

No. 17-1616

IN THE
Supreme Court of the United States

REGENERON PHARMACEUTICALS, INC.,

Petitioner,

v.

MERUS B.V.,

Respondent.

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

**MOTION FOR LEAVE TO FILE AND BRIEF
OF SEVEN CHICAGO PATENT LAWYERS
AS *AMICI CURIAE* IN SUPPORT
OF PETITIONER**

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**MOTION FOR LEAVE TO FILE
AMICI CURIAE BRIEF**

Pursuant to Supreme Court Rule 37(2)(b), Seven Chicago Patent Lawyers respectfully request leave of this Court to file a brief as *amici curiae* in support of Petitioner Regeneron Pharmaceuticals, Inc. in its petition for writ of *certiorari*. *Amici curiae* provided timely notice to Petitioners and Respondents of their intent to file an *amici* brief. In response, Petitioner provided consent and Respondent withheld consent to the filing of this brief, necessitating this motion.

The *amici curiae* are a group of patent practitioners who prosecute and litigate U.S. patents and thus are concerned with preserving the integrity of the legal system that secures innovation to its creators and to the companies that commercialize such innovation in the marketplace.

In this case, the *amici curiae* respectfully submit that the Court should grant the present motion for at least two reasons.

First, the *amici curiae* offer a practitioner's perspective of a district court sanction that was unconstitutional for lack of procedural due process. The sanction – for alleged litigation misconduct – took the form of an inference of a specific intent to deceive the U.S. Patent and Trademark Office (“USPTO”) during the administrative procedures in obtaining a patent by the patent prosecutors and was arrived at without a substantive inquiry. This dearth of fact-finding paired with the natural consequence of a finding of inequitable

conduct – a career-ender for patent prosecutors – is potentially devastating.

A district court's broad powers to sanction misconduct must be exercised with restraint and are inherently limited by statute, rule, and the due process provisions of the Constitution. This Court provides procedural due process protections for attorney disciplinary proceedings, and, in a similar fashion, those protections should be extended to proceedings that involve accusations of inequitable conduct.

Second, the *amici curiae* believe that the district court erred by misapplying the Federal Circuit's *en banc* decision regarding inequitable conduct, *Therasense v. Becton Dickinson*, 649 F.3d 1276 (Fed. Cir. 2011), which carefully reflects this Court's mandates in *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240 (1933), *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944), and *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806 (1945). Based on litigation misconduct rather than any proven misconduct before the USPTO, the district court improperly drew an adverse inference that there was a specific intent to deceive the USPTO by the patent prosecutors during prosecution of the patent-in-suit. The adverse inference foreclosed the ability of the patent practitioners involved in prosecuting the patent-at-issue to present contrary substantive evidence regarding the intent inquiry mandated by *Therasense*. The Federal Circuit's affirmance by a divided panel cemented the damaging effects of the district court's clear legal error.

The *amici curiae* believe that, if permitted to stand, the Federal Circuit's contradiction of this Court's and the Federal Circuit's own precedent could adversely affect every patent practitioner, and seriously and negatively affect the course of patent prosecution.

The *amici curiae* have no stake in the parties or in the outcome of this case, but is deeply invested in having courts apply the law of inequitable conduct correctly and fairly. *Amici curiae* previously submitted briefs with the Federal Circuit in support of the appellant at the merits stage and in support of appellant's petition for rehearing *en banc*. Pet. App. 201a.

The *amici curiae* request that the Court grant leave to file the accompanying brief.

Respectfully submitted,

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INTEREST OF *AMICI CURIAE*¹

The *amici curiae* are a group of patent practitioners who prosecute and litigate U.S. patents and thus are concerned with preserving the integrity of the legal system that secures innovation to its creators and to the companies that commercialize such innovation in the marketplace.

