

No. 17-1616

IN THE
Supreme Court of the United States

REGENERON PHARMACEUTICALS, INC.,
Petitioner,

v.

MERUS N.V.,
Respondent.

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

**BRIEF OF *AMICUS CURIAE*
NEW YORK INTELLECTUAL
PROPERTY LAW ASSOCIATION
IN SUPPORT OF NEITHER PARTY**

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INTEREST OF *AMICUS CURIAE*¹

The New York Intellectual Property Law Association (“NYIPLA”) is a bar association of more than 1,100 attorneys who practice in the areas of patent, copyright, trademark, and other intellectual property law. It is one of the largest regional IP bar associations in the United States.

The NYIPLA’s members include a diverse array of attorneys specializing in patent law, including in-house counsel for businesses that prosecute, enforce, and challenge patents, as well as attorneys in private practice who prosecute patents and represent entities in various proceedings before the U.S. Patent and Trademark Office (“PTO”, or the “Patent Office”). Its members represent inventors, entrepreneurs, businesses, universities, and industry and trade associations. They also regularly participate in patent litigation on behalf of both plaintiffs and defendants. The NYIPLA thus brings an informed perspective to the issues presented.

The NYIPLA, its members, and the clients of its members share an interest in having the standards governing the enforceability of patents be

¹ The NYIPLA and its counsel represent that they have authored the entirety of this brief, and that no person other than the *amicus curiae* or its counsel has made a monetary contribution to the preparation or submission of this brief. Counsel of record for Petitioner and Respondent received timely notice of the NYIPLA’s intention to file this *amicus curiae* brief, and both parties have consented to its filing.

reasonably clear and predictable, and therefore have a strong interest in the issues at stake in this case.²

INTRODUCTION

This case concerns an adverse inference that two prosecuting attorneys intended to deceive the PTO during prosecution of a patent, drawn as a sanction for discovery misconduct by litigation counsel in court proceedings years later, resulting in a judgment nullifying that patent under the inequitable conduct doctrine.

The patent-owner, here Regeneron, accused Merus of infringing its patent relating to the use of transgenic mice to generate therapeutic antibodies for use in humans. Pet. App. 2a, 5a. Merus alleged that the patent was unenforceable for inequitable conduct during patent prosecution, arguing that Regeneron's prosecuting attorneys withheld prior art references material to patentability "with the specific intent to deceive the PTO." *Id.* 3a. Regeneron

² The arguments made in this brief were approved by an absolute majority of the NYIPLA's officers and members of its Board of Directors, but do not necessarily reflect the views of a majority of the members of the Association or of the law or corporate firms with which those members are associated. After reasonable investigation, the NYIPLA believes that no officer, director, or member of the Amicus Briefs Committee who voted in favor of filing this brief, nor any attorney associated with any such officer, director, or committee member in any law or corporate firm, represents a party to this litigation. Some officers, directors, committee members, or associated attorneys may represent entities, including other *amici curiae*, which have an interest in other matters that may be affected by the outcome of this litigation.

responded that the withheld references were cumulative of other art before the Patent Office and therefore not material, and that its patent prosecutors lacked intent to deceive the PTO. *Id.*

The district court scheduled a bifurcated bench trial on these two elements of inequitable conduct: the first on materiality of the undisclosed references; and the second on the prosecuting attorneys' specific intent during PTO proceedings. *Id.* Following the first trial, the court found that the references were but-for material to patentability. *Id.*

"The district court, however, never held the scheduled second trial on Regeneron's specific intent to deceive the PTO." *Id.* 3a-4a. Rather than hear evidence on the issue of intent, the court drew an "adverse inference" that two prosecuting attorneys acted "with the specific intent to deceive the PTO" in securing Regeneron's patent. *Id.* 4a. The court did so as a "sanction[]" for the "discovery misconduct throughout litigation" on the part of other lawyers, Regeneron's litigation counsel. *Id.* 4a.

