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

BRIEF IN OPPOSITION

JOSEPH J ZITO
Counsel of Record
ZITO, *tlp*
1250 Connecticut Ave., NW
Suite 200
Washington, DC 20036
(202) 466-3500
joe@zitotlp.com

Counsel for Plaintiff
CLASSEN
IMMUNOTHERAPIES, INC.

242030

COUNSEL PRESS
(800) 274-3321 • (800) 359-6859

QUESTION PRESENTED

Whether the United States Court of Appeals for the Federal Circuit's interpretation of 35 U.S.C. § 271(e)(1) is faithful to the statutory text, the legislative history evidencing Congress' intent and the policies underlying the Patent Law.

PARTIES TO THE PROCEEDING AND RULE 29.6 CORPORATE DISCLOSURE STATEMENT

Petitioner is GlaxoSmithKline LLC (GSK). 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, Respondent Classen Immunotherapies, Inc., states that there is no parent or publicly-held company owning more than 10% of the corporation's stock.

TABLE OF CONTENTS

Table of Contents

TABLE OF CITED AUTHORITIES

Page

CASES

STATUTES AND REGULATIONS

Page

OTHER AUTHORITIES

STATEMENT OF THE CASE

I. Background of the Case

This civil action for patent infringement was brought by Respondent Classen Immunotherapies, Inc., the owner by assignment from Dr. John Barthelow Classen, of the two original United States Letters Patent Numbers 6,420,139 and 6,638,739, which remain in the case, and 7,008,790 which was added to the case by Respondent by a Second Amended Complaint filed with the District Court on February 3, 2012 ("the Classen Patents"). Petitioner Glaxo Smithkline is a pharmaceutical company engaged in licensing, manufacturing, using, offering for sale, and selling hepatitis B and other vaccines for human use, under the brand names: ENGERIX-B and RECOMBIVAX and other names.

Each of the patents at issue is based upon the research of John Barthelow Classen, M.D. Each patent claims priority to the Classen patent application Serial Number 08/104,529 filed on August 12, 1993. Dr. Classen's research led him to invent a novel "Method and Composition for an Early Vaccine to Protect Against Both Common Infectious Diseases and Chronic Immune Mediated Disorders or Their Sequelae." Dr. Classen's efforts were then, and continue to be, directed toward increasing awareness of the risks associated with different immunization schedules, and the extent to which those schedules do or do not contribute to the development of chronic immune-mediated disorders, such as diabetes, in patients. Dr. Classen developed techniques for reducing risks associated with different immunization schedules and patented these techniques in the form of the therapeutic

methods of use claimed in the patents in suit, in particular those covering improved, safer methods of using vaccines to avoid inducing the development of chronic immune-mediated disorders.

Dr. Classen widely disseminated the findings and conclusions of his research, hoping to bring greater awareness to the need for long term studies of the effects of immunization. Dr. Classen published numerous articles, letters, and papers which explain and document the discoveries which led to his invention. The papers include:

> "The Timing of Pediatric Immunization and the Risk of Insulin-Dependent Diabetes Mellitus" co-authored with David Classen, MD and published in *Infectious Diseases Clinical Practice* in 1997 (A330-335)[1]; and "The timing of Immunization Affects the Development of Diabetes in Rodents" published in *Autoimmunity* in 1996 (A336-A344).

Dr. Classen discovered that benefits could be realized through the administration of vaccines according to different immunization schedules and invented the patented methods for achieving these benefits.

Dr. Classen and his work on immunization risks, which was aired by ABC on World News Tonight (A226-A227), fueled a debate in the medical community

---

1. References to "A_____" are citations to documents found in the Federal Circuit Joint Appendix in *Classen Immunotherapies, Inc. v. Biogen Idec,* 659 F.3d 1057 (Fed. Cir. 2011)(JA)

which has included the Defendants as well as The National Immunization Program of the Centers for Disease Control and Prevention, The National Institutes of Allergy and Infectious Diseases, and The Vaccine Education Center of The Children's Hospital of Philadelphia, as well as many physicians and clinical researchers (e.g., A217-A219 and A220-A225 and A228-A245 among others). The Defendants have sponsored and conducted many studies and evaluations to test Dr. Classen's work and evaluate the risks and benefits associated with vaccine schedules (A392-A397). The Defendants have also sponsored meetings and publications to disseminate these findings (A385A465 and A469-A474).

