


In the
Supreme Court of the United States



REGENERON PHARMACEUTICALS, INC.,

Petitioner,

–v–

MERUS N.V.,

Respondents.

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

**BRIEF OF *AMICUS CURIAE* FOR THE
NATIONAL ASSOCIATION OF PATENT PRACTITIONERS
IN SUPPORT OF NEITHER PARTY**

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INTEREST OF AMICUS CURIAE¹

The National Association of Patent Practitioners (“NAPP”) is an association of hundreds of patent agents and attorneys. Most of NAPP’s members prosecute patent applications before the United States Patent and Trademark Office (“PTO”).

Here, the Federal Circuit affirmed that fraudulent intent to deceive the PTO may be imputed to patent prosecutors who took *no part* in the sanctioned patent litigation misconduct, but instead were merely percipient witnesses in the litigation. NAPP members have a direct and substantial interest in the outcome of this case because, among other things, (1) the ruling injects unworkable uncertainty for patent prosecutors and their clients with respect to practice before the PTO, (2) the sanction of holding a duly-issued patent *unenforceable by inferred but unproven inequitable conduct before the PTO* irreparably tarnishes the professional profiles of patent practitioners without justification, while the actual miscreants face no such Draconian consequence, and (3) it undermines the integrity of the United States patent system as a whole.

¹ Counsel for NAPP authored the present brief in its entirety. No party to the appeal, its counsel, or any other entity besides NAPP has contributed money intended to fund preparation or submission of this brief. Counsel of record for both parties received timely notice of the intent to file this amicus curiae brief, pursuant to Rule 37.2(a), and consent was granted by both parties.



SUMMARY OF THE ARGUMENT

NAPP urges the Court to review and reverse the Federal Circuit’s erroneous affirmance of a final judgment holding Regeneron’s U.S. Patent No. 8,502,018 (“’018 patent”) *unenforceable by adverse inference*. Pet.App.193a-194a. The district court’s *adverse inference* that Regeneron’s patent prosecutors, and others who were involved in procuring the ’018 patent, had *specific intent to deceive the PTO* during its prosecution was a Draconian sanction for completely unrelated litigation misconduct. It was an abuse of discretion that cannot be allowed to stand. The *Regeneron* decision will significantly impair the United States patent system, in a manner that would be exceedingly difficult to correct.

For reasons explained below, NAPP respectfully submits:

1. There is no basis in law or equity for drawing an adverse inference of *specific intent to deceive the PTO* during patent prosecution, for the subsequent misconduct of others having nothing to do with practice before the PTO;

2. Failure to issue a sanction specifically tailored to address litigation misconduct, and instead choosing to impute fraudulent intent to patent prosecutors who had no part in that misconduct, merely to avoid “reopening discovery,” was an abuse of discretion;

3. The “adverse inference” sanction unjustly punishes prosecution counsel, and by extension the patentee, for *post-prosecution misconduct perpetrated*

by others, effectively holding that they procured the patent by fraud on the PTO despite *no evidence* to support that holding; and

4. The imposed sanction does not punish the actual culprits.

The *Regeneron* outcome is profoundly troubling. Under *Regeneron*, a patentee who did nothing wrong can nonetheless be stripped of a patent, simply because it hired the wrong litigation counsel. As a matter of fundamental equity, no court should be permitted an unfettered ability (“discretion”) to draw an “adverse inference” of intent to deceive the PTO as a *litigation* sanction, based upon conduct *not* relating to patent procurement, *not* relating to the integrity of the inventors, and *not* relating to the patent prosecutors’ conduct before the PTO, but instead relating to the misconduct of patent litigators *who had never been involved in the prosecution of the patent*, and *never had a duty to the PTO in procuring it*. Under *Regeneron*, it is not the malfeasant litigators who are punished for their misconduct, but instead, the patentee and the patent prosecutors—each one suffering an irreversible tarnish on their professional profiles, while the true wrongdoers face no such consequence.