The "discovery conduct" that led the district court "to impose the sanction of an adverse inference as to the intent of [two prosecuting attorneys]" (*id.* 193a) included: (1) submission of "infringement contentions that listed each claim as consisting of a single limitation," rather than contentions broken down "element-by-element" (*id.* 169a-170a); (2) taking the position during claim construction that "no terms required construction" (*id.* 171a); (3) failure to produce all documents within the scope of a privilege waiver resulting from production of a memo drafted by a prosecuting attorney (*id.* 176a);

and (4) a second privilege waiver brought on by Regeneron's submission of a prosecuting attorney's affidavit on the eve of trial, which was precluded from evidence (*id.* 188a, 191a-192a).

The district court conducted an *in camera* review of some documents Regeneron had withheld as privileged. *Id.* 189a. According to the court, its review revealed "serious discovery issues," and "documents that should have been produced." *Id.* Rather than order Regeneron to produce the documents and proceed with an evidentiary hearing on the issue of the prosecuting attorneys' specific intent, the district court determined that was "not a fair burden for Merus or this Court." *Id.* 191a. The court instead sanctioned Regeneron for trial counsel's "discovery conduct" by drawing an adverse inference that its two prosecuting attorneys specifically intended to deceive the PTO. *Id.* 193a.

Having thus "determined the but-for materiality of the [w]ithheld [r]eferences and drawn an adverse inference of Regeneron's specific intent to deceive the PTO, the district court concluded that Regeneron had committed inequitable conduct and held [the] patent unenforceable." *Id.* 4a.

A Federal Circuit panel divided 2-1 in affirming the district court's adverse inference of specific intent to deceive the PTO and its resulting judgment holding Regeneron's patent unenforceable for inequitable conduct. *Id.* 2a. Regeneron's patent is therefore nullified, and absent this Court's review, it can no longer be asserted against any party in any proceeding. *See id.* 199a. In a vigorous dissent, Judge Newman criticized the panel majority's

decision as “contrary to fundamental fairness and judicial process.” *Id.* 46a.

The Federal Circuit denied rehearing en banc. *Id.* 197a. Judge Newman, joined by Judge Reyna, dissented, stating that the Federal Circuit’s decision “has produced an irreconcilable split in our jurisprudence, to the detriment of stability of law and practice.” *Id.* 201a.

SUMMARY OF THE ARGUMENT

This petition presents an issue of exceptional importance to the patent system and its many stakeholders: the evidence required for a court to nullify a patent for inequitable conduct before the PTO. By striking down a patent absent evidentiary proof of intent to deceive the PTO during patent prosecution as a sanction for litigation misconduct, the panel majority contravenes this Court’s precedent and creates a split of authority in the Federal Circuit.

Under this Court’s precedent, revoking an issued patent that was improperly obtained requires evidence that the patent applicant acted with a culpable mental state during patent prosecution. In the seminal case involving allegations that Alexander Graham Bell obtained the original telephone patents through fraud on the Patent Office, this Court held that if a patent applicant was “aware, at the time that he filed his specifications, asserted his claims, and procured his patents, that the same matter had been previously discovered and put into operation by other persons,” his patent may be “revoked and annulled” to remedy this “fraud

upon the public.” *U.S. v. Am. Bell Tel. Co.*, 128 U.S. 315, 355 (1888). A culpable mental state during patent prosecution was thus held to be required to revoke the patent, making the patent unenforceable for purposes of any future proceeding. *Id.* at 355, 366.

This Court’s precedent also makes clear that litigation misconduct outside of patent prosecution does not provide a basis to revoke the patent. The remedy for litigation counsel’s misconduct in a suit to *enforce* the patent is dismissal of the lawsuit where the litigation misconduct occurred. In *Keystone Driller Co. v. General Excavator Co.*, this Court held that “the doors of the court will be shut” to a litigant who is not “frank and fair with the court.” 290 U.S. 240, 244-45 (1933). Courts of equity “will refuse to interfere on his behalf, to acknowledge his right, or to award him any remedy.” *Id.* at 245. Thus, in *Keystone*, “the Court established that litigation misconduct can support dismissal of the suit, whereas patent invalidity or unenforceability must be established on the law of validity or unenforceability.” Pet. App. 47a (Newman, J.) (citing 290 U.S. 240). *Keystone* “illustrates that litigation misconduct does not affect the viability of the property right itself.” *Aptix Corp. v. Quickturn Design Sys., Inc.*, 269 F.3d 1369, 1375 (Fed. Cir. 2001) (citing 290 U.S. at 244-45).

