No. 11-1078

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

REPLY BRIEF

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As the Petition demonstrates, the Federal Circuit imposed a temporal limitation on the § 271(e)(1) safe harbor that was based solely on the legislative history, not the statutory text, and that conflicts with this Court's decisions in *Eli Lilly* and *Merck*[1]—both of which rejected similar attempts to impose extra-textual limitations on the statute. In response, Classen principally depends on the statute's use of the word "solely," which, he claims, supports limiting the safe harbor to the "development of information for regulatory approval of generic counterparts of patented products." Pet. App. 27a; see Opp. 6-7, 8-9. This, however, was not the rationale of the Federal Circuit, and for good reasons—Classen did not make this argument to that court, and it lacks merit.

As discussed below, the argument is wrong. The statutory limitation on the safe harbor—"solely for uses reasonably related to the development and submission of [certain] information" refers to the *type* of activity, not the period during which it was conducted. If Congress wanted to limit § 271(e)(1) to "regulatory approval of generic … products," Pet. App. 27a, it could easily have done so. But there is no reason to think it adopted a temporal limitation by using the word "solely"—which means "exclusively," not "regulatory approval of generic products." Congress would not ordinarily hide such a fundamental limitation in a word that means something quite different. See *Whitman* v. *Am. Trucking Ass'ns*, 531 U.S. 457, 468 (2001) ("Congress … does not alter the fundamental details of a regulatory scheme in vague

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[1] *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661 (1990); *Merck KGaA* v. *Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005).

terms or ancillary provisions—it does not, one might say, hide elephants in mouseholes.").

1. Review is warranted first and foremost because the Federal Circuit's imposition of an extra-textual limitation on § 271(e)(1) "is contrary to … Supreme Court precedent." Pet. App. 53a (Moore, J., dissenting); see Pet. 17-20. The Court has previously rejected similar efforts to limit this provision, and emphasized that the text of § 271(e)(1) must be given its plain meaning. The safe harbor "extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under" relevant federal laws. *Merck KGaA* v. *Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005). Accordingly, "[t]here is simply no room in the statute for excluding certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included." *Id.*

Classen seeks to explain away the conflict by arguing that this Court's decisions "appreciated that § 271(e)(1)" is limited to actions in furtherance of "premarketing approval" of drugs. See generally Opp. 10-12. And, he asserts, the Court "applied this limitation." *Id.* at 10 (citing *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 671 (1990)). On the contrary, nothing in either decision imposes any such limitation. Those decisions of course recognized that the safe harbor covers certain pre-marketing activities, but they did not remotely limit the statute to that domain. As Judge Moore explained in dissent, "[w]hile it is true that the Supreme Court decided [*Merck*] in the context of pre-approval activities, the Court repeatedly underscored the breadth of the statute's text." Pet. App. 54a. Thus, the Court explained, Congress has "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." *Merck*, 545 U.S. at 206; accord *id.* at 202.[2]

Furthermore, Classen does not respond at all to a separate aspect of the conflict—namely, GSK's showing that the decision below conflicts with *Eli Lilly* and *Merck* by limiting the safe harbor to *generic drugs*. Pet. 19-20. The word "generic" appears nowhere in the statute, and consistent with that fact, both *Eli Lilly* and *Merck* determined that activities unrelated to generic products qualified for the safe harbor. See *id.* (discussing same). Classen himself at times seems to acknowledge the Federal Circuit's error, stating that § 271(e)(1) extends to the use of patented inventions in seeking FDA approval of "*a new* or generic drug." Opp. 6 (emphasis added); see also *id.* at 10 ("§ 271(e)(1) is directed to premarketing approval of new drugs or generic counterparts").[3] These conflicts are a quintessential basis for this Court's review.

2. Classen's principal defense of the decision below is a merits argument, which the Court should grant

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[2] For similar reasons, Classen is wrong when he characterizes § 271(e)(1) as "narrow in scope." Opp. 6; *accord id.* at 8 ("very narrow exception to patent infringement"), 13 ("narrow safe harbor"). To the contrary, this Court has explained that § 271(e)(1) "provides a wide berth for the use of patented drugs in activities related to the federal regulatory process." *Merck*, 545 U.S. at 202; *see also id.* at 203 (describing § 271(e)(1)'s "breadth").