The *amici curiae* believe that the district court violated due process when it determined that attorneys who represented the patentee before the U.S. Patent and Trademark Office (the “prosecuting patent lawyers”) were guilty of inequitable conduct without conducting an inquiry regarding the attorneys’ lack of an intent to deceive. This due process violation arose when the district court misapplied the analysis required by the Federal Circuit’s *en banc* decision regarding inequitable conduct, *Therasense v. Becton, Dickinson & Co.*, 649 F.3d 1276 (Fed. Cir. 2011), which carefully reflects this Court’s mandates in *Keystone Driller Co. v. Gen. Excavator Co.*, 290 U.S. 240 (1933), *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944), and *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806 (1945). Rather than considering evidence as required under inequitable conduct jurisprudence,

1. Pursuant to Supreme Court Rule 37.6, *amici curiae* state that no counsel for any party authored this brief in whole or in part, and that no person or entity other than *amici curiae* or its counsel made a monetary contribution to the preparation or submission of this brief. *Amici curiae* provided timely notice to Petitioners and Respondents of their intent to file this brief. In response, Petitioner provided consent and Respondent withheld consent to the filing of this brief.

the district court improperly drew an adverse inference that there was an intent to deceive the U.S. Patent and Trademark Office (“USPTO”) during prosecution of the patent-in-suit, based on litigation misconduct rather than any proven misconduct by the prosecuting patent lawyers before the USPTO. This adverse inference foreclosed the ability of the prosecuting patent lawyers to present contrary substantive evidence regarding the intent inquiry mandated by *Therasense*. The Federal Circuit’s affirmance by a divided panel cemented the damaging effects of the district court’s clear legal error.

The *amici curiae* believe that, if permitted to stand, the Federal Circuit’s contradiction of this Court’s and the Federal Circuit’s own precedent could negatively affect every patent practitioner, and seriously and negatively affect the course of patent prosecution. The *amici curiae* urge this Court to grant the petition for *certiorari*, vacate the Federal Circuit’s judgment, and remand to the district court for reconsideration of evidence related to specific intent to deceive the Patent Office by withholding information material to patentability.

The *amici curiae* have no stake in the parties or in the outcome of this case, but is deeply invested in having courts apply the law of inequitable conduct correctly and fairly. *Amici curiae* submitted briefs with the Federal Circuit in support of the appellant at the merits stage and in support of appellant’s petition for rehearing *en banc*. Pet. App. 201a.

SUMMARY OF THE ARGUMENT

The procedural due process protections of the Constitution safeguard private interests, including a prosecuting patent lawyer's interest in her license to practice law before her state bar and before the USPTO. These interests are invoked upon an allegation of inequitable conduct because such accusations put these professional licenses at risk and thus threaten the very livelihood of prosecuting patent lawyers.

Here, the district court erred when it sanctioned alleged litigation misconduct by trial counsel by way of an inference drawn against prosecuting patent lawyers' conduct. Namely, the district court inferred that the prosecuting patent lawyers specifically intended to deceive the USPTO and that this intent regarding non-disclosure of material prior art amounted to inequitable conduct. However, the inference at issue was made without hearing contrary, exculpatory evidence from the very individuals forced to face the career-ending consequences of disbarment before the USPTO and reciprocal discipline from state bars.

The Federal Circuit erred by affirming the district court, contravening its own, and this Court's, jurisprudence in this area of law.

The issues presented in patentee's petition involve this Court's recognition of the inequitable conduct doctrine, which imposes on transgressors a patent-specific equitable remedy (*i.e.*, patent unenforceability) designed to prevent "fraud on the Patent Office." The facts and outcome of this case demonstrate the urgent need for this Court to clarify

what constitutes a proper determination of inequitable conduct in patent litigation cases.

Here, the patent-at-issue was deemed unenforceable after the district court inferred, based on alleged litigation counsel misconduct, that the patentee's prosecuting patent lawyers possessed not only "an intent," but a specific intent, to defraud the Patent Office. First, the purported litigation misconduct that was imputed as prosecution counsel's pre-litigation intent represents an improper basis for a finding of inequitable conduct. But to make matters even worse, no substantive proceedings on such specific intent were conducted and no inquiry was attempted by the district court regarding the prosecuting patent lawyers actual intent (or lack thereof, despite it being proffered). The Federal Circuit affirmed the outcome below and subsequently denied rehearing *en banc*.