Not only is the decision below contrary to this Court’s precedent, it creates an intra-circuit split in the Federal Circuit on the issue of whether intent to deceive the PTO can be inferred, and a patent thereby held unenforceable, as a sanction for

litigation misconduct. In *Aptix*, the Federal Circuit confronted the question of whether litigation misconduct provides a basis for nullifying a patent. Following this Court's cases, the circuit court held unequivocally that it does *not*: "Litigation misconduct, while serving as a basis to dismiss the wrongful litigant, does not infect, or even affect, the original grant of the property right." 269 F.3d at 1375. In so holding, the Federal Circuit added that "neither the Supreme Court nor this court has ever declared a patent unenforceable due to litigation misbehavior." *Id.* The panel majority's decision below is irreconcilable with *Aptix*, and it therefore "produced an irreconcilable split in [Federal Circuit] jurisprudence, to the detriment of stability of law and practice." Pet. App. 201a (Newman, J.).

Further, the decision below raises a serious constitutional question: whether nullifying a patent without providing the patent-owner a meaningful opportunity to be heard on the issue of intent violates procedural due process. Patents are a form of property secured by the Due Process Clause of the Fifth Amendment. *See, e.g.*, 35 U.S.C. § 261; *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 138 S. Ct. 1365, 1379 (2018). Yet, here, the patentee was not afforded a "meaningful opportunity to present [its] case" on the element of intent to deceive the PTO before its property right in the patent was revoked. *Mathews v. Eldridge*, 424 U.S. 319, 349 (1976). As Judge Newman noted in dissent, "no evidentiary record was developed on intent to deceive, with no testimony and no opportunity for examination and cross-examination of witnesses." Pet. App. 46a. The resulting deprivation of property,

absent any hearing or evidentiary record on intent, runs afoul of due process and provides another reason for this Court's review.

Left to stand, the panel majority's decision will have significant consequences for the U.S. patent system. For inventors and patent owners, their patent rights may be stripped due to the conduct of litigation counsel years after their patents were granted. In patent litigation, the decision below invites lawyers to level accusations of litigation misconduct and exploit discovery disputes in the hope of making out inequitable conduct claims, resulting in less efficient and more costly patent litigation. And for patent prosecutors, the decision below permits courts to find them guilty of deceiving the PTO, thereby inflicting lasting career and reputational damage, based on the conduct of *other lawyers* litigating a case *years later*.

This case presents an ideal vehicle for the Court's review. The decision below allows the critical issues presented by the petition to be framed precisely: it is undisputed here that the panel majority affirmed an "adverse inference" that *patent prosecutors* acted with "specific intent to deceive the PTO" as a sanction for *litigation counsel's* "discovery misconduct." Pet. App. 4a. As a result, there is now "an irreconcilable split in [Federal Circuit] jurisprudence" (*id.* 201a), causing confusion for district courts. There is no reason for the Court to

wait for further decisions before resolving the important issues raised by the petition.³

ARGUMENT

I. The Federal Circuit’s Decision Below Is Contrary to This Court’s Precedent

For a court of equity to nullify an issued patent on the basis of improper procurement, this Court’s decisions require proof that the applicant acted with a culpable mental state during patent prosecution. The panel majority’s decision affirming revocation of a patent absent record evidence of intent to deceive the PTO is contrary to that longstanding precedent.

In *American Bell*, this Court established that patents procured by fraud can be cancelled in judicial proceedings. 128 U.S. at 355, 366. The United States brought a civil suit seeking to have Bell telephone patents “declared void and of no effect” on the ground that they had been secured by fraud. *Id.* at 350, 352. “The bill allege[d] that Bell, the patentee, *knew at the time of filing* his application for the patent . . . that he was not the original and first inventor.” *Id.* at 353.⁴ It was charged that the “untrue statements made by said Bell *constituted deception and fraud* upon the government.” *Id.* For a second patent on an improvement to the early

³ The NYIPLA takes no position on the merits of Respondent’s claim that Petitioner’s patent is unenforceable for inequitable conduct.

⁴ All emphases are added.

telephone, Bell was also alleged to have “made another application for a patent,” “*well knowing* that he was not the inventor.” *Id.* at 354.

