No. 11-1078

In the Supreme Court of the United States

GLAXOSMITHKLINE, PETITIONER

v.

CLASSEN IMMUNOTHERAPIES, INC.

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

BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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QUESTION PRESENTED

Under 35 U.S.C. 271(e)(1), it is not an act of patent infringement to use a patented invention "solely for uses reasonably related to the development and submission of information under a Federal law" that regulates the manufacture, use, or sale of drugs. The question presented is as follows:

Whether Section 271(e)(1)'s safe harbor encompasses activities undertaken after the Food and Drug Administration has approved a drug for marketing.

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This brief is filed in response to the Court's order inviting the Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be denied.

STATEMENT

1. a. 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 1984, as part of the Drug Price Competition and Patent Term Restoration Act (Hatch-Waxman Act), Congress created an exemption from that general rule for certain uses of patented inventions in the federal regulatory process. Pub. L. No. 98-417, § 202, 98 Stat. 1585. As amended, that exemption provides:

> 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.

35 U.S.C. 271(e)(1).

b. The Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, is a federal law that "regulates the manufacture, use, or sale of drugs." See 21 U.S.C. 331, 355(a); *Merck KGaA* v. *Integra Lifesciences I, Ltd.*, 545 U.S. 193, 196 (2005); *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 668 (1990). Under the FDCA, a new drug may not be introduced into interstate commerce until the Food and Drug Administration (FDA) has determined that the drug is both safe and effective. 21 U.S.C. 355(a) and (d). To enable the FDA to make that determination, the drug's manufacturer must develop and submit a variety of information to the agency. See *Merck*, 545 U.S. at 196.[1]

To obtain marketing approval for a new drug, a manufacturer must first submit to the FDA an "investigational" new drug application for approval to conduct clinical trials (*i.e.*, tests on humans). 21 U.S.C.

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[1] This case involves vaccines, which are regulated as "biological products" under the Public Health Service Act, 42 U.S.C. 262, 263. The distinction between drugs and biological products is not important here, however, because a vaccine is also a "drug" within the meaning of the FDCA, see 21 U.S.C. 321(g)(1)(B), and the Public Health Service Act relies extensively on the FDCA's scheme governing approval of new drugs by the FDA, see 42 U.S.C. 262(a)(2)(D) and (j) (2006 & Supp. V 2011). The Public Health Service Act is therefore another "Federal law which regulates the manufacture, use, or sale of drugs." 35 U.S.C. 271(e)(1); see *Eli Lilly*, 496 U.S. at 668.

355(i). The application must include data from pre-clinical research, including pharmacological and toxicological studies, "adequate to justify the proposed clinical testing." 21 U.S.C. 355(i)(1)(A); see 21 C.F.R. 312.23(a)(5) and (8). If the application is granted and clinical trials succeed, the manufacturer must submit a "new drug" application for approval in order to bring the drug to market. 21 U.S.C. 355(a). That application must include "full reports of investigations which have been made" to establish the safety and effectiveness of the drug, including all relevant clinical studies and pre-clinical research. 21 U.S.C. 355(b)(1); see 21 C.F.R. 314.50.

A manufacturer wishing to market a generic equivalent of a drug previously approved by the FDA may file an abbreviated new drug application (ANDA). 21 U.S.C. 355(j)(2)(A). Although the ANDA process does not require the applicant to make an independent showing of safety and effectiveness, the applicant must submit information demonstrating that the proposed generic product has the same active ingredients, dosage form, route of administration, and strength as the approved drug, and that the generic and approved drugs are bioequivalent. 21 U.S.C. 355(j)(2)(A) and (8)(B); see *Merck*, 545 U.S. at 196 n.1.

