

No. 12-1086

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**In the Supreme Court of the United States**

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SONY COMPUTER ENTERTAINMENT AMERICA LLC,  
ET AL., PETITIONERS

*v.*

1ST MEDIA, LLC

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

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**BRIEF FOR THE UNITED STATES AS AMICUS CURIAE**

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### QUESTION PRESENTED

This Court has recognized and applied a doctrine of “inequitable conduct,” under which the court in a patent infringement suit may deny relief to a plaintiff that obtained its patent through fraud or deceit. “To prevail on [a] defense of inequitable conduct, the accused infringer must prove,” by clear and convincing evidence, “that the applicant misrepresented or omitted material information with [a] specific intent to deceive.” *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1287 (Fed. Cir. 2011) (en banc). In a case involving nondisclosure of information, deceptive intent can be proved if “the applicant knew of the [information], knew that it was material, and made a deliberate decision to withhold it.” *Id.* at 1290. The question presented in this case is as follows:

Whether the court of appeals erred in reversing the district court’s judgment of inequitable conduct on the ground that there was no finding, and no record evidence, demonstrating that the patent applicant or prosecutor had made a “deliberate decision” to withhold prior art references from the United States Patent and Trademark Office.

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This brief is submitted in response to the Court's order inviting the Solicitor General to express the views of the United States. In the view of the United States, the petition for a writ of certiorari should be denied.

### STATEMENT

1. The doctrine of "inequitable conduct" is an equitable defense that, if proved, may bar enforcement of a patent. The defense has its origin in a series of decisions by this Court that relied on the doctrine of unclean hands or common-law fraud to punish a patentee who had procured the patent through perjury or other affirmative misconduct. See *Precision Instrument Mfg. Co. v. Automotive Maint. Mach. Co.*, 324 U.S. 806, 814-816 (1945) (*Precision Instrument*); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 250-251 (1944) (*Hazel-Atlas*); *Keystone Driller Co. v. General Excava-*

*tor Co.*, 290 U.S. 240, 244-245 (1933). In those cases, the Court sought to protect, *inter alia*, the public’s “paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other inequitable conduct.” *Precision Instrument*, 324 U.S. at 816; see *Hazel-Atlas*, 322 U.S. at 246.

In the ensuing years, the inequitable-conduct doctrine evolved beyond the sort of affirmative misconduct at issue in this Court’s early cases to encompass instances of nondisclosure. The United States Patent and Trademark Office (PTO) has long imposed a “duty of candor and good faith” on “[e]ach individual associated with the filing and prosecution of a patent application,” which includes a “duty to disclose to the [PTO] all information known to that individual to be material to patentability.” 37 C.F.R. 1.56(a) (PTO Rule 56); see PTO, *Manual of Patent Examining Procedure* § 2001.06(a) and (b) (8th ed. 2001, rev. 2012) (duty to disclose prior art and other information brought to applicant’s attention in related co-pending or foreign applications).<sup>1</sup> An applicant’s breach of that obligation could sustain an inequitable-conduct claim if the withheld information was material to patentability and the applicant acted with the requisite intent to deceive. Through the years, however, different courts articulated different formulations of the materiality and intent

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<sup>1</sup> The initial version of PTO Rule 56 was promulgated in 1949 and permitted the PTO to strike an application for “fraud” on the agency. 37 C.F.R. 1.56 (1949). In 1977, the Rule was amended to require applicants to disclose information “that a reasonable examiner would consider \* \* \* important.” 37 C.F.R. 1.56 (1977). The current version was adopted in 1992, 57 Fed. Reg. 2034 (Jan. 17, 1992), but new amendments were recently proposed and remain under consideration, see note 3, *infra*.

requirements, and of the relationship between the two, creating significant uncertainty about the doctrine's scope.

The Federal Circuit's en banc decision in *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (2011), sought to reconcile the competing standards and to clarify the inequitable-conduct doctrine. The court held that, “[t]o prevail on the defense of inequitable conduct, the accused infringer must prove,” by clear and convincing evidence, “that the applicant misrepresented or omitted material information with the specific intent to deceive the PTO.” *Id.* at 1287. Because charging inequitable conduct had become a “common litigation tactic” that had caused “numerous unforeseen and unintended consequences,” including “patent prosecutors regularly bury[ing] PTO examiners with a deluge of prior art references” in order to avoid subsequent charges that they had withheld material information, the court concluded that “the standards for finding both intent and materiality” needed to be “tighten[ed].” *Id.* at 1288-1290.

