

**Patent Law and Policy:
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To the Fifth Edition (2011)**

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CHAPTER 8: INFRINGEMENT

F. INDIRECT INFRINGEMENT

Add to page 927, replace the note on “The Intent Required for Inducing Infringement” with the following new case:

GLOBAL–TECH APPLIANCES, INC. v. SEB S.A.

131 S. Ct. 2060 (2011)

Justice ALITO delivered the opinion of the Court.

We consider whether a party who “actively induces infringement of a patent” under 35 U.S.C. § 271(b) must know that the induced acts constitute patent infringement.

I

This case concerns a patent for an innovative deep fryer designed by respondent SEB S.A., a French maker of home appliances. In the late 1980’s, SEB invented a “cool-touch” deep fryer, that is, a deep fryer for home use with external surfaces that remain cool during the frying process. The cool-touch deep fryer consisted of a metal frying pot surrounded by a plastic outer housing. Attached to the housing was a ring that suspended the metal pot and insulated the housing from heat by separating it from the pot, creating air space between the two components. SEB obtained a U.S. patent for its design in 1991, and sometime later, SEB started manufacturing the cool-touch fryer and selling it in this country under its well-known “T–Fal” brand. Superior to other products in the American market at the time, SEB’s fryer was a commercial success.

In 1997, Sunbeam Products, Inc., a U.S. competitor of SEB, asked petitioner Pentalpha Enterprises, Ltd., to supply it with deep fryers meeting certain specifications. Pentalpha is a Hong Kong maker of home appliances and a wholly owned subsidiary of petitioner Global–Tech Appliances, Inc.

In order to develop a deep fryer for Sunbeam, Pentalpha purchased an SEB fryer in Hong Kong and copied all but its cosmetic features. Because the SEB fryer bought in Hong Kong was made for sale in a foreign market, it bore no U.S. patent markings. After copying SEB’s design, Pentalpha retained an attorney to conduct a right-to-use study, but Pentalpha refrained from telling the attorney that its design was copied directly from SEB’s.

The attorney failed to locate SEB’s patent, and in August 1997 he issued an opinion letter stating that Pentalpha’s deep fryer did not infringe any of the patents that he had found. That same month, Pentalpha started selling its deep fryers to Sunbeam, which resold them in the United States under its trademarks. By obtaining its product from a manufacturer with lower production costs, Sunbeam was able to undercut SEB in the U.S. market.

After SEB’s customers started defecting to Sunbeam, SEB sued Sunbeam in March 1998, alleging that Sunbeam’s sales infringed SEB’s patent. Sunbeam notified Pentalpha of the lawsuit the following month. Undeterred, Pentalpha went on to sell deep fryers to Fingerhut Corp. and Montgomery Ward & Co., both of which resold them in the United States under their respective trademarks.

SEB settled the lawsuit with Sunbeam, and then sued Pentalpha, asserting two theories of recovery: First, SEB claimed that Pentalpha had directly infringed SEB's patent in violation of 35 U.S.C. § 271(a), by selling or offering to sell its deep fryers; and second, SEB claimed that Pentalpha had contravened § 271(b) by actively inducing Sunbeam, Fingerhut, and Montgomery Ward to sell or to offer to sell Pentalpha's deep fryers in violation of SEB's patent rights.

Following a 5-day trial, the jury found for SEB on both theories and also found that Pentalpha's infringement had been willful. Pentalpha filed post-trial motions seeking a new trial or judgment as a matter of law on several grounds. As relevant here, Pentalpha argued that there was insufficient evidence to support the jury's finding of induced infringement under § 271(b) because Pentalpha did not actually know of SEB's patent until it received the notice of the Sunbeam lawsuit in April 1998.

