

No. 17-1616

IN THE
Supreme Court of the United States

REGENERON PHARMACEUTICALS, INC.,
Petitioner,

v.

MERUS N.V.,
Respondent.

**On Petition for a Writ of Certiorari
to the U.S. Court of Appeals
for the Federal Circuit**

**BRIEF OF WASHINGTON LEGAL FOUNDATION
AS *AMICUS CURIAE* IN SUPPORT OF PETITIONER**

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QUESTION PRESENTED

Whether a patent right can be fully extinguished based on misconduct committed by the patentee's counsel during federal district court litigation to enforce the patent right.

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INTERESTS OF *AMICUS CURIAE*

The Washington Legal Foundation (WLF) is a public-interest law firm and policy center with supporters in all 50 States.¹ WLF devotes a substantial portion of its resources to defending free enterprise, individual rights, a limited and accountable government, and the rule of law.

WLF has participated in numerous proceedings before this and other federal courts raising important issues about the scope, validity, and enforceability of patents. *See, e.g., SCA Hygiene Products Aktiebolag v. First Quality Baby Products, LLC*, 137 S. Ct. 954 (2017); *Federal Trade Comm'n v. Actavis, Inc.*, 570 U.S. 136 (2013). In particular, WLF has filed several briefs opposing expansion of the inequitable-conduct doctrine, under which otherwise valid patents can be held unenforceable because of the patentee's misconduct during Patent Office proceedings. *See, e.g. Therasense Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011) (*en banc*); *Purdue Pharma, L.P. v. Endo Pharmaceuticals, Inc.*, 438 F.3d 1123 (Fed. Cir. 2006). WLF previously filed a brief in this case, in support of the petition for rehearing *en banc* in the Federal Circuit.

WLF strongly supports providing patent protection to pharmaceutical manufacturers that

¹ Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, made a monetary contribution intended to fund the preparation and submission of this brief. More than 10 days before filing this brief, WLF notified counsel for Respondent of its intent to file. All parties have consented to the filing.

develop new and useful medical products. WLF believes that if advances in health care are to continue, it is vital that companies that develop new products be afforded a substantial period of exclusivity, during which potential competitors are not permitted to market the same product. That exclusivity period provides an economic incentive for new product development by ensuring that pharmaceutical companies that gamble the substantial sums necessary for the development of new therapies will be able to reap substantial rewards in those few instances in which their research-and-development expenditures bear fruit.

WLF also recognizes that Congress has imposed limits on patent rights and that those limits must be strictly enforced by the courts if competition is to be maintained. Nonetheless, WLF believes that the Federal Circuit's decision, which invalidated a valuable patent on judge-made inequitable-conduct grounds, has the potential to undermine our nation's patent system if allowed to stand. WLF believes that the Federal Circuit's "inequitable conduct" case law has drifted far afield from the Supreme Court decisions on which it ostensibly is based—decisions that authorized the dismissal of patent-infringement lawsuits in which patentees improperly concealed the patent's dubious pedigree. *Hazel-Atlas Glass Co. v. Hartford Empire Co.*, 322 U.S. 238, 251 (1944).

By lowering the bar for those asserting that a patent should be declared unenforceable due to inequitable conduct, the panel has considerably increased the risks to those asserting patent rights and thereby reduced the market value of all patents. WLF

is concerned that if the property rights of patent holders can be so easily eliminated, the public may begin to lose faith in the viability of our patent system.

WLF does not know whether evidence at a trial would have demonstrated that Petitioner Regeneron Pharmaceuticals, Inc. intended to deceive the Patent and Trademark Office (PTO) or obtained its patent fraudulently. But WLF believes that Regeneron was entitled to an evidentiary hearing on those issues, and that the lower courts exceeded their authority when they declared Regeneron's patent unenforceable as a sanction for litigation misconduct.

STATEMENT OF THE CASE

Regeneron obtained the patent at issue in this case (the '018 patent) in 2013; that patent included 20 separate claims for a genetically modified mouse that produces antibodies for use in treating human diseases. Regeneron filed suit against Respondent Merus N.V., asserting that Merus had infringed 13 of the '018 patent's 20 claims. Yet as a result of the district court's finding that Regeneron's trial counsel engaged in litigation abuses, the lower courts invalidated the entire patent, including the seven patent claims that Regeneron had never placed at issue.

