

No. 17-1616

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

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REGENERON PHARMACEUTICALS, INC.,  
*Petitioner,*

v.

MERUS N.V.,  
*Respondent.*

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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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**REPLY BRIEF IN SUPPORT OF CERTIORARI**

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**RULE 29.6 DISCLOSURE STATEMENT**

The disclosure made in the petition for a writ of certiorari remains accurate.

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**INTRODUCTION**

Buried in the middle of the brief in opposition is this remarkable concession about the key cases at issue here: “*Keystone*, *Hazel-Atlas*, and *Precision Instrument* might support the proposition that an inequitable conduct claim should be based on misconduct before the *Patent Office* in acquiring the patent rather than misconduct before a court in asserting it.” Opp. 26. Indeed, they do. Pet. 12-16. And that is exactly why the decision below is so misguided.

The district court extinguished Regeneron’s patent without making any finding as to what actually transpired before the Patent Office. Instead, the

court summarily concluded that Regeneron intended to deceive the Patent Office based on discovery violations—years later—in litigation. That decision contravened the bedrock principle that even Merus now appears to accept.

Merus’s main response is that the district court *did* find misconduct before the Patent Office; it just did so on the basis of an adverse inference. But that is a fiction: The reality is that the district court did not consider record evidence of Regeneron’s intent, and never gave Regeneron the opportunity to tell its side of the story at trial. As Justice Holmes once observed, “great caution should be used not to let fiction deny the fair play that can be secured only by a pretty close adherence to fact.” *McDonald v. Mabee*, 243 U.S. 90, 91 (1917). While a party that engages in litigation misconduct may lose its case, the district court’s adverse inference bypassed eighty years of precedent to strip Regeneron of its patent altogether.

Merus portrays the decision below as a routine application of the Federal Rules. If that were so, one would expect to see at least *one* other example of a court invalidating a patent based on an adverse inference. Yet, as Judge Newman explained in dissent, neither Merus nor the panel identified “a single case—at any level of the federal system—in which litigation misconduct was part of a finding of inequitable conduct.” Pet. App. 50a. That silence continues.

The decision below, by eroding a key limit on the inequitable conduct doctrine, will impact every player in the patent system—inventors and prosecuting attorneys could have their careers and reputations tarnished by inequitable conduct findings that

have nothing to do with them; patentees could lose valuable property rights in contravention of this Court's cases; and all courts will be burdened by more assertions of inequitable conduct. The outpouring of *amicus* support testifies to the importance of the question presented. *See, e.g.*, NYIPLA *Amicus* Br. 19-23; IPLAC *Amicus* Br. 13-18; NAPP *Amicus* Br. 17-24. This Court should grant certiorari, and correct a misguided decision that threatens the balance struck by our patent system.

## ARGUMENT

### I. THE DECISION BELOW UNAVOIDABLY CONFLICTS WITH THIS COURT'S PRECEDENTS.

The inequitable-conduct doctrine is rooted in three cases: *Keystone*, *Hazel-Atlas*, and *Precision Instrument*. Each makes clear that a patentee's litigation conduct has no bearing on its underlying patent rights. Where a patentee engages in misconduct in the district court, the proper sanction is dismissal, not invalidation of the patent. Pet. 12-16. The decision below contravened that principle, significantly expanding the inequitable conduct doctrine. WLF *Amicus* Br. 9-11.

As noted, Merus does not dispute the core principle of the *Keystone* trilogy. Instead it argues that the principle is not controlling here for two unpersuasive reasons.

1. First, Merus contends that this case is different because the inequitable-conduct finding was based on an adverse inference, not imposed as a "free-floating sanction." Opp. 23. That argument exalts form over substance. Whatever label the district court applied to its sanction, the fact remains that it



found misconduct before the Patent Office—and therefore inequitable conduct—based on litigation conduct. It never considered evidence of what actually took place before the Patent Office; “no evidentiary record was developed on intent to deceive, with no testimony and no opportunity for examination and cross-examination of witnesses.” Pet. App. at 46a (Newman, J., dissenting). Under the *Keystone* trilogy, that gap cannot be plugged by fiction.<sup>1</sup>

*Insurance Corp. of Ireland v. Compagnie des Bauxites de Guinee*, 456 U.S. 694 (1982), is not to the contrary. The Court there held that applying an adverse inference under Rule 37(b) “to facts that form the basis for personal jurisdiction over a defendant” did not violate the Due Process Clause. *Id.* at 695. That decision turned on “the nature of personal jurisdiction.” *Id.* at 701. In particular, the Court found that a Rule 37(b) “sanction is nothing more than \*\*\* the finding of a constructive waiver” of a personal jurisdiction objection. *Id.* at 706. The question here is entirely different: whether, as a matter of substantive patent law, a Rule 37(b) sanction can be used to invalidate a patent for inequitable conduct, despite the conceded principle that a patent can only be invalidated for misconduct *before the Patent Office*. *Insurance Corp.* has nothing to say on that question.