2. a. Respondent holds several United States patents relating to methods of optimizing vaccine immunization schedules, including United States Patent Nos. 6,638,739 (filed Oct. 28, 2003) (the '739 patent); 6,420,139 (filed July 16, 2002) (the '139 patent); and 5,723,283 (filed Mar. 3, 1998) (the '283 patent). Pet. App. 4a. According to the patents, which identify Dr. John Barthelow Classen as the sole inventor, the timing of infant immunizations can affect the later devel-

opment of certain chronic disorders, including diabetes, asthma, hay fever, cancer, multiple sclerosis, and schizophrenia. *Ibid.*; see, *e.g.*, '739 patent, col. 7 ll. 39-45. The '739 and '139 patents claim methods of immunization in which potential schedules for administering a vaccine are compared, the schedule associated with the least risk of developing later occurring chronic disorders is identified, and the vaccine is administered to a mammalian subject according to that schedule. Pet. App. 5a; see *id.* at 5a-6a (reproducing a representative claim). The '283 patent claims the first steps of that method—*i.e.*, reviewing and comparing information on the effects of different immunization schedules—without the final step of administering a vaccine. See *id.* at 7a.

b. In the late 1990s, in response to articles published by Dr. Classen positing a relationship between the timing of certain childhood vaccinations and the onset of type 1 diabetes, the Centers for Disease Control and Prevention (CDC) sponsored an epidemiological study to evaluate Dr. Classen's claims. In the study, researchers examined the vaccination records and medical histories of more than 1000 children who had received medical care from four different HMOs. See generally Frank DeStefano et al., *Childhood Vaccinations, Vaccination Timing, and Risk of Type 1 Diabetes Mellitus*, 108 Pediatrics, Dec. 2001 (the CDC study) (C.A. App. A220-A225). A hepatitis B vaccine manufactured by petitioner was among the vaccines that had been administered to those children.

The resulting paper, published in 2001, found no association between childhood vaccines and diabetes, and it rejected as "unfounded" Dr. Classen's contention "that diabetes risk in humans may be altered by

changes in the timing of vaccinations." C.A. App. A225. In 2003, based in part on the CDC study, the FDA denied a citizen petition submitted by Dr. Classen, which requested that the labels of certain childhood vaccines be amended to warn of diabetes risk. *Id.* at A229-A237.

3. a. In 2004, respondent brought this patent infringement action against petitioner and others. The complaint alleged that the defendants had infringed the '739, '139, and '283 patents by "participat[ing] in, facilitat[ing] and/or otherwise conduct[ing]" the CDC study, and by using the results of that and other studies "to determine the administration protocol for vaccinations." C.A. App. A64 (Am. Compl. para. 7).[2] Respondent additionally alleged that the defendants had infringed its patents "through the manufacture and supply of vaccines and by providing instructions and/or recommendations on a proper immunization schedule for vaccines and by administration of vaccines according to the patented method." *Id.* at A72 (Am. Compl. para. 27).[3]

The district court dismissed respondent's claims against petitioner on the ground that petitioner's

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[2] Respondent also initially asserted infringement of United States Patent No. 5,728,385 (filed Mar. 17, 1998), see C.A. App. A73, but later dismissed that count from the complaint, see 04-cv-2607 Docket entry No. 92 (D. Md. Sept. 16, 2005). In 2012, after the court of appeals remanded the case to the district court, respondent amended its complaint to add infringement claims under a fifth patent, United States Patent No. 7,008,790 (filed Mar. 7, 2006) (the '790 patent). See Docket entry No. 172.

[3] Dr. Classen subsequently asserted in a declaration that the CDC also infringes respondent's patents whenever the agency evaluates the safety of vaccine administration schedules. See Docket entry No. 135-1, at para. 7.

principal alleged acts of infringement concerned the CDC study, which the court concluded was protected conduct under Section 271(e)(1). Pet. App. 61a-64a. Citing this Court's then-recent decision in *Merck*, the district court reasoned that petitioner's "participation in a study evaluating risks associated with various vaccination schedules was reasonably related to the development and submission of information" under the FDCA. *Id.* at 63a-64a.