The Federal Circuit upheld the invalidity judgment under the inequitable conduct doctrine, a judge-made equitable defense to patent infringement (a defense that is sometimes, as here, referred to as a "counterclaim"). The doctrine provides that an entire patent will, under certain circumstances, be held

invalid (or, what amounts to the same thing, unenforceable) if the defendant can demonstrate that the patentee acted “inequitably” in proceedings before the PTO—regardless whether the patentee demonstrates that the PTO would have issued the patent in the absence of any inequitable conduct. Because the invalidation of a patent on inequitable-conduct grounds has such a dramatic impact on private property rights, it is unsurprising that many Federal Circuit judges have referred to the inequitable-conduct remedy as the “atomic bomb” of patent law. *See, e.g., Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting), *cert. denied*, 556 U.S. 1208 (2009).

At an early stage of the litigation, the district court effectively determined that Merus had not infringed Regeneron’s patent. The court issued a claims-construction opinion that narrowly construed the ’018 patent. In response, “Regeneron stipulated that its infringement claim as to Merus must fail if the [district court’s] constructions withstand challenge on appeal.” Pet. App. 68a. The case proceeded in the district court for the sole purpose of litigating Merus’s additional defense: its inequitable-conduct defense. *Id.* In other words, the sole basis for the district court’s continued jurisdiction was the possibility that its claims construction would be overturned on appeal, at which point Merus could argue that the rejection of Regeneron’s claims should be upheld on alternative grounds.

The district court bifurcated its bench trial of the inequitable-conduct issue. The first trial would determine whether four documents that Regeneron did

not supply to the PTO were “material” to its patent application. If the district judge held, following the first trial, that the documents were material, then she intended to conduct a second trial to determine whether Regeneron withheld the documents with the intent to deceive the PTO. Pet. App. 3a.²

The district court conducted the initial trial in June 2015 and (in a lengthy opinion issued five months later) concluded that Merus had demonstrated materiality. Pet. App. 67a-194a. It further determined that trial counsel for Regeneron had engaged in litigation misconduct, principally by failing to produce documents relevant to Merus’s intent-to-deceive-the-PTO defense.³

As a sanction for Regeneron’s litigation misconduct, the court adopted an “adverse inference” that Regeneron acted with “the specific intent to deceive the patent office”—thereby obviating any need

² Under Federal Circuit case law, an inequitable-conduct defense requires an alleged infringer to demonstrate, among other things, both materiality and intent to deceive by “clear and convincing evidence.” *Therasense*, 649 F.3d at 1287.

³ Regeneron asserted attorney-client privilege as its basis for withholding numerous documents authored by two attorneys involved in the company’s efforts to obtain the ’018 patent. But Regeneron called those two attorneys as witnesses at the first trial and intended to do so again at the second trial. The trial judge reviewed a sampling of the withheld documents *in camera* and determined that many of them were relevant to the intent-to-deceive issue. She determined that Regeneron waived any privilege with respect to the documents once it determined to call the witnesses at trial and thus should have disclosed those documents well in advance of the second trial. Pet. App. 179a-91a.

for a second trial. Pet. App. 191a. It further concluded, based on that adverse inference, that Regeneron “engaged in inequitable conduct in connection with prosecution of the ’018 Patent,” *id.* at 194a, and so it entered a judgment declaring the entire ’018 patent unenforceable.

A sharply divided Federal Circuit panel affirmed the inequitable-conduct judgment. Pet. App. 1a-66a.⁴ The panel majority rejected Regeneron’s contention that the district court’s litigation sanction, which inexorably led to an inequitable-conduct determination, was unduly harsh. While acknowledging that the sanction deprived Regeneron of valuable property rights based on trial misconduct that was wholly distinct from its alleged misconduct before the PTO, the majority held that the trial court acted within its discretion in imposing the adverse-inference sanction. *Id.* at 41a-42a. It held that the sanction was not equivalent to a dismissal (a sanction which generally requires a predicate finding of bad faith), and that a finding of “ordinary negligence” is sufficient to justify adverse-inference sanctions of the sort at issue here. *Id.* at 42a.

