IN THE

Supreme Court of the United States

BAXTER INTERNATIONAL INC. AND BAXTER HEALTHCARE CORPORATION,

Petitioners,

v.

FRESENIUS USA, INC. AND FRESENIUS MEDICAL CARE HOLDINGS,

Respondents.

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

REPLY BRIEF FOR PETITIONERS

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ARGUMENT

As the four dissenters from the denial of rehearing en banc and the four amicus briefs filed in this Court make clear, this case raises profoundly important questions regarding the finality of judicial decisions and the relationship between patent reexamination and litigation. The Federal Circuit's erroneous resolution of those questions creates a circuit split, erodes the finality of patent judgments, fosters uncertainty, and creates opportunities for gamesmanship and abuse. Although Fresenius attempts to divert attention from these important issues, nothing it says diminishes the need for this Court's review.

I. THE FEDERAL CIRCUIT'S DECISION CONFLICTS WITH QUALCOMM AND FINALITY CASE LAW FROM EVERY OTHER CIRCUIT

A. Fresenius's Attempt To Distinguish *Qualcomm*Fails

Four Federal Circuit judges have noted that Fresenius II creates a circuit split with Qualcomm Inc. v. FCC, 181 F.3d 1370 (D.C. Cir. 1999). See App. 66a, 84a. Fresenius's primary response (at 24-25 & n.8) is to try to distinguish the scope of the remand in Qualcomm. But Fresenius's contention (at 25 & n.8) that, in Qualcomm, the FCC had "specific, ministerial instructions about how to bring the case to finality" and "simply had to give effect mechanically to the appellate court's final judgment" is belied by the opinion's plain language. The decision makes clear that the agency had "discretion ... to fashion an appropriate remedy." Qualcomm, 181 F.3d at 1376 (emphasis added). In fact, the form of relief for Qualcomm was an open question given that the license Qualcomm had sought had already "been awarded" to another company. Id. The Qualcomm court accordingly explained that the earlier panel's decision "recognized that alternative relief remained to be identified and that a remand for 'further proceedings' for that purpose was required." Id. at 1377 (emphasis added). None of these open questions, however, undermined the finality of Qualcomm's entitlement to relief regardless of the intervening action of another branch of government.

The only other potential distinction Fresenius offers (at 23) is that *Qualcomm* "did not involve a claim for damages." But Fresenius never explains why that would matter. The ultimate relief in *Qualcomm*—a "pioneer's preference" that shielded Qualcomm from "competing applications," *Qualcomm*, 181 F.3d at 1372, 1381—was, if anything, more significant than any money judgment.

Qualcomm and Fresenius II squarely conflict, and only this Court can resolve the split.

B. The Federal Circuit's Rigid Approach To Finality Conflicts With Every Other Circuit's Approach

Fresenius dismisses in a single paragraph case law from *every* circuit that rejects *Fresenius II*'s rigid approach to finality. *Compare* Opp. 25-26 *with* Pet. 15-17 & n.10; App. 48a-57a, 80a-82a; PhRMA Br. 15-16, *and* BIO Br. 12-13. But the unanimous consensus among the circuits that finality is a flexible doctrine cannot be so easily written off.

The question whether a decision is sufficiently final to bind the parties requires a pragmatic examination of the decision's firmness and the opportunity for review. See App. 92a. The Federal Circuit replaced this balanced approach with a rigid rule, holding that as long as

any issue remains open on a second appeal, everything done in a case remains subject to revision based on the actions of an administrative agency. For example, Fresenius concedes that *Fresenius I* was sufficiently final that Fresenius "could [be] proscribe[d] ... from challenging [the decision's liability ruling] in a future district court action." Opp. 25. But under the "inapplicable and antiquated view of finality" (App. 80a) in *Fresenius II*, the same decision that would control other Article III proceedings does not control the very case in which it was decided.

The Federal Circuit thus produced an inflexible rule that, unlike other bright-line rules, only serves to *increase* uncertainty by prolonging the period during which a judicial decision can be overridden. This Court's review is required to bring the Federal Circuit back in line with prevailing practice.

II. THIS CASE PRESENTS RECURRING QUESTIONS OF NATIONAL IMPORTANCE REGARDING THE FINALITY OF JUDICIAL DECISIONS

Even apart from the circuit split, this case presents recurring questions of national importance. Fresenius's attempt to downplay those questions does nothing to diminish the need for this Court's review.