These results raise an important constitutional issue: whether a district court improperly withheld procedural due process from prosecuting patent lawyers when it imposed an adverse inference sanction, based on trial counsel misconduct, and bypassed findings of specific intent to deceive the USPTO to establish inequitable conduct.

Additionally, by affirming the district court, the Federal Circuit squarely contradicted its own inequitable conduct jurisprudence set forth over decades in numerous decisions, most recently *en banc* in *Therasense* and in *Aptix*, which reflect this Court's guidance in *Keystone*, *Hazel-Atlas*, and *Precision Instrument*. 649 F.3d 1276, 269 F.3d 1369. Robust *amici* support for the petitioner and strongly worded dissents at the panel and *en banc*

petition stages suggest that the Court’s guidance is needed to clarify the application of the judge-made doctrine of inequitable conduct.

This case represents an appropriate vehicle and opportune moment for this Court to clarify the proper application of inequitable conduct law.²

Amici curiae respectfully request that *certiorari* be granted.

STATEMENT

A. Inequitable Conduct

The origins of the concept of inequitable conduct derive from courts of equity. Specifically, inequitable conduct is a patent-specific variant of the doctrine of “unclean hands”³, which gives an equity court wide discretion in deciding whether and how to refuse to aid an unscrupulous litigant.

This Court mandated that a U.S. patent could only be enforced by patentees who came to the court with

2. The Federal Circuit decided *Therasense* over 7 years ago and decided *Aptix* over 16 years ago. *Amici curiae* submit that it is therefore not “too early” for this Court to grant *certiorari* in an inequitable conduct case. *Cf. Brief of United States Amici curiae Supporting Respondents*, at *18, *Sony Ent’mt Am. LLC v. 1st Media, LLC*, 571 U.S. 951 (2013) (recommending this Court deny *certiorari* where *Therasense* was decided only two years ago). Indeed, as the United States noted in *Sony*, this Court has not reviewed inequitable conduct law in nearly 70 years. *Id.* at *17.

3. “He who comes into equity must come with clean hands.”

“clean hands” in a trio of cases: *Keystone Driller*, *Hazel-Atlas*, and *Precision Instrument*.⁴ 290 U.S. 240, 322 U.S. 238 (overruled on other grounds), and 324 U.S. 806, respectively. Each of these cases dealt with various forms of fraud perpetrated upon courts and the Patent Office regarding litigated patents. Specifically, the patentee in *Keystone Driller* suppressed evidence of prior public use during the course of litigation that would have rendered invalid the patent-in-suit. 290 U.S. at 247. During patent litigation in *Hazel-Atlas*, the patentee introduced a publication, which was secretly prepared by the patentee’s attorney and which endorsed the object of the patent application, in an effort to fraudulently advance patentee’s case at trial. 322 U.S. at 241. In *Precision Instrument*, a patent owner prosecuted an interference by way of false affidavits about inventorship and dates of conception. 324 U.S. at 816. In each of this Court’s foundational cases, the Court found the patents-at-issue to be unenforceable for fraud on the USPTO.

Following these cases, the doctrine of unclean hands was implemented by the USPTO through regulation by imparting an absolute duty on a patent applicant to disclose to the Patent Office information that is material to the patentability of the application at issue. 37 C.F.R. § 1.56.⁵ And for a court to enforce an otherwise valid patent

4. Public interest demands that all facts relevant to such matters be submitted formally or informally to the Patent Office, which can then pass upon the sufficiency of the evidence. Only in this way can that agency act to safeguard the public in the first instance against fraudulent patent monopolies. *Precision Instrument Mfg. Co.*, 324 U.S. at 818.

5. 37 C.F.R. § 1.56(a) (“A patent by its very nature is affected with a public interest. The public interest is best served, and the

right, the asserted patent must have been obtained in compliance with the patentee's duty to disclose material prior art references during patent prosecution or risk the patent being held unenforceable for inequitable conduct in litigation. The remedy for inequitable conduct is an absolute bar to the enforcement of a patent, which in some cases can extend to entire patent families.