Patentees are not litigators. They *must* rely on outside litigation counsel to conduct a patent litigation; they trust that litigation counsel is performing competently and with integrity its professional duties with respect to the parties and the trial court. The Federal Circuit wrongly affirmed a ruling that is unfair, unjustified, and detrimental to the United States Patent Bar and the patent system as a whole. Its affirmance condones a court’s violation of due process

for patentees who have not been given any opportunity to defend against allegations of fraud. It punishes patent practitioners for conduct in which they took no part. For at least these reasons, as detailed below, NAPP respectfully requests review and reversal of this extremely important case.



BACKGROUND FACTS

A. THE DISTRICT COURT'S STATED REASONS FOR ISSUING SANCTIONS ALL RELATE TO LITIGATION MISCONDUCT

Litigation misconduct formed the entire basis of district court's decision to sanction Regeneron. Pet. App.4a. The district court considered Regeneron's repeated violations of its discovery orders and Regeneron's "improper secreting of relevant and non-privileged documents," as litigation conduct warranting sanctions. *Id.* Having already determined (in its first bench trial) that certain Withheld References were material to patentability, the district court held by adverse inference that Regeneron's prosecution counsel had specifically intended to deceive the PTO when they chose not to disclose that material information to the PTO during prosecution of the '018 patent. *Id.* The court then used its adverse inference to conclude that Regeneron had committed inequitable conduct in obtaining the '018 patent, and consequently proclaimed the '018 patent unenforceable. *Id.*

The district court found that there were, in fact, three categories of documents that presented "serious concerns" of litigation misconduct. *Id.* at 37a. The most

egregious included “documents on the privilege log relating to precisely those topics waived by Regeneron when Regeneron filed trial declarations of [its patent prosecutors] Drs. Smeland and Jones,” as part of Regeneron’s defense to an inequitable conduct counterclaim. *Id.* at 38a.² The district court concluded that many documents on Regeneron’s privilege log were “directly relevant to Drs. Smeland and Murphy’s mental impressions of the Withheld References during prosecution of the ’018 patent,” and “would therefore have been relevant to determining if Regeneron specifically intended to deceive the PTO by failing to disclose the Withheld References during prosecution of the ’018 patent.” *Id.* at 39a. “Given the thousands of documents on Regeneron’s privilege log, the district court concluded that it could not possibly learn the full extent” of Regeneron’s misuse of the attorney-client privilege and its defiance of the court’s discovery orders. *Id.* at 38a. Thus, based on a review of the privilege log and its *in camera* review of selected documents on that log, the district court concluded that Regeneron’s behavior in sequestering documents from discovery warranted sanctions. *Id.*

There is no showing in the record that Regeneron’s inventors, prosecutors, or company executives had lied under oath or to the Court in order to advance Regeneron’s litigation against Merus. The litigation behavior deemed “egregious misconduct” warranting

² The district court determined that Regeneron’s failure to make full and adequate production of other documents in compliance with the court’s orders to produce them also warranted serious sanction. Pet.App.38a.

sanctions was solely based on discovery positions taken solely by litigation counsel. *Id.* at 3a.

There is also nothing in the record showing that the court considered sanctioning litigation counsel. Instead, the district court justified its Draconian sanction because other alternatives would be too expensive and “not a fair burden for Merus or this court.” *Id.* at 40a. The district court considered whether striking the trial affidavits and precluding Drs. Smeland and Murphy from testifying at trial, or reopening discovery with a special master, would be sufficient remedies. *Id.* The court concluded that they would not, because doing so would not fully address Regeneron’s improper use of litigation privileges to withhold discoverable documents, and “would not address the delay and disruptions caused by Regeneron’s behavior throughout litigation.” *Id.* Additionally, the district court observed that “it would be unfair to Merus to reopen discovery on the eve of trial and inject further delay in the case entirely due to Regeneron’s [litigation] behavior.” *Id.* The court also concluded that doing so would “impose an unfair burden on the court and require expending substantial additional judicial resources.” *Id.* Thus, the court *sua sponte* drew an adverse inference that “Regeneron” had committed fraud on the PTO in order to procure the ‘018 patent over a year before the litigation began. *Id.* The court cited to no actual evidence of fraud or specific intent to deceive the PTO in making that inference.

The district court found that Regeneron’s litigation conduct created a “pattern” of misconduct warranting sanctions. *Id.* Drs. Smeland, Jones and Murphy,

however, had no apparent role in orchestrating that misconduct. *See* Appendix A at 1a (Summary of Misconduct). The district court’s stated reasons for issuing sanctions all relate to litigation misconduct, and not to conduct before the PTO.