The District Court rejected Pentalpha's argument, as did the Court of Appeals for the Federal Circuit, which affirmed the judgment, *SEB S.A. v. Montgomery Ward & Co.*, 594 F.3d 1360 (2010). Summarizing a recent en banc decision, the Federal Circuit stated that induced infringement under § 271(b) requires a "plaintiff [to] show that the alleged infringer knew or should have known that his actions would induce actual infringements" and that this showing includes proof that the alleged infringer knew of the patent. *Id.*, at 1376. Although the record contained no direct evidence that Pentalpha knew of SEB's patent before April 1998, the court found adequate evidence to support a finding that "Pentalpha deliberately disregarded a known risk that SEB had a protective patent." *Id.*, at 1377. Such disregard, the court said, "is not different from actual knowledge, but is a form of actual knowledge." *Ibid.*

We granted certiorari. 562 U.S. ___, 131 S.Ct. 458, 178 L.Ed.2d 286 (2010).

II

Pentalpha argues that active inducement liability under § 271(b) requires more than deliberate indifference to a known risk that the induced acts may violate an existing patent. Instead, Pentalpha maintains, actual knowledge of the patent is needed.

A

In assessing Pentalpha's argument, we begin with the text of § 271(b)—which is short, simple, and, with respect to the question presented in this case, inconclusive. Section 271(b) states: "Whoever actively induces infringement of a patent shall be liable as an infringer."

Although the text of § 271(b) makes no mention of intent, we infer that at least some intent is required. The term "induce" means "[t]o lead on; to influence; to prevail on; to move by persuasion or influence." Webster's New International Dictionary 1269 (2d ed.1945). The addition of the adverb "actively" suggests that the inducement must involve the taking of affirmative steps to bring about the desired result, see *id.*, at 27.

When a person actively induces another to take some action, the inducer obviously knows the action that he or she wishes to bring about. If a used car salesman induces a customer to buy a car, the salesman knows that the desired result is the purchase of the

car. But what if it is said that the salesman induced the customer to buy a *damaged* car? Does this mean merely that the salesman induced the customer to purchase a car that happened to be damaged, a fact of which the salesman may have been unaware? Or does this mean that the salesman knew that the car was damaged? The statement that the salesman induced the customer to buy a damaged car is ambiguous.

So is § 271(b). In referring to a party that “induces infringement,” this provision may require merely that the inducer lead another to engage in conduct that happens to amount to infringement, *i.e.*, the making, using, offering to sell, selling, or importing of a patented invention. See § 271(a). On the other hand, the reference to a party that “induces infringement” may also be read to mean that the inducer must persuade another to engage in conduct that the inducer knows is infringement. Both readings are possible.

B

Finding no definitive answer in the statutory text, we turn to the case law that predates the enactment of § 271 as part the Patent Act of 1952. As we recognized in *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 377 U.S. 476 (1964) (*Aro II*), “[t]he section was designed to ‘codify in statutory form principles of contributory infringement’ which had been ‘part of our law for about 80 years.’” *Id.*, at 485–486, n. 6 (quoting H.R.Rep. No. 1923, 82d Cong., 2d Sess., 9 (1952)).

Unfortunately, the relevant pre-1952 cases are less clear than one might hope with respect to the question presented here. Before 1952, both the conduct now covered by § 271(b) (induced infringement) and the conduct now addressed by § 271(c) (sale of a component of a patented invention) were viewed as falling within the overarching concept of “contributory infringement.” Cases in the latter category—*i.e.*, cases in which a party sold an item that was not itself covered by the claims of a patent but that enabled another party to make or use a patented machine, process, or combination—were more common.

The pre-1952 case law provides conflicting signals regarding the intent needed in such cases. In an oft-cited decision, then-Judge Taft suggested that it was sufficient if the seller of the component part intended that the part be used in an invention that happened to infringe a patent. He wrote that it was “well settled that where one makes and sells one element of a combination covered by a patent with the intention and for the purpose of bringing about its use in such a combination he is guilty of contributory infringement.” *Thomson–Houston Elec. Co. v. Ohio Brass Co.*, 80 F. 712, 721 (C.A.6 1897).