The seven decades since *Precision Instrument* have been marked by perhaps imprecise interpretations and applications of the inequitable conduct and unclean hands doctrines as remedies for fraud in patent litigation. Initially, this may have been due to a lack of clear legal standards in inequitable conduct jurisprudence. *See, e.g.*, Robert J. Goldman, *Evolution of the Inequitable Conduct Defense in Patent Litigation*, 7 Harv. J.L. & Tech. 37 (1993). As a result, over time, the line between the unclean hands doctrine in litigation and inequitable conduct before the Patent Office became increasingly blurred, resulting in wide variations in the standards of proof for establishing materiality and specific intent underlying an inequitable conduct determination. *Id.*; *see also Gilead*

most effective patent examination occurs when, at the time an application is being examined, the Office is aware of and evaluates the teachings of all information material to patentability. Each individual associated with the filing and prosecution of a patent application has a duty of candor and good faith in dealing with the Office, which includes a duty to disclose to the Office all information known to that individual to be material to patentability as defined in this section.”); *Precision Instrument*, 324 U.S. 806, 816 (1945) (“the public [has] a paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct and that such monopolies are kept within their legitimate scope.”).

Scis., Inc. v. Merck & Co, Inc., No. 13-CV-04057-BLF, 2016 WL 3143943, at *27 (N.D. Cal. June 6, 2016), *aff'd*, 888 F.3d 1231 (Fed. Cir. 2018) (holding the patents at issue unenforceable under the doctrine of unclean hands because of “numerous unconscionable acts” by plaintiff’s patent prosecuting attorney).

In 2001, the Federal Circuit, relying on *Keystone*, distinguished the remedies for litigation misconduct from those of acts of inequitable conduct committed during the acquisition of the patent right. *Aptix*, 269 F.3d 1369. Specifically, while inequitable conduct before the USPTO renders the patent unenforceable against any party, the unclean hands doctrine bars enforcement only against a particular litigant. *Id.* The Federal Circuit took note of a subsequent *Keystone* case, *Keystone Driller Co. v. Nw. Eng’g Corp.*, 294 U.S. 42 (1935) (*Keystone II*), where this Court adjudicated the merits “with no indication that the prior fraud tainted the later case.” *Aptix*, 269 F.3d at 1377.

Almost ten years thereafter, in *Therasense*, an *en banc* Federal Circuit sought to clarify the law of inequitable conduct by separating the requirements of materiality of a prior art reference and deceptive intent into separate prongs, holding that a finding of deceptive intent must be the “single most reasonable inference able to be drawn from the evidence” (in view of the reality that there is rarely direct evidence of an affirmative intent to deceive). 649 F.3d at 1290 (quoting *Star Sci., Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008)). In doing so, the Federal Circuit carefully considered and heavily relied on this Court’s *Keystone*, *Hazel-Atlas*, and *Precision Instrument* cases. 649 F.3d at 1285.

B. Proceedings Below

In this case, the district court bifurcated trial along the two prongs of inequitable conduct, under a rationale that “[materiality] would be addressed by the experts and through documents, and [a determination of Regeneron’s specific intent] (which would have involved testimony from in-house patent prosecutor Dr. Smeland and co-inventor Dr. Murphy) was only necessary if the Court determined the first issue in Merus’s favor.” Pet. App. 192a.

Despite this stated rationale, after making its materiality determination in Merus’s favor, the court did *not* consider evidence regarding whether Regeneron’s prosecuting patent lawyers had a specific intent to deceive the USPTO during prosecution of the patent-in-suit. Instead, the district court imposed an adverse inference of intent based on “implications the discovery [*i.e.*, litigation] conduct has on the entirety of the case.” *Id.* at 193a. In doing so, the district court struck several trial affidavits and precluded substantial trial testimony from the prosecuting patent lawyers. *Id.* No hearing on Regeneron’s prosecuting patent lawyers’ intent was ever conducted at any time by the court. *Id.* at 199a.

On appeal, the panel majority held that the district court did not abuse its discretion in inferring specific intent to deceive the USPTO and invalidating the patent. *Id.* at 25a. Circuit Judge Newman dissented.⁶

6. “Materiality does not establish intent; deliberate withholding of but-for invalidating prior art, with the intent to deceive the examiner, must be established by clear and convincing evidence. The majority’s mechanism whereby dispositive facts are found for the first time on appeal, with no right of traverse

Regeneron petitioned the Federal Circuit for rehearing *en banc* and the court denied the petition. *Id.* at 197a. Circuit Judges Newman and Reyna dissented from the Federal Circuit’s refusal to rehear the case *en banc*.⁷ The petition for writ of *certiorari* followed.