1. The importance of this case has been widely recognized. Three Federal Circuit judges have warned that "[t]he panel majority's decision in this case goes a long way toward rendering district courts meaningless in the resolution of patent infringement disputes." App. 75a. A fourth has cautioned that "[t]he panel decision destabilizes issued patents, by ignoring the rules of finality." *Id.* 6a.

A group of many of the country's most successful corporations has observed that the case presents "an important constitutional issue, touching on the proper role of each of our branches of government." IPO Br. 11. The pharmaceutical and biotechnology industries have warned that the decision below "threatens to undermine the finality of judicial decisions that is necessary to stimulate investment" (PhRMA Br. 2) and "will have a deleterious impact on the courts and the patent system" (BIO Br. 11). Medtronic has noted that the questions presented are of "profound importance to patent holders, companies accused of infringement, and the federal judiciary alike." Medtronic Br. 8.

Individual commentators have called the case "a watershed moment in U.S. patent law" with "long-term, real-world effects." Pet. 3-4. They have also noted that the "issue will only increase in importance." Evanson et al., *The Next Supreme Court Cases To Shape Patent Law*, Law360 (Jan. 1, 2014).

In short, the bench, industry, and the bar have all recognized the significance of the Federal Circuit's decision and the pressing need for this Court's guidance.

2. Contrary to Fresenius's argument (at 29-31), the questions presented in this case will only increase in importance. The protracted proceedings in this case are far from unique. See Pet. 25. Fresenius also fails to account for "the gamesmanship and abuses" encouraged by the decision below. App. 96a. "The Federal Circuit's decision gives infringers a strong incentive to drag out court litigation while pursuing ex parte reexamination." PhRMA Br. 11; see also Pet. 24-25; BIO Br. 8-9. Thus, if allowed to stand, the Federal Circuit's decision all but guarantees that the problem of conflicting judicial and reexamination decisions will recur.

The restructuring of *inter partes* review under the America Invents Act (Opp. 29-30) does not diminish the problem. The AIA "left intact the procedure used in this case, *ex parte* reexamination" (IPO Br. 12), and multiple factors "continue to make [*ex parte*] reexamination an attractive litigation defense strategy" (IPO Br. 13-14). Indeed, if the IPR procedure had existed at the time, Fresenius would have been statutorily barred from initiating an *inter partes* review because it elected to file a declaratory judgment action in court. 35 U.S.C. §315(a)(1).

To be sure, the number of ex parte reexamination requests in FY2013 dropped from the historic high achieved in FY2012. But "the number of reexamination proceedings known to have related litigation jumped 22.5%." IPO Br. 12-13. By the end of FY2013, a stunning 381 pending reexaminations were "known to have related litigation," the highest number in five years. USPTO, Performance & Accountability Report: Fiscal Year 2013 tbl. 14A (last visited Apr. 21, 2014. FY2013 statistics, moreover, fail to account for the impact of this case, in which rehearing en banc was not de-That denial will fuel the nied until November 2013. continued use of ex parte reexamination, particularly by parties in parallel litigation. In fact, ex parte reexamination requests in the first quarter of FY2014 jumped 57% compared to the same quarter of last year. USPTO, Reexaminations - FY 2014, available at http://www. uspto.gov/patents/stats/Reexamination_operational_ statistic_F_14_Q1.pdf (last visited Apr. 21, 2014).

Fresenius's suggestion (at 32) that courts should routinely stay cases pending reexamination is not a solution but rather a symptom of the problem. Stays can rob valid patents of years of effective life. Courts should therefore review stay requests on their own merits, rather than reflexively granting them out of concern that years of work in the courts might later be undone, as has already begun to occur. *See* App. 93a n.9; BIO Br. 10; Pet. 26-27.