On the other hand, this Court, in *Henry v. A.B. Dick Co.*, 224 U.S. 1, 32 S.Ct. 364, 56 L.Ed. 645 (1912), overruled on other grounds, *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502 (1917), stated that “if the defendants [who were accused of contributory infringement] *knew of the patent* and that [the direct infringer] had unlawfully made the patented article ... with the intent and purpose that [the direct infringer] should use the infringing article ... they would assist in her infringing use.” 224 U.S., at 33 (emphasis added and deleted). Our decision in *Metro–Goldwyn–Mayer Studios Inc. v. Grokster, Ltd.*, 545 U.S. 913 (2005), which looked to the law of

contributory patent infringement for guidance in determining the standard to be applied in a case claiming contributory copyright infringement, contains dicta that may be read as interpreting the pre-1952 cases this way. In *Grokster*, we said that “[t]he inducement rule ... premises liability on purposeful, culpable expression and conduct.” *Id.*, at 937.

While both the language of § 271(b) and the pre-1952 case law that this provision was meant to codify are susceptible to conflicting interpretations, our decision in *Aro II* resolves the question in this case. In *Aro II*, a majority held that a violator of § 271(c) must know “that the combination for which his component was especially designed was both patented and infringing,” 377 U.S., at 488, and as we explain below, that conclusion compels this same knowledge for liability under § 271(b).

C

As noted above, induced infringement was not considered a separate theory of indirect liability in the pre-1952 case law. Rather, it was treated as evidence of “contributory infringement,” that is, the aiding and abetting of direct infringement by another party. See Lemley, *Inducing Patent Infringement*, 39 U.C.D.L.Rev. 225, 227 (2005). When Congress enacted § 271, it separated what had previously been regarded as contributory infringement into two categories, one covered by § 271(b) and the other covered by § 271(c).

Aro II concerned § 271(c), which states in relevant part:

“Whoever offers to sell or sells ... a component of a patented [invention] ..., constituting a material part of the invention, *knowing the same to be especially made or especially adapted for use in an infringement* of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer.” (Emphasis added.)

This language contains exactly the same ambiguity as § 271(b). The phrase “knowing [a component] to be especially made or especially adapted for use in an infringement” may be read to mean that a violator must know that the component is “especially adapted for use” in a product that happens to infringe a patent. Or the phrase may be read to require, in addition, knowledge of the patent’s existence.

This question closely divided the *Aro II* Court. In a badly fractured decision, a majority concluded that knowledge of the patent was needed. 377 U.S., at 488, and n. 8; *id.*, at 514 (White, J., concurring); *id.*, at 524–527 (Black, J., dissenting). Justice Black’s opinion, which explained the basis for the majority’s view, concluded that the language of § 271(c) supported this interpretation. See *id.*, at 525, 84 S.Ct. 1526. His opinion also relied on an amendment to this language that was adopted when the bill was in committee. *Id.*, at 525–527.

Four Justices disagreed with this interpretation and would have held that a violator of § 271(c) need know only that the component is specially adapted for use in a product that happens to infringe a patent. See *id.*, at 488–490, n. 8, 84 S.Ct. 1526. These Justices thought that this reading was supported by the language of § 271(c) and the pre-1952

case law, and they disagreed with the inference drawn by the majority from the amendment of § 271(c)'s language. *Ibid.*

While there is much to be said in favor of both views expressed in *Aro II*, the “holding in *Aro II* has become a fixture in the law of contributory infringement under [section] 271(c),” 5 R. Moy, Walker on Patents § 15:20, p. 15–131 (4th ed.2009)—so much so that SEB has not asked us to overrule it, see Brief for Respondent 19, n. 3. Nor has Congress seen fit to alter § 271(c)'s intent requirement in the nearly half a century since *Aro II* was decided. In light of the “ ‘special force’ “ of the doctrine of *stare decisis* with regard to questions of statutory interpretation, see *John R. Sand & Gravel Co. v. United States*, 552 U.S. 130, 139 (2008), we proceed on the premise that § 271(c) requires knowledge of the existence of the patent that is infringed.

Based on this premise, it follows that the same knowledge is needed for induced infringement under § 271(b). As noted, the two provisions have a common origin in the pre-1952 understanding of contributory infringement, and the language of the two provisions creates the same difficult interpretive choice. It would thus be strange to hold that knowledge of the relevant patent is needed under § 271(c) but not under § 271(b).

Accordingly, we now hold that induced infringement under § 271(b) requires knowledge that the induced acts constitute patent infringement.