B. The Court of Appeal’s Stated Reasons for Affirmance All Relate to Litigation Conduct

In affirming the lower court’s judgment, the Federal Circuit cited:

- “*Widespread litigation misconduct*,” including “Appellant’s use of sword and shield tactics to protect Drs. Smeland and Murphy’s thoughts regarding disclosure of the Withheld References to the PTO during prosecution of the ‘018 patent,…” Pet.App.44a;
- “*Regeneron’s litigation misconduct*,” which “obfuscated its prosecution misconduct.”³ *Id.* at 43a;
- Regeneron’s “fail[ure] to disclose documents directly related to its prosecuting attorneys’ mental impressions of the Withheld References during prosecution of the ‘018 patent. *Id.*; and
- “The district court drew an adverse inference to *sanction this litigation misconduct.*” *Id.*

Thus, the appellate court concluded that the district court “did not abuse its discretion by sanctioning Regeneron in this manner,” and affirmed judgment,

³ There is no evidence in the record showing that prosecution misconduct had been “obfuscated” by designating documents as privileged and withholding them from production.

based upon litigation misconduct and not upon prosecution conduct before the PTO. *Id.* at 25a.

C. Conduct Before the PTO Shows No Nefarious Intent With Respect to the '018 Patent Prosecution

Days before the PTO issued its notice of allowance for the '018 patent claims, a third-party filed a submission in its parent application (*i.e.*, to which the '018 patent claimed priority), describing three references of the Withheld References at issue. *Id.* at 9a. A fourth reference was co-invented by a member of Regeneron's Scientific Advisory Board. *Id.* at 10a. Although Regeneron did not disclose these four "Withheld References" during prosecution of the '018 patent, Regeneron did disclose them to the PTO in every related pending application having the same specification and similar claims. *Id.* at 11a.

While he was prosecuting the '018 patent, Dr. Smeland retained Dr. Jones as outside counsel to help with Regeneron's patent prosecution. *See id.* at 9a. During prosecution of the '018 patent, Dr. Jones drafted a chart and memo (the "Jones Memo") in connection with his review of whether to disclose the Withheld References to the PTO. *See id.* at 28a.

The Jones Memo evidences that Dr. Jones had analyzed the prior art and arrived at a legal conclusion about disclosure obligations as part of his advisory role to Regeneron. *See id.* at 29a. He contemporaneously communicated the substance of that conclusion to his client. *See id.* Regeneron thus knew of the Withheld References prior to issuance of the '018 patent and had outside patent counsel analyze them, ultimately declining to disclose them to the PTO. *See*

id. No evidence of specific intent to deceive the PTO with respect to the “Jones Memo” analysis is cited by either the district court or in the appellate court’s opinion.

Separate and distinct from the prosecutors’ decision not to disclose the Withheld References, the district court found that misleading statements had been communicated to the PTO during prosecution of ’018 patent. They included: (1) statements in the specification later disproven by Regeneron’s subsequent patent applications; (2) inaccurate or incomplete statements in the specification; and (3) a presentation to the PTO which contained one or more false statements concerning an alleged commercial embodiment of the claimed invention. *See id.* at 6a-9a. The court cited to no evidence showing that any of those misleading statements were made with specific intent to deceive the PTO. *See id.* at 3a-4a. Consequently, none of those statements were relied upon by either the district court or the court of appeals as a basis for finding the ’018 patent unenforceable.

Although there was no evidentiary basis for finding scienter, the district court nonetheless proclaimed: “The Court finds by clear and convincing evidence, and without need for application of an adverse inference, that Regeneron made false and misleading statements. The Court finds by clear and convincing evidence that this constitutes egregious affirmative misconduct.” *Id.* at 168a-169a. However, there was no evidence cited by the court (or in the appellate court’s review) showing that anyone involved in Regeneron’s prosecution of the ’018 patent knew that any of its

communications to the PTO were false or misleading prior to issuance of the '018 patent. *See id.*

On the other hand, the evidence showed that both Dr. Smeland (prosecuting attorney) and Dr. Murphy (inventor) believed that Regeneron's invention was novel and nonobvious because it taught "targeted insertion" of "gene segments," whereas the prior art taught genes that are "randomly inserted at (unknown) loci." *Id.* at 8a. To buttress its patentability argument, Regeneron asserted to the PTO that it had developed a commercial embodiment of the claimed mouse with surprising results. *See id.* Although the district court later found that Regeneron had not developed any such mouse at the time, the evidence also showed that Inventor Murphy's team "went a year believing that they had target locations for the proximal and distal regions of the locus, but that they had been wrong." *Id.* at 167a. No evidence of specific intent to deceive the PTO, as opposed to simply being mistaken or careless, was found by the court.



