# Supreme Court of the United States

REGENERON PHARMACEUTICALS, INC.,

Petitioner,

v.

MERUS N.V.,

Respondent.

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

#### **BRIEF IN OPPOSITION**

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### **QUESTION PRESENTED**

When a party fails to comply with a district court's orders, Federal Rule of Civil Procedure 37(b)(2)(A)(i) provides that the court may, among other things, enter an order "directing that the matters embraced in the order or other designated facts be taken as established for purposes of the action."

In this case, the district court entered such an order. For more than a year, Petitioner disobeyed orders, and abused attorney-client privilege to obfuscate discovery into the facts concerning an element of Respondent's counterclaim of inequitable conduct. As a sanction, the district court drew an adverse inference, treating that element of Respondent's counterclaim as established against Petitioner.

The question presented is:

Whether the court of appeals properly affirmed the district court's exercise of discretion to sanction Petitioner, where Petitioner's undisputed, extensive pattern of litigation misconduct directly concerned and obfuscated evidence related to the issue for which the district court drew an adverse inference.

### PARTIES TO THE PROCEEDING

Petitioner Regeneron Pharmaceuticals, Inc. was the plaintiff and counterclaim-defendant in district court, and the appellant in the court of appeals.

Respondent Merus N.V. was the defendant and counterclaim-plaintiff in district court, and the appellee in the court of appeals.

### CORPORATE DISCLOSURE

Respondent Merus N.V. has no parent corporation. Incyte Corporation is a publicly traded company that owns 10% or more of Respondent's stock.

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#### PRELIMINARY STATEMENT

This case concerns nothing more than a district court's discretionary selection of an amply-warranted sanction for discovery misconduct. Regeneron repeatedly violated the district court's discovery orders related to Merus' counterclaim for inequitable conduct, including obscuring evidence of its agents' intent to deceive the Patent Office. The district court, in turn, drew an adverse inference, resolving the intent element of that counterclaim Regeneron. Federal Rule of Civil Procedure 37 explicitly permits that sanction. Nothing about that fact-intensive decision, nor the district court's evaluation of Regeneron's misconduct, remotely warrants this Court's review.

Recognizing as much, Regeneron re-writes history, repeatedly contending that the district court took away its patent as a free-floating sanction for unrelated litigation misconduct. Virtually every argument in the Petition depends on that false The decisions below broke no new legal premise. The reason Regeneron's patent was ground. ultimately found unenforceable was unenforceability was at stake in Merus' counterclaim. Regeneron does not dispute the consequence of a judgment of inequitable conduct is that the patent is unenforceable. In other words, Regeneron's patent is unenforceable because Regeneron ultimately lost its case. The court of appeals simply affirmed the district court's findings on materiality, and concluded that the district court's discretionary choice of an adverse inference sanction was reasonable under circumstances—no more and no less.

This Court, of course, does not generally grant certiorari to review whether a district court abused its discretion in imposing a particular discovery sanction based on particular facts. Regeneron, thus, manufactures legal issues where none exist. It would have this Court adopt a novel proposition: that certain sanctions explicitly enumerated in Federal Rule of Civil Procedure 37 can never apply to findings of specific intent for inequitable conduct counterclaims. Regeneron wants a free pass, arguing that dismissal of its infringement case against Merus was the most severe remedy permissible. But that ignores that Regeneron was not just a plaintiff, but also a counterclaim defendant. As the court of appeals recognized, dismissal of the entire case (including Merus' inequitable conduct counterclaim) would only reward Regeneron's behavior of hiding evidence of inequitable misconduct.

Regeneron's behavior was particularly egregious, as the district court and court of appeals both recounted. The same Regeneron attorney both (1) engaged in affirmative misrepresentations and the withholding of material prior art from the Patent Office, and then (2) orchestrated litigation tactics designed to obfuscate discovery in district court relating to that conduct. The district court concluded that the "substantial evidence adduced at trial" showed that "the very birth of this patent was beset by misconduct," Pet.App.68a-69a,¹ and that Regeneron's litigation misconduct—calculated to obscure its

<sup>&</sup>lt;sup>1</sup> "Pet.App." refers to the appendix to the Petition.

<sup>&</sup>lt;u>"CA.App."</u> refers to the court of appeals joint appendix, Fed. Cir. No. 16-1346 (filed May 25, 2016).

prosecution misconduct—was "extraordinary by any standards." Pet.App.138a n.34. The unusual facts make this case a poor vehicle for further review.

After raising a strawman argument that the patent was revoked as a sanction, Regeneron raises a host of "constitutional" issues tied to that argument, none of which it presented below—yet another reason to deny review. But regardless, those alleged concerns about "due process" or "takings" ignore this Court's precedents concerning Rule 37 and litigation sanctions. It is well-settled that trial courts may enforce their discovery orders through sanctions, and that a party's failure to comply can have consequences for the merits of the case. This Court explained that commonsense point in *Insurance Corp.* of *Ireland v.* Compagnie des Bauxites de Guinee, 456 U.S. 694 (1982): "[t]he expression of legal rights is often subject to certain procedural rules: The failure to follow those rules may well result in a curtailment of the rights." *Id.* at 705. To be sure, adverse inferences and other sanctions under Rule 37 mean that litigation misconduct carries a risk that the misbehaving party may ultimately lose the case on the merits. That is as true for patent cases with inequitable conduct claims as in any other case.

At bottom, a patentee defending against an inequitable conduct claim is not immune from ordinary discovery sanctions when it engages in litigation misconduct—and that is all that is at issue here. There is no patent exception to Rule 37, and this Court should not accept Regeneron's invitation to create one. The petition should be denied.

#### PERTINENT RULE

The full text of Federal Rule of Civil Procedure 37 is appended to this brief. Rule 37(b)(2)(A) provides as follows:

### Rule 37. Failure to Make Disclosures or to Cooperate in Discovery; Sanctions

- \* \* \*
- (b) FAILURE TO COMPLY WITH A COURT ORDER.
- \* \* \*
- (2) Sanctions Sought in the District Where the Action Is Pending.
- (A) For Not Obeying a Discovery Order. If a party or a party's officer, director, or managing agent—or a witness designated under Rule 30(b)(6) or 31(a)(4)—fails to obey an order to provide or permit discovery, including an order under Rule 26(f), 35, or 37(a), the court where the action is pending may issue further just orders. They may include the following:
  - (i) directing that the matters embraced in the order or other designated facts be taken as established for purposes of the action, as the prevailing party claims;
  - (ii) prohibiting the disobedient party from supporting or opposing designated claims or defenses, or from introducing designated matters in evidence;
  - (iii) striking pleadings in whole or in part;
  - (iv) staying further proceedings until the order is obeyed;

- (v) dismissing the action or proceeding in whole or in part;
- (vi) rendering a default judgment against the disobedient party; or
- (vii) treating as contempt of court the failure to obey any order except an order to submit to a physical or mental examination.

#### STATEMENT OF THE CASE

Regeneron sued Merus for patent infringement. Merus pled a counterclaim for inequitable conduct, contending that Regeneron's patent was unenforceable because Regeneron obtained it by deceiving the Patent Office. In litigation on that counterclaim, Regeneron engaged in more than a year-long pattern of discovery abuse designed to obfuscate evidence of its agents' misconduct before the Patent Office. As a sanction, the district court applied an adverse inference under Rule 37(b) to an aspect of Merus' inequitable conduct counterclaim.

### I. Legal Background

### A. Adverse Inferences And Related Sanctions

District courts have a range of tools, under the Federal Rules and their inherent power, to manage litigation and enforce their orders. Even before the 1938 adoption of the Federal Rules of Civil Procedure, courts had the authority to resolve some or all of the merits of a case against litigants who disobey orders. See, e.g., Hammond Packing Co. v. Arkansas, 212 U.S. 322, 350-51 (1909) (rejecting Due Process challenge to state trial court ruling striking an answer and

entering a default judgment as a sanction); 1 Stat. 73, 82, §15 (Judiciary Act of 1789, authorizing dismissal orders and default judgments against plaintiffs and defendants who failed to comply with orders requiring production of evidence).