ARGUMENT

- I. **The district court’s sanction was unconstitutional for lack of procedural due process because the court inferred an intent to deceive without substantive inquiry.**
 - A. **District courts’ broad powers to sanction litigation misconduct must be exercised with restraint and are inherently limited by statute, rule, and the due process provisions of the Constitution.**

In *Precision Instrument*, this Court held that the application of equitable doctrines to misbehavior before a court is “not bound by formula or restrained by any limitation that tends to trammel the free and just exercise of discretion.” 324 U.S. at 815 (quoting *Keystone*, 290 U.S. at 246).

by the affected party, is contrary to fundamental fairness and judicial process. If the panel majority indeed believes that the four ‘uncited’ references are but-for material to patentability, we should at least require trial of the question of intent.” Pet. App. 46a (Newman, J. dissenting).

7. “The court’s contrary holding has produced an irreconcilable split in our jurisprudence, to the detriment of stability of law and practice.” Pet. App. 201a (Newman, J. and Reyna, J. dissenting).

Nonetheless, because of their potency, this Court has long maintained that such discretionary powers must be exercised with restraint. *See, e.g., Roadway Exp., Inc. v. Piper*, 447 U.S. 752, 764 (1980); *Gompers v. Buck's Stove & Range Co.*, 221 U.S. 418, 451 (1911); *see also Green v. United States*, 356 U.S. 165, 199 (1958) (Frankfurter, J., dissenting). This restraint is even more necessary when a court considers accusations of inequitable conduct, which by their very nature can trigger career-ending consequences for patent practitioners. To ignore this needed restraint would confer on the judiciary discretionary power to disregard the considered limitations of the laws it is charged with enforcing. *United States v. Payner*, 447 U.S. 727, 737 (1980).

As an initial matter, this Court has recognized that a district courts' discretionary power to impose sanctions, while appropriately broad, is limited by express statutes and judicial norms.⁸ More fundamentally, however, the discretionary power of lower courts to sanction parties is constrained by the Constitution. Here, *amici* submit that a district court must comply with the Due Process Clause of the Fourteenth Amendment when exercising its discretionary powers to determine the merits of an

8. *See, e.g., Ex parte Robinson*, 86 U.S. 505, 511 (1873) (limiting the courts' inherent power to punish for contempt under statute); *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 134 S. Ct. 1749, 1758 (2014) (shaping the discretionary determination of an "exceptional" case and its proper evidentiary burden under the fee-shifting provision of 35 U.S.C. § 285); *Highmark Inc. v. Allcare Health Mgmt. Sys., Inc.*, 134 S. Ct. 1744, 1749 (2014) (establishing an abuse-of-discretion standard in reviewing a district court's determination of an exceptional case for purposes of fee-shifting).

inequitable conduct accusation.⁹ This is what the district court and Federal Circuit did not do in this case.

Procedural due process is not “a technical conception with a fixed content unrelated to time, place and circumstances.” *Mathews v. Eldridge*, 424 U.S. 319, 334 (1976). Instead, procedural due process norms must be “flexible” and applicable protections should be based on the demands of a particular situation. *Id.* This Court has identified three distinct factors that should be weighed when a district court exercises its discretion to impose sanctions: (1) the private interest that will be affected by the official action; (2) the risk of an erroneous deprivation of such interest through the procedures used, and the probable value, if any, of additional or substitute procedural safeguards; and (3) the Government’s interest, including the function involved and the fiscal and administrative burdens that the additional or substitute procedural requirement would entail. *Id.* at 335. In this case, *amici* respectfully submit that the district court and Federal Circuit erred under the factors established in *Mathews*, as set forth below.

B. This Court provides procedural due process protections for attorney disciplinary proceedings, which should likewise be applied to accusations of inequitable conduct.