The district court later granted summary judgment in favor of all defendants, ruling that respondent's patents are invalid under 35 U.S.C. 101 because they are not directed to patent-eligible subject matter. Pet. App. 10a. The court reasoned that the patents describe little more than the abstract, mental process of comparing the risks posed by different vaccination schedules. *Ibid.*

b. The court of appeals affirmed the district court's invalidity ruling in an unpublished order. 304 Fed. Appx. 866 (2008). Because the court of appeals held the patents invalid, it did not address the district court's non-infringement ruling under Section 271(e)(1). Respondent filed a petition for a writ of certiorari (No. 08-1509). While that petition was pending, this Court issued its decision in *Bilski* v. *Kappos*, 130 S. Ct. 3218 (2010). The Court subsequently granted respondent's petition, vacated the court of appeals' judgment, and remanded for reconsideration in light of *Bilski*. 130 S. Ct. 3541 (2010).

4. A divided panel of the court of appeals affirmed in part, vacated in part, and remanded to the district court. Pet. App. 1a-57a.

a. The court of appeals first addressed the question of patent-eligibility under 35 U.S.C. 101. Pet.

App. 4a-23a. The court affirmed the judgment of invalidity as to the '283 patent, explaining that the claimed method does not involve any practical application of human knowledge but rather is "directed to the abstract principle that variation in immunization schedules may have consequences for certain diseases." *Id.* at 21a. The court reversed the district court's invalidity ruling as to the '139 and '739 patents, however, because the methods claimed in those patents "require the further act of immunization in accordance with a lower-risk schedule, thus moving from abstract scientific principle to specific application." *Ibid.*

The court of appeals also reversed the district court's noninfringement ruling under 35 U.S.C. 271(e)(1), concluding that petitioner's role in the CDC study did not come within the safe harbor provision. Pet. App. 26a-30a. The court described Section 271(e)(1) as protecting only "activities conducted to obtain pre-marketing approval of generic counterparts of patented inventions, before patent expiration." *Id.* at 27a. The court therefore concluded that the statute "does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained." *Ibid.*

The court of appeals noted that the legislative history of the Hatch-Waxman Act is "replete with statements that the legislation concerns premarketing approval of generic drugs." Pet. App. 27a. The court also observed that judicial decisions construing Section 271(e)(1) have "appreciated" that the statute is "directed to premarketing approval of generic counterparts before patent expiration." *Id.* at 28a. Accordingly, the court of appeals reversed the dismissal of the infringement claims against petitioner because

petitioner's conduct was "not related to producing information for" a new or generic drug application and was "not a 'phase of research' possibly leading to marketing approval" of a drug by the FDA. *Id.* at 29a.

b. Judge Moore dissented. Pet. App. 38a-57a. As an initial matter, she would have held all of respondent's patent claims invalid under 35 U.S.C. 101. See Pet. App. 43a ("[T]his case is not even close."). Judge Moore emphasized that the patents do not "claim a method of treating a chronic immune-mediated disorder by using a new and specific immunization schedule." *Id.* at 47a-48a. Rather, they "seek to monopolize the process of discovery itself, albeit limited to a single field." *Id.* at 48a.

Judge Moore also dissented from the court of appeals' conclusion that post-approval activities are not entitled to the Section 271(e)(1) safe harbor. Pet. App. 53a-57a. The majority's construction of the safe harbor as "limited to pre-approval activities," she stated, is "contrary to the plain language of the statute and Supreme Court precedent." *Id.* at 53a. Observing that this Court in *Merck* "repeatedly underscored the breadth of [Section 271(e)(1)'s] text," Judge Moore concluded that "the safe harbor extends to *all* uses that are reasonably related to submitting *any* information under the FDCA, including information regarding post-approval uses." *Id.* at 54a.

Judge Moore explained, however, that her reading of Section 271(e)(1) "dispose[d] of only some of the allegations against [petitioner]"—those involving petitioner's reporting of information to the CDC. Pet. App. 55a-56a. Respondent also accused petitioner of infringement through "the administration of vaccines according to the patented method[s]." *Id.* at 56a

(quoting Am. Compl. para. 27). Judge Moore concluded that, because petitioner was not required "by law or regulation" to conduct those vaccinations, such conduct did not come within the safe harbor. *Ibid.*

5. In August 2012, after the Court invited the Solicitor General to express the views of the United States in this case, the Federal Circuit issued its decision in *Momenta Pharmaceuticals, Inc.* v. *Amphastar Pharmaceuticals, Inc.*, 686 F.3d 1348 (2012). In *Momenta*, a divided panel ruled that "the plain language of [Section 271(e)(1)] is not restricted to pre-approval activities." *Id.* at 1358-1359. The panel concluded that "post-approval studies that are 'reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs' fall within the scope of the [Section] 271(e)(1) safe harbor." *Id.* at 1359.