Dr. Classen developed techniques for reducing risks associated with immunization and patented these techniques in the form of methods of immunization claims in the patents in suit. Dr. Classen has not developed any vaccines. Dr. Classen invented methods for reduction of the risks associated with immunization.

A. The Patent Claims

The '139 and '739 patents include a total of 183 claims. The claims of the '139 and '739 patents cover a routine method of therapeutic use and are directed to "immunizing a mammalian subject." They recite two method steps: (I) screening two or more immunization schedules; and (II) immunizing according to the lower risk schedule. The '790 Patent has 213 claims directed to methods of immunization and compositions therefor, which provide for substantially preventing or reducing the symptoms of at least one infectious disease and at least one chronic immune mediated disorder, and recite three

method steps: (I) considering the association between an immunization schedule and one or more chronic immune-mediated disorder, (II) screening one or more potential recipients, and (III) immunizing according to the lower-risk schedule.

The patent claims pertain to "risk evaluation" which is the *possibility* of causation not *proof* of causation. In order to infringe the claims of the Classen Patents, the infringer need only assess the risk, step (I). It is not necessary for the infringer to conduct its own clinical trials or to prove the cause of any risks. It is also not necessary for an infringer to change its recommended schedule after assessment of risks. If the risk assessment demonstrates that the current schedule is the low risk schedule, maintenance of the current schedule is step (II) of the Classen method. If the comparing step occurs before the immunization step, the patent covers a routine therapeutic method of use. If the comparing step occurs after the immunization step, then the patent covers what may be called a "research tool."

B. The Accused Activities

The Respondents participated in, facilitated, conducted and/or otherwise used the results of many studies (e.g., A398-463), including a prominent study published in Pediatrics, in December of 2001, by Frank DeStefano, M.D., entitled *Childhood Vaccinations, Vaccination Timing and Risk of Type I Diabetes Mellitus* (A221-A225), to evaluate the correlation between vaccination schedules and the incidence of chronic immune mediated disorders so that various schedules could be screened to determine a preferred schedule for immunization.

Petitioner Glaxo Smithkline contributes to, induces, and infringes the Classen Patents by participating directly and indirectly in clinical studies, by the manufacture and supply of vaccines, by providing instructions and/or recommendations and or literature for physicians to review and recommendations for proper immunization schedules for vaccines, and by the administration of vaccines according to the patented method. The alleged infringements by the Petitioner occurred long after the vaccines in question received marketing approval from the United States Food and Drug Administration ("FDA"). Therefore, this case is not about INDs (investigational new drug application), NDAs (new drug application), or ANDAs (abbreviated new drug application) or submission of clinical data to the FDA for purposes of obtaining marketing approval. This case is not about the use of drugs in clinical tests. It is not about pre-clinical or clinical testing and is not about drug development "tools." It is not about generic drugs and brand name drugs. Nor is it about barriers to market entry or about drug competition. This case is not about safe harbors during the development of a drug or any of the other issues or policies implicated by the Hatch-Waxman Act.

II. The Federal Circuit's Interpretation of § 271(e)(1) Should Be Upheld

As a result, the Court should deny review and let the Federal Circuit's decision in this case to stand, because its interpretation and application of 35 U.S.C. § 271(e)(1) are faithful to the statutory language, the legislative history which evidences Congress' intent, and the policies underlying the patent law. The Federal Circuit correctly held that the safe harbor to patent infringement provided

by § 271(e)(1) is narrow in scope and limited to otherwise infringing uses of the patented invention that occur prior to a new or generic drug obtaining marketing approval from the FDA. The Federal Circuit's holding in this case is faithful to the language of § 271(e)(1), because the only uses of a patented invention by new or generic drug manufacturers that are "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 . . ." must occur prior to the date on which the FDA approves the drug for commercial marketing. Neither Petitioner nor Amicus Pharmaceutical Researchers and Manufacturers of America ("PRMA") can point to a single post-marketing-approval regulatory or statutory requirement that can be complied with by using a patented invention "*solely* for uses reasonably related" to the development and submission of information under Federal law to a federal agency. That is because the manufacture, use, and sale of a drug after it has been approved for marketing are primarily for commercial profit and cannot, almost by definition, be "*solely* for uses reasonably related" to compiling information required by a statute or FDA regulation.