ARGUMENT

A. THERE IS NO JUSTIFICATION IN LAW OR EQUITY FOR DRAWING AN ADVERSE INFERENCE OF SPECIFIC INTENT TO DECEIVE THE PTO AS A SANCTION FOR LITIGATION MISCONDUCT

A court's frustration and perceived time constraints should never be the basis of assuming malice, especially of third parties such as prosecution counsel, who were merely percipient witnesses in the litigation. Litigation misconduct has nothing to do

with practice before the PTO. The *Regeneron* holding “convicts” a patent applicant, its inventors, and its patent prosecution counsel, without even so much as an opportunity to be heard. *Id.* at 46a (Newman, J. dissenting). If allowed to stand, such unjustified “conviction” will inevitably undermine the public’s confidence that the United States patent system will continue to be a valuable part of American business.

Courts have uniformly held that “inequitable conduct” only arises when material references are *intentionally* withheld by the patent applicant in order to *deceive or mislead* the examiner into granting the patent monopoly. “Both materiality and intent must be proved by *clear and convincing evidence.*” *Id.* at 45a (citing *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011) (emphasis added)).

Here, the district court found that Regeneron’s patent prosecutors had engaged in “affirmative egregious misconduct” during procurement of the ’018 patent, based upon certain misleading statements Regeneron made to the PTO during prosecution of ’018 patent. But that finding was an alternative to “but-for” materiality of the Withheld References, *not* a finding of “specific intent to deceive.” ***But-for materiality is a completely separate inquiry from specific intent to deceive.*** *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1366 (Fed. Cir. 2008) (“materiality does not presume intent, which is a separate and essential component of inequitable conduct”), quoting *GFI, Inc. v. Franklin Corp.*, 265 F.3d 1268, 1274 (Fed. Cir. 2001). Consequently, the district court was still under an obligation to review

the specific intent component of inequitable conduct. It improperly ignored that obligation.⁴

The precedential instances of a successful “unclean hands” defense represented by *Keystone Driller*, *Hazel-Atlas Glass*, and *Precision Instrument*⁵ are all summarized by Petitioner Regeneron and in Judge Newman’s dissenting opinion, and their facts and holdings need no further elaboration here. See Petition for Writ of Certiorari at 4, 12-24; Pet.App. at 44a-50a (Newman, J. dissenting). NAPP agrees with those analyses and their applicability to the case before the Court. Yet, none of this Supreme Court precedent—nor any other applicable precedent—was followed or even cited to provide a legal basis for the district court’s Draconian sanction.

Thus, the district court’s failure to apply the law of inequitable conduct is unjustifiable.

B. THE DISTRICT COURT ABUSED ITS DISCRETION BY IMPUTING FRAUDULENT INTENT TO THOSE WHO TOOK NO PART IN THE LITIGATION MISCONDUCT, THEREBY PUNISHING THE WRONG PARTIES

Litigation conduct has nothing to do with practice before the PTO. Moreover, patent prosecution and

⁴ *All patents are entitled to a presumption of validity and enforceability.* 35 U.S.C. § 282; *Roper Corp. v. Litton Systems, Inc.*, 757 F.2d 1266, 1270 (Fed. Cir. 1985) (“[T]he burden of establishing invalidity of a patent rests on the party asserting such invalidity.”); *Monsanto Co. v. Scruggs*, 459 F.3d 1328, 1334 (Fed. Cir. 2006) (affirmative defenses to infringement include, among others, unenforceability and invalidity).