In so holding, the court of appeals in *Momenta* distinguished its decision in this case as standing only for the proposition that Section 271(e)(1)'s safe harbor "does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained." 686 F.3d at 1357-1358 (quoting Pet. App. 27a). According to the *Momenta* majority, the court of appeals' decision in this case "did not turn" on any "artificial distinction" between pre- and post-approval activities. *Id.* at 1358. Chief Judge Rader, dissenting in *Momenta*, argued that the panel had misconstrued the reasoning of its prior decision in this case and had "come out the exact opposite way." *Id.* at 1368. On November 20, 2012, the Federal Circuit denied rehearing en banc in *Momenta*. See 2012-1062 Docket entry No. 86.

DISCUSSION

The court of appeals erred in stating that Section 271(e)(1)'s safe harbor encompasses only activities undertaken to obtain the FDA's pre-marketing approval of generic products. Congress not only contemplated that drug manufacturers would conduct post-approval scientific studies and clinical trials, but specifically authorized the FDA to require such studies in a variety of circumstances. If such post-approval studies involve the use of patented inventions solely for uses reasonably related to the development and submission of information to the FDA, the plain language of Section 271(e)(1) precludes any claim for patent infringement.

Nevertheless, there is no longer any practical need for this Court's intervention in light of the Federal Circuit's subsequent decision in *Momenta Pharmaceuticals, Inc.* v. *Amphastar Pharmaceuticals, Inc.*, 686 F.3d 1348 (2012). The court in *Momenta* adopted a narrowing construction of the ruling below and held that post-approval studies performed for the FDA "fall within the scope of the [Section] 271(e)(1) safe harbor," *id.* at 1359. In addition, this case would provide a poor vehicle for the Court to consider the application of Section 271(e)(1) to post-approval activities, both because it is unclear whether Section 271(e)(1) applies to patented research methods, and because petitioner is not entitled to the safe harbor even under a proper reading of that provision. Further review therefore is not warranted.

1. Section 271(e)(1) shields from patent-infringement liability any use of 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). Although "the contours of this provision are not exact in every respect," the statutory language "makes clear that it provides a wide berth for the use of patented [inventions] in activities related to the federal regulatory process." *Merck KGaA* v. *Integra Lifesciences I, Ltd.*, 545 U.S. 193, 202 (2005). In particular, it is "apparent from the statutory text" that Section 271(e)(1)'s safe harbor "extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA." *Ibid.* "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." *Ibid.*

The court below nevertheless declared that the statutory safe harbor is "limited to activities conducted to obtain pre-marketing approval of generic counterparts of patented inventions, before patent expiration." Pet. App. 27a. That was error. As this Court recognized in *Merck*, the statutory text contains no such limitation. Nothing in the language of the statute links the availability of Section 271(e)(1)'s safe harbor to the timing of FDA marketing approval. See *Merck*, 545 U.S. at 206 ("Congress did not limit [section] 271(e)(1)'s safe harbor to the development of information for inclusion in a submission to the FDA.").

Nor does anything in the statutory text limit the safe harbor to information related to generic drugs. See *Merck*, 545 U.S. at 206 ("Congress did not * * * create an exemption applicable only to the research relevant to filing an ANDA for approval of a generic drug."). Indeed, the Court in *Merck* applied

the safe harbor provision to experiments that produced the type of information required for the FDA's consideration of new (rather than generic) drug applications. See *id.* at 208. In *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661 (1990), the Court likewise held that Section 271(e)(1) protects research activities related not only to drugs, but also to medical devices, which are also regulated under the FDCA. See *id.* at 673-674. This Court's decisions in *Merck* and *Eli Lilly* leave no room for the court of appeals' belief that Section 271(e)(1) protects only the "development of information for regulatory approval of generic counterparts of patented products." Pet. App. 27a.