III

Returning to Pentalpha's principal challenge, we agree that deliberate indifference to a known risk that a patent exists is not the appropriate standard under § 271(b). We nevertheless affirm the judgment of the Court of Appeals because the evidence in this case was plainly sufficient to support a finding of Pentalpha's knowledge under the doctrine of willful blindness.

A

The doctrine of willful blindness is well established in criminal law. Many criminal statutes require proof that a defendant acted knowingly or willfully, and courts applying the doctrine of willful blindness hold that defendants cannot escape the reach of these statutes by deliberately shielding themselves from clear evidence of critical facts that are strongly suggested by the circumstances. The traditional rationale for this doctrine is that defendants who behave in this manner are just as culpable as those who have actual knowledge. Edwards, *The Criminal Degrees of Knowledge*, 17 Mod. L.Rev. 294, 302 (1954) (hereinafter Edwards) (observing on the basis of English authorities that “up to the present day, no real doubt has been cast on the proposition that [willful blindness] is as culpable as actual knowledge”). It is also said that persons who know enough to blind themselves to direct proof of critical facts in effect have actual knowledge of those facts. See *United States v. Jewell*, 532 F.2d 697, 700 (C.A.9 1976) (en banc).

This Court's opinion more than a century ago in *Spurr v. United States*, 174 U.S. 728 (1899), while not using the term “willful blindness,” endorsed a similar concept. The case involved a criminal statute that prohibited a bank officer from “willfully” certifying a check drawn against insufficient funds. We said that a willful violation would occur “if

the [bank] officer purposely keeps himself in ignorance of whether the drawer has money in the bank.” *Id.*, at 735. Following our decision in *Spurr*, several federal prosecutions in the first half of the 20th century invoked the doctrine of willful blindness. Later, a 1962 proposed draft of the Model Penal Code, which has since become official, attempted to incorporate the doctrine by defining “knowledge of the existence of a particular fact” to include a situation in which “a person is aware of a high probability of [the fact’s] existence, unless he actually believes that it does not exist.” ALI, Model Penal Code § 2.02(7) (Proposed Official Draft 1962). Our Court has used the Code’s definition as a guide in analyzing whether certain statutory presumptions of knowledge comported with due process. See *Turner v. United States*, 396 U.S. 398, 416–417 (1970); *Leary v. United States*, 395 U.S. 6, 46–47, and n. 93 (1969). And every Court of Appeals—with the possible exception of the District of Columbia Circuit, see n. 9, *infra*—has fully embraced willful blindness, applying the doctrine to a wide range of criminal statutes.

Given the long history of willful blindness and its wide acceptance in the Federal Judiciary, we can see no reason why the doctrine should not apply in civil lawsuits for induced patent infringement under 35 U.S.C. § 271(b).

Pentalpha urges us not to take this step, arguing that § 271(b) demands more than willful blindness with respect to *the induced acts* that constitute infringement. See Reply Brief for Petitioners 13–14. This question, however, is not at issue here. There is no need to invoke the doctrine of willful blindness to establish that Pentalpha knew that the retailers who purchased its fryer were selling that product in the American market; Pentalpha was indisputably aware that its customers were selling its product in this country.

Pentalpha further contends that this Court in *Grokster* did not accept the Solicitor General’s suggestion that Grokster and StreamCast could be held liable for inducing the infringement of copyrights under a theory of willful blindness. Reply Brief for Petitioners 14 (citing Brief for United States, O.T.2004, No. 04–480, pp. 29–30). But the Court had no need to consider the doctrine of willful blindness in that case because the Court found ample evidence that Grokster and StreamCast were fully aware—in the ordinary sense of the term—that their file-sharing software was routinely used in carrying out the acts that constituted infringement (the unauthorized sharing of copyrighted works) and that these acts violated the rights of copyright holders. See 545 U.S., at 922–927, 937–940, 125 S.Ct. 2764.