With respect to intent, the court of appeals unanimously held that an accused infringer must demonstrate that the applicant acted with a “specific intent to deceive the PTO,” and that “gross negligence or negligence under a ‘should have known’ standard does not satisfy this intent requirement.” *Therasense*, 649 F.3d at 1290; see *id.* at 1297 (O’Malley, J., concurring in part and dissenting in part); *id.* at 1304 (Bryson, J., dissenting). “In a case involving nondisclosure of information,” the accused infringer must prove “that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.” *Id.* at 1290. The court recognized that “direct evidence of deceptive in-

tent is rare,” and that “a district court may infer intent from indirect and circumstantial evidence.” *Ibid.* The court also emphasized, however, that, “to meet the clear and convincing evidence standard, the specific intent to deceive must be ‘the single most reasonable inference able to be drawn from the evidence.’” *Ibid.* (citation omitted); see *id.* at 1297 (O’Malley, J., concurring in part and dissenting in part).

The court of appeals also tightened the materiality standard, but it was sharply divided on that point.<sup>2</sup> The court rejected, as unduly broad, both the “reasonable examiner” standard and “the definition of materiality” set forth in PTO Rule 56. *Therasense*, 649 F.3d at 1288, 1293-1294.<sup>3</sup> Instead, the court adopted a “but-for” standard, whereby the failure to disclose information would be deemed material only “if the PTO would not

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<sup>2</sup> Judge O’Malley would have found conduct “material” if “(1) but for the conduct \* \* \* , the patent would not have issued \* \* \* ; (2) the conduct constitutes a false or misleading representation of fact \* \* \* ; or (3) the district court finds that the behavior is so offensive that the court is left with the firm conviction that the integrity of the PTO process as to the application at issue was wholly undermined.” *Therasense*, 649 F.3d at 1300. The four judges in dissent would have adopted the materiality standard set forth in PTO Rule 56. *Id.* at 1317; see note 3, *infra*.

<sup>3</sup> The current version of PTO Rule 56 provides that information is “material” if it is not “cumulative,” and if “[i]t establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim,” or “refutes, or is inconsistent with, a position the applicant takes in” opposing an unpatentability argument relied on by the PTO or “[a]sserting an argument of patentability.” 37 C.F.R. 1.56(b). On July 21, 2011, the PTO proposed an amendment that would make the Rule 56 definition coextensive with the definition of “material” adopted in *Therasense*. See 76 Fed. Reg. 43,631. The PTO received public comment on the proposed change, but has not yet issued a final rule.

have allowed a claim had it been aware of the undisclosed” information. *Id.* at 1291. The court recognized “an exception” to the but-for materiality standard, however, “in cases of affirmative egregious misconduct.” *Id.* at 1292.

Finally, the court of appeals explained the relationship between the two elements. The court held that “[i]ntent and materiality are separate requirements,” and it rejected a “sliding scale” approach under which “a weak showing of intent may be found sufficient based on a strong showing of materiality, and vice versa.” *Therasense*, 649 F.3d at 1290; see *id.* at 1297 (O’Malley, J., concurring in part and dissenting in part); *id.* at 1302 (Bryson, J., dissenting). The court also cautioned that “a district court may not infer intent solely from materiality.” *Id.* at 1290; see *id.* at 1297 (O’Malley, J., concurring in part and dissenting in part). But the court did not preclude district courts from considering the degree of materiality, along with other relevant evidence, in determining whether intent to deceive is “the single most reasonable inference.” See *id.* at 1297 n.1 (O’Malley, J., concurring in part and dissenting in part); *id.* at 1304 n.1 (Bryson, J., dissenting).

2. In November 1992, Joseph Sawyer, a patent attorney, filed a patent application on behalf of Dr. Scott Lewis, describing an entertainment system for use in purchasing and storing songs, videos, and multimedia karaoke information. Pet. App. 2a-3a. Although the PTO examiner initially rejected all of the claims as anticipated or obvious in light of five prior art references, the examiner ultimately issued a Notice of Allowance on May 2, 1995. *Id.* at 3a. On August 1, 1995, Sawyer paid the issue fee and, on November 7, 1995, the application

issued as U.S. Patent No. 5,464,946 (the '946 patent or Asserted Patent). *Ibid.*