2. The court of appeals' conclusion that Section 271(e)(1)'s safe harbor protects only pre-approval activities is especially misguided because Congress expressly contemplated that, in a variety of circumstances, drug manufacturers will conduct post-approval research and will submit the results to the FDA, either on their own initiative or in compliance with FDA requirements. Although it may be more difficult in the post-approval context to determine whether a defendant's use of a patented invention was "*solely* for uses reasonably related to the development and submission of information" to the FDA, 35 U.S.C. 271(e)(1) (emphasis added), nothing in the statutory text warrants the court of appeals' categorical exclusion of post-approval activity from the safe harbor.

a. In some circumstances, Congress has authorized the FDA to require manufacturers to conduct post-approval scientific studies or clinical trials. For example, if a manufacturer proposes a new drug for the treatment of a serious or life-threatening medical condition for which existing treatments are inadequate,

the FDA may designate the drug for "fast track" review. See 21 U.S.C. 356; 21 C.F.R. 314.500. If preliminary indicia of safety and effectiveness are present, the FDA may approve the drug for marketing on an expedited basis, "subject to" a requirement that the manufacturer "conduct appropriate post-approval studies" to "validate" the drug's safety and effectiveness. 21 U.S.C. 356(b)(2)(A). Similarly, if the FDA determines that an existing drug would offer a meaningful therapeutic benefit to children if it were appropriately labeled for pediatric uses, the agency may order the manufacturer to submit "data * * * that are adequate * * * to assess the safety and effectiveness of the drug" in children, including appropriate dosing regimens. 21 U.S.C. 355c(a)(2)(A).

The FDA may also require post-approval studies and clinical trials to determine whether, in light of new safety-related information, existing drugs should be withdrawn from the market or should carry different or more prominent warnings. See 21 U.S.C. 355(e) (authorizing Secretary to withdraw approval based on "new evidence" that drug is not safe for use); 21 U.S.C. 355(o)(4)(A) and (E) (Supp. V 2011) (authorizing Secretary to require "a labeling change as the Secretary deems appropriate to address" new safety information). Manufacturers have both business and legal incentives to respond voluntarily to reports of unexpected safety problems with their products. Those that undertake studies and clinical trials to investigate safety-related issues must file periodic reports with the FDA describing their investigations. 21 U.S.C. 355(o)(3)(E)(ii) (Supp. V 2011). But if the FDA becomes aware of new safety information indicating that a drug poses a serious risk to human

health, it may require the manufacturer to undertake post-approval studies and clinical trials if the manufacturer fails to do so voluntarily. 21 U.S.C. 355(o)(3)(A) (Supp. V 2011); see 42 U.S.C. 262(a)(2)(D) (Supp. V 2011). Since 2008, the FDA has used this authority to require 249 post-approval safety studies or clinical trials, based on new information or other reasons. See FDA, Postmarket Requirements and Commitments, http://www.accessdata.fda.gov/scripts/cder/pmc/index.cfm (database last updated Nov. 2, 2012).

Drug manufacturers voluntarily conduct post-approval scientific studies or clinical trials in other circumstances as well. For example, manufacturers conduct such studies in order to prepare "supplemental" new drug applications—applications for the FDA's approval to change the formulation, manufacturing method, or labeling of a drug. See 21 C.F.R. 314.70(b). Such applications are used when a manufacturer seeks the FDA's approval of a new indication of an already approved drug. The FDA evaluates such applications under the same standards that apply to a completely new drug. Thus, drug makers must justify the proposed label change by submitting data from clinical trials supporting the safety and effectiveness of the drug for the new indication. 21 U.S.C. 355(a) and (d); 21 C.F.R. 314.70(b)(3)(iv)-(v). At any given time, a drug maker therefore may be conducting clinical trials for a drug and submitting the resulting information to the FDA, even though the FDA has previously approved the same drug to be marketed for a different medical indication.