Under *Mathews*, proceedings that put certain important private interests at-issue can be subject to protections under constitutional due process. One such

9. “No State shall . . . deprive any person of life, liberty, or property, without due process of law....” U.S. Const. amend. XIV.

example is an attorney disciplinary proceeding, which can result in temporary or permanent disbarment. Such a finding can be detrimental to an attorney's professional reputation, well-being, livelihood, and success in the legal profession. *Dailey v. Vought Aircraft Co.*, 141 F.3d 224, 229 (5th Cir. 1998). An attorney's disbarment will certainly lead to "serious adverse career consequences." *Id.*

Because admission to the bar is an absolute prerequisite for the practice of law, this Court has held that the corresponding private interest has sufficient import to warrant procedural due process protections. *See, e.g., In re Ruffalo*, 390 U.S. 544, 550 (1968); *In re Oliver*, 333 U.S. 257, 273 (1948); *see also, Law Students Civil Rights Research Council, Inc. v. Wadmond*, 401 U.S. 154, 174 (1971) (Black, J. and Douglas, J., dissenting).¹⁰ In recognition of such protections, the circuit courts of appeal have provided specific procedural safeguards for attorney disciplinary proceedings, such as notice and an opportunity to be heard. *See, e.g., In re Prudential Ins. Co. Am. Sales Practice Litig. Agent Actions*, 278 F.3d 175, 191 (3d Cir. 2002); *Dailey*, 141 F.3d 224 (5th Cir. 1998).

10. "[T]he right of a lawyer or Bar applicant to practice his profession is often more valuable to him than his home, however expensive that home may be. Therefore I think that when a State seeks to deny an applicant admission or to disbar a lawyer, it must proceed according to the most exacting demands of due process of law. . . . When it seeks to deprive a person of the right to practice law, a State must accord him the same rights as when it seeks to deprive him of any other property." *Law Students Civil Rights Research Council, Inc.*, 401 U.S. at 174 (1971).

Furthermore, in *Zauderer v. Office of Disciplinary Counsel of Supreme Court of Ohio*, 471 U.S. 626, 655 (1985), this Court held that notice and an opportunity to respond provided in a disciplinary proceeding were “sufficient to satisfy the demands of due process.” *Amici* submit that similar due process demands should apply to proceedings involving allegations of inequitable conduct before a district court.

Prosecuting patent lawyers accused of inequitable conduct face the same potential career-ending consequences as those subject to attorney disciplinary proceedings. A finding of inequitable conduct can inflict severe personal costs on patent practitioners, including public reprimand, disbarment, malpractice liability, and damage to reputation. Christopher A. Cotropia, MODERNIZING PATENT LAW’S INEQUITABLE CONDUCT DOCTRINE, 24 *Berkeley Tech. L.J.* 723, 775 (2009). Allegations of inequitable conduct made in a patent litigation regarding a prosecuting patent lawyer’s intent to deceive the USPTO subject them to intense scrutiny regarding actions usually taken many years prior to judicial inquiry. *See Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1349–50 (Fed. Cir. 2008) (Rader, J., dissenting) (noting that the “allegation of inequitable conduct opens new avenues of discovery” targeted at the prosecuting patent lawyer, not the patent).

Furthermore, because the inequitable conduct doctrine inherently focuses on “moral turpitude” by the patentee or its counsel, any such finding can work “ruinous consequences for the reputation of his patent attorney.” *Therasense*, 649 F.3d at 1288. One study of patent lawyers involved in cases of inequitable conduct showed that most

withdraw from the profession altogether.¹¹ Even for those who remain in their profession, multi-year suspensions from practicing before the USPTO are a common consequence of an inequitable conduct determination. Flores, *supra* note 11.