Judge Newman dissented. Pet. App. 44a-66a.

⁴ The panel did not address Regeneron’s appeal from the district court’s claims-construction ruling, a ruling that effectively determined that Marus had not infringed the ’018 patent and thereby provided Marus with a complete defense to Regeneron’s claims. Pet. App. 44a. The panel deemed it unnecessary to address that issue in light of its far broader ruling that “Regeneron’s inequitable conduct renders the ’018 patent unenforceable.” *Ibid.*

Citing this Court’s *Hazel-Atlas* decision, she argued that “the Supreme Court repeatedly stressed” that while a finding of litigation misconduct may warrant refusal to grant judicial relief to a patentee asserting infringement claims, it is not a sufficient predicate for a judgment invalidating the patent. *Id.* at 47a. She stated:

No case law from the Supreme Court or this court provides a basis for nullifying property rights granted by the United States when such property rights did not themselves accrue through inequitable conduct.

Id. at 48a (quoting *Aptix Corp. v. Quickturn Design Systems, Inc.*, 269 F.3d 1369, 1377 (Fed. Cir. 2001)).

The Federal Circuit thereafter denied Regeneron’s petition for rehearing *en banc*. Pet. App. 195a-201a. Judge Newman, joined by Judge Reyna, issued an opinion dissenting from the denial. *Id.* at 198a-201a.

SUMMARY OF ARGUMENT

The petition raises issues of exceptional importance. This Court has repeatedly recognized that patents issued by the federal government are private property entitled to protection under the Due Process and Takings Clauses of the Fifth Amendment. *See, e.g., Oil States Energy Services, LLC v. Greene’s Energy Group, LLC*, 138 S. Ct. 1365, 1379 (2018). Yet the decision below authorizes district courts to deprive patentees of those property rights based on findings of

litigation misconduct, even in the absence of any finding that the patent was improperly issued or that the patentee acted with an intent to deceive the PTO. Review is warranted to determine whether federal courts are authorized to treat private property rights in such a cavalier manner.

The Federal Circuit justified its decision to invalidate Regeneron's patent by invoking a rule of its own creation: the inequitable-conduct doctrine. The appeals court contends that it derived the inequitable-conduct doctrine from a trilogy of early 20th-century Supreme Court decisions that penalized patentees who came into federal court with "unclean hands." But the Federal Circuit's inequitable-conduct case law has drifted far afield from its unclean-hands roots. As the appeals court itself has recognized, it has repeatedly expanded the scope of the doctrine so that the doctrine has come

to embrace a broader scope of misconduct, including not only egregious affirmative acts of misconduct intended to deceive both the PTO and the courts but also the mere nondisclosure of information to the PTO. Inequitable conduct has also diverged from the doctrine of unclean hands [articulated in the Supreme Court trilogy] by adopting a different and more potent remedy—unenforceability of the entire patent rather than mere dismissal of the instant suit.

Therasense, 649 F.3d at 1287.

The decision below has taken the inequitable-conduct doctrine to new extremes. While previous appeals court decisions had limited the doctrine to instances in which the alleged infringer demonstrated through clear-and-convincing evidence that the patentee had intended to deceive the PTO, the court below permitted findings of litigation misconduct to serve as a substitute for such proof. Moreover, previous decisions also required district courts, if materiality and intent-to-deceive were proven, to “weigh the equities to determine whether the applicant’s conduct before the PTO warrants rendering the entire patent unenforceable,” *id.*; the court below upheld the unenforceability judgment even though the district court skipped over the weigh-the-equities step entirely.