During prosecution of the '946 patent, three related patent applications (two domestic and one foreign), filed by Sawyer on Lewis's behalf, were rejected in whole or in part on the basis of one of three prior art references: (1) Baji, (2) Hoarty, or (3) Bush. Pet. App. 3a-5a. On July 16, 1993, a different PTO examiner, based on, *inter alia*, the Baji reference, rejected several claims in an application that had been filed the same day as the '946 application. *Id.* at 4a. The rejected claims were cancelled and the application issued. *Id.* at 3a-4a. On June 12, 1995, a third PTO examiner cited the Hoarty reference in rejecting one claim in another related application. *Id.* at 4a-5a. The rejected claim was replaced and the application issued. *Id.* at 3a, 5a. Finally, on July 24, 1995, eight days before paying the issue fee on the Asserted Patent, Sawyer received a report from the European Patent Office (EPO) that identified the Bush reference as "relevant" to an identical European patent application. *Id.* at 3a. After the Asserted Patent issued, the EPO rejected the European counterpart, relying in part on the Bush reference. *Id.* at 3a-4a. The claims were never amended, and the foreign application eventually was deemed withdrawn. *Id.* at 3a, 38a.

During prosecution of the Asserted Patent, Sawyer and Lewis did not disclose, and the PTO examiner did not consider, Baji, Hoarty, or Bush. Pet. App. 4a-5a.<sup>4</sup>

3. Respondent filed suit against petitioners, alleging infringement of the '946 patent. In defending against the suit, petitioners asserted, *inter alia*, that the patent was unenforceable because Lewis and Sawyer had en-

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<sup>4</sup> The '946 patent expired on February 11, 2013, and is currently under reexamination by the PTO.

gaged in inequitable conduct before the PTO by failing to disclose the three prior art references during prosecution of the Asserted Patent. Pet. App. 5a.<sup>5</sup>

The district court bifurcated the proceedings and, after a two-day bench trial, concluded that Lewis and Sawyer had engaged in inequitable conduct. Pet. App. 22a-26a. At trial, Sawyer testified that he had been running a “very active” solo practice out of his home during the relevant time period; that he had received the Bush reference outside his “‘active prosecution’ window” for the Asserted Patent, *i.e.*, after the Notice of Allowance; and that disclosure of the Baji and Hoarty references “did not occur” to him because he believed that those references related to different technology. *Id.* at 6a-7a, 25a, 47a (citations omitted). Lewis testified that nondisclosure of the Bush reference was an “oversight that got lost in the cracks,” and that he too believed the Baji and Hoarty references involved different technology. *Id.* at 6a (citation omitted).

The district court decided this case approximately one year before the en banc Federal Circuit issued its decision in *Therasense*. Applying pre-*Therasense* law, the court found that the three prior art references “were each highly material to claims” in the Asserted Patent because there was “a substantial likelihood that a reasonable examiner would consider the information important in deciding whether to allow the application to issue as a patent.” Pet. App. 24a, 27a; see *id.* at 39a-42a,

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<sup>5</sup> Petitioners also alleged, and the district court found, that Sawyer and Lewis had engaged in inequitable conduct by failing to disclose the rejection of claims in the co-pending domestic patent applications. Pet. App. 6a, 24a. Petitioners did not rely on those rejections on appeal, however, and the court of appeals did not address them. *Id.* at 6a.

59a-64a. The court also found that Sawyer and Lewis had intended to deceive the PTO because they had known that the prior art was material but had failed to disclose it. *Id.* at 24a, 28a, 45a; see *id.* at 43a-45a, 68a-70a. The court further found that Sawyer and Lewis's explanations for failing to disclose the references were "not credible." *Id.* at 24a; see *id.* at 45a-50a, 72a-83a. Based on those findings, the court concluded that "the single most reasonable inference drawn from all the evidence offered at trial is that Dr. Lewis and Mr. Sawyer withheld this information with a specific intent to deceive." *Id.* at 25a, 50a-51a, 77a, 81a. "After carefully balancing the proof of materiality and intent in light of all the evidence and the equities," the court found those individuals' conduct "sufficiently culpable to constitute inequitable conduct that renders the '946 Patent unenforceable." *Id.* at 25a-26a, 28a-29a, 83a-84a.

4. The court of appeals reversed. Pet. App. 1a-19a. The court did not decide "whether any of the references were but-for material," *id.* at 19a, or whether Lewis or Sawyer had known that they were material, *id.* at 18a. Instead, the court reversed because the district court, applying pre-*Therasense* law, had issued no finding that Lewis or Sawyer had made a "deliberate decision" to withhold the prior art references. *Id.* at 14a-19a. The court also faulted the district court for "relying on Lewis and Sawyer's inability to offer a good faith explanation as a basis to infer a deliberate decision to withhold," stating that this failure standing "alone is insufficient to find specific intent to deceive." *Id.* at 16a (citation omitted). The court concluded that "[b]ecause [petitioners] cannot prove on this record that either Lewis or Sawyer made a deliberate decision to withhold references from the PTO and because [petitioners] acknowledged that

the record is complete,” the judgment of the district court should be reversed. *Id.* at 19a.