Federal Rule of Civil Procedure 37 enumerates overlapping, nonexclusive sanctions available to trial courts. These include the authority to resolve aspects of the merits of a case against the disobedient party. Harsher sanctions include dismissal orders or default judgments. Fed. R. Civ. P. 37(b)(2)(A)(v)-(vi). Milder sanctions include orders directed to part of a claim or defense—e.g., "directing that the matters embraced in the order or other designated facts be taken as established for purposes of the action." *Id.* 37(b)(2)(A)(i). Orders sanctioning misconduct by treating otherwise-disputed matters as established are sometimes called "adverse inferences."<sup>2</sup>

Rule 37's sanctions both ensure that parties do not benefit from disobeying orders, and deter further misconduct. *NHL v. Metro. Hockey Club, Inc.*, 427 U.S. 639, 643 (1976). Trial courts have broad discretion to select a sanction appropriate for those purposes. *Id.* at 642-43 (reversing court of appeals'

<sup>&</sup>lt;sup>2</sup> See Pet.21. A court can instruct a jury that it may or must infer that evidence wrongfully missing from a case was unfavorable to the party responsible for the evidence's absence. Residential Funding Corp. v. DeGeorge Fin. Corp., 306 F.3d 99, 108-10 (2d Cir. 2002). Or, in bench trials and other matters, a court may draw the "adverse inference" itself, by resolving disputed matters against a party. See Marquis Theatre Corp. v. Condado Mini Cinema, 846 F.2d 86, 90 (1st Cir. 1988); cases cited n.3, infra.

reversal of dismissal sanction); *Ins. Corp. of Ir.*, 456 U.S. at 707 (citing *id.*); *Lee v. Max Int'l, LLC*, 638 F.3d 1318, 1320-21 (10th Cir. 2011) (Gorsuch, J.).

In *Insurance Corp. of Ireland*, this Court rejected a Due Process challenge to the application of an adverse inference to personal jurisdiction. 456 U.S. at 694-95. district court sanctioned a defendant's noncompliance with orders compelling personaljurisdiction-related discovery by treating personal jurisdiction as established. *Id.* at 695, 699. Discussing Rule 37 at length, the Court reasoned that personal jurisdiction (like many other issues in litigation) could be forfeited, waived, or conceded, and that it was within the district court's discretion to treat a defendant's failure to produce jurisdictional discovery as a constructive waiver of that defense. *Id.* at 706.

In the eight decades since the Federal Rules were adopted, this Court has clarified Rule 37's scope and purposes, e.g., Ins. Corp. of Ir., 456 U.S. at 707; NHL, 427 U.S. at 642-43; Societe Internationale v. Rogers, 357 U.S. 197, 206-07 (1958), and courts have applied Rule 37's sanctions to a broad range of legal and factual issues, including in patent cases and on intent-related issues.<sup>3</sup>

<sup>&</sup>lt;sup>3</sup> See, e.g., Ins. Corp. of Ir., 456 U.S. at 699-700 (personal jurisdiction deemed admitted as sanction for defendant's refusal to produce personal-jurisdiction discovery); Chevron Corp. v. Donziger, 833 F.3d 74, 145-50 (2d Cir. 2016) (striking personal jurisdiction defense); Alexsam, Inc. v. IDT Corp., 715 F.3d 1336, 1342-45 (Fed. Cir. 2013) (patent infringement deemed established); Steed v. EverHome Mort'g. Co., 308 F. App'x 364, 370-71 (11th Cir. 2009) ("establishing as true the fact about which EverHome lied" in discovery responses); Okla. Federated Gold & Numismatics, Inc. v. Blodgett, 24 F.3d 136, 139-41 (10th

### B. Inequitable Conduct

In this case, the district court sanctioned Regeneron by drawing an adverse inference as to an element of Merus' inequitable conduct counterclaim. Pet.App.25a; Pet.App.42a-44a; Pet.App.138a & n.34; Pet.App.193a-194a.

An inequitable conduct claim contends that an opposing party's patent was obtained from the Patent Office through deception. If inequitable conduct is proved, the result is a judgment that the patent is unenforceable. See Therasense, Inc. v. Becton, Dickinson & Co., 649 F.3d 1276, 1288 (Fed. Cir. 2011) (en banc); Pet.5-6 & n.1; 35 U.S.C. §282(b)(1) (codifying "unenforceability" defense); United States v. Am. Bell Tel. Co., 128 U.S. 315, 355 (1888) (patents obtained by fraud on the Patent Office could historically be cancelled in litigation).

Inequitable conduct is rooted in unclean hands and common-law fraud doctrine, and primarily based on Hazel-Atlas Glass Co. v. Hartford-Empire Co., 322 U.S. 238, 245 (1944) (fraud); Precision Instrument Manufacturing. Co. v. Automotive Maintenance Machinery Co., 324 U.S. 806 (1945) (fraud); and Keystone Driller Co. v. General Excavator Co., 290 U.S.

Cir. 1994) (defendant precluded from defending civil fraud claim); Chilcutt v. United States, 4 F.3d 1313, 1319-21 (5th Cir. 1993) (elements of negligence claim deemed established); Smith v. Schlesinger, 513 F.2d 462, 466-67 & nn.10-11 (D.C. Cir. 1975) (government precluded from contradicting certain allegations, leading to summary judgment against the government); Linde v. Arab Bank PLC, 269 F.R.D. 186, 202-05 (E.D.N.Y. 2010) (culpable state of mind deemed established), mandamus denied, 706 F.3d 92 (2d Cir. 2013), cert. denied, 134 S. Ct. 2869 (2014).

240 (1933) (unclean hands). *See Therasense*, 649 F.3d at 1306-12 (describing origins of inequitable conduct doctrine) (Bryson, J., concurring and dissenting).

The rationale behind the doctrine is based in part on the *ex parte* nature of the patent examination process. The Patent Office depends critically on the duties of candor and disclosure that applicants and their representatives owe to the Office—which includes the duty to disclose material prior art, 37 C.F.R. §1.56—and depends in part on private litigation to uncover failures of candor. *Kingsland v. Dorsey*, 338 U.S. 318, 319 (1949); *Therasense*, 649 F.3d at 1310 (Bryson, J., concurring and dissenting).

Inequitable conduct may be presented as a declaratory judgment claim or an affirmative defense, and can be based on various types of deceptions toward the Patent Office. For a claim based on an applicant deliberately withholding material prior art from the Patent Office, there are two elements: materiality and intent. *Therasense*, 649 F.3d at 1290. Materiality requires proof that "the PTO would not have allowed a claim had it been aware of the undisclosed prior art." *Id.* at 1291. Intent requires proof "by clear and convincing evidence that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it." *Id.* at 1290.

The Federal Circuit also recognizes another category of claims based on "affirmative egregious misconduct"—"such as the filing of an unmistakably false affidavit." *Id.* at 1292.

## II. Factual And Procedural BackgroundA. Patent Office Proceedings

The district court's opinion comprehensively describes the patent, its deficiencies in context of the relevant technology, and Regeneron's conduct before the Patent Office. Pet.App.80a-97a (technical background); Pet.App.98a-108a (Patent Office proceedings); see also Pet.App.4a-11a (court of appeals opinion).

Regeneron's patent (U.S. Patent No. 8,502,018, or "the '018 patent") concerns methods for inserting human DNA into mouse cells, to make antibodies with therapeutic potential. When Regeneron applied for its patent, the Patent Office repeatedly rejected the application's claims as not new or inventive. These rejections included repeated findings that an earlier patent application ("Lonberg") disclosed the entire invention Regeneron tried to claim for itself. Pet.App.7a-9a; Pet.App.98a-100a.

Regeneron's attorney, Dr. Tor Smeland, was responsible for Regeneron's patent application. Two of his tactics are relevant here.

First, Smeland tried to convince the examiner that Regeneron should receive a patent because it invented features (such as "targeted insertion") that were new, and not taught or suggested in prior art. That was not true, and Smeland knew it.

Smeland had, in hand, four prior art references that disclosed *the very features* (including "targeted insertion") that Smeland told the Patent Office the prior art lacked. Pet.App.9a-10a (listing "Withheld References"). Smeland had a duty to disclose those

references to the Patent Office, but did not. Smeland admitted in depositions that he knew of the references, knew what they disclosed, and knew that the "Brüggemann" reference had led the Patent Office to reject highly similar claims in related patent applications—and yet he still deliberately did not disclose them. Pet.App.162a (citing trial exhibits and transcript); Pet.App.10a-12a; deposition Appellee Br. 21-24, No. 16-1346 (filed Apr. 14, 2016). Those references refuted the very arguments Smeland made to the examiner. Pet.App.136a-162a; Pet.App.13a-25a.

Without the benefit of the references Smeland withheld, the Patent Office issued a Notice of Allowance, relying on Smeland's arguments and issuing Regeneron a patent. Pet.App.9a (quoting notice). After Regeneron received its patent, it sued Merus, with Smeland in charge of the litigation. Smeland then (and only then) disclosed the "Withheld References" in every other related application having the same specification and similar claims. Armed with those references, three different examiners from the U.S. Patent Office rejected Regeneron's more than ten related pending applications, Pet.App.157a-161a, and a European office revoked claims of an issued counterpart patent. Pet.App.161a-162a.

