

No. 13-1071

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IN THE  
**Supreme Court of the United States**

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BAXTER INTERNATIONAL INC.  
AND BAXTER HEALTHCARE CORPORATION,  
*Petitioners,*

*v.*

FRESENIUS USA, INC.  
AND FRESENIUS MEDICAL CARE HOLDINGS, INC.,  
*Respondents.*

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

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BRIEF FOR BIOTECHNOLOGY  
INDUSTRY ORGANIZATION AS  
AMICUS CURIAE SUPPORTING PETITIONERS

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## **QUESTION PRESENTED**

Whether an administrative decision of the U.S. Patent and Trademark Office (“USPTO”) cancelling patent rights nullifies a prior Federal District Court patent infringement award, which was mandated on appeal, simply because the scope of the post-verdict remedies remains to be finalized.

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## INTEREST OF AMICUS CURIAE

The Biotechnology Industry Organization (“BIO”) is the world’s largest biotechnology trade association, representing over 1,100 companies, academic institutions, and biotechnology centers in all 50 states and in countries spanning the globe.<sup>1</sup> BIO members are actively involved in cutting edge research and development of biotechnology products.

At its simplest, biotechnology is technology that employs the biological processes of cells and biomolecules to produce useful products. Mankind has been using biotechnology for millennia. For example, cheese, bread, and beer are all historical examples of humans harnessing the power of biotechnology to produce useful products.

Modern biotechnology builds on this history by using cutting-edge biological research to create innovative products. BIO’s membership ranges from large corporations to small start-ups that have yet to launch a successful product. With product development costs for biologic medicines typically exceeding one billion dollars, and development timelines close to a decade, these companies make, or seek from third parties, significant investments long before they see any possible return. These companies, in turn, heavily rely on patent protection to secure and maintain such substantial investments. Without robust and predictable patent protection, justifying or securing such investments,

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<sup>1</sup>Each party has consented to the filing of this brief and the parties’ letters of consent have been lodged with the Clerk. Pursuant to Supreme Court Rule 37.6, no counsel for a party authored this brief in whole or in part, and no party or counsel for a party made a monetary contribution intended to fund the preparation or submission of this brief. A list of BIO’s members is available at <http://www.BIO.org>.



and developing the innovative products that depend on them, is jeopardized.

## SUMMARY OF ARGUMENT

Biotechnology products touch virtually every aspect of modern society: healthcare, pharmaceuticals, agriculture, fuel production, and the environment. In order to create such a broad array of innovative products, biotechnology companies depend upon the protections afforded by our patent system to secure and maintain the substantial investments supporting their research and development efforts. It is therefore also critical to those developing biotechnology products—and the nation benefiting from their development—to have a predictable and efficient system to assert and adjudicate those patent rights.

In the appeal at issue in Baxter’s petition to this Court, the United States Court of Appeals for the Federal Circuit sets an extraordinarily high bar for finality of a federal court patent infringement judgment and thus allows that judgment to be nullified by a reexamination decision in the United States Patent and Trademark Office (“USPTO”). The net result of this erroneous finality standard—as applied to future cases<sup>2</sup>—will be deleterious to the patent system, the courts, and the development of innovative products, including biologic medicines.

If allowed to stand, this high finality standard will incentivize infringers to pursue duplicative, dual-track litigation in the federal courts and the USPTO because it allows the infringer a second bite at the apple to cancel the patent claims after losing fair and square in court. This potential outcome has

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<sup>2</sup> BIO expresses no views on the outcome of this case or disposition of issues other than those addressed in this brief.

the unintended consequences of raising the costs of litigation and clogging the federal district court dockets, or disincentivizing federal judges altogether from hearing patent cases, producing uncertainty of patent rights, and ultimately devaluing the patent and judicial systems on which innovations in the biotechnology industry rely.

Appropriately correcting this erroneous finality standard is critical because there are a significant number of patents in dual-track litigation in federal courts and the USPTO, a number likely to increase if this standard is permitted to continue.<sup>3</sup> While reexamination proceedings play an important role in giving accused infringers—and the public at large—a cheaper forum to remove erroneously granted patents, such a route should not be available to an infringer after a district court has finally adjudicated patent validity and awarded infringement damages against it, as was the case here.