⁵ See 290 U.S. 240 (1933); 322 U.S. 238 (1944); 324 U.S. 806 (1945).

patent litigation is most often handled by different attorneys. An enforcement action cannot even occur before the patent issues, and often commences years after its issuance. No patent applicant or prosecuting attorney should ever be punished for the unpredictable discovery abuses perpetrated by unknown, future litigation counsel.

The purpose of Rule 37 sanctions is to deter litigation misconduct. Fed. R. Civ. P. 37. Here, however, the result of the district court's sanction was to punish the wrong players for the actual misconduct found—*i.e.*, litigation abuses, not prosecution misconduct. (See Appendix A at 1a.) Thus, the court's Draconian sanction cannot serve as a deterrence for the litigation misconduct of plaintiff's counsel. The sanction did not punish the culprits.

Even more troubling is the fact that the sanction is wholly unrelated to the *prosecution conduct* found by the court which, when considered in isolation, demonstrates no intentional misconduct before the PTO. In fact, as explained in further detail below, the Jones Memo demonstrates that the prosecutors acted with prudence, not misconduct, in their review and handling of the Withheld References under the guidance provided by the PTO itself.

Further, the doctrine of inequitable conduct “focuses on the moral turpitude of the patentee with ruinous consequences for the reputation of his patent attorney,” as previously recognized by the Federal Circuit. *Therasense*, 649 F.3d at 1298. NAPP cannot overemphasize the reality that any ruling declaring a patent unenforceable under an adverse inference of “specific intent to deceive the PTO” stigmatizes a

prosecuting attorney, as well as the patent applicant, for the sake of punishing a patent plaintiff (who is not always the patent applicant) for the misguided actions or malfeasance of its litigation counsel.

NAPP respectfully submits that the dismissal of Regeneron's suit against Merus, with an award of reasonable fees (and perhaps an additional monetary sanction against litigation counsel), would have been a more balanced and appropriate alternative sanction. Such alternative outcome is moreover well-founded in the law of *Aptix Corp. v. Quickturn Design Systems, Inc.*, 269 F.3d 1369 (Fed. Cir. 2001). There, the Federal Circuit affirmed the trial court's dismissal of a patent suit and an award of attorney's fees, but *reversed* the district court's order declaring the patent unenforceable, holding that litigation misconduct, as opposed to fraud on the Patent Office, can never lead to extinguishing a patent, even when the inventor himself has committed the litigation misconduct. The *Aptix* holding is fundamentally rooted in the principles of equity at stake in the present case. It should be applied here.⁶

If not reversed, the *Regeneron* holding promises to disrupt patent prosecution practice in the United States—profoundly—for both patent practitioners (most NAPP members), as well as for their clients. Patent practitioners are now, under *Regeneron*, obligated to inform clients, at the very beginning of the patenting

⁶ Judge Newman's dissenting opinions aptly summarize the law of *Aptix* and applicable Supreme Court precedent. NAPP respectfully incorporates all of those expressed opinions here. See Pet.App.44a (Newman, J. dissenting; See also *id.* at 198a (*denying en banc review*; J. Newman, *dissenting*)).

process, that perhaps many years from now (up to twenty years from the date of filing), if a patent is asserted in litigation, the hard work of the inventors and the patent prosecutor(s) could all be for not, *regardless* of the validity of the patent claims (often times patented in numerous other countries by the time U.S. litigation commences), and *regardless* of the whether defendants are infringing those claims. This ruling will most hard hit the solo inventor and small businesses, who traditionally have limited resources to develop their intellectual property into innovative businesses constituting the backbone of the United States economy.

In short, by failing to issue a sanction tailored to address litigation misconduct, and instead imputing fraudulent intent to the patent prosecutors who had no part in conducting the litigation, the district court did not merely punish the wrong actors. It did not merely abuse its discretion. It opened up an entire new world of obscurity and uncertainty in the United States patent system, which now only the Supreme Court can enlighten and correct.

C. A COURT OF JUSTICE IS NOT EMPOWERED TO ESTABLISH SPECIFIC INTENT TO COMMIT FRAUD PURELY BY ADVERSE INFERENCE

The Federal Rules of Civil Procedure, among other things, requires that fraud must be pled with particularity. Fed. R. Civ. P. 9(b) (“In alleging fraud or mistake, a party must state with particularity the circumstances constituting fraud or mistake. Malice, intent, knowledge, and other conditions of a person's mind may be alleged generally.”). So must any complaint alleging inequitable conduct before the PTO.