Second, Smeland submitted a false slide presentation to the Patent Office, which had been prepared by inventor Murphy. Pet.App.104a-105a. In that presentation, Regeneron falsely described a commercial embodiment of its purported invention and asserted that the embodiment yielded unexpected results. Pet.App.8a. The "unexpected results" were

offered to contend that the patent claims are not obvious. *E.g.*, *In re Soni*, 54 F.3d 746, 750 (Fed. Cir. 1995). As the court of appeals noted, "[i]t is undisputed that [Regeneron's] assertion was false." Pet.App.8a (citing CA.App.7563). The truth was that Regeneron failed for years to produce such an embodiment, and that what it referred to as unexpected results had already been achieved by others and documented in the prior art Regeneron withheld from the Patent Office. Pet.App.102a-108a; Pet.App.162a-169a. Indeed, another Regeneron scientist had specifically told Murphy that data in the slide presentation were "misleading." Pet.App.105a.

Nonetheless, Smeland attached the false presentation to a reply, and attended a meeting with the Patent Office where he relied on the "misleading presentation." Pet.App.9a. It worked. The following month, the Patent Office decided to grant Regeneron's patent. *Id*.

### **B.** Trial Court Proceedings

Regeneron sued Merus for patent infringement. Merus pled counterclaims that Regeneron's patent was unenforceable for inequitable conduct. Pet.App.3a; SDNY No. 14-CV-1650, ECF#225 at 13-93 (Dec. 8, 2014) (answer and counterclaims).

### 1. Regeneron's misconduct in district court

Smeland—the same attorney who prosecuted the patent for Regeneron—"oversaw" Regeneron's outside counsel and managed Regeneron's district-court litigation against Merus. Pet.App.116a.

Regeneron repeatedly refers to its "alleged" or "purported" misconduct, Pet.3, 9, 10, 17, 21, 22, 23, 32, but it did not challenge the district court's factfinding on appeal, nor does it do so now. Pet.App.25a. The opinions below explain Regeneron's litigation misconduct at length, Pet.App25a-40a (court of appeals): Pet.App169a-193a (district court)—a "pattern" (Pet.App.192a-193a) the district court called "highly unusual," Pet.App.193a, and "extraordinary by any standards." Pet.App.138a n.34. The following is an abridged summary.

From the outset, "Regeneron's behavior in district beset with troubling misconduct," Pet.App.25a. For approximately a year, Regeneron violated orders and rules, abused attorney-client privilege with sword-and-shield tactics, and made overt misstatements in pleadings and testimony—to withhold unfavorable evidence of Regeneron's agents' state of mind in their dealings with the Patent Office, while selectively disclosing evidence that Regeneron considered favorable. See, e.g., Pet.App.69a; Pet.App.169a; Pet.App.33a-34a; Pet.App.44a; Pet.App.174a-176a & n.48.

Regeneron struggled from the beginning to "define its invention" in a way that would somehow "fit a cognizable theory of infringement" without also implicating the references it withheld from the Patent Office or the false presentation it submitted. Pet.App.68a-69a.

Shortly before the deposition of Regeneron's outside counsel, Dr. Jones (who worked with Smeland in prosecution), Regeneron disclosed a handful of Jones's documents purporting to interpret the prior

art withheld from the Patent Office. Pet.App.28a; CA.App.1916-19. Merus canceled the deposition and moved to compel discovery. Regeneron opposed, contending that it had not waived the attorney-client privilege. Regeneron denied (falsely) that a certain document had been a privileged communication, and asserted that Jones' document had not been shared with Regeneron. Id. As the district court's in camera review revealed, Regeneron's assertion was "seriously incorrect." Pet.App.30a; Pet.App.173a-174a; CA.App.1916-19. The district court ordered Regeneron to produce "all relevant documents" concerning its decision to withhold prior art from the Patent Office. Pet.App.30a-31a. Despite Regeneron's numerous representations to the court that it produced such documents, the court later discovered that was untrue. Pet.App.172a-179a; Pet.App.188a-191a.

Further, contrary to court rules, Regeneron refused to identify documents concerning inventors' alleged conception of the invention. response to a motion to compel, Regeneron contended, falsely, that it produced all it had (a handful of pages). Pet.App.169a; Pet.App.26a. Merus later uncovered a document sent from Murphy to Smeland—which the district court called a "smoking gun"—that showed Regeneron was actually unable to make the transgenic mice claimed in the patent. Pet.App.169a n.44. In other words, that document demonstrated the falsity of the presentation Smeland submitted to the Patent Office. Pet.App.102a-104a; Pet.App.167a-168a. Regeneron tried to claw that document back as privileged, but the district court found Regeneron's privilege claim was baseless and yet another effort at obscuring its misconduct at the Patent Office. Pet.App.169a n.44.

After the court entered a claim construction order, Regeneron stipulated that all claims of its patent were invalid for indefiniteness, and not infringed. CA.App.8. Thus, Merus' inequitable conduct counterclaim was the only claim remaining for trial. Initially, the court scheduled a single bench trial on all issues concerning Merus' counterclaim.

Days before the trial, Regeneron submitted sworn declarations from its attorney Smeland and the inventor as their direct trial testimony purporting to explain away the evidence of their intent to deceive the Patent Office. Pet.App.179a-189a. Merus filed an emergency motion, leading the district court to conclude that Regeneron had "waived privilege. Extensively." CA.App.5533(30:8-9). The district court asked Regeneron point-blank whether it had provided discovery on the entire privileged subject matter it had submitting Smeland's Regeneron stated (falsely) that it had "produced everything." CA.App.5534(35:3-8); see Pet.App177a. The district court conducted a limited in camera review. Examining just a few of the thousands of documents on Regeneron's privilege log revealed that Regeneron withheld clearly relevant evidence, including "statements directly contradictory" Smeland's declaration. Pet.App.191a. At that point, on the eve of the bench trial, it became clear to the court that Regeneron, and its prosecution and litigation manager Smeland, had violated several discovery orders, misrepresented the state of its production, and abused the attorney-client privilege

with sword-and-shield tactics—all to give the court and Merus an improperly selective view of the evidence of Smeland's state of mind. Regeneron proposed to have Smeland testify about his views of certain topics—to defend against Merus' inequitable conduct claim—but had withheld documents "on precisely those topics on the basis of privilege." Pet.App.33a-34a; see also Pet.App.44a; Pet.App.174a-176a & n.48.

With trial about to begin, participants "flown in from overseas" and witnesses "ready to be called," CA.App.3428, the district court addressed the "Pandora's Box" that Regeneron opened through its late-breaking waiver of attorney-client privilege and vearlong concealment of evidence on the same topic. Pet.App.37a; Pet.App.189a. The court proceeded with a trial on the materiality element of inequitable conduct. The court reserved the issue of Regeneron's specific intent pending post-trial briefing addressing the impact of Regeneron's privilege waiver and withholding of documents concerning that issue. Pet.App.192a n.51. Merus' post-trial brief requested an adverse-inference sanction under Rule 37, with respect to Regeneron's agents' intent to deceive the Patent Office, explaining that Regeneron had wrongfully obfuscated discovery into that topic for more than a year. SDNY No. 14-CV-1650, ECF#389 at 20-23, 29-30 (July 7, 2015).

### 2. Adjudication of Merus' inequitable conduct claim

After presiding over a weeklong bench trial on materiality, receiving post-trial briefing, and having read the written testimony the parties would have offered at the intent phase of the trial,<sup>4</sup> the district court issued a thorough opinion concluding that Regeneron had committed multiple types of inequitable conduct and that its patent would therefore be ruled unenforceable. Pet.App.67a-194a.

First, the court found inequitable conduct based on Regeneron withholding material prior art from the Patent Office. The court found, and Regeneron no longer disputes, that the materiality element was met—i.e., that the Patent Office would not have granted Regeneron's patent had it known of the withheld references. Pet.App.136a-162a.

For intent, the district court explained that Regeneron's pattern of litigation misconduct had obstructed any prospect of a fair, orderly adjudication. Pet.App.169a-193a. The court was, thus, left with a quandary. Pet.App.191a; Pet.App.39a-40a. The court considered a range of possible sanctions. Pet.App.191a-193a. It concluded that simply striking Regeneron's declarations and precluding certain testimony would reward Regeneron's misconduct, Pet.App.192a, and would "treat as isolated and remediable" what was in fact "a long pattern of litigation choices that have caused delay, inefficient use of resources, and diversion from the merits." Pet.App.193a.

"Under these highly unusual circumstances," the court concluded that it was "appropriate ... to impose the sanction of an adverse inference" regarding

<sup>&</sup>lt;sup>4</sup> Regeneron's direct examinations were submitted in writing. Live witnesses would have been called only for cross-examination by Merus and redirect by Regeneron. Pet.App.179a-180a.

Regeneron's intent in withholding prior art from the Patent Office. Pet.App.193a-194a. Based on that ruling, coupled with Merus' proof of materiality, the court ruled in Merus' favor on the inequitable conduct claim. *Id*.