B

While the Courts of Appeals articulate the doctrine of willful blindness in slightly different ways, all appear to agree on two basic requirements: (1) the defendant must subjectively believe that there is a high probability that a fact exists and (2) the defendant must take deliberate actions to avoid learning of that fact. We think these requirements give willful blindness an appropriately limited scope that surpasses recklessness and negligence. Under this formulation, a willfully blind defendant is one who takes deliberate actions to avoid confirming a high probability of wrongdoing and who can almost be said to have actually known the critical facts. See G. Williams, *Criminal Law* § 57, p. 159 (2d ed. 1961) (“A court can properly find willful blindness only where it can

almost be said that the defendant actually knew”). By contrast, a reckless defendant is one who merely knows of a substantial and unjustified risk of such wrongdoing, see ALI, Model Penal Code § 2.02(2)(c) (1985), and a negligent defendant is one who should have known of a similar risk but, in fact, did not, see § 2.02(2)(d).

The test applied by the Federal Circuit in this case departs from the proper willful blindness standard in two important respects. First, it permits a finding of knowledge when there is merely a “known risk” that the induced acts are infringing. Second, in demanding only “deliberate indifference” to that risk, the Federal Circuit’s test does not require active efforts by an inducer to avoid knowing about the infringing nature of the activities.

In spite of these flaws, we believe that the evidence when viewed in the light most favorable to the verdict for SEB is sufficient under the correct standard. The jury could have easily found that before April 1998 Pentalpha willfully blinded itself to the infringing nature of the sales it encouraged Sunbeam to make.

SEB’s cool-touch fryer was an innovation in the U.S. market when Pentalpha copied it. App. to Brief for Respondent 49. As one would expect with any superior product, sales of SEB’s fryer had been growing for some time. *Ibid.* Pentalpha knew all of this, for its CEO and president, John Sham, testified that, in developing a product for Sunbeam, Pentalpha performed “market research” and “gather[ed] information as much as possible.” App. 23a. Pentalpha’s belief that SEB’s fryer embodied advanced technology that would be valuable in the U.S. market is evidenced by its decision to copy all but the cosmetic features of SEB’s fryer.

Also revealing is Pentalpha’s decision to copy an overseas model of SEB’s fryer. Pentalpha knew that the product it was designing was for the U.S. market, and Sham—himself a named inventor on numerous U.S. patents, see *id.*, at 78a–86a—was well aware that products made for overseas markets usually do not bear U.S. patent markings, App. in No.2009–1099 etc. (CA Fed.), pp. A–1904 to A–1906. Even more telling is Sham’s decision not to inform the attorney from whom Pentalpha sought a right-to-use opinion that the product to be evaluated was simply a knockoff of SEB’s deep fryer. On the facts of this case, we cannot fathom what motive Sham could have had for withholding this information other than to manufacture a claim of plausible deniability in the event that his company was later accused of patent infringement. Nor does Sham’s testimony on this subject provide any reason to doubt that inference. Asked whether the attorney would have fared better had he known of SEB’s design, Sham was nonresponsive. All he could say was that a patent search is not an “easy job” and that is why he hired attorneys to perform them. App. 112a.

Taken together, this evidence was more than sufficient for a jury to find that Pentalpha subjectively believed there was a high probability that SEB’s fryer was patented, that Pentalpha took deliberate steps to avoid knowing that fact, and that it therefore willfully blinded itself to the infringing nature of Sunbeam’s sales.

The judgment of the United States Court of Appeals for the Federal Circuit is
Affirmed.

Justice KENNEDY, dissenting.

The Court is correct, in my view, to conclude that 35 U.S.C. § 271(b) must be read in tandem with § 271(c), and therefore that to induce infringement a defendant must know “the induced acts constitute patent infringement.” *Ante*, at 2068.

Yet the Court does more. Having interpreted the statute to require a showing of knowledge, the Court holds that willful blindness will suffice. This is a mistaken step. Willful blindness is not knowledge; and judges should not broaden a legislative proscription by analogy. See *United States v. Jewell*, 532 F.2d 697, 706 (C.A.9 1976) (en banc) (Kennedy, J., dissenting) (“When a statute specifically requires knowledge as an element of a crime, however, the substitution of some other state of mind cannot be justified even if the court deems that both are equally blameworthy”) In my respectful submission, the Court is incorrect in the definition it now adopts; but even on its own terms the Court should remand to the Court of Appeals to consider in the first instance whether there is sufficient evidence of knowledge to support the jury’s finding of inducement.