#### DISCUSSION

The Federal Circuit’s recent en banc decision in *Therasense, Inc. v. Becton, Dickinson & Co.*, 649 F.3d 1276 (2011), tightened the standards for proving inequitable conduct. The United States agrees with the specific-intent standards unanimously adopted by the en banc court in that case, and petitioners do not directly challenge that aspect of the *Therasense* decision. Instead, petitioners contend that, as applied in this case, the *Therasense* standards unduly constrict a district court’s discretion to infer intent from circumstantial evidence. The categorical rules to which petitioners object, however, cannot be found in *Therasense* itself, and the decision below does not clearly adopt them either. Although the court of appeals should have remanded the case to allow the district court to apply the *Therasense* standards to the circumstances presented here, that case-specific error does not warrant the Court’s review.

In any event, this is neither the time nor the case to address the inequitable-conduct doctrine more generally. Any review would be incomplete without considering materiality (in addition to intent), but that issue is not presented here, and ongoing rulemaking by the PTO could be relevant to the analysis. And it is too soon to assess the practical impact of the two-year-old *Therasense* standards—standards that were not applied by the district court in this case—on the operation of the patent system. The petition for a writ of certiorari should be denied.

**A. The Intent Standard Adopted By The Unanimous En Banc Federal Circuit In *Therasense* Is Correct And Does Not Unduly Limit A District Court's Discretion**

1. In *Therasense*, the en banc Federal Circuit held that, to prove inequitable conduct, an accused infringer must demonstrate that the patentee acted with a “specific intent to deceive the PTO”; that “gross negligence or negligence” is insufficient; that a district court could “infer intent from indirect and circumstantial evidence”; that a deceptive intent must be the “single most reasonable inference”; and that “[t]he absence of a good faith explanation” cannot, “by itself,” prove the requisite intent. 649 F.3d at 1290-1291; see *id.* at 1297 (O’Malley, J., concurring in part and dissenting in part); *id.* at 1302-1304 (Bryson, J., dissenting). The court explained that, in a case involving the nondisclosure of information, the accused infringer must prove “that the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.” *Id.* at 1290; see *id.* at 1296. The court also clarified the relationship between the intent and materiality prongs, rejecting a “sliding scale” approach and holding that intent may not be inferred “solely from materiality.” *Id.* at 1290.

The intent standard unanimously adopted in *Therasense* largely mirrors the intent standard advocated by the United States as amicus curiae in that case. Compare U.S. Amicus Br. at 18-25, *Therasense*, *supra*, No. 08-1511 (Aug. 2, 2010), with *Therasense*, 649 F.3d at 1290-1291. It best comports with this Court’s early cases, which all involved patentees who had engaged in deliberate and egregious misconduct in an effort to procure or enforce a patent. See *Precision Instrument Mfg. Co. v. Automotive Maint. Mach. Co.*, 324 U.S. 806,

816 (1945) (conduct “steeped in perjury and undisclosed knowledge of perjury”); *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238, 245-246 (1944) (“[A] deliberately planned and carefully executed scheme to defraud not only the Patent Office but the Circuit Court of Appeals.”); *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240, 243-244 (1933) (patentee conspired with prior-art user to “suppress the evidence” in a “corrupt transaction” that involved use of a false affidavit). And it properly balances the interest in “foster[ing] full disclosure to the PTO” with the “numerous unforeseen and unintended consequences” created by less demanding standards. *Therasense*, 649 F.3d at 1288.

Although this Court’s inequitable-conduct cases involved affirmative acts of fraud or deceit, the doctrine was subsequently expanded to encompass nondisclosure of information that might have affected the PTO’s decision. That development greatly expanded the range of cases in which inequitable conduct could plausibly be alleged. As petitioners acknowledge (Pet. 14-15), before *Therasense*, inequitable-conduct claims had become “a significant litigation strategy” that increased “the complexity, duration and cost of patent infringement litigation.” *Therasense*, 649 F.3d at 1288 (citation omitted); *id.* at 1289 (describing study estimating that 80% of patent infringement cases included inequitable-conduct allegations); U.S. Br. at 2, *Therasense*, *supra* (No. 08-1511) (same). The threat of an inequitable-conduct charge incentivized patent applicants to “bury” the PTO with a “deluge” of information, “most of which ha[d] marginal value.” *Therasense*, 649 F.3d at 1289. That practice had “strain[ed] the agency’s examining resources,” had “directly contribute[d] to the backlog” before the PTO, and had burdened “not only the courts

but also the entire patent system.” *Id.* at 1289-1290 (quoting U.S. Br. at 17-18, *Therasense*, *supra* (No. 08-1511)).