Second.the court found that Regeneron's submission and reliance on a false slide presentation to the Patent Office was a separate, independent basis for a judgment of inequitable conduct. Pet.App.168a-169a. That ruling did not depend on inferences or sanctions. Pet.App.168a-169a ("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 affirmative egregious misconduct.") (emphasis added).

Under the final judgment, Regeneron's patent claims were invalid for indefiniteness, unenforceable for two types of inequitable conduct, and not infringed. Regeneron appealed.

### C. Appeal

The court of appeals affirmed, reaching only Regeneron's inequitable conduct in withholding material prior art from the Patent Office. Pet.App.2a; Pet.App.10a n.3.

The court of appeals' decision recounted Smeland's "undisputed" "false" submissions to the Patent Office, as well as the fact that "Drs. Smeland and Murphy knew of the Withheld References and did not disclose them to the PTO." Pet.App.8a-11a, Pet.App.17a.

The court of appeals affirmed the finding that each of the four withheld references was "material"—*i.e.*, the Patent Office would not have granted Regeneron's patent had it been aware of them. Pet.App.13a-25a.

Turning to the intent element, the court observed that Regeneron "d[id] not meaningfully dispute any of the factual findings underlying the district court's decision." Pet.App.25a; see also Oral Arg. at 3:30-3:45, Fed. Cir. No. 16-1346 (Feb. 13, 2017), at http://oralarguments.cafc.uscourts.gov/

default.aspx?fl=2016-1346.MP3 (Regeneron's counsel: "It's too hard under the standard of review for us to raise those."). Given the largely uncontested, amply supported findings concerning Regeneron's obfuscation of discovery into intent to deceive the Patent Office, the court of appeals found the district court was well within its discretion to draw an adverse resolving the inference intent issue against Regeneron. Pet.App.25a-44a. The court thus affirmed the judgment of inequitable conduct based on Regeneron's withholding material prior art references from the Patent Office, Pet.App.44a, and did not reach issues of invalidity, infringement, or the separate ground of inequitable conduct based on affirmative egregious misconduct. Pet.App.3a-4a n.1.

In its analysis, the majority responded to arguments that the district court had revoked Regeneron's patent as a free-floating sanction for litigation misconduct. The dissent relied on that premise to contend that the district court had contravened *Aptix Corp. v. Quickturn Design Systems, Inc.*, 269 F.3d 1369 (Fed. Cir. 2001), a case Regeneron had not previously mentioned. Pet.App.46a-50a.

As the majority explained, the premise was false, and *Aptix* is inapposite. Pet.App.42a-44a. In *Aptix*, unlike here, the district court was not adjudicating any actual claim for inequitable conduct. Instead, the court *sua sponte* declared the patent unenforceable as a "penalty" for the patentee-plaintiff's submission of false evidence at trial. 269 F.3d at 1375, 1377-78. The Federal Circuit reversed, reasoning that inequitable conduct doctrine does not extend to "misconduct during litigation." *Id.* at 1378.

Here, nothing of the sort happened. Merus pled an inequitable conduct counterclaim predicated on Regeneron's misconduct at the Patent Office in applying for the patent (intentionally withholding material prior art that contradicted arguments Regeneron made to the Patent Office). In the course of litigation—on that undisputedly properly-pled counterclaim—Regeneron disobeyed district orders and Regeneron disobeyed district orders and, "Regeneron's litigation misconduct" "obfuscated its prosecution misconduct." Pet.App.43a. As a sanction, the district court drew the adverse inference that Regeneron's agents intended to deceive the Patent Office—a sanction Rule 37(b)(2)(A)(i)Pet.App.42a-44a. As the court of appeals explained, "[t]he district court did not punish Regeneron's litigation misconduct byholding the patent after Merus proved the unenforceable. Only remaining elements of inequitable conduct did the district court hold the patent unenforceable." Pet.App.43a-44a (emphasis added).

Regeneron petitioned for rehearing en banc, which the court denied by a 10-to-2 vote. Pet.App.197a.

#### REASONS TO DENY THE PETITION

### I. The Petition Does Not Warrant Review.

# A. The Court of Appeals Correctly Affirmed The Trial Court's Factbound, Discretionary Choice Of Sanction.

District courts' authority to enforce their orders by drawing adverse inferences against disobedient parties is longstanding, and not the subject of substantial disagreement among courts of appeals. By its terms, Fed. R. Civ. P. 37(b)(2)(A)(i) grants broad discretion to sanction parties who disobey discovery orders by entering orders "directing that the matters embraced in the order or other designated facts be taken as established for purposes of the action." That is precisely what the district court did here, Pet.App.193a-194a, and the court of appeals appropriately affirmed under the abuse-of-discretion standard. Pet.App.13a, 25a-44a. Nothing about those fact-intensive decisions warrants this Court's review.

This Court has affirmed and reaffirmed that the selection of a sanction is committed to the district court's discretion. *NHL*, 427 U.S. at 642-43; *Ins. Corp. of Ir.*, 456 U.S. at 707 (citing *id.*). In *NHL*, this Court reversed the court of appeals' reversal of the trial court's dismissal order, and cautioned against the "natural tendency on the part of reviewing courts" to be unduly influenced by the severity of a sanction in a particular case. *NHL*, 427 U.S. at 642-43; *see also Lee*, 638 F.3d at 1320-21; 8B Wright & Miller, *Federal Practice & Procedure* §2284 (3d ed.).

To be sure, a district court's discretion is not unbounded. The chosen sanction "must be 'just," and

"must be specifically related to the particular 'claim' which was at issue in the order to provide discovery." Ins. Corp. of Ir., 456 U.S. at 707. Those fact-intensive requirements were amply satisfied here. The district court comprehensively detailed Regeneron's extensive "pattern" of obfuscation, Pet.App.192a-193a which "highly unusual," Pet.App.193a, was "extraordinary by any standards." Pet.App.138a n.34; see also Pet.App.25a-40a (court of appeals opinion). The sanction was also tailored to the precise issue Regeneron's misconduct affected: evidence Regeneron's intent in withholding material information from the Patent Office. Pet.App.43a-44a; Pet.App.192a-193a.

Rather than present an issue on which the courts are divided or where the decision below is out-of-step with prevailing law, it is Regeneron that seeks to have this Court craft a new, patent-unique exception to Rule 37, to supplant district-court discretion with a rigid rule that would insulate patent owners from the consequences of their own misconduct. E.g., Pet.14, 34. There is no basis in precedent or principle for such a unique Rule 37 exception for patent owners. This Court has consistently rejected such patent-law exceptions. SCA Hygiene Prods. Aktiebolag v. First Quality Baby Prods., LLC, 137 S. Ct. 954, 964 (2017); see also Halo Elecs., Inc. v. Pulse Elecs., Inc., 136 S. Ct. 1923, 1935-36 (2016) (no patent-policy basis for restricting district-court discretion conferred by statute); Octane Fitness, LLC v. ICON Health & Fitness, Inc., 134 S. Ct. 1749, 1755-58 (2014) (same); Teva Pharms. USA, Inc. v. Sandoz, Inc., 135 S. Ct. 831, 836-37 (2015) (no patent-claim-construction exception to Fed. R. Civ. P. 52(a)); Medtronic, Inc. v.

Mirowski Family Ventures, L.L.C., 571 U.S. 191, 198-88 (2014) (no patent-licensee exception to Declaratory Judgment Act burdens of proof); *eBay Inc. v. MercExchange, LLC*, 547 U.S. 388, 393 (2006) (no patent-infringement, discretion-restricting exception to equitable principles concerning injunctions). It should reject Regeneron's invitation to craft such an exception here.

### B. The Petition Depends On The False Premise That A Patent Was Revoked As A Free-Floating Sanction For Litigation Misconduct.

To manufacture an argument for review. Regeneron repeatedly asserts that the district court eliminated its patent "based on" only Regeneron's litigation misconduct. See, e.g., Pet.i ("Whether a patent right can be fully extinguished based on [litigation] misconduct"), 21 ("deem[ed] the patent unenforceable—based on nothing more than the alleged misconduct of Regeneron's lawyers in court."). Regeneron repeats that premise on most of the Petition's pages, id. at i, 3, 4, 10, 11, 12, 13, 15, 16, 18, 19, 20, 21, 22, 27, 30, 32, 33, 34, and every argument Regeneron makes depends on it.

As the court of appeals explained, however, the premise is false. Pet.App.42a-44a. Regeneron did not lose its patent as a free-floating sanction. All the district court did was to draw an adverse inference regarding the intent element of Merus' inequitable conduct counterclaim, as Rule 37 permits. Fed. R. Civ. P. 37(b)(2)(A)(i). In other words, Regeneron lost the same thing any other party loses when it is sanctioned under Rule 37: the opportunity to prove or defend the

aspect of the merits (which it obfuscated with its misconduct), that the court resolves against it. After Merus proved the remaining elements of its counterclaim, the district court entered judgment in Merus' favor on that counterclaim. As Regeneron acknowledges, unenforceability of the patent is the consequence of a litigation judgment of inequitable conduct. Pet.2 (citing Hazel-Atlas Glass). (If the counterclaim had been for damages, the consequence could have been that the losing party owed money.) That is why Regeneron's lost its patent—not because of some indiscriminate sanction, as Regeneron misleadingly suggests.