The FDCA thus unambiguously contemplates that drug manufacturers will conduct post-approval scientific studies or clinical trials for the purpose of devel-

oping and submitting information about their products to the FDA. Such post-approval studies serve the same essential function in the federal regulatory process—ensuring the safety and effectiveness of the drugs consumed by the American public—as the pre-approval activities that the court of appeals recognized are shielded by Section 271(e)(1). When the post-approval development and submission of information to the FDA requires the use of a patented invention, Section 271(e)(1) insulates that research from liability for patent infringement.

b. The court of appeals identified nothing in the statutory text that would justify the court's categorical ruling to the contrary. Instead, it rested its interpretation principally on the legislative history of Section 271(e)(1). The court emphasized that the history is "replete with statements that the legislation concerns premarketing approval of generic drugs." Pet. App. 27a; see *id.* at 27a-28a.

That observation is true but is unsurprising. As this Court recognized in *Eli Lilly*, a principal object of the Hatch-Waxman Act was to eliminate "distortions" caused by the interaction of the patent laws with the requirement of FDA pre-marketing approval for generic drugs. 496 U.S. at 669. The legislative history of Section 271(e)(1) therefore focuses on the safe harbor's expected role in facilitating market entry by generic drug manufacturers. See, *e.g.*, H.R. Rep. No. 857, 98th Cong., 2d Sess. 15 (1984). In addition, the purpose of the safe harbor is to immunize conduct *that would otherwise constitute patent infringement*. The practical value of Section 271(e)(1) therefore is likely to be greatest in the context of efforts by generic drug manufacturers to obtain FDA approval for generic

versions of *other* companies' patented drugs. By contrast, because a brand-name manufacturer's performance of additional studies on its *own* approved drug is less likely to spawn allegations of patent infringement, the question whether such conduct falls within the safe harbor may have less practical significance.

As this Court also recognized in *Eli Lilly*, however, "[i]t is not the law that a statute can have no effects which are not explicitly mentioned in its legislative history." 496 U.S. at 669 n.2 (citation omitted). Indeed, as the dissent below observed, "[n]one of the legislative history cited by the majority * * * speak[s] to the question at issue here—whether the statute as enacted also covers post-approval activities." Pet. App. 55a. On that question, "[t]he language Congress chose to enact and that was signed into law by the President is plain on its face. There is no 'pre-approval' limitation." *Ibid.* And "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).

c. Although the court of appeals grounded its holding in the legislative history rather than in the statutory text, respondent focuses (Br. in Opp. 9-10) on the statutory term "solely" in defending the court of appeals' limitation of the safe harbor provision to pre-approval activities. In respondent's view, once a drug maker has obtained the FDA's approval to market a drug, any post-approval scientific study concerning that drug cannot be "solely" for purposes related to the development and submission of information to the FDA because the drug maker is also engaged in the ordinary commercial distribution of the drug. That

argument rests on a misinterpretation of the safe harbor provision.

Section 271(e)(1) states that "[i]t 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 federal laws regulating drugs. 35 U.S.C. 271(e)(1). The word "solely" indicates that, in applying the safe harbor, the court should focus on the particular "use[]" that is alleged to be an "act of infringement." A particular "use[]" may be "reasonably related to the development and submission of information," and therefore may fall within the safe harbor, even if it serves other purposes as well. Thus, a researcher's use of a patented invention in conducting an experiment reasonably related to the development and submission of information to the FDA is protected by Section 271(e)(1), even if that experiment also advances other commercial objectives, such as product development. See *Abtox, Inc.* v. *Exitron Corp.*, 122 F.3d 1019, 1030 (Fed. Cir. 1997). By contrast, if a defendant makes multiple "uses" of a patented invention (*e.g.*, by selling a patented drug commercially while simultaneously administering it to research subjects during a controlled study), one "use[]" may provide a basis for infringement liability even though the other falls within the safe harbor. See p. 18, *infra*.

