

No. 13-1071

IN THE
Supreme Court of the United States

BAXTER INTERNATIONAL, INC., *ET AL.*,
Petitioners,

v.

FRESENIUS USA, INC., *ET AL.*,
Respondents.

On Petition for a Writ of Certiorari
to the United States Court of Appeals
for the Federal Circuit

**BRIEF FOR THE PHARMACEUTICAL
RESEARCH AND MANUFACTURERS OF
AMERICA AS *AMICUS CURIAE* IN SUPPORT
OF PETITIONERS**

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INTEREST OF AMICUS CURIAE

The Pharmaceutical Research and Manufacturers of America (“PhRMA”) is a voluntary, nonprofit association representing the nation’s leading research-based pharmaceutical and biotechnology companies.¹ PhRMA often participates as *amicus curiae* in cases before this Court that have the potential for far-reaching effects on the nation’s patent system.²

PhRMA’s members are the primary source of the many new drugs and biologics introduced each year. See PhRMA Member Companies, <http://www.phrma.org/about/member-companies> (last visited Apr. 7, 2014). In 2012, PhRMA members invested nearly \$50 billion in researching and

¹ Pursuant to Rule 37.6, *amicus curiae* and its counsel affirm that no counsel for a party authored this brief in whole or in part, and that no person other than *amicus* or its counsel made a monetary contribution to the preparation or submission of this brief. Counsel of record for all parties received notice at least 10 days prior to the due date of *amicus*’s intention to file this brief. Counsel for Baxter International has filed a blanket consent to the filing of *amicus* briefs, and a letter from Fresenius USA granting consent has been filed with the Clerk. No party to this case is a member of PhRMA. See PhRMA Member Companies, <http://www.phrma.org/about/member-companies> (last visited Apr. 7, 2014) (listing PhRMA member companies).

² See, e.g., *Ass’n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013); *Caraco Pharm. Labs., Ltd. v. Novo Nordisk A/S*, 132 S. Ct. 1670 (2012); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 132 S. Ct. 1289 (2012); *Microsoft Corp. v. i4i Ltd. P’ship*, 131 S. Ct. 2238 (2011); *Bilski v. Kappos*, 130 S. Ct. 3218 (2010); *Medimmune, Inc. v. Genentech, Inc.*, 549 U.S. 118 (2007).

developing new medications and vaccines that help patients live longer, healthier, and more productive lives. See PhRMA, 2013 Biopharmaceutical Research Industry Profile 30 (2013), <http://www.phrma.org/sites/default/files/pdf/PhRMA%20Profile%202013.pdf> (last visited Apr. 7, 2014). The development of new medicines is an inherently risky and uncertain endeavor. To manage this risk, PhRMA's members depend on certainty and predictability in patent law and on the finality of judicial adjudications regarding patent rights.

PhRMA's members have a direct and substantial interest in the questions presented in this case. The Federal Circuit held that a U.S. Patent and Trademark Office ("PTO") *ex parte* reexamination decision can negate a prior Federal Circuit judgment upholding the validity of patent claims, as well as a prior district court judgment regarding past damages that had not even been appealed. The Federal Circuit's decision to allow a PTO administrative decision to reopen and reverse a final judgment of an Article III court threatens to undermine the finality of judicial decisions that is necessary to stimulate investment in research and development that leads to important innovations. Incentives provided by secure patents rights are particularly important to the pharmaceutical industry because of the very high research and development costs required to develop new medicines. See Joseph A. DiMasi & Henry G. Grabowski, *The Cost of Biopharmaceutical R&D: Is Biotech Different?*, 28 *Managerial & Decision Econ.* 469 (2007).

If the Federal Circuit's decision is allowed to stand, it will increase uncertainty with respect to

patent rights, and discourage investments that are necessary for innovation in the biopharmaceutical and other sectors.