As the legislative history of § 271(e)(1) sets forth in clear detail, Congress intentionally inserted the "solely reasonably related" language into the Hatch-Waxman Act in order to delineate the boundaries of the safe harbor to patent infringement that it wanted to carve out for individuals or companies who were performing research directed to obtaining FDA approval for a pharmaceutical drug. Congress intended that the safe harbor apply only to otherwise infringing activities that took place during the time period prior to the date on which a pharmaceutical drug receives marketing approval from the FDA for it

to be sold commercially. Congress expressed this intent, and this clear temporal delineation, through the "*solely* for uses reasonably related" language set forth in the statute. Petitioners would have the Court read the "solely" language out of the statute and focus instead on the "uses reasonably related" component.

This action would dramatically expand the statute's scope beyond Congress's intent and what any reasonable interpretation of the language would support. If Petitioner's and Amicus PRMA's interpretation of § 271(e)(1) were adopted by this Court, it would completely eviscerate the patent right enshrined in the United States Constitution in the field of pharmaceutical and medical device patents. Since, as pointed out by Petitioner and Amicus PRMA, there are many statutory and regulatory requirements for pharmaceutical drug and medical device manufacturers to comply with after FDA marketing approval for a drug or device has been obtained, extending § 271(e)(1) to encompass uses of a patented invention to comply with those requirements would provide 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, whichever expired first. To hold that owners of patents on pharmaceutical drugs or, in the case of the Classen patents, methods of treating patients using those drugs, cannot exercise their Constitutional and statutory rights under the patent laws to exclude infringers from making, using, or selling their inventions or inducing or contributing to infringement by others, as Petitioner and Amicus PRMA advocate, would be unprecedented. No reasonable reading of § 271(e)(1) would support such an extreme result.

ARGUMENT

I. The Federal Circuit's Interpretation of § 271(e)(1) Is Consistent with This Court's Precedents, the Statutory Text, and the Legislative History

This Court should deny certiorari and let the Federal Circuit's decision in this case stand. The Federal Circuit's interpretation of 35 U.S.C. § 271(e)(1) is consistent with the plain meaning of the statutory language and is consistent with Congress' intent to provide a very narrow exception to patent infringement in cases where an otherwise infringing use of a patented invention is *solely* for purposes of developing information that would be used to obtain marketing approval for a new or generic drug from the FDA. The Federal Circuit's interpretation of § 271(e)(1) is also fully consistent with this Court's prior decisions in *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661 (1990), and *Merck KGaA* v. *Integra Lifesciences I, Ltd.*, 545 U.S. 193 (2005). As set forth in more detail below, both Petitioner and Amicus PRMA mischaracterize the import of those two seminal cases to the Federal Circuit's interpretation of § 271(e)(1). When their true import is revealed, they fully support the Federal Circuit's statutory interpretation, leaving no precedent to support Petitioner and Amicus PRMA's position.

A. The Federal Circuit's Interpretation Comports with the Plain Language of This Provision and This Court's Precedents

The Federal Circuit properly limited the safe harbor provided by § 271(e)(1) to uses of the patented invention that are *solely* directed to activities reasonably related

to obtaining approval from the FDA to market generic drugs prior to the expiration of the patent in question. The whole purpose of the Hatch-Waxman Act is to provide a simplified and expedited process for generic drug manufacturers to use a patented invention to compile required bioequivalency data and obtain FDA premarketing approval for their generic drug prior to the expiration of the patent covering the brand-name drug that the generic drug would compete with. To narrow the scope of the safe harbor provided by § 271(e)(1) so that it was consistent with this express purpose of the Hatch-Waxman Act, Congress inserted the language "*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 . . ." (emphasis added).

The word "solely" is of critical importance to the Federal Circuit's interpretation of this provision. In this context "solely" is commonly understood to mean "for no other purpose." The only time that a drug may be made and used "solely," or for no other purpose than to obtain regulatory approval for a pharmaceutical drug, is in the premarketing phase of its development, as the Federal Circuit correctly understood. After a drug is approved by the FDA to be marketed, the purpose of any use of the drug shifts from an experimental or investigative purpose covered by § 271(e)(1) to a predominantly commercial and profit-seeking business purpose that is not (and cannot be) "*solely*" reasonably related to developing information to comply with a Federal law, as required by the statute. *Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1265 (Fed. Cir. 2008) (excluding commercial activity from the safe harbor). The Petitioner's and Amicus PRMA's arguments, which extend the safe harbor

of § 271(e)(1) forward into the postmarketing approval period, would by necessity require that the term "solely" be read out of § 271(e)(1). Tellingly, nowhere in the Petition for Certiorari or in Amicus PRMA's Brief do they explain how extending the safe harbor of § 271(e)(1) into the postmarketing approval period would be consistent with the use being "solely" reasonably related to the development and submission of information required by Federal law. The fact is it would not.