2. Petitioners do not directly challenge the intent standard adopted in *Therasense*. They suggest (Pet. 13, 15-17), however, that the “rules” adopted by the *Therasense* court are “too rigid” because they purportedly divest district courts of their “equitable” and “remed[ial]” discretion. That argument, raised for the first time in this Court, is without merit.

In their brief to the panel, petitioners argued that the district court had “unquestionably” and properly “applied the standard for intent approved by *Therasense*.” Pet. C.A. Br. 52. In their petition for rehearing en banc, petitioners endorsed the *Therasense* framework and argued that the panel had simply “misapplied” that decision. Pet. C.A. Pet. for Reh’g 4-5; see also, *e.g.*, *id.* at 2 (arguing that the panel “misapplie[d] the holding[] of *Therasense*” and adopted a “rigid application of the *Therasense* framework”); *id.* at 3 (decision is “inconsistent with the framework outlined in *Therasense*”); *id.* at 4 (“panel decision will disrupt the careful balance sought by the en banc Federal Circuit in *Therasense*”); *id.* at 12 (panel decision is “inconsistent with the flexible test outlined in *Therasense*”). This Court ordinarily does not consider arguments neither pressed nor passed upon below, see *United States v. Williams*, 504 U.S. 36, 41 (1992), and there is no reason to depart from that rule here.

In any event, petitioners were right then and they are wrong now. The only “rules” specific to the intent standard that the *Therasense* court adopted afford district courts their usual discretion to draw reasonable inferences from circumstantial evidence. Indeed, the

court recognized that “a district court may infer intent from indirect and circumstantial evidence.” 649 F.3d at 1290. And while a district court cannot infer the requisite intent from the absence of a good faith explanation *alone*, *id.* at 1291, *Therasense* does not preclude a district court from drawing adverse inferences from discredited testimony. Similarly, the *Therasense* court held that intent must be proved separately from materiality, and that a high degree of materiality cannot compensate for a negligible degree of intent. *Id.* at 1290. Under *Therasense*, however, the level of materiality is not irrelevant to the question of intent and may be used, along with other evidence, to demonstrate intent circumstantially. See *id.* at 1297 n.1 (O’Malley, J., concurring in part and dissenting in part); *id.* at 1304 n.1 (Bryson, J., dissenting).

Petitioners do not suggest that a district court should have discretion (equitable or otherwise) to make a finding of inequitable conduct in the absence of a “deliberate decision” to withhold material information. Instead, petitioners contend (Pet. 17-25) that Lewis and Sawyer made a “deliberate decision”; that the record evidence supports such a finding; and that the district court should have discretion to infer as much from the circumstantial evidence and adverse credibility findings. Those objections, however, are directed at the panel’s application of the *Therasense* standards to a particular set of facts, not at *Therasense* itself.<sup>6</sup>

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<sup>6</sup> Petitioners’ reliance (Pet. 15-17) on Judge O’Malley’s opinion in *Therasense* is similarly misplaced. Although Judge O’Malley argued that the majority should have adopted a more “flexible” approach to materiality and to the choice of an appropriate remedy, *Therasense*, 649 F.3d at 1297-1300, she “concur[red]” in the majority’s intent standard, *id.* at 1297 & n.1. The panel below did not address materi-

3. Petitioners contend that, in applying *Therasense*, the court of appeals adopted a “rigid test” that “forecloses district courts from considering the entire circumstantial record.” Pet. i, 13. According to petitioners, the decision below (1) precludes district courts from drawing adverse inferences from discredited testimony, Pet. 18-19, and (2) prevents them from inferring deceptive intent from a patentee’s knowledge that the withheld information is material, Pet. 19-20, 22-23. Although the panel erred in applying *Therasense* to the record in this case, it did not clearly adopt any of the categorical rules petitioners suggest.