STATEMENT

1. In 2003, Respondent Fresenius USA, Inc. (“Fresenius”) filed suit against Baxter International, Inc. (“Baxter”), seeking a declaratory judgment of invalidity and non-infringement with respect to patents regarding hemodialysis machines. Pet. App. 2a-3a. As relevant here, Fresenius stipulated to infringement of one patent, the ’434 patent. *Id.* 3a. A jury returned a verdict for Fresenius, finding the relevant claims in the ’434 patent invalid, but the district court granted judgment as a matter of law (“JMOL”) to Baxter on the ground that Fresenius failed to present sufficient evidence to support the jury’s verdict of invalidity of Baxter’s patent. *Id.* In October 2007, the district court held a jury trial on damages, and the jury awarded Baxter \$14.266 million for infringement of the ’434 and other patents at issue. *Id.* In April 2008, the district court entered and stayed a permanent injunction and awarded Baxter ongoing post-verdict royalties on items sold by Fresenius. *Id.* 3a-4a.

Both parties appealed. Fresenius challenged the ’434 patent validity holding, as well as the permanent injunction and the post-verdict damages royalty award; it did not challenge the \$14.266 million past damages award. *See* A1372; A1404-05; A1427-30; A1435.³ In *Fresenius USA, Inc. v. Baxter*

³ “A” refers to the Appendix filed with the Federal Circuit.

Int'l, Inc., 582 F.3d 1288 (Fed. Cir. 2009) (“*Fresenius I*”), the Federal Circuit affirmed the district court’s judgment for Baxter with respect to the validity of the ’434 patent, but reversed the district court’s judgment for Baxter with respect to other patents at issue. Pet. App. 4a-5a. The court of appeals remanded for the district court to reconsider its injunction and post-verdict royalty award. *Id.*

On remand, the district court reduced the royalty rate for the post-verdict damages Fresenius owed to Baxter and entered final judgment for Baxter on March 16, 2012. *Id.* 5a.⁴ Fresenius again appealed to the Federal Circuit.

2. While the district court litigation was pending, Fresenius sought *ex parte* reexamination by the PTO of the ’434 patent in 2005. *Id.* 6a.

In 2010, well after the district court granted JMOL to Baxter with respect to the ’434 patent and after the Federal Circuit’s affirmance of the ’434 patent’s validity, the PTO determined that under the preponderance of the evidence standard employed in reexamination proceedings, certain claims in the ’434 patent were obvious and therefore invalid. *Ex parte Baxter Int’l, Inc.*, No. 2009-006493, 2010 WL 1048980, at *12, *14-*15 (B.P.A.I. Mar. 18, 2010).

On appeal, the Federal Circuit affirmed, over a dissent by Judge Newman, who noted the conflict between the PTO’s decision and *Fresenius I*. *See In re Baxter Int’l Inc.*, 678 F.3d 1357 (Fed. Cir. 2012);

⁴ The injunction was no longer at issue because the ’434 patent had expired in April 2011. Pet. App. 5a.

id. at 1369-70 (Newman, J., dissenting). The PTO issued a certificate cancelling the challenged claims of the '434 patent on April 20, 2013. Pet. App. 8a (citing Ex Parte Reexamination Certificate, U.S. Pat. No. 5,247,434 C1 (P.T.O. Apr. 30, 2013)).

3. In the wake of the PTO's cancellation of claims in the '434 patent, the Federal Circuit issued the decision below ("*Fresenius II*"). The panel majority held that the PTO's cancellation of the claims in the '434 patent rendered the entire litigation moot. *Id.* 32a. As a result, the Federal Circuit vacated the royalty award the district court set on remand as well as the past damages award that *Fresenius* chose not to appeal in *Fresenius I*. The majority concluded that "[t]he intervening decision invalidating the patents unquestionably applies in the present litigation, because the judgment in this litigation was not final." *Id.* 26a.

Judge Newman dissented. She explained that "the constitutional structure does not permit the executive branch to override judgments of the courts," and in particular, "[t]he PTO can neither invalidate, nor revive, a patent whose validity the court has adjudicated." *Id.* 35a-36a. She noted that the majority's view of finality—that "the final adjudication of patent validity can be redecided by the courts and thus by the PTO, because of the remand to assess post-judgment damages"—is "contrary to the precedent of every circuit," each of which "impose[s] finality and preclusion as to issues that were finally decided in full and fair litigation." *Id.* 48a.

