information-submission requirements that the Federal Circuit's decision would appear to exclude based solely on when the information is submitted. For instance, FDA has authority to require "[p]ostmarket studies and clinical trials" to assess certain specified types of risks. 21 U.S.C.

Under the Federal Circuit's new rule governing § 271(e)(1), such post-approval activities seemingly cannot qualify for this exemption, no matter what the relationship between their activities and the development of information for submission to FDA. It serves both science and the public interest, however, for holders of NDAs and BLAs to do research to improve their products, free from the threat of senseless infringement liability. This is not to say that *all* post-approval activity will qualify for the safe harbor; on the contrary, such activity will be circumscribed by the same "solely for" and "reasonably related" limitations that appear in the statutory text, and which apply to pre-marketing activity even under the Federal Circuit's understanding of the statute. *Cf. Proveris Scientific Corp.* v. *Innovasystems, Inc.*, 536 F.3d 1256, 1265 (Fed. Cir. 2008) (excluding commercial activity from the safe harbor).

But, what is clear is that there is no support in the text for categorically *excluding* activity from § 271(e)(1)'s safe harbor, based solely on the activity's timing, when the very same activity would be *included* in the safe harbor if it had occurred before marketing approval. As this Court explained, there "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." 545 U.S. at 202. The Court should grant the petition to restore the § 271(e)(1) safe harbor to its proper textual bounds.

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§ 355(o); *see also* Pet. App. 55a-56a (Moore, J., dissenting) (holders of NDAs and BLAs are required to "review and report adverse information to the FDA") (citing 21 C.F.R. §§ 600.80, 601.70).

CONCLUSION

For the foregoing reasons, the Court should grant the petition for a writ of certiorari.

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