In the pre-approval context, determining whether a defendant's use of a patented invention in drug-development research was "solely for uses reasonably related to the development and submission of information" to the FDA will normally be a straightforward inquiry. In the post-approval context, that in-

quiry may be substantially more difficult because the drug maker simultaneously may be engaged in the ordinary commercial manufacture and sale of the product in question. In such circumstances, a more nuanced analysis is required. A drug maker's use of a patented invention in routine commercial activity is not immune from infringement liability merely because, for example, the company may periodically report adverse reactions to the FDA. See 21 C.F.R. 314.80 and 600.80. That is because the ordinary commercial exploitation of a patented invention is not "reasonably related to the development and submission of information" for the FDA, even if such exploitation sometimes generates information useful to the FDA. That conclusion is reinforced by the ordinary meaning of the statutory term "development," which implies more than merely the collection of information incidental to commercial transactions.

In some cases, however, post-approval research activities will fall squarely within the ambit of Section 271(e)(1). If the FDA has approved a drug for acne, for example, and its manufacturer separately conducts a clinical trial of the same drug as a treatment for melanoma, the clinical trial (but not the routine sales of the drug for acne treatment) will be protected under the plain terms of the statute. Likewise, if the FDA directs a manufacturer to conduct a clinical trial of a blood pressure drug to determine whether a different dosing regimen would mitigate dangerous side effects of which the agency recently became aware, see 21 U.S.C. 355(o)(3)(A) (Supp. V 2011), that research will be protected from infringement claims by Section 271(e)(1).

3. Although the court of appeals erred in its interpretation of Section 271(e)(1), this Court's review is not warranted. The Federal Circuit has subsequently interpreted the opinion below narrowly in a manner that will cabin the adverse impact of that decision. It is unclear, moreover, whether Section 271(e)(1) applies to patented research methods like those at issue here. Finally, notwithstanding its cramped understanding of the safe harbor, the court of appeals reached the correct result in this case.

a. Although the decision below appeared seriously to misconstrue Section 271(e)(1), the Federal Circuit has since clarified that its ruling in this case does not limit application of the safe harbor provision to pre-approval activities relating to the marketing of generic drugs. After the Court invited the Solicitor General to express the views of the United States in this case, the court of appeals recognized that "the plain language of [Section 271(e)(1)] is not restricted to pre-approval activities." *Momenta*, 686 F.3d at 1358-1359; see *id.* at 1359 ("[P]ost-approval studies that are 'reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs' fall within the scope of the [Section] 271(e)(1) safe harbor."). The court of appeals explained that its decision in this case "did not turn" on any "artificial distinction" between pre- and post-approval activities. *Id.* at 1358. Instead, that decision held only that Section 271(e)(1)'s safe harbor "does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained." *Id.* at 1357-1358 (quoting Pet. App. 27a).

The *Momenta* court's interpretation of the opinion below is not the most natural reading. Nevertheless, the Federal Circuit has authoritatively construed its earlier decision and has held, as a matter of controlling circuit precedent, that Section 271(e)(1) is not limited to pre-approval activities for generic drugs. See *Momenta*, 686 F.3d at 1358-1359 ("[T]he plain language of the statute is not restricted to pre-approval activities."); *id.* at 1355; see also 2012-1062 Docket entry No. 86 (Fed. Cir. Nov. 20, 2012) (denying petition for rehearing en banc). The court of appeals has thus correctly recognized that, if "the use of the patented invention is done to generate information that will be submitted pursuant to a relevant federal law, that use falls within the safe harbor." *Momenta*, 686 F.3d at 1360.[4] Accordingly, no practical reason remains for this Court's intervention.

b. It is an open question whether Section 271(e)(1) applies at all to patented research methods of the kind at issue in this case. Although Section 271(e)(1) on its face encompasses any "patented invention," it is unclear whether Congress intended to shield drug makers from claims of infringement concerning patented research tools—*i.e.*, devices, substances, or processes, such as laboratory test equipment or methods of chemical analysis, that are used to study *other* sub-

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[4] The *Momenta* court additionally held that, for purposes of Section 271(e)(1), 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. See 686 F.3d at 1357. We express no view on the correctness of that conclusion or of the court of appeals' ultimate disposition of *Momenta*.