a. Contrary to petitioners’ contention (Pet. 18-19), the court of appeals’ decision should not be read as prohibiting district courts from drawing adverse inferences from discredited testimony. The court held that “the district court clearly erred in relying on Lewis and Sawyer’s inability to offer a good faith explanation as a basis to infer a deliberate decision to withhold [prior art].” Pet. App. 16a; see *id.* at 17a. If that language is read to mean that the district court should have entirely disregarded discredited exculpatory testimony in deciding whether the failure to disclose was deliberate, such a rule would unduly constrict the district court’s role as factfinder. But the sentence could also be read as restating a more modest conclusion: the district court’s finding that the testimony of Lewis and Sawyer was “lacking in credibility” is “*alone* \* \* \* insufficient to find specific intent to deceive.” *Id.* at 16a (citation omit-

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ality. Pet. App. 19a. And while petitioners suggest (Pet. 17) that *Therasense* unduly constrains district courts’ discretion to choose among potential remedies in inequitable-conduct cases, the only remedy petitioners sought was a directive that the Asserted Patent be treated as unenforceable.

ted and emphasis added). As petitioners acknowledge (Pet. 19), “[a]n equitable doctrine” could properly “embrace” such a “notion.” Cf. *Bose Corp. v. Consumers Union of U.S., Inc.*, 466 U.S. 485, 512 (1984) (“When the testimony of a witness is not believed, the trier of fact may simply disregard it. Normally the discredited testimony is not considered a sufficient basis for drawing a contrary conclusion.”).

Petitioners also contend (Pet. 19) that the court of appeals established a sequential framework, whereby a district court must “ignore the impact of witness testimony until after some undefined threshold has been triggered.” Petitioners overread the decision below. The court relied on the proposition that a patentee “need not offer any good faith explanation unless the accused infringer first carried his burden to prove a threshold level of intent to deceive by clear and convincing evidence.” Pet. App. 16a (citation omitted). If that statement is construed to require district courts to ignore evidence casting doubt on a witness’s credibility until after some threshold showing has been made, it would place unwarranted constraints on the factfinder’s weighing of evidence. The statement is better read, however, as establishing a “burden-shifting” framework that, as petitioners acknowledge (Pet. 19), fits comfortably within the “equitable doctrine.”

b. Similarly, the court of appeals did not clearly preclude district courts from considering a patentee’s knowledge of materiality in determining whether the patentee had made a deliberate decision not to disclose particular information. The court stated that “[k]nowledge of the reference and knowledge of materiality *alone* are insufficient after *Therasense* to show an intent to deceive.” Pet. App. 14a (emphasis added). If read to

suggest that “separate” and “independent” evidence is always needed to demonstrate that a “deliberate decision” has been made, that would be too “rigid” a formulation. Pet. 19-20. In the next sentence of its opinion, however, the court explained that “it is not enough to argue carelessness, lack of attention, poor docketing or cross-referencing, or anything else that might be considered negligent or even grossly negligent.” Pet. App. 14a. That is, even if a patentee is aware of prior art, and aware that the prior art is material, his failure to disclose it does not invariably mean that he has made a deliberate decision to withhold the information. Because the failure to disclose a known material reference could be inadvertent or even grossly negligent, a district court must also find, in addition to “[k]nowledge of the reference and knowledge of materiality,” that the patentee made a “deliberate decision” not to disclose that information to the PTO. *Ibid.*

c. In this case, the district court, applying pre-*Therasense* law, made no finding that Sawyer or Lewis had made a “deliberate decision” to withhold any of the three prior art references. The court of appeals therefore correctly reversed the district court’s inequitable-conduct determination.

The court of appeals should have remanded the case, however, to allow the district court to assess in the first instance whether the evidence and its credibility determinations support a finding of specific intent to deceive under the *Therasense* standard. See *Pullman-Standard v. Swint*, 456 U.S. 273, 291-292 (1982) (“When an appellate court discerns that a district court has failed to make a finding because of an erroneous view of the law,” or “where findings are infirm because of an erroneous view of the law, a remand is the proper course unless the

record permits only one resolution of the factual issue.”). The en banc court in *Therasense* took that approach, see 649 F.3d at 1296, and on remand the district court reaffirmed its finding of inequitable conduct. *Therasense, Inc. v. Becton, Dickinson & Co.*, 864 F. Supp. 2d 856 (N.D. Cal. 2012). At least one other post-*Therasense* Federal Circuit panel followed a similar approach, see *American Calcar, Inc. v. American Honda Motor Co.*, 651 F.3d 1318, 1336 (2011), and the district court in that case likewise reaffirmed on remand that the patentee had engaged in inequitable conduct, *American Calcar, Inc. v. American Honda Motor Co.*, No. 06-2433, 2012 WL 1328640 (S.D. Cal. Apr. 17, 2012), appeal pending, No. 13-1061 (Fed. Cir. filed Nov. 2, 2012).