As currently articulated by the Federal Circuit, the inequitable-conduct doctrine conflicts sharply with this Court’s case law. The Court has held that the doctrine of unclean hands “gives wide range to the equity court’s use of discretion in refusing to aid the unclean litigant” and thus authorizes federal courts to refuse relief to patentees asserting infringement claims if they have not “acted fairly and without fraud or deceit as to the controversy in issue.” *Precision Instrument Mfg. Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806, 815 (1945) (citing *Keystone Drilling Co. v. General Excavator Co.*, 290 U.S. 240, 245 (1933)). But while the Court has denied relief to patentees who come to court with unclean hands, it has balked at authorizing federal courts to invalidate patents as a remedy in infringement actions, *Hazel-Atlas*, 322 U.S. at 251, and certainly has never endorsed extinguishing property rights as a remedy for

litigation misconduct. Review is warranted to resolve the conflict between the Federal Circuit's inequitable-conduct doctrine (especially as articulated by the panel majority below) and this Court's case law.

Review is particularly warranted because the inequitable-conduct doctrine authorizes a federal court to destroy property rights that were never at issue before the court. If a patentee is determined to have engaged in inequitable conduct before the PTO, the Federal Circuit requires that the *entire* patent be rendered unenforceable, even those patent claims that the patentee never asserted were infringed by the defendant. *J.P. Stevens & Co. v. Lex Tex Ltd.*, 747 F.2d 1553, 1561 (Fed. Cir. 1984). Thus, based on a finding of litigation misconduct, the courts below invalidated all 20 claims in the '018 patent, even though Regeneron asserted that Merus infringed only 13 of those 20 claims and never placed the other seven claims at issue.

Finally, review is warranted given the importance of the inequitable-conduct doctrine in all patent litigation. Even though the Federal Circuit continues to adhere to the doctrine, many judges on the appeals court have come to view inequitable-conduct claims as "an absolute plague" on the patent system. *Burlington Industries, Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988). Such claims are asserted by defendants in the great majority of infringement lawsuits, thereby driving up the costs of patent litigation and imperiling property rights to an unwarranted extent. There is every reason to fear that the decision below, by significantly expanding the scope of the inequitable conduct doctrine, will exacerbate the

plague by prompting even more defendants to invoke the doctrine.

REASONS FOR GRANTING THE PETITION

I. THE DECISION BELOW, AS WELL AS THE FEDERAL CIRCUIT’S INEQUITABLE-CONDUCT DOCTRINE, CONFLICT WITH THIS COURT’S CASE LAW

The judge-made inequitable-conduct doctrine has inexorably grown in strength over the past several decades. At its inception, it consisted of little more than a recognition that patent holders, like all other litigants seeking equitable relief, must “come with clean hands” if they wish to obtain relief from the courts. But in recent decades, the doctrine has morphed into a powerful tool that the Federal Circuit wields freely to punish patentees whose conduct it disapproves—by not only denying them judicial relief but also depriving them of their private property. This Court has never endorsed the inequitable-conduct doctrine; indeed, that doctrine directly conflicts with the Court’s case law. Review is warranted to resolve that conflict.

Review of the decision below is particularly warranted because it has taken the inequitable-conduct doctrine to new extremes. While previous Federal Circuit decisions had limited the doctrine only to instances in which the alleged infringer demonstrated through clear-and-convincing evidence that the patentee had intended to deceive the PTO, the court below permitted findings of litigation misconduct to serve as a substitute for such proof. In other words,

the Federal Circuit now claims the right to destroy property rights by declaring a patent invalid based not on any impropriety in obtaining the patent but because the patentee's counsel years later engaged in misconduct during the course of infringement litigation.

A. The Court's Unclean-Hands Case Law Does Not Authorize Invalidation of Patents

In three cases decided between 1933 and 1945, the Court addressed the circumstances under which federal courts should grant relief to patentees who sought to enjoin infringement but who were deceitful in their dealings with the courts. In each instance—*Keystone Driller*, *Hazel-Atlas*, and *Precision Instrument*—the Court invoked the doctrine of unclean hands to deny relief to the deceitful patentee, but it made clear that appropriate relief did *not* include invalidation of the underlying patents.

The validity of the patent at issue in *Keystone* (covering parts of a ditching machine) was subject to question because of evidence of prior use of the device by Bernard Clutter. Before filing suit against an alleged infringer, the patentee paid Clutter to keep silent about his prior use. *Keystone*, 290 U.S. at 243. The Court concluded that the effort to suppress Clutter's testimony was a "corrupt transaction" and was directly connected to the patentee's infringement action. *Id.* at 244-46. Accordingly, it invoked the doctrine of unclean hands to affirm the appeals court's decree dismissing the complaints "without prejudice."