The courts need a workable finality standard that better balances the interests in final adjudication of patent infringement awards with the prompt and efficient cancellation of erroneously granted rights. If such a workable standard were adopted, a patentee who prevails against an infringer in the district court, after a full and fair opportunity to litigate, would not face unexpected administrative nullification of that award. Additionally, this standard would encourage early reexaminations of patent claims rather than late

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<sup>3</sup> From July 1, 1981 through September 30, 2013, the percentage of patents in *ex parte* reexamination that were also involved in litigation was 32%. See USPTO, *Ex Parte Reexamination Historical Statistics* (2013), available at: [http://www.uspto.gov/patents/stats/ex\\_parte\\_historical\\_stats\\_roll\\_up\\_EOY2013.pdf](http://www.uspto.gov/patents/stats/ex_parte_historical_stats_roll_up_EOY2013.pdf)

requests designed solely to re-litigate a finally adjudicated issue.

BIO therefore supports Baxter's petition for a writ of certiorari to review the judgment of the Court of Appeals and adopt a workable standard of finality.

## ARGUMENT

### I. THIS COURT'S GUIDANCE HAS PROVEN CRITICAL TO CLARIFYING BIOTECHNOLOGY PATENT RIGHTS

Over the past several decades, this Court has provided critical guidance in the area of biotechnology patents that has both clarified and provided predictability to these rights. Most notable is this Court's landmark decision in *Diamond v. Chakrabarty*, 447 U.S. 303 (1980). In *Chakrabarty*, this Court faced the task of deciding whether engineered bacteria designed to digest crude oil constituted patentable subject matter. *Id.* at 305. In finding this biotechnology-based invention patentable, this Court observed that, for biotechnology as for other innovative industries, patent law is exercised in the hope that "the productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes into the economy, and the emanations by way of increased employment and better lives for our citizens." *Id.* at 307.

Positive effects soon materialized. Within only a few years after this Court's decision, the first genetically-engineered medicines became available. Insulin, previously extracted from pig or cow pancreas, was approved in human, recombinant form in 1982. In 1985, recombinant human growth hormone became available for treating children with dwarfism who previously depended on crude pituitary gland extracts from human cadavers. This Court continued its guidance in 2001, affirming the

availability of patent protection for modern high-yield seed products in *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred, International, Inc.*, 534 U.S. 124 (2001).

This Court's guidance is credited with providing investor confidence in biotechnology patents.<sup>4</sup> Of course, patent rights are without much value unless an equally robust process for adjudicating disputes arising under them exists, including guidance on how USPTO decisions will impact district court litigation.

In the appeals decision at issue in Baxter's petition to this Court, the Federal Circuit sets an extraordinarily high standard for finality of a federal court patent infringement judgment and thus allows that judgment to be nullified by a USPTO reexamination decision. As a result of this unduly high finality standard, which is inconsistent with both the Federal Circuit's own precedent and that of

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<sup>4</sup> See Sarah Hughes, *Making Dollars Out of DNA: The First Major Patent in Biotechnology and the Commercialization of Molecular Biology, 1974-1980*, 92 *Isis* 541, 569 (2001):

[*Diamond v. Chakrabarty*] was a critical ruling for commercial biotechnology: the patent system henceforth was to be used for securing property rights on all manner of living organisms and their components. Partly on the strength of the decision, Genentech went public on 14 October. Within minutes after the opening bell, frantic investors on the New York Stock Exchange purchased one million shares and the stock price rose from \$35 to \$89. Without an immediately marketable product, Genentech had in a few short hours raised \$38.5 million, and Boyer and Swanson had gained a paper profit of \$60 million on an initial investment of \$500 each.

*Id.*

the other circuits, significant uncertainty regarding the value of patent rights has been created. It is therefore necessary for this Court to review this erroneous finality standard and provide guidance to clarify these patent rights not only for the biotechnology companies that rely on patents, but for the nation as a whole.