See *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir 2009) (“to plead the ‘circumstances’ of inequitable conduct with the requisite ‘particularity’ under Rule 9(b), the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO.”) Thus, there is an implicit, basic tenant embodied in our judicial system that a “pattern of misconduct” by litigation counsel should not, and cannot, be imputed to prosecuting attorneys to infer and conclude that fraud was committed against the United States government in order to secure a patent grant from the PTO. There must be sufficient facts known before the complaint is even filed that support the fraud allegation.

NAPP respectfully submits that a court has no legal basis for inferring the *mens rea* element of inequitable conduct. There is no legal precedent to support it, and no justification in equity to permit it. Even if there was “egregious misconduct” in presenting false statements regarding commercial embodiments to the PTO, the district court’s factual findings support, at most, a theory of negligence, and negligence is not equivalent to specific intent.⁷ Indeed, the district court did not use this finding as evidence of

⁷ The citations by the district court to the Davis trial declaration are to Regeneron’s independent expert, and not citations to Regeneron’s patent prosecutors’ testimony or sworn affidavits. See Pet.App.161a-162a (citing Davis Tr. Decl. ¶¶ 257-72, and ¶¶ 273-87). Murphy (inventor) and Davis (expert) statements are cited as proof that the PTO presentation contained false statements. *Id.* However, no evidence is presented or cited that the prosecuting attorneys, or even the inventor, knew this fact when arguing for patentability before the PTO.

specific intent to deceive the PTO on the part of the prosecuting attorneys or inventors. In fact, *the district court recognized the absence of evidence that the prosecutors specifically intended to mislead the PTO*, when it lamented the need for re-opening discovery. Without reference to any authority (aside from its inherent power), the court decided to treat that evidence-gathering exercise as optional. NAPP respectfully submits that it was not, and that the court had a duty to mandate and conduct the discovery required to either establish or disprove specific intent.

Materiality of known references not disclosed to the PTO during prosecution of a patent does not, by itself, support a finding of inequitable conduct: “A district court may *not* infer intent solely from materiality.” *Therasense*, 649 F.3d at 1290 (emphasis added). Instead, a court must weigh the evidence of intent to deceive independent of its analysis of materiality. *Id.* “Proving that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO does not prove specific intent to deceive.” *Id.*

D. REGENERON INJECTS UNWORKABLE UNCERTAINTY FOR PROSECUTORS AND THEIR CLIENTS WITH RESPECT TO PRACTICE BEFORE THE PTO

The Federal Court should not have inferred nefarious motivations based on the fact that Regeneron did not disclose the Withheld References during prosecution of the '018 patent, but did disclose them to the PTO in every other related application having the same specification and similar claims. *See* Pet. App.11a. The rules of practice before the PTO mandate that “the filing of an information disclosure statement

shall not be construed to be an admission that the information cited in the statement is, or is considered to be, material to patentability as defined in § 1.56(b).” 37 CFR 1.97(h). Thus, the fact that Regeneron’s patent prosecutors disclosed the Withheld References in all pending related applications cannot be held as an admission of materiality.

By the same token, a prosecuting attorney, inventor, or applicant is under no obligation to disclose known references during prosecution if they are not material to the patentability of the claims. 37 CFR 1.56 and 1.97. The MANUAL OF PATENT EXAMINING PROCEDURE (“MPEP”) 2001.05 explains that, “information is not material unless it comes within the definition of 37 CFR 1.56(b) (1) or (2). ***If information is not material, there is no duty to disclose the information to the Office.***” (Emphasis added). Under 37 CFR 1.56(b), there is no automatic requirement to cite all references known to a prosecutor or inventor relating to the invention—for example, cumulative prior art or art not touching upon the patentability of the pending claims. (See Appendix B at 11a, MPEP 2001.5—Materiality Under 37 CFR 1.56(b))

Recognizing the difficulty in evaluating materiality, the MPEP 2004 further provides “Aids to Compliance with Duty of Disclosure.” (See Appendix C at 13a) These aids include (among others):

It is desirable to avoid the submission of long lists of documents if it can be avoided. ***Eliminate clearly irrelevant and marginally pertinent cumulative information.*** If a long list is submitted, highlight those

documents which have been specifically brought to applicant's attention and/or are known to be of most significance.