Undaunted, Petitioner and Amicus PRMA argue extensively that this Court's decisions in *Eli Lilly* and *Merck v. Integra* held that the § 271(e)(1) safe harbor is not, and should not be, limited to the premarketing period. However, as the Federal Circuit correctly found, that position is false. Nonetheless, Petitioner and Amicus PRMA persist in mischaracterizing the import of *Eli Lilly* and *Merck v. Integra* to this case. As the Federal Circuit in this case realized, every controlling decision examining the statute has appreciated that § 271(e)(1) is directed to premarketing approval of new drugs or generic counterparts before patent expiration. This Court even applied this limitation to medical devices in *Eli Lilly,* 496 U.S. at 671, stating that § 271(e)(1) "allows competitors, prior to the expiration of a patent, to engage in otherwise infringing activities necessary to obtain regulatory approval."

The Court stated in *Eli Lilly & Co.* that activities "could not constitute infringement if they had been undertaken to develop information reasonably related to the development and submission of information necessary to obtain regulatory approval under the [Food, Drug, and Cosmetic Act]." *Id.* at 664. The Court went on to explain

that "the [Hatch-Waxman] Act 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." *Id.* at 669. The first "distortion" was the exhaustion of patent life while the patentee was obtaining regulatory approval by procedures that usually consumed several years. The second distortion was that would-be competitors experienced delay in market entry while obtaining regulatory approval for their generic counterparts after patent expiration. The Hatch-Waxman Act remedied both distortions, striking a careful balance that is embodied in the statute and reflected throughout this Court's and the Federal Circuit's precedent.

In *Merck KGaA* this Court again analyzed the statutory purpose and held that § 271(e)(1) applies to pre-approval and pre-marketing activities using a patented drug to compile information in anticipation of an IND and an NDA to be submitted to the FDA:

> We decline to read the "reasonable relation" requirement so narrowly as to render § 271(e)(1)'s stated protection of activities *leading to FDA approval* for all drugs illusory. Properly construed, § 271(e)(1) leaves adequate space for experimentation and failure *on the road to regulatory approval*: At least where a drugmaker has a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the

> FDA, that use is "reasonably related" to the "development and submission of information under . . . federal law."

545 U.S. at 207 (emphasis added). The Court further held that preclinical research, whether or not ultimately included in a submission to the Food and Drug Administration, is exempted from infringement by § 271(e)(1) "as long as there is a reasonable basis for believing that the experiments will produce 'the types of information that are relevant to an IND or NDA.'" *Id.* at 208 (quoting Brief for United States as *Amicus Curiae* 23). No mention was made anywhere in the opinion as to whether post-approval activities would be covered by § 271(e)(1).

In contrast, the Biogen and Glaxo activities charged with infringement in this case are not related to producing information for an IND or NDA and are not a "phase of research" possibly leading to marketing approval. All of the accused-infringing activities occurred long after FDA approval was obtained for the drugs that form the basis of the vaccines in question. As if to remove any doubt, *Merck* was specifically limited to preclinical uses:

> This case presents the question whether uses of patented inventions **in preclinical research**, the results of which are not ultimately included in a submission to the Food and Drug Administration (FDA), are exempted from infringement by 35 U.S.C § 271(e)1.

Merck at 195 (emphasis added). Therefore, contrary to Petitioner's and Amicus PRMA's false characterization of it, *Merck v. Integra* does not provide a § 271(e)(1) safe harbor for their postmarketing-approval activities.

Extensive and long-standing Federal Circuit precedent similarly recites the purpose of § 271(e)(1) to facilitate market entry upon patent expiration. *See, e.g., Warner-Lambert Co. v. Apotex Corp.*, 316 F.3d 1348, 1358 (Fed. Cir. 2003) ("[§ 271(e)(1)] enabled generic manufacturers to test and seek approval to market during the patent term"); *Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256, 1265 (Fed. Cir. 2008) (examining for purposes of the exemption whether the infringer is "seeking FDA approval for a product in order to enter the market to compete with patentees"). From this, there can be no dispute as to the statutory purpose behind § 271(e)(1), and there is no contrary precedent that supports the position of Petitioner and Amicus PRMA.