As further direct consequences to a finding of inequitable conduct, patent practitioners are often subject to multiple, parallel sanctions from their respective state and federal bars in addition to the USPTO registration bar. For example, upon a finding of inequitable conduct, prosecuting patent lawyers have been suspended or disbarred from one bar only to face reciprocal discipline before other ones.¹²

For at least these reasons, *amici* contend that an important private interest – that of a prosecuting patent lawyer’s ability to practice law before the USPTO and/or that practitioner’s own state bar – is invoked and at issue upon an allegation of inequitable conduct. Accordingly,

11. Edwin S. Flores, Ph.D. & Sanford E. Warren, Jr., *Inequitable Conduct, Fraud, and Your License to Practice Before the United States Patent and Trademark Office*, 8 Tex. Intell. Prop. L.J. 299, 322 (2000). 8 Tex. Intell. Prop. L.J. 299 (2000)

12. See, e.g., *Intellect Wireless, Inc. v. HTC Corp.*, 910 F. Supp. 2d 1056, 1061 (N.D. Ill. 2012), *aff’d*, 732 F.3d 1339 (Fed. Cir. 2013) (finding inequitable conduct for submitting false Rule 131 declarations during patent prosecution), which led to *In re Robert K. Tendler*, Proc. No. D2013-17 (USPTO Dir. Jan. 8, 2014) (conferring a four-year suspension from practice before the USPTO) and *In re: Robert K. Tendler*, No. BD-2014-044 (Suffolk County, MA, Sept. 22, 2014) (reciprocal discipline at the state bar, conferring an absolute six-month suspension from the practice of law in the state of Massachusetts).

constitutional procedural due process protections, such as notice and opportunity to be heard, apply to inequitable conduct proceedings.

In this case, the district court improperly prevented Regeneron's prosecuting patent lawyers involved in prosecuting the patent-at-issue from presenting evidence of their lack of an intent to deceive the USPTO to counter the assertion of any such intent; instead, the district court drew an adverse inference of such intent based on the conduct of separate litigation counsel. The district court refused to consider evidence even when proffered by the patent prosecution lawyers regarding their actual lack of an intent to deceive. This decision sidestepped the clear and convincing evidence standard required by this Court for establishing fraud and required by the Federal Circuit for establishing inequitable conduct. *See, e.g., Schneiderman v. United States*, 320 U.S. 118, 123 (1943) (holding that the burden of proof for fraud "must be met with evidence of a clear and convincing character"); *see also Therasense*, 649 F.3d at 1290. In fact, on the issue of intent, the record below lacks any evidentiary inquiry whatsoever. Such a scenario, if not rejected by this Court, makes it probable, if not inevitable, that a patent practitioner's private interests will be erroneously taken by a district court without due process of law.

To avoid such improper deprivations, these (and all) patent practitioners must be entitled to a fair and genuine opportunity to respond to serious, career-threatening inequitable conduct allegations made against them, just as any accused attorney is afforded an opportunity to provide exculpatory evidence in disbarment proceedings. At a minimum, *amici* submit that this Court should require

that any findings on intent to deceive and, as a result, inequitable conduct be amply supported by significant probative evidence. *Kingsland v. Dorsey*, 338 U.S. 318, 320 (1949) (finding a charge of unfairness in the hearing resulting in disbarment wholly without support). Proper determinations of inequitable conduct under *Therasense* (which reflects this Court’s guidance in *Keystone*, *Hazel-Atlas*, and *Precision Instrument*) already consist of dual inquiries into materiality and specific intent, which the district court was bound to undertake. Thus, implementing such protections would place no increased burden on district courts.

The remedy of inequitable conduct impacts both a public interest in the patent monopoly along with a compelling private interest – that of the individual patent practitioners who are subject to Patent Office sanctions and possible USPTO and/or state disbarment. By denying patent practitioners an opportunity to be heard, the district court in this case put them at risk of being deprived of their career, reputation, and livelihood—all without due process.

Accordingly, this Court should grant the petition to address the unconstitutionality of the district court’s lack of due process that failed to provide an opportunity for substantive inquiry into the patentee’s specific intent to deceive the Patent Office.

II. The Federal Circuit has created uncertainty and discord in district courts by directly contravening its own inequitable conduct case law that is grounded in this Court’s precedent.

A. The Federal Circuit failed to follow *Aptix*, which expressly distinguishes between remedies for litigation misconduct and those for inequitable conduct.