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<sup>1</sup> Merus asserts “Regeneron \*\*\* seeks to have this Court craft a new, patent-unique exception to Rule 37.” Opp. 22. Not so. Regeneron seeks only to vindicate the principles announced in *Keystone*, *Hazel-Atlas*, and *Precision Instrument*. While a district court can punish a patentee by preventing him from recovering against a particular party, it cannot use Rule 37 to invalidate a patent without making the requisite findings.

Merus remains unable to identify a single case where an adverse inference was used to establish patent invalidity. The closest is the Ninth Circuit's decision in *Von Brimer v. Whirlpool Corp.*, 536 F.2d 838, 844 (9th Cir. 1976). But that case involved neither an adverse inference nor a question of patent validity. The issue was whether the plaintiff had an ownership interest in a patent when he filed suit. The district court excluded certain evidence relevant to that question as a sanction under Rule 37. *Id.* at 843. The Ninth Circuit affirmed, but it did *not* indicate that Rule 37 could be used to invalidate a patent. Nor did it suggest that factual questions underlying the invalidity determination could be settled as a sanction; indeed, it specifically noted that the district court had "received foundation testimony and made findings of fact concerning the[] [excluded] exhibits." *Id.* at 844. Merus's best case is far afield.

Merus also suggests that review is unnecessary because the district court's "sanction was \*\*\* tailored to the precise issue Regeneron's misconduct affected: evidence of Regeneron's intent in withholding material information from the Patent Office." Opp. 22. Even if true, that would not cure the fundamental flaw in the district court's decision. A court cannot, by the fiction of an adverse inference, render a patent invalid against the world, whether the sanction is "tailored" or not. Indeed, in *Keystone* and *Hazel-Atlas*, the fraud was directly related to the validity of the patent. Pet. 12-15. Moreover, the district court here justified its sanction, in part, on "Regeneron's *litigation* tactics" going back to the "outset" of the case, looking to "the implications [of] the discovery conduct \*\*\* on the *entirety of the case.*"

Pet. App. at 169a, 193a (emphases added). It did not tether its sanction to the particulars of the supposed wrongdoing. *Id.*

2. Merus's second argument is no more persuasive. Merus tries to evade the clear upshot of the *Keystone* trilogy by arguing that those defendants "did not ask the Court to invalidate the patent through an affirmative counterclaim based on misconduct before the Patent Office." Opp. 27. That misses the point: The *Court* clearly distinguished between misconduct before the Patent Office and misconduct before a court in subsequent litigation. Where a patent is "obtained by fraud," the Court explained, it can be "vacated." *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 251 (1944) (emphasis added). But when the patentee's "corrupt activities in suppressing the truth" occur during *litigation*, the Court said only that the lower courts could "dismiss[] the appeal," and that the patentee could "be denied relief" in the infringement suit. *Id.* at 250-251. That crucial distinction does not turn on the parties' litigation strategy.

Alternatively, Merus contends that the adverse inference here was a "milder sanction" than a default judgment on its counterclaim. Opp. 29. Merus is mistaken: A default judgment would not have extinguished Regeneron's patent right against the world as the district court's sanction effectively did here. "[I]ssue preclusion requires that the issues actually have been litigated, and that the issues underlying a default judgment are not actually litigated." *Nasalok Coating Corp. v. Nylok Corp.*, 522 F.3d 1320, 1330 n.9 (Fed. Cir. 2008); *see also* Restatement (Second) of Judgments § 27 cmt. e (1982) ("In the case of a judgment entered by \* \* \* default, none of the issues is

actually litigated.”). Although a default judgment on an inequitable-conduct counterclaim may be res judicata *between the parties*, it does not establish fraud on the Patent Office as a matter of issue preclusion in a subsequent infringement suit against a different defendant. And that is the key point: A sanction for litigation conduct cannot, consistent with the *Keystone* trilogy, extinguish a patent, even if it can prevent recovery from a particular infringer.