*Id.*⁵

But the Court never suggested that the patentee's litigation misconduct warranted invalidation of the patent, even though the misconduct was directly related to the patent's potential invalidity (based on prior use). To the contrary, the Court explained that the unclean-hands doctrine is applied for the purpose of denying relief to litigants who have not been honest in their dealings with a court, "not by way of punishment for extraneous transgressions." *Id.* at 245. Indeed, as the Petition explains, the patent at issue in *Keystone* came back before the Court two years later, yet the Court never suggested in the later proceedings that the patent should be deemed invalid as a result of the patentee's earlier litigation misconduct. Pet. 14.

In *Hazel-Atlas*, the Court applied equitable principles to set aside an earlier infringement judgment because the patentee (in response to a

⁵ The Court explained the unclean-hands doctrine by quoting Joseph Story:

It is one of the fundamental principles upon which equity jurisprudence is founded, that before a complainant can have a standing in court he must first show that not only has he a good and meritorious cause of action, but he must come into court with clean hands. He must be frank and fair with the court, nothing about the case under consideration should be guarded, but everything that tends to a full and fair determination of the matters in controversy should be placed before the court.

Id. at 244 (quoting *Story's Equity Jurisprudence* (14th Ed.) § 98).

defense that the device in question was obvious and thus unpatentable) had submitted to the Third Circuit (the earlier court) a fraudulent trade journal article—and the Third Circuit had relied heavily on the article in concluding that the patent was valid. The Court cited *Keystone* for the proposition that a trial judge is warranted in dismissing an infringement suit upon learning that the patentee has deceived the court, *Hazel-Atlas*, 290 U.S. at 246, and concluded that similar considerations justified setting aside a 12-year-old judgment obtained by fraud. *Ibid.*

Yet the Court declined to order that the patent be invalidated. The Court acknowledged evidence that the patentee might have defrauded not only the Third Circuit but also the Patent Office. It held that if convincing evidence that the Patent Office was defrauded were brought before an appropriate forum, an order invalidating the patent would be proper. *Id.* at 251. But the issue before the Court was the appropriate remedy for the patentee's *litigation* fraud in the Third Circuit. The Court concluded that while setting aside the Third Circuit's judgment was an appropriate remedy, the patentee's litigation misconduct was not by itself an appropriate basis for deeming the patent unenforceable/invalid. *Id.*

In *Precision Instrument*, the third decision in the Supreme Court trilogy, the Court once again invoked the unclean-hands doctrine to deny relief to a patentee who asserted infringement claims in federal court despite knowing (and failing to reveal) that one of the patents it sought to enforce had been obtained by fraud. 324 U.S. at 819. Yet although the Court concluded that the patentee's litigation misconduct

barred it from obtaining equitable relief from the courts, it never suggested that the misconduct warranted invalidation of the patents.

B. The Federal Circuit’s Inequitable-Conduct Case Law Has Drifted Far Afield from Its Unclean-Hands Roots

The Federal Circuit asserts that it derived its inequitable-conduct doctrine from the Court’s decisions in *Keystone*, *Hazel-Atlas*, and *Precision Instrument*. There is little resemblance between the doctrine and this Court’s precedents, however. Indeed, the Federal Circuit’s invocation of the doctrine to invalidate patents on the basis of litigation misconduct directly conflicts with those precedents and warrants the Court’s review.

As noted above, the Federal Circuit candidly acknowledged in *Therasense* the wide disparity between the inequitable-conduct doctrine as currently understood by the appeals court and this Court’s unclean-hands trilogy. *Therasense*, 649 F.3d at 1287. Among the disparities it cited:

- While the unclean-hands precedents all involved “egregious affirmative acts of misconduct” in court proceedings, the inequitable-conduct doctrine has now come to embrace “a broader scope of misconduct,” including “mere nondisclosure of information to the PTO.”
- The doctrine has “diverged from the doctrine of unclean hands” by adopting “a different and more potent remedy—unenforceability of the

entire patent rather than dismissal of the instant suit.”