This Court and others have rejected similarly misleading arguments. To sanction a defendant who resists personal-jurisdiction discovery by treating personal jurisdiction as conceded does not "create that jurisdiction by judicial fiat." Ins. Corp. of Ir., 456 U.S. at 696. To sanction a plaintiff by excluding belatedlyproduced evidence from trial is not the same as ordering a dismissal sanction, if it turns out that the plaintiff's remaining evidence supporting its claim is legally insufficient to meet its burden of proof. Von Brimer v. Whirlpool Corp., 536 F.2d 838, 844 (9th Cir. 1976) ("To argue that the trial judge imposed the 'most extreme sanction' of dismissal is to distort what actually occurred."). Regeneron's distortion here is even more egregious: To sanction Regeneron by resolving part of Merus' inequitable conduct counterclaim against it is not to "deem the patent unenforceable based on nothing more than the alleged misconduct of Regeneron's lawyers in court." Pet.21.

Regeneron defends its false framing by asserting that any reference to Rule 37(b) or "the 'adverse inference' label" is "an end-run" around the substantive elements of the claim (here, inequitable conduct). (Pet.21-22). But any litigant sanctioned under Rule 37(b) could say the same; "end-run" is just a derisive label for how Rule 37(b) actually works. Courts can order that otherwise-disputed matters be "taken as established for purposes of the action," Fed. R. Civ. P. 37(b)(2)(A)(i)—to prevent disobedient parties from benefiting from their misconduct. NHL, 427 U.S. at 642-43; Ins. Corp. of Ir. 456 U.S. at 705. Were it otherwise—i.e., if misconduct carried no risk of affecting the ultimate result on the merits—Rule 37(b) would be ineffective.

Regeneron likewise contends that the Federal Circuit's affirmance "expanded the inequitable doctrine." Pet.3, 4, 30. Again, any sanctioned litigant could say the same thing about the particular claim at issue in its case. The inequitable conduct doctrine was no more "expanded" here than any other doctrine is "expanded" when a court applies a sanction under Rule 37(b). The issue is not doctrine-expansion, but the commonsense point that litigants who disobey rules and orders run an increased risk of ultimately losing their cases. *See Ins. Corp. of Ir.*, 456 U.S. at 705 ("failure to follow those rules may well result in a curtailment of the rights.").

### II. Petitioner's Remaining Arguments Are Unsound.

Regeneron's arguments for review depend on the premise that its patent was revoked as a free-floating sanction for litigation misconduct. The falsity of the premise is reason enough to deny review. Regeneron's arguments are also meritless on their own terms.

# A. The Decision Below Is Consistent With Keystone, Hazel-Atlas, And Precision Instruments.

According to Regeneron, *Keystone*, *Hazel-Atlas*, and *Precision Instrument* "make clear that courts cannot invalidate a patent or render it unenforceable against the world based on litigation misconduct by the patentee's counsel, rather than misconduct before the Patent Office." Pet.12. Again, Regeneron's contention that the decision below runs afoul of any such principle depends on the erroneous premise that Regeneron's patent was revoked as a free-floating sanction for litigation misconduct. Pet.12-18, 23-24. It was not. §I, *supra*.

Keystone, Hazel-Atlas, and Precision Instrument might support the proposition that an inequitable conduct claim should be based on misconduct before the Patent Office in acquiring the patent rather than misconduct before a court in asserting it. But they do not stand for the further proposition that courts may not apply Rule 37's sanctions when adjudicating a properly-pled claim for inequitable conduct. Those cases did not involve adverse inferences or Rule 37 at all.

Thus, when Regeneron states that in *Keystone* and *Hazel-Atlas*, "the Court did not treat the trial lawyer's misconduct as a basis for deeming the patent unenforceable," Pet.23, it is misleading. Regeneron suggests that this Court's cases hold that litigation misconduct can lead only to dismissal of an action, but that fraud on the Patent Office can result in voiding a

patent. But Hazel-Atlas concerned not just litigation misconduct, but also "a deliberately planned and carefully executed scheme to defraud ... the Patent 322 U.S. at 245. Office." Regeneron ignores the posture of Keystone, Hazel-Atlas, and Precision *Instrument*. The defendants did not ask the Court to patent through an invalidate  $_{
m the}$ affirmative counterclaim based on misconduct before the Patent Office—they just wanted the cases dismissed. It is no surprise, then, that the Court did not grant relief no one asked for. Indeed, before 1971, a judgment of patent invalidity was functionally no different from a dismissal—neither would prevent a patentee from suing a different defendant on the same patent. See Triplett v. Lowell, 297 U.S. 638, 652 (1936), overruled by Blonder-Tongue Labs., Inc. v Univ. of Ill. Found., 402 U.S. 313, 350 (1971).

Here, by contrast, Merus pled an inequitable conduct claim, seeking a declaration that the patent is unenforceable, and founded on Regeneron's misconduct at the Patent Office.<sup>5</sup> As explained above, §I.B, supra, and as the court of appeals explained, Pet.App.42a-44a, the only role Regeneron's litigation misconduct played was in triggering the adverse inference—exactly what Rule 37(b) permits.

Finally, the Petition purports to derive the broader principle from *Keystone* and court-of-appeals cases that "dismissal of the case is the most severe sanction the district court can impose in response to litigation misconduct." Pet.25; *see also id.* at 14. Those arguments fundamentally confuse the difference

<sup>&</sup>lt;sup>5</sup> "Unenforceability" was added in the 1952 Patent Act.

between plaintiffs and defendants, and the posture of this case.

Dismissal may be the most severe sanction to punish a plaintiff. See Fed. R. Civ. P. 37(b)(2)(A)(v). counterclaim-defendant like Regeneron, however, dismissal would be a reward. severe sanction for a defendant is a default judgment, not dismissal. Fed. R. Civ. P. 37(b)(2)(A)(vi); SEC v. Razmilovic, 738 F.3d 14, 24 (2d Cir. 2013) (affirming default-judgment sanction, noting "the most severe of these sanctions for a disobedient plaintiff is the dismissal of his action; the most severe for a disobedient defendant is the imposition of a default."); Newman v. Metro. Pier & Exposition Auth., 962 F.2d 589, 591 (7th Cir. 1992) (similar); 1 Stat. 82, §15 (Judiciary Act of 1789, authorizing dismissal orders to sanction plaintiffs, and default judgments to sanction defendants).

An invalidity or unenforceability counterclaim is separate from—not dependent on or necessarily mooted by—a claim for patent infringement. *Cardinal Chem. Co. v. Morton Int'l, Inc.*, 508 U.S. 83, 93-94 (1993).<sup>6</sup> A rule requiring dismissal of Merus' counterclaims would only reward Regeneron's misconduct, and would create perverse incentives. Once a party like Regeneron decides that it prefers dismissal of the entire case to a loss on its opponent's counterclaims, it could bring about that result by disrupting the case with rampant misconduct and

<sup>&</sup>lt;sup>6</sup> Amicus Washington Legal Foundation is thus wrong to contend that this case involves "property rights that were never joined." WLF.Amicus.17-18.

arguing, as Regeneron does, that "[d]ismissal of the case is the most severe sanction the district court can impose." Pet.25.

No authority exempts counterclaim-defendants from a district court's sanctioning power in that way. Rule 37's sanctions are "not mutually exclusive." 8B Wright & Miller §2289. In a case involving claims and counterclaims, Rule 37 applies to both. See Comput. Task Grp., Inc. v. Brotby, 364 F.3d 1112, 1116-17 (9th 2004) (affirming dismissal of defendant's counterclaims and default judgment on plaintiff's claims); Isr. Travel Advisory Serv., Inc. v. Isr. Identity Tours, Inc., 61 F.3d 1250, 1254-55 (7th Cir. 1995) (district court could have entered default judgment on plaintiff's claims and dismissed defendant's counterclaims, but "chose a milder sanction" by only dismissing counterclaims).

In this case, rather than entering default judgment on Merus' inequitable conduct counterclaim, the district court chose the milder sanction of resolving an element of the claim against Regeneron. Pet.App.42a; Fed. R. Civ. P. 37(b)(2)(A)(i). Nothing about that decision warrants this Court's review. It neither implicates any split of authority, nor does it run afoul of *Keystone*, in which there was no analogous affirmative counterclaim asserted.