- Although Fresenius tries to downplay the Article III issue this case, the limited role of the Federal Circuit in reviewing reexamination decisions does not transform the administrative nature of those decisions. The divided Federal Circuit panel that affirmed the PTO's invalidity ruling did so only after applying a highly deferential standard of review. See In re Baxter Int'l, *Inc.*, 678 F.3d 1357, 1361 (Fed. Cir. 2012) ("The scope of our review in an appeal from a [PTO] decision is limited."); see also id. at 1364 (concluding not that the prior art actually disclosed an element of the claims but only that it "appear[s] similar"). The initial decision to invalidate Baxter's claims despite the Federal Circuit's upholding of the same claims and the operative legal act of cancelling Baxter's claims were entirely the PTO's. Indeed, the PTO was free to reconsider its earlier decision at any time before it issued its reexamination certificate. See In re Bass, 314 F.3d 575, 577 (Fed. Cir. 2002) ("Until a matter has been completed"—i.e., "upon the statutorily mandated issuance of a reexamination certificate"—the "PTO may reconsider an earlier action.").
- 4. Fresenius's contention (at 34) that a ruling for Baxter would harm "true innovators" is difficult to comprehend. Fresenius did not innovate; it copied Baxter's invention, and then later *stipulated* that it had infringed. App. 1a. The real harm to innovation will come if the Federal Circuit's decision is not reversed, thereby creating uncertainty and undermining the value of patents. BIO Br. 9-10; PhRMA Br. 8-10, 12.

Nor is there anything "unjust" (Opp. 33) about requiring Fresenius to pay damages here. Far from being a "poor-quality patent" (Opp. 31), Baxter's invention revolutionized the field (Pet. 5), and was invalidated only years later—indeed, after the patent had already expired—in a deeply flawed process driven by hindsight (Pet. 28). But just as Baxter is bound by that decision however much it might disagree, Fresenius is bound by the decision it received after selecting its own forum and having its day in court.

III. THIS CASE IS AN IDEAL VEHICLE TO PROVIDE GUIDANCE

This case is an ideal vehicle to provide guidance on when a judicial decision upholding patent claims becomes sufficiently final to withstand the subsequent cancellation of those claims in reexamination. The case includes a final judgment of past damages that was not challenged on appeal, an appellate decision resolving all liability issues, and a second final judgment—all before the Federal Circuit issued its decision in the reexamination appeal or the PTO issued the final certificate cancelling Baxter's claims. Having these multiple elements of finality in a single case provides an opportunity for this Court to provide comprehensive guidance on where the line should be drawn.

1. Fresenius tries to muddy the waters by arguing (at 17-18 & n.5) that the judgment of past damages was never final. But in vacating the "royalty award," Fresenius I made clear it was addressing only the "ongoing royalty" for post-verdict damages. Fresenius USA, Inc. v. Baxter Int'l, Inc., 582 F.3d 1288, 1303 (Fed. Cir. 2009). As the district court explained,

Fresenius did not argue at trial or on appeal that the calculation of past damages depended on the number of patents infringed. The Federal Circuit vacated only the injunction and the royalty award, but did not vacate the damages award ...

The Federal Circuit clearly understood that only one of the three asserted patents remained following its reversal, but did not remand for purpose of a new trial on damages. ... Nothing in the mandate in this case indicates that damages for infringement was an issue for remand[.]

Fresenius USA, Inc. v. Baxter Int'l, Inc., 2011 WL 2160609, at *2 (N.D. Cal. May 26, 2011). 1

Fresenius does not dispute that it failed to challenge past damages in *Fresenius I* based on the number of patents infringed. Instead, Fresenius argues (at 17) that a new trial on damages is "the normal rule" when some patents are invalidated. But recent Federal Circuit precedent refutes this claim. *ActiveVideo Networks, Inc.* v. *Verizon Commc'ns, Inc.*, 694 F.3d 1312, 1343 (2012) ("Because Verizon has not argued either before the district court or on appeal that a finding of non-infringement of the '582 patent should result in a reduction of damages, we affirm the damages award

¹ The bookends to this ruling cannot bear the weight Fresenius gives them. The Magistrate Judge's decision Fresenius cites (at 17 n.5) held only that Fresenius's interpretation of the mandate was not so unreasonable as to warrant *sanctions*, and it correctly noted that "Baxter's arguments may well prevail" when considered by the district court. A1686. The district court's statement at the case's end that the second final judgment "appears to super[s]ede" the first meant only that the court would allow Fresenius to bond the entire amount it owed pending appeal. A995.

against Verizon in full."). Not once during fact discovery, expert discovery, trial, or appeal did Fresenius argue that the number of patents at issue mattered to the damages amount.

In short, the judgment of past damages was *final* and, by definition, could not be affected by any issue that remained open on remand.