The Federal Circuit denied rehearing en banc, over the dissent of four judges. Judge O'Malley,

joined by Chief Judge Rader and Judge Wallach, criticized the majority's approach to finality. Judge O'Malley explained that after this Court denied certiorari in *Fresenius I*,

Fresenius' liability for infringement, its failure to prove invalidity, and its responsibility for past damages were firmly established and beyond challenge. The only live issues remaining in the case related to *post-verdict* relief. And, even the live issues regarding post-verdict relief did not concern the right to such relief—which was established; the remand only asked that the court reconsider the scope of and formula used for such relief. All other aspects of the case had been conclusively resolved.

Id. 79a. In overturning the judgment, the majority relied, Judge O'Malley concluded, on an “antiquated view of finality” that is “significantly out of step with the law as it stands today.” *Id.* 80a.

Judge O'Malley further highlighted the conflict the majority's opinion created with the D.C. Circuit's decision in *Qualcomm Inc. v. FCC*, 181 F.3d 1370 (D.C. Cir. 1999). In *Qualcomm*, the D.C. Circuit held that an earlier decision it had issued regarding award of an FCC license was final (despite a remand to the FCC with respect to remedy issues), and therefore that an intervening act of Congress that removed the basis for the court's original decision had no effect on the prevailing party's right to a remedy before the agency on remand. *Id.*; *see also*

Pet. App. 84a. Judge O'Malley explained that “[a]s in *QUALCOMM*, [the Federal Circuit’s] mandate established that Baxter was entitled to a remedy because infringement—and the right to damages—were established and litigated to finality.” *Id.* Therefore, “[w]hile Baxter lost its *prospective* patent rights because of the PTO action,” the PTO “may not undermine a final determination of past liability, damages, and the right to appropriate post-verdict relief in *this* case between *these* parties.” *Id.* 85a.

Judge Newman separately dissented, emphasizing that the Federal Circuit had “weakened” the incentive for innovation “by reducing the reliability of the patent grant, even when the patent has been sustained in litigation.” *Id.* 95a. She noted that “[t]his loss cannot be underestimated, especially for technologies that incur heavy development costs yet are readily copied.” *Id.* She further highlighted that the “ensuing instability replaces innovation incentive with litigation costs.” *Id.* 96a.

ARGUMENT

I. The Federal Circuit's Decision Discourages Innovation And Creates Inefficiencies.

A. The Federal Circuit's Decision Undermines The Certainty And Predictability Necessary To Support Innovation.

This Court has long recognized that patents are “meant to encourage invention by rewarding the inventor” with a time-limited right to “exclude others from the use of his invention.” *Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 229 (1964); *see also Pennock v. Dialogue*, 27 U.S. (2 Pet.) 1, 19 (1829) (Story, J.) (patent system, “by holding out a reasonable reward to inventors, and giving them an exclusive right to their inventions for a limited period,” serves “to stimulate the efforts of genius”). The patent system “embodie[s] a careful balance between the need to promote innovation and the recognition that imitation and refinement through imitation are both necessary to invention itself and the very lifeblood of a competitive economy.” *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 146 (1989).

The Federal Circuit's decision in this case undermines incentives to innovate by “creating a new regime wherein a district court's final adjudication can be undone by later decisions of the” PTO. Pet. App. 75a. This “new regime” undermines the certainty and finality upon which patent holders depend in making decisions about investing in

research necessary to develop new innovations. As Judge Newman observed, the Federal Circuit “has weakened” the incentive “for the creation, development, and commercialization of new technology . . . by reducing the reliability of the patent grant even when the patent has been sustained in litigation.” *Id.* 95a. In short, the Federal Circuit upset the “carefully crafted bargain for encouraging the creation” of new technologies. *Bonito Boats*, 489 U.S. at 150-51.