For similar reasons, Regeneron's analogy to a homeowner who sues for trespass and "lose[s] her home as a sanction for her lawyer's misdeeds in the case" is misdirected rhetoric. Pet.3. If Party A sues for trespass, but Party B files a counterclaim challenging Party A's ownership of the house, Rule 37 would apply to both the trespass claim and the

counterclaim. If Party A fails to follow rules and discovery orders, the court is not limited to "dismissal" of the entire case.

### B. Petitioner's "Constitutional" Arguments Are Unsound And Waived.

Regeneron contends that the result below raises "constitutional" concerns, Pet.18-21, and "constitutional avoidance" principles support different result. Pet.22-23. As an initial matter, these newly-minted, undeveloped arguments are waived. Regeneron said not a word of such purported concerns below, even in its rehearing petition. This is "a court of review, not of first view," and does not pass on questions not raised below. Cutter v. Wilkinson, 544 U.S. 709, 718 n.7 (2005); see Campbell v. Ohio, 138 S. Ct. 1059, 1059 (2018) (Sotomayor, J., respecting denial of certiorari); Leonard v. Texas, 137 S. Ct. 847, 850 (2017) (Thomas, J., respecting denial of certiorari). At a minimum, Regeneron's waiver makes this a poor vehicle for addressing such issues.

The arguments are meritless, in any event. "Constitutional avoidance" is a canon of construction, not a get-out-of-jail-free card. It applies "only when, after the application of ordinary textual analysis, the statute is found to be susceptible of more than one construction; and the canon functions as a means of choosing between them." Clark v. Martinez, 543 U.S. 371, 385 (2005); Milavetz, Gallop & Milavetz, PA v. United States, 559 U.S. 229, 239 (2010) (quoting id.). Regeneron has not offered any textual analysis at all, nor has it even identified any provision as requiring construction. The argument is a nonstarter. To the extent Regeneron would seek a judicial exception to

Rule 37(b) for patent holders, Warger v. Shauers, 135 S. Ct. 521, 528-29 (2014) rejected a similar argument for a constitutional-avoidance-based exception to a Rule of Evidence. The Rule's text was unambiguous, so "constitutional avoidance ha[d] no role to play." Id.; see also McFadden v. United States, 135 S. Ct. 2298, 2307 (2015) (similar). So too here.

Moreover, Regeneron's "due process" argument is unsound on its own terms. Regeneron contends that the decision below allows courts to "invalidate patents without a hearing or any opportunity for the patentee to present evidence regarding whether the patentee committed intentional misconduct." Pet.20. That is patent-revocation-as-a-sanction Regeneron's false premise rearing its head yet again. Regeneron had the opportunity to defend against every aspect of Merus' counterclaim with evidence. Regeneron simply forfeited that opportunity (with respect to part of that claim) by its misconduct obstructing discovery concerning the issue of intent. Rule 37(b) explicitly authorizes the district court's resulting sanction, and this Court has squarely rejected the notion that such sanctions violate Due Process. See, e.g., Ins. Corp. of Ir., 456 U.S. at 704-05. The principle that failure to follow rules may result in curtailment of rights, id. at 705, applies to patent cases too.

Regeneron's "Takings" argument borders on frivolous. Pet.18-19. There is no exercise of eminent domain or anything similar afoot, as in *Horne v. Dep't of Agric.*, 135 S. Ct. 2419 (2015) (cited Pet.18). Stop the Beach Renourishment, Inc. v. Fla. Dep't of Envtl. Prot., 560 U.S. 702 (2010) (cited Pet.19) is further afield: it unanimously rejected the Takings claim

before it, and nowhere suggested that every property owner who loses its lawsuit has a Takings claim against the court. Patent rights are defined by, and subject to, the provisions of the Patent Act. Anyone who acquires or transfers a patent knows that the patent may be rendered invalid or unenforceable in litigation. 35 U.S.C. §282(b). An unenforceability judgment does not mean that patent has been "taken for public use, without just compensation." U.S. Const., amend. V; see Patterson v. People, 205 U.S. 454, 461 (1907) (Holmes, J.). That is equally true when the patentee's litigation misconduct leads to sanctions under Rule 37(b).

### C. The Decision Below Implicates No Split Of Authority.

Regeneron identifies no split of authority concerning the principles the lower courts actually applied here. A district court's authority to sanction misconduct as the court did here is longstanding and uncontroversial. §§I.A-B, *supra*.

The Federal Circuit reviews non-patent issues, such as adverse-inference sanctions, under the applicable regional circuit's law—here, the Second Circuit. Pet.App.13a. Regeneron does not argue that the Federal Circuit is internally divided on how or when to apply regional circuit law. Rather, Regeneron contends that the Federal Circuit is divided concerning an aspect of the law of inequitable conduct. But Regeneron's only evidence is the existence of a dissent and a 10-2 vote against rehearing in this case. Neither evinces any deep division within the Federal Circuit, and the majority's response to the dissent was plainly correct. Pet.App.42a-44a; pp.19-20, *supra*.

Regeneron's cursory suggestions of three different *inter*-circuit splits (Pet.4, 25-28) are likewise meritless and depend on the mistaken premise that its patent was taken away as a sanction for litigation misconduct. See §I.B, supra.

First, Regeneron asserts a conflict between this case and other circuits' statements that "[d]ismissal of the case is the most severe sanction the district court can impose in response to litigation misconduct." As explained above, that is true, at most, of misbehaving plaintiffs who do not face any counterclaims. See pp.27-30, supra. No circuit holds that counterclaims are somehow exempt from Rule 37; quite the opposite. Computer Task, 364 F.3d at 1116-17; Israel Travel, 61 F.3d at 1254-55. The district court could have entered a default judgment against Regeneron. Fed. R. Civ. P. 37(b)(2)(A)(v). The decision to impose an adverse inference is a far milder sanction, explicitly authorized by Rule 37(b)(2)(A)(i). There is no split of authority.

Second, Regeneron's suggestion of a conflict with copyright and trademark cases (Pet.26-27) likewise ignores the posture of this case. As the Petition notes, the consequence of a judgment on a claim of inequitable conduct is that the patent is unenforceable. Pet.2 (citing Hazel-Atlas). None of the cases Regeneron cites involves anything analogous (such as a copyright or trademark holder committing misconduct while defending against a claim to cancel or revoke the copyright or mark).

Finally, none of the pre-Federal-Circuit-era cases Regeneron cites involved Rule 37 sanctions or inequitable conduct counterclaims. Pet.27-28. Regeneron quotes dicta out of context, but none of

those cases held, or even suggested, that invalidity or unenforceability counterclaims are somehow exempt or immune from a trial court's authority to impose sanctions that resolve some or all of the merits of a claim against the misbehaving party.

# D. The Decision Below Implicates No Important, Unsettled Questions Of Law.

The decision below breaks no new ground. Had the Federal Circuit crafted the patent-unique exception to Rule 37 that Regeneron now seeks, *that* would have warranted review.

Nor does the decision "open[] up a whole new avenue for accused infringers to establish inequitable conduct." Pet.30. "To establish inequitable conduct" requires a properly-pled *claim* for inequitable conduct before the Patent Office (as there undisputedly was here), pled with particularity under Rule 9(b). Exergen Corp. v. Wal-Mart Stores, Inc., 575 F.3d 1312, 1328-29 (Fed. Cir. 2009). The application of an adverse inference sanction is hardly "new"; it has been explicit in Rule 37 for eighty years, and is milder than the default judgments authorized under the 1789 Judiciary Act, 1 Stat. 82 §15, and Rule 37(b)(2)(A)(v).

Regeneron's amici nonetheless all appear to have uncritically accepted Regeneron's premise that the Federal Circuit expanded the inequitable conduct doctrine, rather than look at what the district court actually did and the Federal Circuit actually affirmed. No amicus brief reflects any awareness of this Court's precedents (such as *Insurance Corporation of Ireland, NHL*, and *Hammond*) regarding adverse inferences and similar sanctions. *E.g.*, NAPP.Amicus.15-17. Worse, some appear to have been misled by

Regeneron's account of the facts. NAPP, for example, states that Regeneron's patent prosecutors "took no part in the sanctioned patent litigation misconduct." NAPP.Amicus.1; id. at 7; see also IPLAC.Amicus.4 ("prosecution counsel and trial counsel were not the same"). Not true. Smeland oversaw the district court litigation and committed misconduct before the Patent Office. Pet.App.116a.8

Regeneron contends that this case threatens "the vitality of the attorney-client privilege in patent cases." Pet.32. Not so. Sword-and-shield tactics like Regeneron's are a long-recognized abuse of the privilege. See, e.g., W. Union Tel. Co. v. Baltimore & Ohio Tel. Co., 26 F. 55, 57 (C.C.S.D.N.Y. 1885) (patent case); United States v. Bilzerian, 926 F.2d 1285, 1292 (2d Cir. 1991) (privilege "cannot at once be used as a shield and a sword"). Sanctioning abuse of a privilege does not threaten its vitality. Clark v. United States, 289 U.S. 1, 15 (1933) ("The privilege takes flight if the relation is abused.").