The Court reversed the circuit court’s decree dismissing the bill, and remanded with leave to defendants to answer. *Id.* at 373. The lower court was instructed: “if Bell was *aware, at the time that he filed his specifications, asserted his claims, and procured his patents*, that the same matter had been previously discovered and put into operation by other persons,” his patents could be “revoked and annulled.” *Id.* at 355.

Ten years after *American Bell*, this Court again declared that a suit “to cancel the patent” is appropriate in limited circumstances where “the original patent [was] *procured by fraud or deception.*” *McCormick Harvesting Mach. Co. v. Aultman*, 169 U.S. 606, 612 (1898). Consistent with *American Bell* and *McCormick Harvesting*, this Court held over fifty years later that “to grant full protection to the public against a patent *obtained by fraud*, that patent must be vacated.” *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 251 (1944). Thus, under this Court’s precedent, reaching back to revoke an issued patent requires evidence that the applicant acted with a culpable mental state during patent prosecution. *Id.*; *McCormick Harvesting*, 169 U.S. at 612; *American Bell*, 128 U.S. at 355, 366.

As this Court’s precedent requires a culpable mental state during patent prosecution to void a patent, it follows that misconduct by the patentee’s trial counsel in a later suit to enforce the patent does not provide a basis to strip the underlying property

right. Indeed, this Court's precedent further establishes that while litigation misconduct in a patent enforcement action can form a basis to dismiss the patentee's lawsuit, deceit of the PTO must be shown to revoke the patent itself. *Hazel-Atlas*, 322 U.S. at 251; *Keystone*, 290 U.S. at 244-45.

In *Keystone*, the patentee "suppress[ed] the evidence" of prior use, and thereby secured a judgment of validity and infringement. 290 U.S. at 242, 243. The patentee then "used the decree of validity there obtained in support, if not indeed as the basis" of "subsequent infringement suits." *Id.* at 246, 247. This Court held that these acts of litigation misconduct—suppression of evidence and the use of a judgment obtained through deceit to advance subsequent suits—were grounds for dismissing the patentee's causes of action, not for voiding the plaintiff's patent. *Id.* at 246. As this Court explained, "the doors of the court will be shut against" a litigant who is not "frank and fair with the court." *Id.* at 244. Courts of equity will refuse to "interfere on his behalf" or "award him any remedy." *Id.* at 245. *Keystone* thus demonstrates that "litigation misconduct can support dismissal of the suit, whereas patent invalidity or unenforceability must be established on the law of validity or unenforceability." Pet. App. 47a (Newman, J.) (citing 290 U.S. at 244-45).

This Court applied *Keystone* ten years later in *Hazel-Atlas*, a case involving both fraud at the PTO and litigation misconduct by the patentee, Hartford-Empire. 322 U.S. at 240-41. Hartford's officials and prosecuting attorneys fabricated a trade journal

article that touted their device as a “remarkable advance” (*id.* at 240), “in an effort to persuade a hostile Patent Office to grant their patent application.” *Id.* at 247. Then, on appeal of a judgment of noninfringement in a later suit to enforce the patent, Hartford’s litigation counsel “directed the [circuit court’s] attention” to the spurious article, leading the circuit court to reverse the district court’s judgment and hold the patent valid and infringed, “[q]uoting copiously from the article.” *Id.* at 241.

After evidence of the scheme emerged, Hazel-Atlas asked the circuit court, based “upon proof that fraud was perpetuated on it by a successful litigant, to vacate its own judgment entered at a prior term.” *Id.* at 239. The circuit court denied relief, and Hazel-Atlas appealed to this Court. *Id.* at 240, 251. Citing the “total effect of all this fraud, practiced on the Patent Office and the courts,” this Court set aside the judgment in favor of Hartford. *Id.* at 250. However, in addressing the separate question of whether Hartford’s patent should be revoked, this Court considered only the *prosecution misconduct* before the PTO, stating: “[t]o grant full protection to the public against a patent *obtained by fraud*, the patent must be vacated.” *Id.* at 251. In analyzing patent revocation, this Court did not mention litigation counsel’s misconduct in the later lawsuit to enforce Hartford’s patent. *See id.*

In sum, under this Court’s precedent, patent revocation is an appropriate remedy for intentional misconduct before the PTO in securing the patent, whereas dismissal is the appropriate penalty for

litigation misconduct in a later suit to enforce the patent. *Hazel-Atlas*, 322 U.S. at 251; *Keystone*, 290 U.S. at 244-45; *American Bell*, 128 U.S. at 355, 366.