## II. THE FEDERAL CIRCUITS' HIGH FINALITY STANDARD IS ERRONEOUS, INCONSISTENT WITH ITS OWN PRECEDENT ON FINALITY, CLASHES WITH OTHER CIRCUITS' FINALITY STANDARDS, AND FRUSTRATES CONGRESSIONAL INTENT FOR USPTO PROCEEDINGS

### A. The Federal Circuit's Finality Standard

After several years selling a product that it later stipulated infringed Baxter's patents, Fresenius chose the forum for its challenge to those patents—filing a declaratory judgment action for invalidity in district court. Over two years into the litigation, Fresenius filed for reexamination of the patent claims in the USPTO. Fresenius stipulated to infringement, *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, No. C 03-1431 (N.D. Cal. June 15, 2006) (joint stipulation), and, after a full and fair opportunity to litigate patent validity, lost in the district court. Baxter was awarded damages for past infringement, No. C 03-1431 (N.D. Cal. Mar. 21, 2008) (order granting motion for award of damages), and the district court ordered a transitional, post-verdict royalty and an injunction against future infringement, No. C 03-1431 (N.D. Cal. Mar. 21, 2008) (order granting motion for entry of permanent injunction). The district court entered final judgment.

Fresenius appealed the final judgment of the district court but did not raise on appeal the award of past damages. The Federal Circuit affirmed the

validity decision and liability as to some, but not all, of the asserted patent claims. *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 582 F.3d 1288, 1304 (Fed. Cir. 2009) [hereinafter *Fresenius I*]. The Federal Circuit vacated the transitional royalty and injunction in light of the reduced number of infringed claims and remanded to the district court to review the scope of this post-verdict relief. *Id.* There was, of course, no remand for consideration of past damages as that issue had not been appealed.<sup>5</sup>

After *Fresenius* exhausted all potential avenues for review of *Fresenius I*—Federal Circuit panel rehearing and Federal Circuit rehearing *en banc*—the mandate issued.<sup>6</sup> On remand, the district court modified the transitional royalty and injunction and entered a second final judgment reaffirming the past damages award. *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, No. C 03-1431, 2012 WL 761712 at \*16 (N.D. Cal. Mar. 8, 2012). *Fresenius* appealed this second judgment. While on appeal, the USPTO cancellation of the patent claims at issue was mandated by the Federal Circuit. *In re Baxter Int'l, Inc.*, 678 F.3d 1357 (Fed. Cir. 2012).

*Fresenius* used that cancellation to argue in *Fresenius II*<sup>7</sup> that the case should be dismissed and the past damages award erased. The Federal Circuit

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<sup>5</sup> Despite this, *Fresenius* requested on remand a new trial on past damages, a motion that was denied by the district court. *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, No. C 03-1431, 2011 WL 2160609 at \*2 (N.D. Cal. May 26, 2011).

<sup>6</sup> A petition to this Court for a writ of certiorari was similarly denied. *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 559 U.S. 1070 (2010).

<sup>7</sup> *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 721 F.3d 1330 (Fed. Cir. 2013).

panel in a 2-1 decision accepted Fresenius' argument thereby allowing Fresenius to escape all liability, including for the past damages that had been awarded in a final judgment and had never been appealed. The panel held that because the USPTO cancelled the claims while the second final judgment was pending on appeal, Baxter no longer had a cause of action against Fresenius and the suit had to be dismissed. *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, 721 F.3d 1330, 1347 (Fed. Cir. 2013).

The *Fresenius II* panel majority thus held that the second judgment was not sufficiently final despite the appeal of only the post-verdict remedies remaining. *Id.* at 1341. This holding sets the finality bar extraordinarily high, requiring resolution of *all* issues to prevent nullification of past infringement damages by a USPTO reexamination decision.

#### B. The Federal Circuit's Erroneous Finality Standard Will Have A Deleterious Impact On The Judicial And Patent Systems

The Federal Circuit's extraordinarily high finality bar will have damaging effects on the judicial and patent systems. First, setting the bar so high invites patent infringers who have lost on infringement to delay entry of final judgment on all issues in the district court so that they can seek nullification of a damages award through a USPTO reexamination proceeding.