The uncertainty created by the Federal Circuit’s decision is particularly detrimental to the pharmaceutical industry because of the extremely high costs and long timeframes required for research and development of new medicines. In the aggregate, PhRMA members invested nearly \$50 billion in R&D in 2012 alone. *See* PhRMA, *2013 Biopharmaceutical Research Industry Profile*, at 30. The cost to develop a single new drug (including the cost of failures) has increased dramatically over time, rising from an average of about \$140 million in the mid-1970s to \$800 million in the late-1990s to \$1.2 billion in the early-2000s. *Id.* at 38 fig. 14. More recent studies estimate the cost to be \$1.5 billion to more than \$1.8 billion. *See id.* at 42 n.25 (citing studies).⁵ Patent protection for medicines is crucial because during the patent term, “the

⁵ *See* Jorge Mestre-Ferrandiz, Jon Sussex & Adrian Towse, Office of Health Economics, *The R&D Cost of a New Medicine* 39 (Dec. 2012) (proposing average cost of \$1.5 billion); Steven M. Paul, *et al.*, *How to Improve R&D Productivity: The Pharmaceutical Industry’s Grand Challenge*, 9 *Nature Reviews Drug Discovery* 203, 204 (2010) (proposing \$1.8 billion).

medicine must earn enough revenue to fund the drug development pipeline for other candidates that may someday become new drugs.” *Id.* at 36.

Studies have demonstrated that “patents are a more critical stimulus factor for pharmaceutical innovation” than for other high-tech industries because of the “characteristics of the pharmaceutical R&D process.” Henry Grabowski, *Patents, Innovation and Access to New Pharmaceuticals*, 5 J. Int’l Econ. L. 849, 850-51 (2002). In particular, secure patent protection is essential for pharmaceuticals because “imitation costs in pharmaceuticals are extremely low relative to the innovator’s costs for discovering and developing a new compound.” *Id.* at 851.

Because the biopharmaceutical industry is highly dependent on patent protections, the Federal Circuit’s decision subjecting patent rights that have been adjudicated in court to invalidation by the PTO will have a disproportionate effect on the pharmaceutical industry. As Judge Newman noted in dissent, the loss of incentives for innovation that stable patent rights provide “cannot be underestimated, especially for technologies that incur heavy development costs yet are readily copied.” Pet. App. 95a.

B. The Federal Circuit’s Decision Fosters Duplicative Challenges And Dilatory Litigation Tactics.

In addition to discouraging innovation, the Federal Circuit’s decision incentivizes duplicative challenges to patents. Already “PTO records show

pervasive duplication of litigation and reexamination of the same patents,” *id.* 96a (citing PTO statistical reports); the decision in this case will accelerate that trend.

PTO statistics through September 30, 2013 show that the number of *ex parte* reexamination filings has increased over time, and that the PTO agrees to reexamine a very high percentage (92%) of the patents that are subject to such a filing. U.S. PTO, *Ex Parte* Reexamination Filing Data - September 30, 2013, http://www.uspto.gov/patents/stats/ex_parte_historical_stats_roll_up_EOY2013.pdf. A staggering 32% of all reexamination filings involve patents “known to be in litigation,” *id.*, and upon reexamination, 78% of patents have some or all claims canceled or narrowed, *id.* (12% of *ex parte* reexamination certificates cancel all claims, and 66% of certificates change claims).

The Federal Circuit’s decision gives infringers a strong incentive to drag out court litigation while pursuing *ex parte* reexamination. So long as some aspect of the litigation remains pending, *ex parte* reexamination by the PTO provides an opportunity to erase earlier losses in court. See Courtenay Brinckerhoff, *Fresenius Escapes \$25 Million Damages Award, Based on Invalidation of Baxter Patent in Ex Parte Reexamination*, PharmaPatents (July 8, 2013), <http://www.pharmapatentsblog.com/2013/07/08/fresenius-escapes-25-million-damages-award-based-on-invalidation-of-baxter-patent-in-ex-part-reexamination/>. As Baxter’s petition notes, infringers have already invoked *Fresenius II* as a way to escape prior damages judgments. Pet. 22.