[3] Elsewhere, Classen makes the contradictory assertion that "[t]he Federal Circuit properly limited the safe harbor" to activities related to "obtaining approval from the FDA to market generic drugs." Opp. 8-9.

the Petition to review. Specifically, although the Federal Circuit majority identified no textual basis in the statute to restrict the safe harbor to "premarketing approval of generic counterparts," Pet. App. 28a, Classen now proposes one for the first time. He argues that such a limitation finds its home in the use of the word "solely" in § 271(e)(1) (which exempts the use of patented inventions "solely for uses reasonably related" to the submission of information under certain federal laws).

As an initial matter, Classen never made this argument to the Federal Circuit,[4] and it therefore is not the theory adopted by that court. Rather, the majority's restriction of § 271(e)(1) was based on its interpretation of the legislative history. See Pet. 20; Pet. App. 27a-28a. It simply is not true, as Classen claims, that the "word 'solely' is of critical importance to the Federal Circuit's interpretation of this provision." Opp. 9. The majority used the word "solely" just once: in a block quotation of § 271(e)(1) at the outset of its opinion. Pet. App. 26a. The Court should reject Classen's invitation to let the "Federal Circuit's decision in this case stand" on the basis of his newly minted theory. Opp. 8.

Classen's new argument also is wrong. Section 271(e)(1) provides that the use of a patented invention "shall not be an act of infringement" when done "solely for uses reasonably related to the development and submission of information" under certain federal laws. 35 U.S.C. § 271(e)(1). By its plain terms, therefore, the safe harbor is focused on the uses to which

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[4] *See generally* Br. for Appellant Classen Immunotherapies, Inc. at 24-34, No. 2006-1634 (Fed. Cir. filed Nov. 20, 2006); Reply Br. of Appellant at 7-10, No. 2006-1634 (Fed. Cir. filed Apr. 10, 2007).

the patented invention is put. If the patented invention is used exclusively ("solely") for purposes that are reasonably related to developing and submitting the requisite information, there is no infringement. Nothing about the word "solely" imposes a temporal limitation based on the phase of agency review.

Classen's response is made of whole cloth. He asserts that the "only time that a drug may be made and used 'solely' … to obtain regulatory approval for a pharmaceutical drug, is in the premarketing phase of its development." Opp. 9. This assertion is wrong for multiple reasons. The statute does not link the word "solely" to the purpose for which "the drug" is made and used. Rather, the question is whether the use of the *patented invention* (here, Classen's supposedly "novel" "techniques," *id.* at 1) is reasonably related to the development and submission of specified information. The safe harbor also is not limited to "regulatory approval," *id.* at 9, but rather focuses on "the development and submission of information under" certain federal laws. 35 U.S.C. § 271(e)(1). And, the statute does not tie the word "solely" to the "phase of research," *Merck*, 545 U.S. at 202, during which the activity occurred. That the *drug* has received initial marketing approval does not mean that the use of the *patented invention* cannot be reasonably related to the development and submission of information to FDA. Post-marketing-approval studies are not purely or necessarily commercial, as Classen asserts, Opp. 9; they may be experimental in nature and design, and undertaken to probe safety and efficacy or to expand, assess, and change the approved uses. This case itself demonstrates as much.

The DeStefano study at the center of Classen's allegations was a retrospective study to determine whether schedules for administering certain vaccines

should be altered. See Pet. 10-11. This CDC-sponsored study, which evaluated the past efficacy of vaccination schedules in response to Classen's theories among others, was not tethered to any ongoing commercial sales of the vaccines. The study, according to Classen, required the use of his patents because it involved the assessment of vaccine administration schedules and the decision to change to (or stick with, depending on the circumstance) the safer schedule. Opp. 3-4.[5] Depending on the results of the study, FDA could have required a labeling change to reflect a new schedule for administration. Pet. 24. The alleged use of Classen's "techniques" was, therefore, solely for uses that were reasonably related to developing and submitting information to FDA. There is no basis in the statute to treat these activities differently based on whether they came before or after marketing approval.

As GSK showed previously, there are a variety of circumstances in which drug manufacturers will undertake the "development and submission of information under a Federal law," see 35 U.S.C. § 271(e)(1), after a drug has received initial marketing approval—and indeed they may be *required* to do so. Pet. 22-25. This can be true of studies begun prior to initial marketing approval but finished thereafter; for combination therapies involving an already approved drug; and for other reasons as well. *Id.* If the uses of the patented invention all are reasonably related to the development and submission of such information, then there is no infringement. Sometimes the use may not meet the test of a reasonable relationship.