This behavior is harmful to the courts and litigants because it prolongs litigation that should be in its final stages. Instead of being spent resolving the dispute, judicial resources will have been squandered, or at the very least, the damages award will have been needlessly delayed in an attempt to nullify it in a different forum. Importantly, there is

no downside for the infringer in a USPTO reexamination, making it the perfect second bite at the apple.

This dilatory behavior is also deleterious to the patent system overall because the patentee is unable to rely on the infringement judgment it received during these unjustified delays. As a result, the patentee is left completely exposed to loss of its infringement damages despite winning fair and square in the district court. This absolute risk as a result of the infringer's gamesmanship undermines the predictability and value of patent rights protecting innovative technology investments.

The Federal Circuit's standard further undermines the value of an issued patent. In the district court, the patentee should be afforded a statutory presumption of validity<sup>8</sup> that requires the district court to use the "clear and convincing" evidence standard for validity challenges. *See Ethicon, Inc. v. Quigg*, 849 F.2d 1422, 1429 n.3 (Fed. Cir. 1988). In the USPTO, however, the patent claims are given a broader claim scope and examined under the lower "preponderance of the evidence" standard. *See* USPTO, Manual of Patent Examining Procedure §§ 706(I), 2280 (2014); *see also* 37 C.F.R. § 1.555 (2010). This disparity between the standards of proof—coupled with the Federal Circuit's erroneous finality approach that allows nullification by a decision under the lower standard—effectively nullifies the statutory presumption of validity because a patentee will be subject to retroactive cancellation of its claims under the lower standard until every issue in the case is decided, not just the validity challenge. It would be as if the statutory presumption of validity never applied.

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<sup>8</sup> *See* 35 U.S.C. § 282.



The *Fresenius II* panel majority, however, argues that this disparate treatment was authorized by Congress under the reexamination and reissue statutes.<sup>9</sup> 721 F.3d at 1336-1340. This argument makes little sense here because those statutes address the situation where patent claims are amended during the USPTO process, a situation not present here. By contrast, the dispute here is whether the USPTO cancelled the claims before the district court's infringement finding was sufficiently final for the infringer to avoid liability.

The gamesmanship encouraged by the panel's high finality standard will have a lasting effect on the district courts as well. As the district courts seek to avoid squandering their resources as a result of this gamesmanship in future cases, they may feel compelled to stay every case where the infringer requests reexamination, thus effectively abdicating their discretion to grant such stays.<sup>10</sup> And even in the cases that move forward, the district courts will be forced to wade through the delay tactics in an effort to fully resolve all issues in a case.

It is therefore apparent that the extraordinarily high finality standard set by the Federal Circuit

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<sup>9</sup> In the main decision on which the panel relies (721 F.3d at 1339), the issue addressed was whether infringement could be found for claims amended during a reexamination, not whether an infringement award that was not appealed should be nullified as a result of a reexamination decision. *Bloom Eng'g Co. v. N. Am. Mfg. Co.*, 129 F.3d 1247, 1250 (Fed. Cir. 1997).

<sup>10</sup> The district court noted *Fresenius's* dilatory conduct and attempt to "game the system" by abusing the reexamination process, saying *Fresenius* should not have waited until after protracted, expensive discovery to request a stay. *Fresenius USA, Inc. v. Baxter Int'l, Inc.*, No. C 03-1431 (N.D. Cal. June 6, 2007) (order denying motion to stay).

majority in *Fresenius II* will have a deleterious impact on the courts and the patent system.