MPEP 2004, ¶ 13 (emphasis added; citations omitted)

[I]f information was specifically considered and discarded as not material, this fact might be recorded in an attorney's file or applicant's file, including the reason for discarding it. If judgment might have been bad or something might have been overlooked inadvertently, a note made at the time of evaluation might be an invaluable aid in explaining that the mistake was honest and excusable. Though such records are not required, they could be helpful in recalling and explaining actions in the event of a question of "fraud" or "inequitable conduct" raised at a later time.

MPEP 2004, ¶ 18 (emphasis added))

Given the above prosecution rules and guidelines, it was not surprising that Regeneron's patent prosecutor Jones set out to analyze the materiality of prior art that had been identified by a third party in connection with prosecuting the '018 patent's parent application. This is an important and frequent prosecution task. Dr. Jones then prepared a memorandum recording his analysis, as the MPEP guidelines recommend, after reaching a conclusion that the references need not be disclosed. This memorandum evidences the fact that Regeneron's patent prosecutors were keenly aware of the need to determine whether or not the Withheld References were (a) material, and (b) not cumulative.

The *Regeneron* holding injects unworkable uncertainty for prosecutors, inventors, and applicants with respect to their duties and obligations relating to practice before the PTO. Here, for example, Dr. Jones had created the “Jones Memo” as part of his personal notes memorializing his analysis of the Withheld References, and the reasons why he came to the conclusion that they need not be disclosed. Following the MPEP guidelines quoted above, such a memorandum is the recommended course of action and the most prudent prosecution practice. *See* MPEP 2004, ¶ 18. There is no evidence that the Jones Memo contained statements suggesting or supporting an inference of intent to deceive the PTO. To the contrary, the existence of the Jones Memo, in fact, suggests a prudent prosecutor, not a bad actor. Yet, “specific intent to deceive the PTO” has now been imputed to Dr. Jones for reasons completely unrelated to his conduct, state of mind, or his duty of candor while representing a client in a patent matter back in 2013.

Regeneron’s prosecuting attorneys only became aware of the Withheld References “days before” the ’018 patent claims were allowed. *See* Pet.App.9a-10a. This short time frame does not support an inference of nefarious intent. Innocent delays can occur during prosecution that have nothing to do with the prosecutor’s conduct or intent. The facts here simply do not support any inference whatsoever of a deliberately planned and carefully executed scheme to defraud the PTO (or the court), as represented by the *Keystone Driller*, *Hazel-Atlas Glass*, and *Precision Instrument* decisions.

Additionally, although the district court found “egregious misconduct” in providing inaccurate statements to the PTO during prosecution, NAPP has seen nothing in the court’s opinion demonstrating that the prosecutors were aware that any statement—regarding the existence of a “commercial embodiment,” or any other statement about the invention—was false at the time it was presented to the PTO, or before the ’018 patent issued. The court’s finding is therefore not supported by the evidence of record, so this would also indicate and abuse of discretion. *Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, 528 F.3d 1365, 1376 (Fed. Cir. 2008) (“Whenever evidence proffered to show either materiality or intent is susceptible of multiple reasonable inferences, a district court clearly errs in overlooking one inference in favor of another equally reasonable inference.”). A district court’s factual findings regarding what reasonable inferences may be drawn from the evidence are reviewed for clear error. *See Star Scientific* 537 F.3d at 1365.

Notably, the district court’s findings relating to patent prosecution conduct relied primarily upon the testimony of Regeneron’s independent expert, Dr. Davis, not upon testimony from those having a duty of candor to the PTO during prosecution of the ’018 patent (prosecutors, inventors, applicant). Presenting “false and misleading statements” through negligence is not the same as intending to deceive. The patent prosecutors are not experts like Dr. Davis. They should not have been expected to know that “some of the results referenced in the presentation could not have existed.” Pet.App.167a.

That the prosecutors relied upon a misleading presentation regarding the development of a commercial embodiment of the claimed mouse is not evidence of intent to deceive the PTO. There is no evidence cited by the court that either Smeland or Jones knew of the false statement at the time, only the court's bald assertion.