Ibid. That latter divergence creates considerable tension with the Court’s unclean-hands trilogy, which balked at authorizing unenforceability remedies and affirmatively barred such relief as a remedy for litigation misconduct.

Recognizing a need to reconsider the Federal Circuit’s inequitable-conduct case law, *Therasense* somewhat tightened the requirements for asserting an inequitable-conduct defense. It heightened the evidentiary showings necessary to establish that documents withheld from the PTO were “material” and that the patentee acted with “intent to deceive.” *Id.* at 1290. If those two elements are established, one hurdle still remains: the district court must “weigh the equities” to determine whether the patentee’s misconduct before the PTO “warrants rendering the entire patent unenforceable.” *Id.* at 1287. The court explained that the doctrine “hinges on basic fairness” and that “[b]ecause inequitable conduct renders an entire patent (or even a family of patents) unenforceable, as a general rule, this doctrine should only be applied in instances where the patentee’s misconduct resulted in the unfair benefit of receiving an unwarranted claim.” *Id.* at 1292.

While *Therasense* sought to eliminate some of the more extreme excesses of the inequitable-conduct doctrine, the decision below took a giant step in the opposite direction. The panel majority jettisoned the evidentiary standards articulated in *Therasense*, effectively rendering those standards inapplicable if

the defendant can demonstrate that the patentee has engaged in litigation misconduct. The panel upheld the district court’s imposition of an “adverse inference” (a non-evidence-based finding that Regeneron withheld four documents from the PTO with the intent to deceive) as a sanction for Regeneron’s litigation misconduct. It did so even though the adverse inference led inexorably (in the district court’s estimation) to entry of a judgment invalidating the entire ’018 patent. Pet. App. 41a-44a. Indeed, the panel apparently deemed the litigation misconduct as sufficient justification for overlooking the district court’s failure to engage in Step 2 of the inequitable-conduct process: a “weigh[ing] of the equities” to determine whether the punishment fits the crime. *Id.*

The panel’s conclusion that litigation misconduct can serve as a basis for depriving a patentee of its property rights—as opposed to merely providing justification for dismissing an infringement suit—directly conflicts with the unclean-hands trilogy. That conflict is particularly glaring because it places extremely valuable patent rights in jeopardy of judicial abrogation without regard to whether a patentee engaged in any misconduct before the PTO. Review is warranted to address that conflict.

II. THE INEQUITABLE-CONDUCT DOCTRINE AUTHORIZES A FEDERAL COURT TO DESTROY PROPERTY RIGHTS THAT WERE NEVER JOINED IN THE CASE

Review is also warranted because the inequitable-conduct doctrine, as applied by the courts below, deprives patentees of a much broader range of

property rights than can plausibly be justified by the patentees' alleged wrongdoing. The Federal Circuit applies an "all claims" rule: once the patent holder is deemed to have engaged in inequitable conduct before the PTO with respect to one patent claim, "all the claims—not just the particular claims to which the inequitable conduct is directly connected—are unenforceable." *J.P. Stevens*, 747 F.2d at 1561. Thus, based on a finding of litigation misconduct, the courts below invalidated all 20 claims in the '018 patent, even though Regeneron asserted that Merus infringed only 13 of those 20 claims and did not place the other seven claims (Claims 3, 4, 5, 13, 14, 15, and 20) at issue.

Moreover, the district court's materiality analysis was limited to Claims 1 through 5, and thus it never determined that the four documents withheld from the PTO were material to the other 15 claims. Yet as a result of the its inequitable-conduct finding, the district court invalidated Claims 6 through 20 without ever having found that Regeneron withheld *any* documents from the PTO that were material to those claims. *See* Pet. App. 118a-19a & n.26; Joint Stipulation and Order of Invalidity and Non-Infringement, ¶ 4 (Dkt. #271, Feb. 24, 2015).

The Federal Circuit's "all claims" rule conflicts with this Court's understanding of the proper role of courts of equity. A judgment declaring a patent to be unenforceable is equitable in nature. Equity courts have "traditionally [been afforded] broad discretion in deciding appropriate relief." *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 310 (1982). That discretion "must include the ability to deny as well as grant" equitable relief. *Id.* at 320. As the Court has

explained:

The essence of equity jurisdiction has been the power of the Chancellor to do equity and to mould each decree to the necessities of the particular case. Flexibility rather than rigidity has distinguished it.