C. The Federal Circuit's Erroneous Finality Standard Is Inconsistent With Its Own Precedent

The Federal Circuit previously set the finality standard far lower than in *Fresenius II*. In *Robert Bosch, LLC v. Pylon Manufacturing Corp.*, 719 F.3d 1305 (Fed. Cir. 2013), an *en banc* Federal Circuit held that liability determinations in patent cases are final for purposes of interlocutory appeal under 28 U.S.C. § 1292(c)(2), even when a jury trial on both damages and willfulness remains. *Id.* at 1320. In this context, the Federal Circuit confers appellate jurisdiction for “a judgment in a civil action for patent infringement . . . [that] is final except for an accounting.” *Id.* at 1332. But unlike in *Fresenius I* where past damages had already been determined, in *Bosch* the Federal Circuit was willing to accept a less complete adjudication as “final,” a much lower bar indeed. The *Bosch* finality standard is therefore inconsistent with the one chosen in *Fresenius II*.

Moreover, several of the decisions, relied upon by the majority in *Fresenius II*, do not require as high a finality standard. The majority cites *Mendenhall v. Barber-Greene Co.*, 26 F.3d 1573 (Fed. Cir. 1994.), to support its high finality bar. *See* 721 F.3d at 1341. In *Mendenhall*, the Federal Circuit held that an interlocutory appeal pursuant to 28 U.S.C. § 1292(c)(2) was not final enough to be immune to collateral estoppel. 26 F.3d at 1580-81. *Fresenius I*, by contrast, did not involve an interlocutory appeal but rather an appeal under 28 U.S.C. § 1295(a)(1) from a final judgment of no invalidity and an award of past damages. Despite the majority's insistence, *Mendenhall* does not support such a high standard.

The majority also cites *John Simmons Co. v. Grier Bros. Co.*, 258 U.S. 82 (1922), in support of its holding in *Fresenius II*. See 721 F.3d at 1342. This Court in *Simmons* addressed whether a district court could overrule its prior patent validity ruling as a result of an intervening mandate from this Court. 258 U.S. 82 (1922). As the district court had not entered a final judgment in the matter, this Court found that the district court was free to modify its judgment “at any time.” *Id.* at 88. This ruling has nothing to do with an administrative agency’s ruling modifying a district court’s final infringement award—the issue here.

#### D. The Federal Circuit’s Erroneous Finality Standard Clashes With Those Of Other Circuits

As pointed out in Judge Newman’s dissent to Baxter’s petition for an *en banc* rehearing, the finality rule announced by the Federal Circuit in *Fresenius II* clashes with those of every other circuit. 721 F.3d at 1355 (Newman, J., dissenting). For example, the Second Circuit in *Zdanok v. Glidden Co.*, 327 F.2d 944 (2d Cir. 1964), held that finality is not restricted to situations where the only step left in the action is execution of the judgment:

“Finality’ in the context here relevant may mean little more than that the litigation of a particular issue has reached such a stage that a court sees no really good reason for permitting it to be litigated again.” . . . The mere fact that the damages of the Zdanok plaintiffs have not yet been assessed should not deprive that ruling of any effect as collateral estoppel it would otherwise have.

*Id.* at 955 (citation omitted). This standard clashes with the holding in *Fresenius II*, where the Federal

Circuit premised its finality standard on the remaining issues in the action.

Similarly, the Eleventh Circuit held that a preliminary contract interpretation by a district court that was based on extensive fact finding did not require a final judgment on all issues to preclude re-litigation of the issue. *Christo v. Padgett*, 223 F.3d 1324, 1338-39 (11th Cir. 2000). And in the Eighth Circuit, it was held that a basis for vacating an arbitration ruling was that it was precluded by a jury verdict on the same issue despite the damages phase of the trial not being complete. *Morrell & Co. v. Local Union 304A of United Food & Commercial Workers*, 913 F.2d 544, 563-64 (8th Cir. 1990). These cases, among others, demonstrate that the absolute finality standard the Federal Circuit seeks to impose in *Fresenius II* clashes with the standards applied in other circuits.

E. The Federal Circuit's Erroneous Finality Standard Frustrates Congressional Intent under the AIA

Under the Leahy-Smith America Invents Act ("AIA"), Congress enacted *inter partes* review ("IPR") to provide an expeditious and less costly adversarial process for the public to challenge the validity of patents. In doing so, Congress recognized that this new process, if allowed to proceed independently from a district court action, could create inefficiencies due to the overlap and could also be abused by parties looking for multiple venues to challenge validity. Thus Congress included within 35 U.S.C. § 315(a) provisions to prevent this overlap by limiting the time frames to file for IPR. Congress also provided several estoppel mechanisms to prevent re-litigation of validity issues in the separate forums. 35 U.S.C. § 315(e).