3. The decision below also raises serious concerns under the Takings and Due Process Clauses, which inform the answer to the question presented. Merus argues that Regeneron waived any reliance on constitutional avoidance principles. But the point is that the district court’s sanction extinguished a patent right for litigation misconduct. That issue was clearly pressed and passed on below. *See* C.A. Opening Br. 62-64; Pet. App. 41a-44a. Constitutional avoidance is an additional argument in support of that unquestionably preserved contention. Pet. App. 46a (Newman, J., dissenting). And, as this Court has explained many times, a petitioner can “formulate[] any argument [he] like[s] in support of” a properly raised claim. *Yee v. City of Escondido*, 503 U.S. 519, 535 (1992).

“The provisions of Rule 37 \* \* \* must be read in light of the provisions of the Fifth Amendment that no person shall be deprived of property without due process of law,” and “there are constitutional limitations upon the power of courts, even in aid of their own valid processes, to dismiss an action without affording a party the opportunity for a hearing on the merits of his cause.” *Societe Internationale Pour Participations Industrielles et Commerciales, S.A. v. Rogers*, 357 U.S. 197, 209 (1958). That is doubly true

here: The district court not only “dismiss[ed] an action,” it extinguished the patent that was the basis of that action. *Id.* The district court thus “convict[ed] Regeneron, its counsel, and its scientists, with no trial, no evidence, and no opportunity to respond in their defense,” without even making a predicate finding that Regeneron acted in bad faith. Pet. App. 46a (Newman, J., dissenting); *cf. Nat’l Hockey League v. Metro. Hockey Club, Inc.*, 427 U.S. 639, 643 (1976) (per curiam) (affirming “extreme sanction of dismissal” under Rule 37 in case of “flagrant bad faith”); *see* Seven Chicago Patent Lawyers *Amicus* Br. 10-17.

On the Takings Clause, Merus’s only answer is that “[p]atent rights are defined by, and subject to, the provisions of the Patent Act.” Opp. 32. But at the time “unenforceability” was encoded in the Patent Act in 1952, this Court had made clear that a patent could only be rendered unenforceable based on misconduct before the *Patent Office*, not a district court. Pet. 19 n.2. To say, then, that a patentee holds a patent subject to the provisions of the Patent Act simply assumes the answer to the question presented in this case.

## **II. THE SPLIT IS SQUARE.**

In addition to the panel majority’s departure from this Court’s precedent, the petition showed that the decision below was the rare Federal Circuit decision to create both an intra-circuit and an inter-circuit split. Pet. 24-28. Merus’s response rests, once again, on its exaltation of form over substance.

1. Merus tries (at 19-20, 32) to reconcile the panel majority’s decision with *Aptix Corp. v. Quickturn Design Systems, Inc.*, 269 F.3d 1369 (Fed. Cir. 2001),

by pointing out that *Aptix* did not involve a counterclaim of inequitable conduct. But *Aptix* considered the inequitable-conduct doctrine at length. *See id.* at 1375-77. It concluded that the doctrine was inapplicable because “the record disclose[d] no misconduct in [the] acquisition of the patent right.” *Id.* at 1377 (emphasis added). Nothing in *Aptix* even hints that the procedural device of a counterclaim would have permitted the trial court to dispense with the requirement that “[t]he record”—rather than some inference drawn as a “penalty” for litigation conduct—establish that the patentee’s rights “accrue[d] through inequitable conduct.” *Id.* at 1377-78 (emphasis added).

2. Merus’s cursory response to the three inter-circuit splits produced by the decision below is no more persuasive. The petition showed that the courts of appeals unanimously treat dismissal as the harshest sanction for litigation misconduct. Pet. 25-26. Merus counters (at 33) that Rule 37 authorizes the supposedly harsher sanction of a default judgment. But, as explained *supra* pp. 6-7, a default judgment of inequitable conduct is no different in practical effect from a dismissal. In either case, the upshot is that the patentee cannot assert its patent against the party claiming inequitable conduct. By affirming the district court’s judgment of invalidity, which bars Regeneron from asserting its patent against *anyone*, the panel majority here blessed a far more sweeping remedy for Regeneron’s litigation conduct than its sister circuits would permit.