Hecht Co. v. Bowles, 321 U.S. 321, 329 (1944). Equitable relief is “never awarded as of right” and “does not follow from success on the merits as a matter of course.” *Winter v. Natural Resources Defense Council, Inc.*, 555 U.S. 7, 24, 32 (2008).⁶

The Federal Circuit’s “all claims” rule is inconsistent with this Court’s case law (cited above) governing federal court’s exercise of equitable powers. It is the antithesis of the “flexibility” demanded by *Hecht*; it establishes a hard-and-fast rule requiring invalidation of *all* related claims—and the resulting destruction of valuable property rights—once a patentee has been determined to have engaged in

⁶ Congress is free, of course, to adopt legislation altering traditional equitable rules governing adjudication of statutorily created rights. *See, e.g., Romero-Barcelo*, 456 U.S. at 313. But courts “do not lightly assume that Congress has intended to depart from established principles” governing equitable relief, *id.*, and there is no evidence that Congress has intended such a departure in connection with inequitable-conduct claims. The provision generally understood to serve as the statutory basis for inequitable-conduct defenses, 35 U.S.C. § 282, states merely that “unenforceability” is a defense “in any action involving the validity or infringement of a patent” and does not elaborate regarding when an unenforceability judgment is warranted.

inequitable conduct with respect to a single patent claim. See Nicole M. Murphy, *Inequitable-Conduct Doctrine Reform: Is the Death Penalty for Patents Still Appropriate?*, 93 MINN. L. REV. 2274, 2298 (2009).⁷

While recognizing that litigation sanctions that determine the outcome of litigation should be adopted very sparingly, the Federal Circuit sought to justify the district court’s sanction by asserting that it “was not a dismissal” but instead “was a properly drawn adverse inference against Regeneron.” Pet. App. 42. The distinction that the appeals court attempted to draw makes little sense and has been rejected by every other federal appeals court to address the issue. See, e.g. *Esposito v. Home Depot U.S.A., Inc.*, 590 F.3d 72, 78 (1st Cir. 2009) (litigation sanction that precluded the deposition of the plaintiff’s expert witness had the practical effect of a dismissal sanction and should be reviewed on appeal as such); *Ali v. Sims*, 788 F.3d 954, 957 (3d Cir. 1986) (an order directing that, as a litigation sanction, the allegations of the plaintiff’s complaint should be deemed admitted had the practical effect of a default-judgment sanction and should be reviewed on appeal as such).

Here, the inevitable results of the district court’s litigation sanction—an adverse inference regarding intent-to-deceive—were not only the dismissal of Regeneron’s infringement claims but also the invalidation of the entire ’018 patent and the

⁷ The “all claims” rule also conflicts with decisions from other federal appeals courts. See, e.g., *In re Multidistrict Litigation Involving Frost Patents*, 540 F.2d 601, 611 (3d Cir. 1976).

destruction of Regeneron’s private property. The Federal Circuit should have reviewed the litigation sanction under the stricter appellate standards properly applied to sanctions of that nature.

Case law from other federal appellate courts uniformly holds that litigation sanctions whose effect is to decide the case for one side or the other are “drastic sanctions” that can only be justified in “extreme circumstances.” *Halaco Engineering Co. v. Costle*, 843 F.2d 376, 380 (9th Cir. 1988). *See, e.g., Bergstrom v. Frascone*, 744 F.3d 571, 575 (8th Cir. 2014); *Wilson v. Volkswagen of America, Inc.*, 561 F.2d 494, 503-04 (4th Cir. 1977); *see also* 8B Wright & Miller, *Federal Practice & Procedure: Civil*, § 2284 (3d ed.) (2018) (“[C]ourts should make the punishment fit the crime and should take care not to impose a drastic sanction that will prevent adjudication of a case on its merits except on a clear showing that this course is required.”). Yet the Federal Circuit held that the district court’s litigation sanction—whose effect was far more serious than the mere dismissal of Regeneron’s infringement claim—was “properly drawn” and could be justified on a showing of “ordinary negligence.” Pet. App. 42a.