The decision below is therefore contrary to this Court's precedent in two ways. First, the panel majority affirmed a judgment nullifying Regeneron's patent without requiring *any* evidence that its prosecuting attorneys intended to deceive the PTO during patent prosecution. Pet. App. 46a-47a (Newman, J.). Second, the panel majority affirmed the district court's "adverse inference" of intent to deceive the PTO and its resulting judgment nullifying Regeneron's patent as a sanction for *litigation misconduct*, which may have merited dismissal of the lawsuit, but not patent revocation. *Id.* 47a-49a.

Consistent with this Court's precedent, sanctionable litigation misconduct may result in a discretionary procedural sanction as to the lawsuit itself, such as its dismissal, but not an adverse inference with respect to a requirement of inequitable conduct—specific intent by prosecution counsel at the time of prosecution—which nullifies the patent right. *Hazel-Atlas*, 322 U.S. at 251; *Keystone*, 290 U.S. at 244-45.

II. There Is an Intra-Circuit Split in the Federal Circuit

The decision below has caused an intra-circuit split in the Federal Circuit—the exclusive avenue for appellate jurisdiction in patent infringement actions. Specifically, the panel majority's decision in this case diverges from the Federal Circuit's *Aptix* decision,

among others, establishing that litigation misconduct in a patent enforcement suit cannot provide a basis for nullifying the patent.

In *Aptix*, the Federal Circuit reviewed a district court decision dismissing an infringement suit and holding the asserted patent unenforceable based on its finding that the inventor had submitted falsified notebooks to the court. 269 F.3d at 1371. The district court found the inventor's notebook, submitted as evidence of conception, to be "a complete fraud from bark to core, a notebook without a single genuine entry." *Id.* at 1373. Following a hearing, the district court concluded that Aptix "had attempted to defraud the Court and to strengthen its patent through a premeditated and sustained campaign of lies and forgery." *Id.*

On appeal, the Federal Circuit affirmed dismissal based on the substantial evidence of litigation misconduct. *Id.* at 1374-75. The circuit court further held that "the district court possessed ample discretion to award Quickturn attorney fees and costs" under 35 U.S.C. § 285. *Id.* at 1375. However, the Federal Circuit reversed the portion of the decision declaring Aptix's patent unenforceable. *Id.*

Applying this Court's *Keystone* and *Hazel-Atlas* cases, the Federal Circuit held in *Aptix* that "[l]itigation misconduct, while serving as a basis to dismiss the wrongful litigant, does not infect, or even affect, the original grant of the property right." *Id.* The court further held that "[t]he doctrine of unclean hands does not reach out to extinguish a property right based on misconduct during litigation to

enforce the right.” *Id.* Under *Aptix*, “[t]he property right itself remains independent of the conduct of the litigant.” *Id.* The reason for this is that the doctrine of inequitable conduct “render[s] the patent itself unenforceable to prevent ‘the enforcement of patents secured by fraud.’” *Id.* at 1376 (quoting *Smith Int’l, Inc. v. Hughes Tool Co.*, 759 F.2d 1572, 1578 (Fed. Cir. 1985)).

In reaching its holding, the *Aptix* court observed that “neither the Supreme Court nor this court has ever declared a patent unenforceable due to litigation misbehavior.” *Id.* at 1375.⁵

The panel majority’s attempt to distinguish *Aptix* does not resolve the intra-circuit split. The decision below acknowledges that *Aptix* “held that courts may not punish a party’s post-prosecution misconduct by declaring the patent unenforceable.” Pet. App. 43a. It then attempts to reconcile the holding in this case with that precedent by arguing that “[h]ere, Regeneron is *accused* not only of post-prosecution misconduct but also of engaging in inequitable conduct during prosecution.” *Id.* However, regardless of what Regeneron was “accused” of (*id.*), the court made no *evidentiary finding*, and indeed left no evidentiary record, as to whether Regeneron’s prosecuting attorneys acted