Regeneron and an amicus note that an inequitable conduct judgment may lead to disciplinary proceedings or "reputational harm" for the attorney(s)

<sup>&</sup>lt;sup>7</sup> "Seven Chicago Patent Lawyers" (from the same firm) are less than forthcoming about their interest in this case. Their firm prosecuted Regeneron patents while this case was pending. *E.g.*, U.S. Patent No. D748,253 (issued Jan. 26, 2016, listing Regeneron as an assignee and applicant, and McDonnell Boehnen Hulbert & Berghoff LLP as responsible for prosecution).

<sup>&</sup>lt;sup>8</sup> NAPP and other amici make similar misguided assertions about the facts without having access to the full record, much of which Regeneron insisted on sealing. *See* Pet.App.21a-22a n.4; Pet.App.103a n.20; Pet.App.106a-107a n.21.

who prosecuted the patent. Pet.32-33; IPLAC.Amicus.16. Those arguments are tellingly vague.

Attorneys who prosecute patents are subject to Patent Office regulations, 35 U.S.C. §§2(b)(2)(D), 32; 37 C.F.R. §§11.19-.60, and Rules of Professional 37 C.F.R. §§11.101-.901. Conduct. A litigation judgment of inequitable conduct has no automatic disciplinary consequences. At most, a judgment may lead to a referral, which may lead to disciplinary proceedings in which the attorney will have his own day in court—separate from the patentee in the inequitable-conduct litigation. The Patent Office conducts an investigation before even filing a disciplinary complaint, 77 Fed. Reg. 457, 458 (Jan. 5, 2012), and bears the burden of proof in any ensuing proceedings. 37 C.F.R. §11.49. The attorney's rights include an internal agency appeal, id. §11.55, districtcourt review (and appeal rights), 35 U.S.C. §32; 37 C.F.R. §11.56, and the ability to petition for reinstatement. 37 C.F.R. §11.60. This case creates no more risk of discipline than any case where Patent-Office misconduct is later uncovered in litigation.

### III. The Petition Is A Poor Vehicle For Examining Aspects Of The Inequitable Conduct Doctrine.

Several considerations make this case a poor vehicle for addressing issues surrounding the inequitable conduct doctrine.

*First*, the salient facts are unique and unlikely to recur. This is the rare case where an applicant made misrepresentations to the Patent Office, and then compounded those representations by covering them

up in the subsequent litigation over its inequitable conduct. Pet.App.42a-43a. If there is any lesson in this case for future litigants, it is that it is a bad idea to mislead the court and conceal evidence at your own inequitable conduct trial. Failure to follow procedural rules "may well result in a curtailment of [substantive] rights." Ins. Corp. of Ir., 456 U.S. at 705.

This is also the rare inequitable conduct case where the same attorney responsible for misconduct at the Patent Office also oversaw the inequitable conduct litigation based on that misconduct. There are obvious practical, legal, and prudential reasons why most litigants would not have an attorney in Smeland's shoes overseeing litigation concerning his own misconduct.

Second, the amicus briefs underscore the factbound nature of this case and confused nature of Regeneron's petition. Though Regeneron did not dispute the district court's factfinding, Pet.App.25a, and though the record is voluminous and largely sealed, amici such as NAPP apparently believe that the main problem with the decisions below turns on specific factual findings by the district court. NAPP.Amicus.4-6, 8-10, 16 & n.7.

Conversely, Washington Legal Foundation asks this Court to review a question entirely different from Regeneron's. The real problem, in WLF's view, is the so-called "all claims" rule, where a judgment of inequitable conduct renders the entire patent unenforceable. WLF.Amicus.22. There are numerous reasons why that question does not warrant this Court's review. Most important is that the Petition does not present it.

Of course, were this Court to examine the inequitable conduct doctrine here, there are antecedent questions *Merus* raised below—including whether *Therasense*'s intent standard is actually too stringent, and resembles the artificially heightened, trial-court-discretion-restricting standards this Court has consistently struck down in other patent cases. *See* SDNY No. 14-CV-1650, ECF#328 at 19-25 (May 21, 2015) (motion-in-limine #6); *id.* at 24 (citing *eBay*, *Teva*, *Octane*, *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007) and *Bilski v. Kappos*, 561 U.S. 593 (2010)); ECF#392 at 96-97 (June 3, 2015) (hearing transcript).

Third, it bears noting that very little was actually disputed concerning the intent element of the inequitable conduct claim the court of appeals reached and affirmed. Merus had to prove that Regeneron "[1] knew of the [withheld] reference, [2] knew that it was material, and [3] made a deliberate decision to withhold it." Therasense, 649 F.3d at 1291. The first and third sub-elements were undisputed. Pet.App.10a-11a; Pet.App.17a; Pet.App.162a. For the second sub-element, Smeland undisputedly knew that at least one withheld reference had led the Patent Office to reject similar and related Regeneron claims, CA.App.9011-12, 4692-714, and he undisputedly submitted a knowingly false presentation to the Patent Office. Pet.App.8a-9a. Further, the district reviewed the written direct-examination testimony Smeland intended to present at the intent CA.App.3427, which "directly phase of the trial, contradict[ed]" documents Regeneron improperly withheld. Pet.App.191a. It is thus not accurate to contend, as Regeneron does, and amici repeat, that "the sole basis for the finding of intent to deceive the Patent Office was the alleged litigation misconduct." Pet.22. There was a mountain of undisputed evidence on that score, some of which the district court and court of appeals opinions discuss. *E.g.*, Pet.App.8a-11a; Pet.App.101a-108a.

Finally, the district court found that Regeneron committed multiple acts of inequitable conduct, and its finding for at least one of those (the false slide presentation) did not depend on any sanction. Pet.App.168a-169a. The court of appeals did not reach that ground because it did not need to. Pet.App.3a-4a n.1. Indeed, there are many reasons why the district court's decision was ultimately correct—and why review of the gerrymandered issue Regeneron presents would only run up litigation costs and drag out a case that has been plagued by Regeneron's misconduct since the beginning. Pet.App.69a.

### CONCLUSION

The petition should be denied.

Respectfully submitted,

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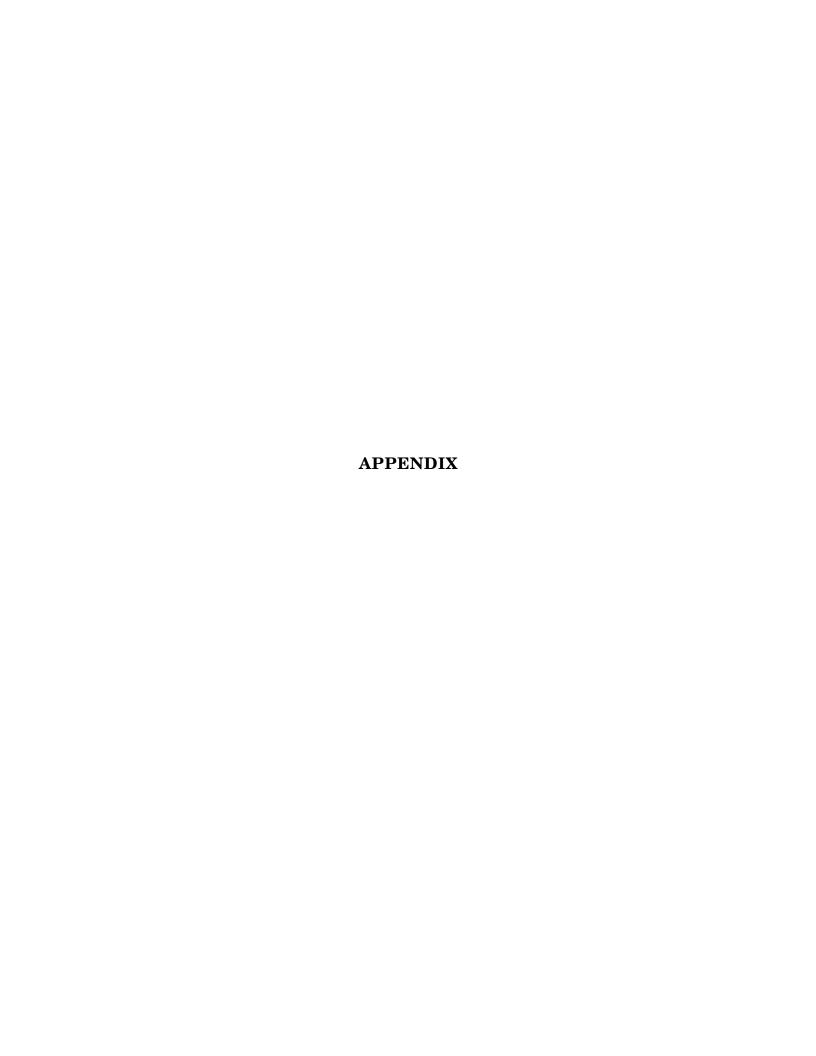
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### APPENDIX: Federal Rule of Civil Procedure 37