As an equitable doctrine, inequitable conduct hinges on principles of basic fairness. *Therasense*, 649 F.3d at 1292. In *Columbus Board of Education v. Penick*, 443 U.S. 449, 465 (1979), this Court ruled that a remedy imposed by a court of equity should be commensurate with the offending violation and should be aimed at rectifying such violations.¹³ In other words, a discretionary sanction should be tailored to the type and extent of the misbehavior – the punishment should fit the crime (particularly where, as here, what a court is determining is whether there *is* a crime).

In *Aptix*, the Federal Circuit, relying on *Keystone* and *Keystone II*, held that the remedies available for litigation misconduct differ from the types of remedies available for inequitable conduct (misconduct committed in the course of acquisition of a patent property right). 269 F.3d at 1376. Namely, the remedies for litigation misconduct should serve to punish the wrong-doing party, but should not

13. See also *Chambers v. NASCO, Inc.*, 501 U.S. 32, 44–45 (1991) (“A primary aspect of the discretionary inquiry is to fashion an appropriate sanction for conduct which abuses the judicial process.”).

affect the property right claimed in the suit because the patent did not accrue *because of* any misconduct during litigation. *Id.* at 1375 (citing *McClintock on Equity* (2d ed. 1948) § 26).

Contrary to *Aptix*, *Keystone*, and *Keystone II*, however, the district court in this case sanctioned litigation misconduct by one set of actors (litigation counsel) by inferring a specific intent to deceive the Patent Office by other actors (prosecuting patent lawyers) *who had nothing to do with the sanctioned litigation misconduct*. In doing so, the district court used its sanction to improperly impact both the underlying patent right *and* the prosecuting patent lawyers themselves. This error was not corrected by the Federal Circuit, directly contravening this Court's and its own precedent.

B. The Federal Circuit ignored *Therasense*, which expressly requires inquiries into the separate prongs of materiality and intent.

In *Therasense*, the Federal Circuit held that intent and materiality are separate requirements of the inequitable conduct determination and that a court must weigh evidence of intent to deceive independent from its analysis of materiality. 649 F.3d at 1290. The Federal Circuit's holding in *Therasense* is well-grounded in this Court's *Keystone*, *Atlas-Hazel*, and *Precision Instrument* decisions. *Id.* at 1285.

While the question of materiality is an objective inquiry based on the prior art and patent claims, the subjective nature of the intent inquiry permits a district court to infer intent from indirect and circumstantial

evidence. *Larson Mfg. Co. of S.D., Inc. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1340 (Fed. Cir. 2009). Even so, after conducting the required findings of fact¹⁴ on intent, *Therasense* requires that a finding of a specific intent to deceive must be “the single most reasonable inference able to be drawn from the evidence.” 649 F.3d at 1290. Yet further, the evidence must be sufficient to require a finding of deceitful intent in light of all circumstances. *Id.*

Under the framework of *Therasense*, district courts are obliged to provide patentees and their prosecuting patent lawyers with an opportunity to be heard on the issue of the specific intent to deceive. *See Advanced Magnetic Closures, Inc. v. Rome Fastener Corp.*, 607 F.3d 817, 829 (Fed. Cir. 2010) (“In evaluating intent, the district court must consider evidence that the patent applicants withheld information from the PTO in good faith.”). In particular, the district court should take into account any evidence that may “militate[] against a finding of deceptive intent.” *Larson*, 559 F.3d at 1341.

In this case, the district court never conducted a trial or even received evidence on this issue. Instead, the district court inferred the prosecuting patent lawyers’ intent to deceive the USPTO based on the court’s adverse inference against litigation counsels’ misconduct. This action was directly contrary to Federal Circuit precedent in *Therasense* as well as this Court’s guidance in *Keystone*, *Hazel-Atlas*, and *Precision Instrument*.

14. *Am. Calcar, Inc. v. Am. Honda Motor Co.*, 768 F.3d 1185, 1191 (Fed. Cir. 2014) (stating that specific findings of fact are required under *Therasense*).

Certiorari should be granted here because, if permitted to stand, similar interpretations of inequitable conduct could negatively affect patent practitioners and the entire patent prosecution landscape. This Court should intervene to clarify the law of inequitable conduct.

CONCLUSION

The petition for a writ of *certiorari* should be granted.

Respectfully submitted,

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