⁵ District courts have consistently adhered to the *Aptix* rule that litigation misconduct cannot provide a basis for revoking a patent. *See, e.g., PetEdge, Inc. v. Yahee Techs. Corp.*, 2017 U.S. Dist. LEXIS 66663, at *9 (D. Mass. May 2, 2017); *Apple Inc. v. WI-LAN, Inc.*, 2014 U.S. Dist. LEXIS 193620, at *5 (S.D. Cal. Dec. 12, 2014); *In re Gabapentin Patent Litig.*, 649 F. Supp. 2d 340, 348 (D.N.J. 2009).

with specific intent to defraud the PTO during prosecution. *Id.* 3a-4a, 46a.

The panel majority also suggests that because Merus “proved the remaining elements of inequitable conduct”—*i.e.*, materiality of the withheld references—that Regeneron’s patent was not revoked as a sanction for litigation misconduct. *Id.* 43a-44a. That is not correct. Proof of materiality is necessary, but not sufficient, to prove an inequitable conduct claim. Without drawing an “adverse inference that Regeneron’s agents failed to disclose the [w]ithheld [r]eferences to the PTO with the specific intent to deceive the PTO,” as a “sanction[]” for “discovery misconduct” (*id.* 4a), the district court would not have had a basis to nullify Regeneron’s patent. As Judge Newman observed in dissent, the panel majority’s decision in this case is the first and only “at any level of the federal system” in which “litigation misconduct was part of a finding of inequitable conduct.” *Id.* 50a.

Consistent with the holding of *Aptix*, the Federal Circuit has also held that conduct after the patent already issued cannot provide the basis for finding intent to deceive the PTO during patent prosecution. Applying *Keystone* and its progeny in *SSIH Equipment S.A. v. U.S. International Trade Commission*, the Federal Circuit “reject[ed] . . . as a matter of law” the notion that the patentee’s “‘unclean hands’ with respect to the later patents renders the [earlier] patent unenforceable.” 718 F.2d 365, 378 (Fed. Cir. 1983). The Federal Circuit reasoned that a patent cannot be held unenforceable where the alleged misconduct “all occurred after the

[] patent issued,” and thus “is not said to have occurred in connection with procurement of the [] patent.” *Id.* In *Pharmacia Corp. v. Par Pharmaceutical, Inc.*, the Federal Circuit likewise rejected an inequitable conduct claim where the “patent had already issued before the inequitable conduct occurred.” 417 F.3d 1369, 1375 (Fed. Cir. 2005). And in *Star Scientific, Inc. v. R.J. Reynolds Tobacco Company*, the Federal Circuit found it “clear that the events in June 2002 and the events that followed cannot render the [] patent unenforceable due to inequitable conduct because the [] patent had already issued.” 537 F.3d 1357, 1370 n.10 (Fed. Cir. 2008). The decision below is at odds with these Federal Circuit cases, as well as with *Aptix*.

III. The Decision Below Raises Due Process Concerns

The decision below raises the significant constitutional question of whether nullifying a patent right without providing the patent-owner a meaningful opportunity to be heard on the issue of intent violates procedural due process.

The Fifth Amendment prohibits the federal government from depriving any person of “property . . . without due process of law.” U.S. CONST. amend. V. This Court has long viewed patent rights as a form of property secured by the Constitution. Today, the Patent Act states that “[s]ubject to the provisions of this title, patents shall have the attributes of personal property.” 35 U.S.C. § 261. And this Court’s recent decisions follow the principle that patents are property afforded Constitutional protection under the Due Process Clause and the

Takings Clause. In the Takings Clause context, for instance, the Court recently stated that a patent “confers upon the patentee an exclusive property in the patented invention.” *Horne v. Dep’t of Agric.*, 135 S. Ct. 2419, 2427 (2015) (Roberts, C.J.). And with regard to due process, this Court declared last term in *Oil States* that its decision “should not be misconstrued as suggesting that patents are not property for purposes of the Due Process Clause or the Takings Clause.” 138 S. Ct. at 1379.