B. The Federal Circuit's Interpretation Is Consistent with Congress' Intent to Limit the Safe Harbor to Premarketing Activity

The Federal Circuit's interpretation of § 271(e)(1) is exactly consistent with Congress' stated intent to provide for a narrow safe harbor from patent infringement for experimental uses of a patented drug that are solely reasonably related to obtaining FDA approval. Section 271(e)(1) was not written for and does not protect any class of infringing activity for a drug after it has received final FDA approval and is on the market as a commercial drug. It is in this pre-approval activity that Congress encouraged, and therefore the "wide berth" repeatedly pointed to by Petitioner and Amicus PRMA is provided to protect only this activity. It is settled law that the legislative history of a statute is relevant to its interpretation. As Petitioner and Amicus PRMA concede, reports to Congress, as this Court has explained, may of course "aid the courts in

reaching the true meaning of the legislature in cases of doubtful interpretation." *Caminetti* v. *United States,* 242 U.S. 470, 490 (1917). 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).

The legislative history of § 271(e)(1) does not vary or contradict the language of the statute. It is instead essential to an understanding of what is meant by the critical phrase "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 . . ." in terms of its temporal scope, in the context of the structure, purpose, and operation of the Hatch-Waxman Act. The House Report explains that the Act "provides that it is not an act of patent infringement for a generic drug maker to import or to test a patented drug in preparation for seeking FDA approval if marketing of the drug would occur after expiration of the patent." H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 1, at 15 (1984), *reprinted in* 1984 U.S.C.C.A.N. 2647, 2648.

The Report is replete with statements that the legislation concerns premarketing approval of generic drugs. The Report emphasizes that "The information which can be developed under this provision is the type which is required to obtain approval of the drug." *Id.* at 45, 1984 U.S.C.C.A.N. at 2678. This purpose was emphasized throughout the legislative process: "The purpose of § 271(e)(1) and (2) is to establish that experimentation with a patented drug product, when the purpose is to prepare for commercial activity which will begin after a valid patent expires, is not a patent infringement." *Id*. Again in H.R. Rep. No. 857, 98th Cong., 2d Sess., pt. 2, at 8 (1984),

reprinted in 1984 U.S.C.C.A.N. 2686, 2692, the Report is explicit 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 Report states that "the generic manufacturer is not permitted to market the patented drug during the life of the patent; all that the generic can do is test the drug for purposes of submitting data to the FDA for approval." *Id.* at 30, 1984 U.S.C.C.A.N. at 2714. The activities of which Biogen and GlaxoSmithKline are accused by Respondent Classen cannot be stretched into this role, nor can any reasonable interpretation of § 271(e)(1) extend the safe harbor beyond it.

II. The Policies Underlying the Hatch-Waxman Act, the Patent Law, and the Public Interest All Support Denying Certiorari

Petitioner and Amicus PRMA point to several Federal statutory and regulatory provisions which require them to continue compiling information concerning their pharmaceutical drugs and submitting that information to the FDA and other governmental agencies. For instance, Petitioner and Amicus point to statutes and regulations such as 21 U.S.C. §§ 321(p) and 355(a) and (b)(2) and 21 C.F.R. § 310.3(h), which are directed to developing and submitting information concerning improvements on, or new uses of, already approved drugs, or new drug combinations including an already-approved drug. According to Petitioner and Amicus PRMA, these improvements may be directed to new dosing regimens or combination therapies. The FDA can also require manufacturers to conduct post-approval safety studies to ensure that a new drug does not have detrimental

effects. Under § 355, the FDA may require a holder of an approved NDA or Biological License Application (BLA) to conduct post-approval studies to "assess a known serious risk" related to the use of the drug involved, or to assess "signals" or a "potential" of risk concerning the drug. 21 U.S.C. § 355(o)(3)(B).

In addition, there may exist other 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 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). Finally, the reporting requirements under 21 C.F.R. § 600.80 for adverse events were mandated in 1994 by the FDA. This post-approval mandate to report "any adverse event associated with the use of a biological product in humans" occurs during commercial drug sales by the manufacturer.

However, nowhere does Petitioner or Amicus PRMA even attempt to explain to the Court how their post-approval compliance with these provisions would be "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 . . .," which is, of course, the legal standard that they must meet to be eligible for protection under the § 271(e)(1) safe harbor. That is because they simply cannot. This is

so, because during the period after the drug has been approved by the FDA, Petitioner, and the membership of Amicus PRMA are marketing their drugs commercially in order to maximize business profits. Therefore, their efforts to improve their drugs and comply with the various reporting requirements that they cite may be just as much attributable to their desire to create an even more safe, useful, saleable, and profitable product that the FDA and other regulatory agencies will allow to remain on the market, thus allowing the manufacturers, users and sellers of the drug to continue to profit. These post-approval uses cannot, either operationally or logically, be "solely" related to complying with the above-cited legal requirements.