Moreover, the Federal Circuit's decision in *Fresenius II*, combined with its decision in *Robert Bosch, LLC v. Pylon Manufacturing Corp.*, 719 F.3d 1305 (Fed. Cir. 2013) (en banc), increases the likelihood that district court litigation will become more drawn out, extending the opportunity for decisions of the PTO to disrupt or nullify previously issued judicial decisions. In *Bosch*, the Federal Circuit held that liability determinations in patent cases may be appealed before an adjudication of damages or a determination of willfulness. *Id.* at 1316, 1319-20. *Bosch* "created an incentive for district courts to bifurcate liability determinations from damages and willfulness trials," which in turn will "drag out the litigation, causing multiple appeals and probably multiple remands." Pet. App. 93a. Pursuant to the decision below, "years of litigated decisions, which may be affirmed piecemeal, could be rendered meaningless by much later PTO decisions." *Id.*

As Judge O'Malley noted in dissenting from denial of rehearing en banc, this system "goes a long way toward rendering district courts meaningless in the resolution of patent infringement disputes." *Id.* 75a. It also lengthens the time during which a patent holder's rights are subject not just to review by the courts, but to cancellation by the PTO. As a result, the Federal Circuit's decision will have a chilling effect on innovation.

II. The Federal Circuit's Decision Conflicts With Decisions Of Other Circuits And Raises A Serious Constitutional Issue.

The decision below raises important legal questions that warrant this Court's review. First, the Federal Circuit's decision creates a circuit conflict over whether a final judicial determination of liability that has been affirmed on appeal may be reversed by an administrative agency so long as an appeal of the post-verdict remedy remains pending. Second, the decision in this case raises a serious constitutional issue, by allowing an Executive Branch agency to reverse final judgments of Article III courts.

A. The Federal Circuit's Decision Conflicts With Precedents Of Other Circuits.

The Federal Circuit's decision conflicts with the D.C. Circuit's decision in *Qualcomm Inc. v. FCC*, 181 F.3d 1370, regarding the finality of judicial determinations and the ability of other branches of government to interfere with judicial judgments. In both cases, the circuit courts resolved the merits of an appeal and remanded on narrow remedy-related issues. Before the circuit courts decided the appeal of the remand, another branch of government took action, and the losing party in the litigation asserted that the action of another branch negated the court's merits ruling. The Circuits' divergent views of finality led them to address the situation differently.

In the D.C. Circuit case, Qualcomm had applied for and been denied an FCC license. On appeal, the D.C. Circuit vacated the denial of the license and

remanded to the FCC “for further proceedings to remedy” the agency’s erroneous denial. *Id.* at 1371. After the court’s mandate issued, but before the FCC had granted a remedy, Congress enacted legislation eliminating the FCC’s authority to issue the license. The FCC then dismissed Qualcomm’s pending license application on the ground that the statute “withdrew the FCC’s authority” to grant the requested license. *Id.* at 1371, 1375. On appeal from the dismissal, the D.C. Circuit explained that “the question is whether Congress intended its withdrawal of the FCC’s authority to grant [the license] to foreclose the FCC from carrying out the mandate of a *final judicial decision.*” *Id.* at 1375 (emphasis added). The D.C. Circuit concluded that construing the statute to eliminate Qualcomm’s right to relief on remand would “pose a constitutional question of whether Congress could change the result of a *final judicial decision,*” *id.* (emphasis added), and that the mandate from the Court’s prior decision provided the FCC with independent authority to provide Qualcomm with a remedy, *id.* at 1376. Thus, the D.C. Circuit held that after the court decides the merits of an appeal and the mandate has issued, a remand on remedial issues does not deprive the court’s decision of finality, and therefore the court’s merits decision may not be undone by an action of another branch of government.

In *Fresenius II*, by contrast, the Federal Circuit held that the PTO’s cancellation of the ’434 patent claims mooted the litigation, despite the fact that the merits of the invalidity claim had been finally adjudicated and the remand to the district court (and

subsequent appeal to the Federal Circuit) involved only post-verdict damages. Pet. App. 32a. Thus, in effect, the Federal Circuit held that even after the merits of a claim have been adjudicated and the court's mandate has issued, the court's ruling on the merits is not final and can be negated or rendered moot by another branch of government (in this case, the Executive Branch) so long as *any* issue remains open. *See id.* 20a-21a.