Importantly, the district court made no finding that Regeneron’s litigation misconduct prejudiced Merus’s ability to present its inequitable-misconduct defense. The most significant discovery abuse identified by the district court was the improper assertion of privilege for documents involving two Regeneron witnesses. Pet. App. 191a. The court concluded that *if* those two witnesses were permitted to testify at the second trial, then “fairness” would

require re-opening discovery regarding the documents in question. *Id.* It further concluded that the additional discovery “would consume substantial time and costs.” *Id.* “Time and costs” were the *sole* reasons cited by the court as its basis for drawing an adverse inference that effectively invalidated the ’018 patent: “At this point in the litigation, this is not a fair burden for Merus or this Court.” *Id.*

But the district court failed to explain why a lesser penalty could not adequately compensate Merus for the “time and costs” necessary to re-open discovery. Under those circumstances, the sanction imposed was grossly disproportionate to the offense. As the Third Circuit has explained, “the basic thrust of the Supreme Court jurisprudence is that sanctions that [a]ffect the outcome of the trial should only be imposed in order to compensate for violations that may plausibly be thought likely to affect the outcome of the trial.” *Estate of Spear v. Comm’r of IRS*, 41 F.3d 103, 115 (3d Cir. 1994).

More importantly, the severity of the district court’s extreme litigation sanction was greatly magnified by the Federal Circuit’s “all claims” rule. That rule guaranteed that the district court’s inequitable-conduct sanction would result in a penalty that deprived Regeneron of its property rights in all 20 claims in the ’018 patent. Review is warranted because the “all claims” rule conflicts with this Court’s understanding of the proper role of courts of equity.

III. THE PETITION RAISES AN ISSUE OF MAJOR IMPORTANCE IN VIRTUALLY ALL PATENT INFRINGEMENT LITIGATION

Review is also warranted because the Petition raises an issue—the proper scope of the inequitable-conduct doctrine—that is of major importance in virtually all patent infringement litigation.

Even though the Federal Circuit continues to adhere to the doctrine, many judges on the appeals court have come to view inequitable-conduct claims as “an absolute plague” on the patent system. *Burlington Industries*, 849 F.2d at 1422. In its *Therasense* decision, the Federal Circuit cited seven of its prior opinions that included the “absolute plague” lament. *Therasense*, 649 F.3d at 1289. It also cited a recent study that “estimated that eighty percent of patent infringement cases included allegations of inequitable conduct.” *Id.* Given the ubiquity of inequitable-conduct defenses, the proper contours of the doctrine are of significant interest to a large number of patent litigants.

Moreover, there is every reason to fear that the decision below, by significantly expanding the scope of the inequitable conduct doctrine, will exacerbate the plague by prompting even more defendants to invoke the doctrine. The history of the inequitable-conduct doctrine demonstrates that virtually all defendants will assert an inequitable-conduct defense if it has *any* plausible chance of succeeding. The decision below provides that plausible chance to virtually all accused infringers. It allows them to circumvent the evidentiary barriers to a successful inequitable-conduct

defense by pointing to evidence of litigation misconduct, even when the misconduct occurs years after issuance of the patent and thus is irrelevant to the materiality and intent-to-deceive issues.

Therasense chronicles at length the reasons why too-frequent invocation of the inequitable-conduct doctrine is bad for the patent system and unfair to patent holders. In this case, it has led to imposition of draconian penalties on Regeneron despite the absence of an evidentiary hearing on whether it intended to deceive the PTO. It besmirches the reputations of those who prosecuted the '018 patent before the PTO. It has deprived a patent holder of all power to enforce its property rights, not only with respect to the alleged infringer but also the rest of the world. It renders unenforceable patent claims that were wholly unrelated to the alleged inequitable conduct or that were never placed at issue in the infringement proceedings. The property rights of countless other patent holders are similarly threatened. Review is warranted to determine whether this massive assault on property rights constitutes an appropriate exercise of judicial power.

CONCLUSION

The Court should grant the Petition.

Respectfully submitted,

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