Although the evidence before the district court did not *compel* the conclusion that Lewis and Sawyer had made a deliberate decision to withhold material information from the PTO, it was sufficient to support such a finding. Questions of intent are ordinarily treated as factual issues whose resolution is primarily entrusted to the trial court. See, e.g., *Amadeo v. Zant*, 486 U.S. 214, 225-226 (1988); cf. *Merck & Co. v. Reynolds*, 130 S. Ct. 1784, 1796 (2010) (“Scienter is assuredly a ‘fact.’”). But while the court of appeals erred in failing to remand for further district court proceedings, that case-specific mistake does not warrant the Court’s review.

**B. This Court’s Consideration Of The Inequitable-Conduct Doctrine Is Not Warranted In This Case Or At This Time**

Petitioners ask this Court to review the inequitable-conduct doctrine for the first time in nearly 70 years. This is neither the right time nor the right case to do so. The Court could not meaningfully clarify the

inequitable-conduct doctrine without fully considering the standard that should be used to determine whether information not presented to the PTO was “material.” No issue of materiality is presented in this case, however, and the PTO is currently engaged in a rulemaking to address that issue. In any event, the en banc court decided *Therasense* only two years ago, and it is still too early to assess the practical impact of that decision on the functioning of the patent system.

1. To establish that a patent holder engaged in inequitable conduct by failing to disclose information during the application process, an alleged infringer must show both that the nondisclosed information was material and that the patent holder acted with the intent to deceive the PTO. Although “[i]ntent and materiality are separate requirements,” *Therasense*, 649 F.3d at 1290, the two are not hermetically sealed. To the contrary, the degree of materiality can be considered, along with other evidence, as part of the intent analysis. See *id.* at 1297 n.1 (O’Malley, J., concurring in part and dissenting in part); *id.* at 1304 n.1 (Bryson, J., dissenting). And, in a nondisclosure case, intent to deceive is proved if “the applicant knew of the reference, knew that it was material, and made a deliberate decision to withhold it.” *Id.* at 1290. The materiality standard is thus a critical component of the inequitable-conduct doctrine, and any attempt to clarify that doctrine would be incomplete without an analysis of what it means for nondisclosed information to be “material.”

This case, however, does not present any disputed question of materiality. The district court applied a pre-*Therasense*, “reasonable examiner” standard in finding the nondisclosed prior art “highly material,” and in concluding that Sawyer and Lewis “knew” that the ref-

erences were “material.” Pet. App. 27a, 42a, 43a-50a, 61a, 63a, 68a-70a. Both in their brief to the Federal Circuit panel and in their petition for rehearing en banc, petitioners declined to take issue with the “but-for” standard of materiality adopted in *Therasense*. Instead, petitioners “acknowledge[d] that the district court’s analysis” had proceeded under a different standard, and they argued that the record also demonstrated “but-for” materiality. Pet. C.A. Br. 53-66. The court of appeals, however, did not decide “whether any of the references were but-for material,” Pet. App. 19a, or whether Lewis and Sawyer knew that the references were “material,” *id.* at 18a. This Court should not consider issues of materiality in the abstract—and the record here lacks the necessary findings.

An ongoing PTO rulemaking may also impact the materiality component of the inequitable-conduct doctrine. Two months after the decision in *Therasense*, the PTO published a notice of proposed rulemaking stating that the agency was reconsidering PTO Rule 56’s definition of “material.” 76 Fed. Reg. 43,632 (July 21, 2011). The agency proposed to adopt a definition of materiality under PTO Rule 56 that would mirror “the standard for materiality required to establish inequitable conduct as defined in *Therasense*.” *Ibid.* The PTO’s expectation, noted in the preamble, was that incorporation of the *Therasense* standard into Rule 56 will “reduce the frequency” of inequitable-conduct charges and, in turn, “reduce the incentives” for applicants to submit “only marginally relevant information,” while still ensuring that applicants do not breach the “duty of candor and good faith.” *Ibid.*

The amicus brief for the United States in *Therasense* urged the court to adopt the definition of materiality

reflected in current PTO Rule 56. See U.S. Amicus Br. at 8-12, *Therasense, supra* (No. 08-1511); see also note 3, *supra*. In opposing the use of a “but-for” standard, the brief argued that “if the ‘but for’ standard were to be applied, then applicants would be free to engage in a wide-variety of misconduct, *e.g.*, lying to the agency in an attempt to influence the examiner’s patentability determination, so long as it cannot be proven later that the patent would not have issued ‘but for’ the misconduct.” *Id.* at 13. The brief did not discuss the possibility that a different materiality standard might be used in pure nondisclosure cases than in cases involving affirmative misrepresentations or other affirmative misconduct.