Four judges of the Federal Circuit recognized that the Federal Circuit's opinion in *Fresenius II* creates a circuit split with *Qualcomm*. *See id.* 84a; *see also id.* 66a. In dissenting from denial of rehearing en banc, three judges explained "the majority creates a circuit split" with *Qualcomm* regarding the finality of a circuit court's decision when the decision includes a remand merely regarding a remedy issue. *Id.* 84a. The dissenters explained that in *Qualcomm*, "the decision resolving the merits was *final* despite the remand to fashion an appropriate remedy." *Id.* They further argued that the *Fresenius II* majority's attempt to distinguish *Qualcomm* "falls flat" because the remand in *Fresenius I* was even narrower than the remand the D.C. Circuit in *Qualcomm* held did not preclude finality. *Id.* 85a. In dissenting from the panel decision, Judge Newman similarly recognized, "There is no basis in fact or law to hold that our decision in *Fresenius I* is any less final than that considered in *QUALCOMM*." *Id.* 66a.

Second and more broadly, the decision below conflicts with the decisions of other circuits regarding finality of judicial decisions more generally. As Judge Newman explained, the majority's theory of finality "is contrary to the

precedent of every circuit” because all circuits besides the Federal Circuit in this case “impose finality and preclusion as to issues that were finally decided in full and fair litigation.” *Id.* 48a. Judge O’Malley, dissenting from denial of rehearing en banc, similarly explained that “[w]ell-established law recognizes finality in situations like the one presented here—where the merits are conclusively decided—even though other issues may remain.” *Id.* 81a. Judge Newman’s dissent and the petition for certiorari cite numerous judicial decisions that reject the Federal Circuit’s narrow conception of finality. *See id.* 49a-55a (citing cases); Pet. 15-17 (same).

In sum, the Federal Circuit’s decision in this case conflicts with the D.C. Circuit’s decision in *Qualcomm* on the issue of finality with respect to the actions of other branches of government, as well as with decisions of every other circuit regarding the finality of judicial decisions more generally.

B. The Federal Circuit’s Decision Raises An Important Constitutional Question.

This Court has recognized that “Congress cannot vest review of the decisions of Article III courts in officials of the Executive Branch.” *Plaut v. Spendthrift Farm, Inc.*, 514 U.S. 211, 218 (1995). Doing so would violate the constitutionally mandated separation of powers. Despite *Plaut*’s clear instruction, the Federal Circuit has decided that an Executive Branch agency may overrule decisions of Article III courts upholding the validity of patent claims.

The Federal Circuit concluded that *Plaut* has no application to this case because “the suit is not over and there has been no final judgment.” Pet. App. 28a; *id.* (“It is . . . quite clear that we have not reached the stage at which *Plaut* precludes reopening a case.”). The Federal Circuit’s decision rests entirely on its narrow understanding of finality. The Federal Circuit majority’s only answer to the separation of powers problem is its insistence that a district court judgment, affirmance by the Federal Circuit, and denial of certiorari by this Court did not result in a final judgment on the \$14.266 million award for past damages that Fresenius never appealed.

Four judges of the Federal Circuit agree that the Federal Circuit’s finality defense does not remedy the constitutional concerns. Judge Newman concluded that the Federal Circuit’s decision

authorizes the [PTO], an administrative agency within the Department of Commerce, to override and void the final judgment of a federal Article III Court of Appeals. . . .

This holding violates the constitutional plan, for “Judgments, within the powers vested in courts by the Judiciary Article of the Constitution, may not lawfully be revised, overturned or refused faith and credit by another Department of Government.”

Pet. App. 33a (quoting *Chi. & S. Air Lines, Inc. v. Waterman S.S. Corp.*, 333 U.S. 103, 113 (1948)); see also *Chi. & S. Air Lines, Inc.*, 333 U.S. at 113-14 (noting the “firm and unvarying practice of Constitutional Courts to render no judgments . . . that are subject to later review or alteration by administrative action”). In dissenting from denial of rehearing en banc, Chief Judge Rader and Judges O’Malley and Wallach echoed Judge Newman’s concern. Pet. App. 75a n.1 (concluding that “the panel majority’s decision has constitutional implications arising from principles dating back to *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 177 (1803”).

The Federal Circuit’s decision thus raises a serious constitutional issue that warrants review by this Court.

CONCLUSION

The Court should grant the petition for certiorari.

Respectfully submitted,

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