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[5] Indeed, Classen's patents expressly purport to cover studies concerning safety and efficacy. *See, e.g.*, U.S. Patent No. 6,420,139 col.55 ll.60-62 ("clinical trial for demonstrating efficacy against an infection or for demonstrating safety").

But here, the court did not even undertake this inquiry; instead, it focused solely on pre- versus post-marketing approval, about which the statute says nothing. Section 271(e)(1) does not ask who took particular actions, or when they did so (as Classen advocates). Rather, the statute establishes a qualitative test which asks whether the use of the patented invention was sufficiently related to the regulatory process. See *id.* at 16-17, 18-19. As this Court explained in *Merck*, nothing in the text of § 271(e)(1) restricts the safe harbor to "the phase of research" for which information is developed or "the particular submission in which it could be included." *Merck*, 545 U.S. at 202.

3. Classen also seeks support for his interpretation in the statute's legislative history. See Opp. 11, 13-15. He claims that the legislative history shows that "Congress intentionally inserted the 'solely reasonably related' language" in order to limit the safe harbor to pre-marketing approval. *Id.* at 6-7. It is telling that he provides no citation to support this assertion, see *id.*, and we are aware of none.

More fundamentally, there is no basis in the statutory text to justify importing Classen's proposed limitation from the legislative history. Use of legislative history must be "anchored in the text of the statute." *Shannon* v. *United States*, 512 U.S. 573, 583 (1994); see Pet. 21-22. Here, there is no textual anchor, as the opinion of the panel majority effectively demonstrates: The majority had no response to Judge Moore on this issue other than a bare assertion, see Pet. 15 (quoting Pet. App. 30a n.4), which is why Classen has felt it necessary to devise a new argument in this Court. Accordingly, the decision below conflicts with the numerous decisions of this Court explaining that the 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); see Pet. 21-22. Nor is it dispositive that when Congress enacted this language, its attention was focused on certain particular problems that were reflected in the legislative history. Opp. 14-15; Pet. 20-21. This Court has explained—in the course of rejecting a limiting construction of this very provision—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 & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 669 n.2 (1990) (quoting *Pittston Coal Grp.* v. *Sebben*, 488 U.S. 105, 115 (1988)). The decision below, and Classen's more recent assertions, run squarely afoul of *Eli Lilly* in this regard.

4. Finally, Classen makes an appeal to policy. He broadly asserts that reading the statute according to its plain terms would "completely eviscerate the patent right enshrined in the United States Constitution" by "provid[ing] pharmaceutical and medical device manufacturers with a complete defense to a claim of patent infringement that would last throughout the life of the patent or the life cycle of the drug or device." Opp. 7. It would be extraordinary if GSK and the members of PhRMA, whose businesses depend on robust patent protection, were advocating the "effective[] eliminat[ion of] all drug and medical device patents," *id.* at 17, and of course they are not.

As the Petition took pains to explain, § 271(e)(1) is not limitless. Pet. 19, 25. It imposes the same limit on conduct *following* initial marketing approval that it applies to *pre*-marketing activities—namely, the requirement that the uses be "reasonably related to the development and submission of information" under relevant federal laws. 35 U.S.C. § 271(e)(1); see Pet.

19, 25; *Merck*, 545 U.S. at 205-06. The statute thereby focuses on the type of activity at issue, not the period during which it was conducted. This limitation may be satisfied in a variety of circumstances. See Pet. 5-6, 22-24. Here, however, the Federal Circuit imposed a different, temporal limitation that finds no support in the statutory text. Classen's problem is not that the statute imposes no limitation on the scope of the safe harbor; it is that he would prefer a different one. To the extent policy considerations are relevant here, it is because the decision below curtails 35 U.S.C. § 271(e)(1) in a way that threatens the development of information that makes drugs and biological products safer, more useful, and more effective. See Pet. 22-25; PhRMA Br. 8-16. This is not a question of "judicial intervention" to modify a statute, as Classen suggests (Opp. 18); it is a question of faithfully reading the statute the way that Congress wrote it and this Court previously interpreted it.

CONCLUSION

For the foregoing reasons and those stated in the Petition, the Court should grant the Petition for a Writ of Certiorari.

Respectfully submitted,

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