But in view of the panel's ruling in *Fresenius II*, potential infringers may be encouraged to file reexaminations instead of IPRs. By allowing *ex parte* reexamination petitions to duplicate arguments made during litigation without any risk of estoppel, the Federal Circuit is undermining Congressional intent to encourage use of IPR as an administrative alternative to expensive and time consuming district court litigation. And infringers may avoid IPRs because they can now challenge a patent's validity in the district court, and even if they lose, attempt to nullify the result using reexamination by delaying final resolution of all issues in the district court.

### III. A WORKABLE STANDARD IS NEEDED TO BALANCE THE PREDICTABLE ASSERTION OF PATENT RIGHTS GRANTED BY THE USPTO WITH EFFICIENT REVOCATION OF ERRONEOUSLY GRANTED PATENT RIGHTS

As the Federal Circuit's extraordinarily high bar for finality is erroneous, a workable standard is needed to balance the predictable assertion of patent rights granted by the USPTO with efficient revocation of erroneously granted patent rights.

Our proposal for a workable standard would be one where a patentee who has successfully asserted its patent rights in federal court would not have its damages award nullified by a subsequent USPTO cancellation once the infringer is precluded from further litigating that award in the infringement action. This proposed standard would provide predictability to the resolution of patent infringement rights because it relies on a well-developed body of case law to dictate the result.

This workable standard is supported by finality determinations used in several contexts. For example, the well-developed doctrine of issue preclusion would similarly dictate such a result in a

subsequent district court action.<sup>11</sup> Similarly, the well-developed doctrine of law of the case would also lead to such a result within the same infringement action.<sup>12</sup>

This workable finality standard would possess many benefits over the extraordinarily high bar set by the Federal Circuit. First, this standard would preserve the presumption of validity afforded issued patents during the district court action by not allowing an infringer to erase an infringement award by arguing invalidity in the USPTO under the lower standard of review used during reexamination.

Second, this standard would disincentivize infringers from delaying final resolution of the district court case because the reexamination outcome would not apply once infringement has been adjudicated in the district court. This standard would further disincentivize infringers from raising collateral issues late in a case or other acts of gamesmanship to avoid final resolution on all issues.

Third, this standard encourages accused infringers to promptly petition the USPTO to cancel the patent claims through reexamination and only while it can still pursue invalidity defenses in the district court. And it would protect other alleged

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<sup>11</sup> Indeed, in denying *en banc* review, Judge Dyk, speaking for the majority, did not dispute that the *Fresenius I* decision was “sufficiently final to be given collateral estoppel effect in another infringement litigation” between the parties. *Fresenius USA, Inc. v. Baxter Int’l, Inc.*, 733 F.3d 1369, 1371 (Fed. Cir. 2013).

<sup>12</sup> *Fresenius USA, Inc. v. Baxter Int’l, Inc.*, 733 F.3d 1369, 1379 (Fed. Cir. 2013) (“The district court was correct to note that ‘[t]he mandate rule requires that the district court follow an appellate decree as the law of the case.’”).

infringers who have not yet had an opportunity to fully litigate their affirmative defenses in pending district court actions.

Encouraging early reexamination petitions also benefits the public by removing erroneously granted patent rights faster, and benefits the courts, by sparing them from expending resources on validity disputes that can be more efficiently resolved in the USPTO.

\* \* \*

Baxter's petition is the ideal vehicle to review the question presented because it is undisputed that the infringer could no longer raise a defense to its infringement liability in the district court due to the appellate court's mandate issued in *Fresenius I*.

## CONCLUSION

The Court should grant Baxter's petition for a writ of certiorari to consider a more workable standard of finality for infringement awards that better serves the interests of patentees and the public alike.

Respectfully submitted.

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