The en banc court, however, distinguished between the two situations. Although the *Therasense* court adopted a “but-for” materiality standard for nondisclosure cases, it explained that “[b]y creating an exception to punish affirmative egregious acts without penalizing the failure to disclose information that would not have changed the issuance decision, this court strikes a necessary balance between encouraging honesty before the PTO and preventing unfounded accusations of inequitable conduct.” 649 F.3d at 1293. The PTO’s subsequent Federal Register preamble acknowledged that the agency had previously rejected a “but-for” standard of materiality in the inequitable-conduct context, but stated that “[t]he affirmative egregious misconduct exception set forth in *Therasense* addresses the [PTO’s] longstanding concern about the types of unscrupulous conduct that could occur unchecked under a pure ‘but-for’ standard.” 76 Fed. Reg. at 43,632. The period for commenting on the proposed rule has expired, but no final rule has been issued.

2. It is also too soon to assess the impact of *Therasense* on patent prosecutions and patent infringement litigation. The standards adopted in *Therasense* have been in place for slightly more than two years, during which the Federal Circuit has applied the specific-intent standard in only a handful of cases. In at least two of those cases, the Federal Circuit affirmed findings of inequitable conduct. See *Aventis Pharma S.A. v. Hospira, Inc.*, 675 F.3d 1324 (2012); *Apotex, Inc. v. Cephalon, Inc.*, 500 Fed. Appx. 959 (2013).<sup>7</sup> In one case, the Federal Circuit remanded in light of *Therasense*, and the district court reaffirmed its inequitable-conduct finding. See *American Calcar*, 2012 WL 1328640, at \*1, \*11. And in three other cases, the Federal Circuit affirmed pre-*Therasense* district court findings of no deceptive intent. See *In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511, 520-522 (2012); *Santarus, Inc. v. Par Pharm., Inc.*, 694 F.3d 1344, 1348-1349 (2012); *Cordis Corp. v. Boston Scientific Corp.*, 658 F.3d 1347, 1360-1361 (2011).

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<sup>7</sup> Contrary to petitioners' contention (Pet. 23-25), *Aventis* did not turn on evidence of "selective disclosure," *i.e.*, evidence that the applicant had submitted some prior art while withholding other material references. That was only one of several factors that led the court of appeals to affirm the district court's finding of deceptive intent. *Aventis*, 675 F.3d at 1335-1337. Nor should the brief discussion of *Aventis* in the decision below, see Pet. App. 15a, 17a, incentivize applicants to disclose no prior art in order to shield themselves from "allegations of selective disclosure," Pet. 23-25. Selective (and strategic) disclosures may well provide compelling evidence of deceptive intent, but there are other ways to demonstrate the requisite state of mind. See, *e.g.*, *Therasense*, 864 F. Supp. 2d at 865-869 (finding deceptive intent in a case that did not involve selective disclosure).

Indeed, since *Therasense*, only one other decision has reversed a district court finding of intent to deceive—and it did so after concluding that the nondisclosure was neither deliberate nor material. See *Outside the Box Innovations, LLC v. Travel Caddy, Inc.*, 695 F.3d 1285, 1291-1292 (Fed. Cir. 2012).<sup>8</sup> That limited set of decisions does not reflect a “rigid” (*e.g.*, Pet. 13, 19, 20) application of the inequitable-conduct standards announced in *Therasense*.

### CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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<sup>8</sup> Other decisions have focused solely on the accused infringer’s failure to prove materiality. See, *e.g.*, *Novo Nordisk A/S v. Caraco Pharm. Labs.*, 719 F.3d 1346, 1357-1359 (Fed. Cir. 2013) (reversing finding of inequitable conduct on materiality grounds); *Powell v. Home Depot U.S.A., Inc.*, 663 F.3d 1221, 1234-1235 (Fed. Cir. 2011) (affirming finding of no inequitable conduct on materiality grounds); *August Tech. Corp. v. Camtek, Ltd.*, 655 F.3d 1278, 1290 (Fed. Cir. 2011) (same).