It follows that patent rights cannot be revoked without affording the patentee procedural due process. *Mathews*, 424 U.S. at 332; *see also Oil States*, 138 S. Ct. at 1379. And “[t]he fundamental requirement of due process” afforded is “the opportunity to be heard at a meaningful time and in a meaningful manner.” *Mathews*, 424 U.S. at 333.

The patent-owner here was afforded no such opportunity. “The district court . . . never held the scheduled second trial” on whether Regeneron’s prosecuting attorneys intended to deceive the PTO. Pet. App. 3a-4a. “[N]o evidentiary record was developed on intent to deceive, with no testimony and no opportunity for examination and cross-examination of witnesses.” *Id.* 46a (Newman, J.). “The panel majority thus convicts Regeneron, its counsel, and its scientists, with no trial, no evidence, and no opportunity to respond in their defense.” *Id.* The due process implications of this decision provide yet another important reason for this Court’s review.

IV. This Case Has Important Ramifications for Patent Litigation and the Patent System

A. The Decision Below Encourages Defendants to Allege Litigation Misconduct for Tactical Advantage

Inequitable conduct claims are a powerful weapon in the patent defendant's arsenal. "[A] charge of inequitable conduct conveniently expands discovery into corporate practices before patent filing," "cast[s] a dark cloud over the patent's validity and paint[s] the patentee as a bad actor." *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1288 (Fed. Cir. 2011). Further, "inequitable conduct regarding any single claim renders the entire patent unenforceable"; a finding of inequitable conduct can "spawn anti-trust and unfair competition claims"; and a finding of inequitable conduct "may also prove the crime or fraud exception to the attorney-client privilege." *Id.* at 1288, 1289. "With these far-reaching consequences," inequitable conduct can "become a common litigation tactic." *Id.* at 1289.

Following the decision below, not only will tactically motivated charges of inequitable conduct increase, allegations will focus on the conduct of opposing counsel *during litigation* instead of prosecuting attorneys' mental state during PTO proceedings. And nearly any patent case will be ripe for litigation-based inequitable conduct allegations, as disputes about the breadth and scope of infringement contentions, proposed constructions of disputed claim terms, and the proper scope of

attorney-client privilege are common in patent litigation.

The decision below thus invites accused infringers to exploit discovery disputes to make out inequitable conduct claims, imposing heavy burdens on the courts and detracting from the merits of validity and infringement. In fact, a review of district court dockets shows that patent defendants are already relying on the decision below to do just that. See, e.g., Parties' Ltr. (Dkt. No. 179) at 5, *Immunomedics, Inc. v. Roger Williams Med. Ctr.*, No. 15-4526 (D.N.J. filed Jan. 10, 2018) ("Defendants reserve the right to seek . . . adverse inferences" in dispute concerning plaintiff's privilege log); Defs.' Br. (Dkt. No. 380) at 16, *The Cal. Inst. of Tech. v. Broadcom Ltd.*, No. 2:16-CV-3714-GW-AGR (C.D. Cal. filed Dec. 20, 2017) (arguing "an adverse inference is appropriate" to support inequitable conduct claim due to plaintiff's counsel's "eleventh-hour reversal on its representation of . . . two witnesses").

B. The Decision Below Has a Direct Impact on the Prosecution Bar

The decision below affects the patent prosecution bar at the most basic level: their careers and personal reputations. Patent prosecutors now face the prospect of being found guilty of inequitable conduct before the PTO as a result of alleged discovery misconduct by litigation counsel, that the patent prosecutors have no connection to and do not control, in court proceedings years later.

The personal and professional consequences for a prosecuting attorney of an inequitable conduct finding are stark. Where inequitable conduct is found—or even where inequitable conduct is alleged but not ultimately found—prosecuting attorneys may become subject to onerous disciplinary proceedings at the PTO Office of Enrollment and Discipline (“OED”). *See* 37 C.F.R. §§ 11.19, 11.22, 11.32. An OED proceeding “typically triggers anxiety for the practitioner, may interfere with the practitioner’s practice, and may cause the practitioner to incur legal expenses in responding to investigative inquiries by OED.” 77 Fed. Reg. 457, 458 (Jan. 5, 2012).