# Rule 37. Failure to Make Disclosures or to Cooperate in Discovery; Sanctions

- (a) MOTION FOR AN ORDER COMPELLING DISCLOSURE OR DISCOVERY.
  - (1) In General. On notice to other parties and all affected persons, a party may move for an order compelling disclosure or discovery. The motion must include a certification that the movant has in good faith conferred or attempted to confer with the person or party failing to make disclosure or discovery in an effort to obtain it without court action.
  - (2) Appropriate Court. A motion for an order to a party must be made in the court where the action is pending. A motion for an order to a nonparty must be made in the court where the discovery is or will be taken.
  - (3) Specific Motions.
    - (A) To Compel Disclosure. If a party fails to make a disclosure required by Rule 26(a), any other party may move to compel disclosure and for appropriate sanctions.
    - (B) To Compel a Discovery Response. A party seeking discovery may move for an order compelling an answer, designation, production, or inspection. This motion may be made if:
      - (i) a deponent fails to answer a question asked under Rule 30 or 31;
      - (ii) a corporation or other entity fails to make a designation under Rule 30(b)(6) or 31(a)(4);

- (iii) a party fails to answer an interrogatory submitted under Rule 33; or
- (iv) a party fails to produce documents or fails to respond that inspection will be permitted—or fails to permit inspection—as requested under Rule 34.
- (C) *Related to a Deposition*. When taking an oral deposition, the party asking a question may complete or adjourn the examination before moving for an order.
- (4) Evasive or Incomplete Disclosure, Answer, or Response. For purposes of this subdivision (a), an evasive or incomplete disclosure, answer, or response must be treated as a failure to disclose, answer, or respond.
- (5) Payment of Expenses; Protective Orders.
  - (A) If the Motion Is Granted (or Disclosure or Discovery Is Provided After Filing). If the motion is granted—or if the disclosure or requested discovery is provided after the motion was filed—the court must, after giving an opportunity to be heard, require the party or deponent whose conduct necessitated the motion, the party or attorney advising that conduct, or both to pay the movant's reasonable expenses incurred in making the motion, including attorney's fees. But the court must not order this payment if:
    - (i) the movant filed the motion before attempting in good faith to obtain the disclosure or discovery without court action;

- (ii) the opposing party's nondisclosure, response, or objection was substantially justified; or (i) the movant filed the motion before attempting in good faith to obtain the disclosure or discovery without court action;
- (iii) other circumstances make an award of expenses unjust.
- (B) If the Motion Is Denied. If the motion is denied, the court may issue any protective order authorized under Rule 26(c) and must, after giving an opportunity to be heard, require the movant, the attorney filing the motion, or both to pay the party or deponent who opposed the motion its reasonable expenses incurred in opposing the motion, including attorney's fees. But the court must not order this payment if the motion was substantially justified or other circumstances make an award of expenses unjust.
- (C) If the Motion Is Granted in Part and Denied in Part. If the motion is granted in part and denied in part, the court may issue any protective order authorized under Rule 26(c) and may, after giving an opportunity to be heard, apportion the reasonable expenses for the motion.
- (b) FAILURE TO COMPLY WITH A COURT ORDER.
  - (1) Sanctions Sought in the District Where the Deposition Is Taken. If the court where the discovery is taken orders a deponent to be sworn or to answer a question and the deponent fails to obey, the failure may be treated as contempt of court. If a deposition-related motion is transferred

to the court where the action is pending, and that court orders a deponent to be sworn or to answer a question and the deponent fails to obey, the failure may be treated as contempt of either the court where the discovery is taken or the court where the action is pending.

- (2) Sanctions Sought in the District Where the Action Is Pending.
  - (A) For Not Obeying a Discovery Order. If a party or a party's officer, director, or managing agent—or a witness designated under Rule 30(b)(6) or 31(a)(4)—fails to obey an order to provide or permit discovery, including an order under Rule 26(f), 35, or 37(a), the court where the action is pending may issue further just orders. They may include the following:
    - (i) directing that the matters embraced in the order or other designated facts be taken as established for purposes of the action, as the prevailing party claims;
    - (ii) prohibiting the disobedient party from supporting or opposing designated claims or defenses, or from introducing designated matters in evidence;
    - (iii) striking pleadings in whole or in part;
    - (iv) staying further proceedings until the order is obeyed;
    - (v) dismissing the action or proceeding in whole or in part;
    - (vi) rendering a default judgment against the disobedient party; or

- (vii) treating as contempt of court the failure to obey any order except an order to submit to a physical or mental examination.
- (B) For Not Producing a Person for Examination. If a party fails to comply with an order under Rule 35(a) requiring it to produce another person for examination, the court may issue any of the orders listed in Rule 37(b)(2)(A)(i)—(vi), unless the disobedient party shows that it cannot produce the other person.
- (C) Payment of Expenses. Instead of or in addition to the orders above, the court must order the disobedient party, the attorney advising that party, or both to pay the reasonable expenses, including attorney's fees, caused by the failure, unless the failure was substantially justified or other circumstances make an award of expenses unjust.
- (c) Failure to Disclose, to Supplement an Earlier Response, or to Admit.
  - (1) Failure to Disclose or Supplement. If a party fails to provide information or identify a witness as required by Rule 26(a) or (e), the party is not allowed to use that information or witness to supply evidence on a motion, at a hearing, or at a trial, unless the failure was substantially justified or is harmless. In addition to or instead of this sanction, the court, on motion and after giving an opportunity to be heard:
    - (A) may order payment of the reasonable expenses, including attorney's fees, caused by the failure:

- (B) may inform the jury of the party's failure; and
- (C) may impose other appropriate sanctions, including any of the orders listed in Rule 37(b)(2)(A)(i)—(vi).
- (2) Failure to Admit. If a party fails to admit what is requested under Rule 36 and if the requesting party later proves a document to be genuine or the matter true, the requesting party may move that the party who failed to admit pay the reasonable expenses, including attorney's fees, incurred in making that proof. The court must so order unless:
  - (A) the request was held objectionable under Rule 36(a);
  - (B) the admission sought was of no substantial importance;
  - (C) the party failing to admit had a reasonable ground to believe that it might prevail on the matter; or
  - (D) there was other good reason for the failure to admit.
- (d) PARTY'S FAILURE TO ATTEND ITS OWN DEPOSITION, SERVE ANSWERS TO INTERROGATORIES, OR RESPOND TO A REQUEST FOR INSPECTION.
  - (1) In General.
    - (A) *Motion; Grounds for Sanctions*. The court where the action is pending may, on motion, order sanctions if:
      - (i) a party or a party's officer, director, or managing agent—or a person designated

- under Rule 30(b)(6) or 31(a)(4)—fails, after being served with proper notice, to appear for that person's deposition; or;
- (ii) a party, after being properly served with interrogatories under Rule 33 or a request for inspection under Rule 34, fails to serve its answers, objections, or written response.
- (B) *Certification*. A motion for sanctions for failing to answer or respond must include a certification that the movant has in good faith conferred or attempted to confer with the party failing to act in an effort to obtain the answer or response without court action.
- (2) Unacceptable Excuse for Failing to Act. A failure described in Rule 37(d)(1)(A) is not excused on the ground that the discovery sought was objectionable, unless the party failing to act has a pending motion for a protective order under Rule 26(c).
- (3) Types of Sanctions. Sanctions may include any of the orders listed in Rule 37(b)(2)(A)(i)—(vi). Instead of or in addition to these sanctions, the court must require the party failing to act, the attorney advising that party, or both to pay the reasonable expenses, including attorney's fees, caused by the failure, unless the failure was substantially justified or other circumstances make an award of expenses unjust.
- (e) FAILURE TO PRESERVE ELECTRONICALLY STORED INFORMATION. If electronically stored information that should have been preserved in the anticipation or conduct of litigation is lost because a party failed to take reasonable steps to preserve it, and it cannot be

restored or replaced through additional discovery, the court:

- (1) upon finding prejudice to another party from loss of the information, may order measures no greater than necessary to cure the prejudice; or
- (2) only upon finding that the party acted with the intent to deprive another party of the information's use in the litigation may:
  - (A) presume that the lost information was unfavorable to the party;
  - (B) instruct the jury that it may or must presume the information was unfavorable to the party; or
  - (C) dismiss the action or enter a default judgment.
- (f) Failure to Participate in Framing a Discovery Plan. If a party or its attorney fails to participate in good faith in developing and submitting a proposed discovery plan as required by Rule 26(f), the court may, after giving an opportunity to be heard, require that party or attorney to pay to any other party the reasonable expenses, including attorney's fees, caused by the failure.