Merus’s effort to deny the split with decisions in the analogous contexts of trademark and copyright litigation is equally misguided. As the petition explained, courts consistently hold that the cancella-

tion of a copyright or mark for misconduct is appropriate only where the misconduct tainted the acquisition of the right. Pet. 26 & n.4. Merus suggests (at 33) that the cases cited in the petition are distinguishable because none involved litigation misconduct committed “while defending against a claim to cancel or revoke” a copyright or mark. But the cases the petition cites each required *evidence* of the claimant’s intent to deceive the PTO or Copyright Office—evidence that an adverse inference drawn to punish subsequent litigation conduct cannot possibly supply.<sup>2</sup>

Merus’s response to the panel majority’s break with pre-Federal Circuit case law fails for the same reason. Neither Merus’s assertion of a “counter-claim” of inequitable conduct nor the district court’s invocation of Rule 37 changes the fact that the panel majority approved a judgment of unenforceability based on litigation conduct. That holding cannot be reconciled with the rule that litigation conduct cannot retroactively taint a patentee’s conduct in the PTO. *See, e.g., Republic Molding Corp. v. B.W. Photo Utils.*, 319 F.2d 347, 349 (9th Cir. 1963).

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<sup>2</sup> *See, e.g., Whimsicality, Inc. v. Rubie’s Costume Co.*, 891 F.2d 452, 456 (2d Cir. 1989) (relying on “evidence demonstrat[ing]” the copyright holder’s intent); *Money Store v. Harriscorp Fin., Inc.*, 689 F.2d 666, 673 (7th Cir. 1982) (finding no “evidence that [the trademark holder] intended to mislead the Patent Office”); *Aromatique, Inc. v. Gold Seal, Inc.*, 28 F.3d 863, 878 (8th Cir. 1994) (opinion of Arnold, J.) (relying on documentary evidence of claimant’s intent); *Sovereign Military Hospitaller Order of Saint John of Jerusalem of Rhodes & of Malta v. Fla. Priory of Knights Hospitallers of Sovereign Order of Saint John of Jerusalem*, 702 F.3d 1279, 1289 (11th Cir. 2012) (fraud must be proven “by clear and convincing evidence.”).

### III. THIS CASE IS AN IDEAL VEHICLE TO ADDRESS AN IMPORTANT QUESTION.

Merus suggests (at 36-37) that the facts of this case render it unsuitable for review. But the only fact relevant to the question presented is that Regeneron's purported litigation conduct was the sole basis relied on by the district court for its finding that Regeneron acted with the specific intent to deceive the Patent Office. Pet. App. 193a.

Contrary to Merus's assertion (at 36), that fact pattern is likely to recur. The Federal Circuit has for years lamented the "overuse of the inequitable conduct doctrine," with lawyers making a "habit of charging inequitable conduct in almost every major patent case." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1285, 1289 (Fed. Cir. 2011). As the *amici* warn, the panel majority's rule means that baseless charges of *litigation* misconduct will now revivify the "plague[]" of inequitable conduct claims "routinely brought on the slenderest grounds." *Id.* at 1289 (internal quotation marks omitted).

To distract from these concerns, Merus nitpicks (at 34-35, 37) a handful of the arguments presented in some of the many *amicus* briefs urging this Court's review. But Merus cannot obscure the fact that this case has attracted an unusual degree of participation at the certiorari stage. That engagement counsels strongly in favor of review.

Trying a different tack, Merus attempts to downplay the significance of the decision below. It argues that certiorari is unwarranted because the decision to impose a Rule 37 sanction is "fact-intensive" and "committed to the district court's discretion," and because the sanction here was supposedly propor-



tionate. Opp. 21. That argument misconceives the basis of the petition. Regeneron does not seek review of whether a particular sanction is warranted in the individual circumstances of a particular case; the question is whether the district court had the authority *at all* to enter such a draconian sanction. *Highmark Inc. v. Allcare Health Mgmt. Sys., Inc.*, 134 S.Ct. 1744, 1748 n.2 (2014) (“A district court \*\*\* necessarily abuse[s] its discretion if it based its ruling on an erroneous view of the law.”). That is a question of law, well-suited to review.

Merus also claims (at 38-39) that there was record evidence of Regeneron’s intent. But the district court eschewed any reliance on the record of Regeneron’s conduct before the Patent Office, choosing instead to “*infer[]*” intent based on Regeneron’s “discovery conduct.” Pet. App. 193a (emphasis added). Regeneron, of course, disputes that evidence, as well as the alternative findings Merus claims (at 39) did not depend on the court’s sanction. The place to resolve those disputes—and Merus’s arguments (at 38) regarding the burden of proof—is a trial on Regeneron’s intent.

**CONCLUSION**

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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