Further, a court’s finding of inequitable conduct damages the patent attorney’s professional reputation, within the legal community and before the PTO. Christopher A. Cortopia, *Modernizing Patent Law’s Inequitable Conduct Doctrine*, 24 BERKELEY TECH. L.J. 723, 766 (Spring 2009); *see also* *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334, 1349-50 (Fed. Cir. 2008) (Rader, J., dissenting) (“[T]he allegation of inequitable conduct . . . impugns the integrity of the patentee, its counsel, and the patent itself.”). The patent attorney can lose his license to practice before the PTO, and the matter may be referred to his state bar. Cortopia, *supra*, at 766. Inequitable conduct charges can also lead to malpractice claims against the prosecuting attorney. *Id.* at 763.

Given the enormous costs to patent prosecuting attorneys, the patent bar is not surprisingly alarmed by the decision below. *See*

Ryan Davis, *Patent Prosecutors Alarmed By Inequitable Conduct Ruling*, LAW360 (Aug. 2, 2017), <https://www.law360.com/articles/950683/patent-prosecutors-alarmed-by-inequitable-conduct-ruling> (last accessed Jun. 28, 2018). Indeed, the decision permits courts to conclude that patent prosecutors intended to deceive the PTO by *adverse inference* without review of the evidence, when the evidence could show the opposite.

The NYIPLA and its members are invested in a patent system where intent to deceive the PTO during patent prosecution is determined by the evidentiary record and witness examination—not inferred as a sanction for the conduct of others years later.

C. The Decision Below Makes Patent Enforcement More Costly and Less Predictable

The decision below makes patent enforcement more costly and less predictable. The decision invites defendants to use ordinary discovery disputes to inject litigation-based inequitable conduct claims into patent cases in the hope of striking down patents. These satellite disputes will detract from the merits and increase the complexity and duration of patent litigation. *See Therasense*, 649 F.3d at 1288.

Further, the decision below “add[s] confusion to precedent” for district courts by diverging from settled law from this Court and the Federal Circuit that had been followed consistently for decades. Pet. App. 45a (Newman, J.); *see supra* note 5. As

defendants increasingly seek adverse inferences over discovery disputes, courts will reach inconsistent results applying irreconcilable caselaw, muddling the inequitable conduct doctrine. And because the decision below allows courts to find intent to deceive the PTO by *adverse inference* absent review of the evidence (whether direct or circumstantial), even thorough pre-suit investigation of the facts surrounding patent prosecution cannot bring predictability to patent owners. *See* Pet. App. 193a.

V. This Case Is an Ideal Vehicle for the Court to Resolve these Critical Issues

The proceedings and decision below precisely frame the question of law for the Court, and thus provide an ideal vehicle for the Court's review.

Indeed, the panel majority in no uncertain terms affirmed the district court's drawing of an "adverse inference" that *patent prosecutors* acted with "specific intent to deceive the PTO" as a "sanction[]" for *litigation counsel's* "discovery misconduct." Pet. App. 4a. The panel majority did so even though: "[t]he district court . . . never held the scheduled second trial on Regeneron's specific intent to deceive the PTO" (*id.* 3a-4a); the prosecuting attorneys were precluded from testifying (*id.* 40a, 193a); and documents concerning their intent were not made part of the record or considered (*id.* 39a-40a, 191a-193a). The proceedings below therefore precisely frame the issue for this Court's review: whether a sanction for litigation misconduct by trial counsel after issuance of the patent can substitute for the evidentiary *proof* required to find

inequitable conduct by prosecution counsel and extinguish an issued patent.

The issue in this case has also been fully developed through extensive briefing by the parties and *amici* at the Federal Circuit, as well as through multiple judicial opinions and dissents in proceedings below. There is already an “irreconcilable” intra-circuit split with significant consequences for the patent community. *Id.* 201a.

Absent this Court’s review, a new wave of litigation-focused inequitable conduct claims will proliferate. It is critical that this Court consider the question presented at this juncture in order to correct the Federal Circuit’s course and confirm that intent to deceive the PTO must be proven before a patent is nullified, not inferred as a litigation sanction.

CONCLUSION

For the foregoing reasons and authorities, this Court should grant the petition for a writ of certiorari on the Question Presented.

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Respectfully submitted,

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