stances in order to generate useful information. The Court in *Merck* specifically reserved that question. 545 U.S. at 205 n.7. And the Federal Circuit has since held that Section 271(e)(1) does not exempt from infringement claims the use of a patented research apparatus. See *Proveris Scientific Corp.* v. *Innovasystems, Inc.*, 536 F.3d 1256, 1265-1266 (2008). Respondent could defend the court of appeals' judgment on that alternative ground, see, *e.g.*, *Bennett* v. *Spear*, 520 U.S. 154, 166 (1997), and resolution of that threshold question in respondent's favor would obviate the need (and the opportunity) for the Court to decide the question presented.

c. Finally, even under a proper construction of Section 271(e)(1), the court of appeals did not err in reversing the district court's safe harbor ruling.[5] The district court believed that the safe harbor barred any claim for patent infringement predicated on petitioner's "participation" in the 2001 CDC study. Pet. App. 63a-64a. That study, however, involved only an after-the-fact examination by CDC scientists of the vaccination records and medical histories of children who had received vaccines (including petitioner's vaccine) in the ordinary course of their medical care. See C.A. App. A220-A225 (CDC study). Although the CDC scientists' evaluation was a use "reasonably related to the development and submission of information" to the FDA, petitioner "participated" in the study only in the sense that, by manufacturing and selling the ad-

[5] Because petitioner has not sought review of the court of appeals' holding that the '139 and '739 patents are valid, the United States assumes for present purposes that the patents are directed to patent-eligible subject matter under 35 U.S.C. 101. See pp. 6-7, *supra*.

ministered vaccines as part of its regular business, it generated data that the CDC later examined. The fact that public health authorities ultimately gathered data about those sales does not mean that petitioner's alleged infringement of respondent's patents retroactively became "reasonably related to the development and submission of information" under the FDCA.

The court of appeals' unanimous ruling that respondent's '283 patent is invalid under 35 U.S.C. 101, see Pet. App. 20a-22a; *id.* at 40a-50a, makes it particularly unlikely that a decision of this Court clarifying the proper application of Section 271(e)(1) would affect the ultimate disposition of this case. Because the methods claimed in the '283 patent did not require the step of actually immunizing a patient, respondent could plausibly contend that petitioner had infringed that patent simply by evaluating the pertinent medical evidence in order to determine appropriate dosing regimens. See *id.* at 25a. The court of appeals held the '283 patent invalid, however, precisely because it claimed only "the abstract principle that variation in immunization schedules may have consequences for certain diseases," without "any movement from principle to application." *Id.* at 21a.

All of the other patents asserted in this litigation require, as the final step of the claimed methods, the actual immunization of a patient. See '139 patent claim 1; '739 patent claim 1; '790 patent claim 1. In order to establish petitioner's liability for infringing those patents, respondent must prove, *inter alia*, either that petitioner performed actual immunizations, or that it induced doctors and hospitals to do so. See 35 U.S.C. 271(b) and (c). Respondent's amended complaint alleged that petitioner had infringed respond-

ent's patents "through the manufacture and supply of vaccines * * * and by administration of vaccines according to the patented method." C.A. App. A72 (Am. Compl. para. 27); see Pet. App. 56a (Moore, J., dissenting).

That allegation, which asserts that petitioner infringed the patented methods in the routine conduct of its business, does not implicate Section 271(e)(1). If petitioner or others provided actual immunizations to patients (as opposed to research subjects) in the course of performing respondent's claimed methods, those "uses" of the patented invention were not "reasonably related to the development and submission of information under" the federal drug laws. 35 U.S.C. 271(e)(1). As the dissent below explained, "[t]he fact that [petitioner] would have to report to the FDA any adverse reaction after administering a vaccine does not mean that the administration itself is noninfringing." Pet. App. 56a-57a.

Thus, if respondent can ultimately prove the facts alleged in its complaint, and if those facts would otherwise support a determination that petitioner infringed the patents that remain at issue in this case, Section 271(e)(1) would not insulate petitioner from liability. This case therefore would not provide the Court with the opportunity to interpret Section 271(e)(1) against the backdrop of a genuine claim of entitlement to the protection of the statutory safe harbor.

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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DECEMBER 2012