The logical extension of Petitioner's and Amicus PRMA's safety and compliance policy argument would effectively eliminate all drug and medical device patents, and all patents claiming methods of using those drugs or devices for a therapeutic benefit. When drugs and medical devices are sold, data about adverse events are generated as a result of use, and the data are reported to the FDA. If the report is considered to be a post-approval "submission" activity, as Petitioner and Amicus PRMA advocate, the sale and use would then become "development" activity under their arguments. Section § 271 protects "use and sale of . . . a patented invention [the drug] . . . for uses reasonably related to the development and submission of information . . . ." Such sale and use would thus be transformed into the "development" activity protected by the safe harbor, when combined with the "submission" of an adverse event report, according to Petitioner and Amicus PRMA, even though it is all post-approval commercial activity. In light of this, Petitioner's

and Amicus PRMA's arguments amount to nothing more than a thinly-veiled attempt to shield virtually *all* of their post-approval use of a patented invention from *any* claim of patent infringement.

What Petitioner's and Amicus PRMA's arguments come down to in this regard is that the Court should extend the § 271(e)(1) safe harbor to post-approval statutory and regulatory compliance activities, because that would encourage the development of better, safer, and more beneficial drugs and medical devices for the consuming public. While it may be a good idea for Congress to pass a new law allowing freedom to infringe when safety or critical need is the concern, similar to the law excluding life-saving medical surgeries from infringement, 35 U.S.C. § 287(c), such a "safety first" law has yet to be proposed, much less passed. It would be inappropriate judicially to change § 271(e)(1) into such a law without Congressional action.

As noted above, Petitioner and Amicus PRMA dedicate a significant portion of their briefs to the need for judicial intervention here to allow drug manufacturers to perform important safety studies and make improvements on drugs which are already on the market. However, drug manufacturers are free to perform any such important studies, just like their counterparts in any other industry, subject to payment of reasonable royalties if patents cover such activities. Seatbelts and anti-lock brakes on cars provide vital safety, yet they are subject to patent licensing requirements. And the users of those technologies must respect an owner's patent rights. Research into new safety devices is also subject to patent rights, despite the fact that such activity is reported to the NHTSA. Manufacturing

processes and the research that goes into developing new and useful processes that produce safer materials for construction are subject to patent licensing, even though construction is highly regulated and reporting to the government is intensive. Underwriters Laboratories, for instance, reviews and approves all forms of electrical safety, yet patents that cover these products are not exempt from infringement. Just because something is good for the public does not mean that all of its patent rights should be stripped away, as Petitioner and Amicus PRMA argue here.

More importantly, neither Petitioner nor Amicus PRMA provides any guidelines for ascertaining when post-approval activity would be commercial, and therefore subject to patent infringement, and when the same activity would be solely for uses reasonably related to the development and submission of information, and thus protected. Neither Petitioner nor Amicus PRMA gives any examples of patents, or even the types of patents that would cover the proposed protected activities. There is no nexus set forth for the new test proposed, no factual explanation concerning where activities are protected and unprotected. If implemented, the § 271(e)(1) exception to claims of patent infringement would become the rule in the pharmaceutical industry. Petitioner's proposal is thus unworkable.

The Drug Price Competition and Patent Term Restoration Act, as currently written and properly interpreted and applied by the courts, is workable. The Act was specifically written for and properly addresses a subset of commercial activity, the launch of a new drug which requires an IND, NDA or ANDA filing. And it

addresses the two distortions created by this particular regulatory requirement. It would be wholly improper under these circumstances to expand the Drug Price Competition and Patent Term Restoration Act to cover all drug regulation or transform it into "The Drug Safety Testing Act," as Petitioner and Amicus PRMA argue.

CONCLUSION

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

Respectfully submitted this 23rd day of May 2012.

JOSEPH J ZITO
Counsel of Record
ZITO, *tlp*
1250 Connecticut Ave., NW
Suite 200
Washington, DC 20036
(202) 466-3500
joe@zitotlp.com

Counsel for Plaintiff
CLASSEN
IMMUNOTHERAPIES, INC.