2. Fresenius also confuses the record by asserting (at 20) that "the accounting had not reached its conclusion before the asserted claims were finally invalidated." See also Opp. 1. In fact, the remand had concluded and a second final judgment had been entered before Baxter's claims were cancelled: The second final judgment was entered in March 2012 (App. 5a), In re Baxter was not decided until May 2012 (id. 9a), and the PTO certificate cancelling Baxter's claims did not issue until April 2013 (id. 8a). Thus, even apart from the final judgment of past damages, Fresenius's liability had already been affirmed on appeal, the limited remand had concluded, and a second final judgment had been entered—all before Baxter's claims were invalidated.

IV. Fresenius's Defense Of The Federal Circuit's Decision Fails

Fresenius devotes a substantial portion of its brief to arguing the merits, but fails in its effort to defend the Federal Circuit's decision.

1. Fresenius's reliance on John Simmons Co. v. Grier Bros. Co., 258 U.S. 82 (1922), is misplaced. As an initial matter, Fresenius misstates the facts of the case. Simmons did not involve "a subsequent ruling by this Court" that "extinguished the district court proceedings" in the sense here. Opp. 20. Rather, this Court's decision revived the patent. Simmons simply ordered

the Third Circuit to recognize the authority of this Court's holding that the patent was valid and could still be enforced. 258 U.S. at 87-92.

Additional distinctions abound. Simmons involved the interaction between two court decisions, rather than between an agency decision and a court decision. More importantly, Simmons dealt with the relationship between this Court and a lower court that had blithely disregarded its ruling. In Simmons, an "accounting" was still pending in the lower court and significant issues remained to be decided. And Simmons involved the peculiarities of equity practice. Pet. 30-31; App. 87a n.6.

This Court has not cited *Simmons* in 60 years, and never in this context. Medtronic Br. 22 n.7. Even if it were not so readily distinguishable, the division over the meaning of the decision only reinforces the need for this Court's review. *Id.* 22.

2. The remaining cases Fresenius cites (at 19-23, 27) are also inapposite. Blonder-Tongue Laboratories, Inc. v. University of Illinois Foundation, 402 U.S. 313 (1971), and Mendenhall v. Barber-Greene Co., 26 F.3d 1573 (Fed. Cir. 1994), involved court-to-court relations rather than competing agency and court rulings. Pet. 29; App. 42a-43a, 87a. Moreover, Mendenhall was an interlocutory ruling, and the Federal Circuit's assertion that "nothing in Mendenhall suggests that the statutory basis for the first appeal controlled whether it would be given res judicata effect" is simply wrong. Pet. 29-30 & n.12 (quoting language from Mendenhall).²

² Additionally, *Mendenhall* and the two non-precedential Federal Circuit decisions Fresenius discusses (at 21-22) are not binding on this Court. The latter do not even bind the Federal Circuit, and their extreme brevity robs them of any persuasive value.

Finally, Moffitt v. Garr, 66 U.S. 273 (1861), actually supports Baxter. While Moffitt stated that a patent must be "in force at the time of trial and judgment," it emphasized that once judgment has been entered, "[t]he title to [monetary damages] does not depend upon the patent, but upon ... the judgment of the court." Id. at 283 (emphasis added). This conclusion reflects the well-established doctrine of merger, which provides that upon judgment the underlying "claim is extinguished and rights upon the judgment are substituted for it." Restatement (Second) of Judgments §18 cmt. a (1982); see also App. 82a n.5.

Here, Baxter's right to past damages arises directly from judgment on that issue—not challenged on appeal—rather than from the underlying patent. Further, Baxter's patent claims were "in force" at the time the district court entered the second judgment. It was only later, when that judgment was on appeal and Baxter's rights under its patent had already merged into it rights under the judgment, that the claims were cancelled. As this Court made clear in Mevs v. Conover, 131 U.S., appx. cxlii, 23 L.Ed. 1008 (Mar. 13, 1877), reprinted in Tilghman v. Proctor, 125 U.S. 136, 144 n.1 (1888), a judgment's vulnerability to administrative cancellation of the underlying patent does not extend to appeal. In *Conover*, the infringer argued that the case should be dismissed because "the patentee ha[d] surrendered the patent upon which the decree was founded" as part of PTO reissue proceedings while the case was on appeal. Id. This Court held that the surrender was "immaterial" because "a surrender after final judgment or decree can have no effect upon a right passed previously into judgment ... The right of the patentee then rests on his judgment or decree, and not on his patent." Id. That is exactly the case here, and

demonstrates the error in the Federal Circuit's approach.

CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted.

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