E. THE *REGENERON* HOLDING WILL CREATE A CHILLING EFFECT ON PATENTEES AND RENDER THE ENTIRE PATENT SYSTEM INEFFECTIVE TO PROTECT UNITED STATES INNOVATION

Specific intent to deceive the PTO cannot be inferred without evidence. “*Specific intent*” connotes “a purpose to disobey the law.” See e.g. *Ratzlaf Et Ux. v. United States*, 510 U.S. 135, 141 (1994) (holding that to establish that a defendant had the requisite “specific intent” to violate the law at issue, it must be proven that defendant acted with knowledge that his conduct was unlawful.) There was no such finding here. Discovery was not re-opened to obtain any evidence whatsoever on specific intent.

Yet, the adverse inference of specific intent led to a finding of inequitable conduct, known to be the “atomic bomb” of patent law. *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting). Inequitable conduct regarding any single claim renders the entire patent unenforceable. *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 877 (Fed. Cir. 1988). Unlike other deficiencies, inequitable conduct cannot be cured by reissue, *Aventis*, 525 F.3d at 1341, n.6, or reexamination, *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1182 (Fed. Cir. 1995). Moreover, the taint of a finding

of inequitable conduct can spread from a single patent to render unenforceable other related patents and applications in the same technology family. *See, e.g., Consol. Aluminum Corp. v. Foseco Int'l Ltd.*, 910 F.2d 804, 808-12 (Fed. Cir. 1990). A finding of inequitable conduct may also spawn antitrust and unfair competition claims. *See Dow Chemical Co. v. Exxon Corp.*, 139 F.3d 1470, 1471 (Fed. Cir. 1998) (unfair competition claim); *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172, 178 (1965) (antitrust action for treble damages). Prevailing on a claim of inequitable conduct often makes a case “exceptional,” leading potentially to an award of attorneys’ fees under 35 U.S.C. § 285. *Brasseler, U.S.A. I, L.P. v. Stryker Sales Corp.*, 267 F.3d 1370, 1380 (Fed. Cir. 2001). A finding of inequitable conduct may also prove the crime or fraud exception to the attorney client privilege. *See In re Spalding Sports Worldwide, Inc.*, 203 F.3d 800, 807 (Fed. Cir. 2000).

There is nothing in the record showing that Regeneron’s inventors, prosecutors, or company executives had lied under oath or to the Court in order to advance Regeneron’s litigation against Merus. The district court never made an evidentiary finding that the patentee had intended to commit fraud on the PTO. Yet, an atomic bomb was dropped. Such catastrophic decision not only flies in the face of established Supreme Court precedent, but, if allowed to stand, will completely stifle a patentee’s right to enforce its patent, out of fear that hiring incompetent or unscrupulous litigation counsel could have the same outcome. “*Regeneron*” (like “*Festo*”) will become a verb in the patent litigation vernacular. The ultimate chilling effect could conceivably render our entire

United States patent system deeply dysfunctional and irreparably ineffective.



CONCLUSION

The Court of Appeals for the Federal Circuit affirmed a judgment that is inherently unfair to patent practitioners, who have no control over what happens after a patent issues during enforcement of a patent, often occurring many years after a patent issues. Here, in particular, the facts show that patent counsel acted prudently under the circumstances and consistently under the guidance provided to them by the PTO. Here, the *Regeneron* decision obliterates all forms of guidance on how a United States patent practitioner and a patent applicant are to comply with their duty to disclose under 37 C.F.R. 1.56 (“Rule 56”).

Moreover, patent plaintiffs are not litigators. A patentee relies on the advice of its legal experts, namely, outside litigation counsel, to conduct a patent litigation. *A patent plaintiff must confidently assume that litigation counsel is performing competently and with integrity their professional duties with respect to the parties and the trial court.* NAPP foresees that an affirmance of the *Regeneron* holding would have significant repercussions, not only in the patent procurement phase, but in the enforcement landscape as well, by undermining the necessary trust between clients and counsel.

NAPP therefore urges the Supreme Court to review and overturn the Federal Circuit’s holding in this troubling case, to avoid an otherwise inevitable under-

mining of the United States patent system as we know it today.

Respectfully submitted,

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