The Court invokes willful blindness to bring those who lack knowledge within § 271(b)’s prohibition. Husak & Callender, *Willful Ignorance, Knowledge, and the “Equal Culpability” Thesis: A Study of the Deeper Significance of the Principle of Legality*, 1994 Wis. L.Rev. 29, 35; see also L. Alexander & K. Ferzan, *Crime and Culpability: A Theory of Criminal Law* 34–35 (2009) (cautioning against the temptation to “distort” cases of willful blindness “into cases of knowledge”); G. Williams, *Criminal Law: The General Part* § 57, p. 157 (2d ed.1961). The Court’s definition of willful blindness reveals this basic purpose. One can believe that there is a “high probability” that acts might infringe a patent but nonetheless conclude they do not infringe. *Ante*, at 2070; see also *ibid.* (describing a willfully blind defendant as one “who can almost be said to have actually known the critical facts”). The alleged inducer who believes a device is noninfringing cannot be said to know otherwise.

The Court justifies its substitution of willful blindness for the statutory knowledge requirement in two ways, neither of which is convincing.

First, the Court appeals to moral theory by citing the “traditional rationale” that willfully blind defendants “are just as culpable as those who have actual knowledge.” *Ante*, at 2063. But the moral question is a difficult one. Is it true that the lawyer who knowingly suborns perjury is no more culpable than the lawyer who avoids learning that his client, a criminal defendant, lies when he testifies that he was not the shooter? See Hellman, *Willfully Blind for Good Reason*, 3 *Crim. L. & Philosophy* 301, 305–308 (2009); Luban, *Contrived Ignorance*, 87 *Geo. L.J.* 957 (1999). The answer is not obvious. Perhaps the culpability of willful blindness depends on a person’s reasons for remaining blind. *E.g.*, *ibid.* Or perhaps only the person’s justification for his conduct is relevant. *E.g.*, Alexander & Ferzan, *supra*, at 23–68. This is a question of morality and of policy best left to the political branches. Even if one were to accept the substitution of equally blameworthy mental states in criminal cases in light of the retributive purposes of the criminal law, those purposes have no force in the domain of patent law that controls

in this case. The Constitution confirms that the purpose of the patent law is a utilitarian one, to “promote the Progress of Science and useful Arts,” Art. I, § 8, cl. 8.

Second, the Court appeals to precedent, noting that a “similar concept” to willful blindness appears in this Court’s cases as early as 1899. *Ante*, at 2069. But this Court has never before held that willful blindness can substitute for a statutory requirement of knowledge. *Spurr v. United States*, 174 U.S. 728, 735, 19 S.Ct. 812, 43 L.Ed. 1150 (1899), explained that “evil design may be presumed if the [bank] officer purposefully keeps himself in ignorance of whether the drawer has money in the bank or not, or is grossly indifferent to his duty in respect to the ascertainment of that fact.” The question in *Spurr* was whether the defendant’s admitted violation was willful, and with this sentence the Court simply explained that wrongful intent may be inferred from the circumstances. It did not suggest that blindness can substitute for knowledge. Neither did *Turner v. United States*, 396 U.S. 398, 90 S.Ct. 642, 24 L.Ed.2d 610 (1970), or *Leary v. United States*, 395 U.S. 6, 89 S.Ct. 1532, 23 L.Ed.2d 57 (1969). As the Court here explains, both cases held only that certain statutory presumptions of knowledge were consistent with due process. *Ante*, at 2069 – 2070. And although most Courts of Appeals have embraced willful blindness, counting courts in a circuit split is not this Court’s usual method for deciding important questions of law.

The Court appears to endorse the willful blindness doctrine here for all federal criminal cases involving knowledge. It does so in a civil case where it has received no briefing or argument from the criminal defense bar, which might have provided important counsel on this difficult issue.

There is no need to invoke willful blindness for the first time in this case. Facts that support willful blindness are often probative of actual knowledge. Circumstantial facts like these tend to be the only available evidence in any event, for the jury lacks direct access to the defendant’s mind. The jury must often infer knowledge from conduct, and attempts to eliminate evidence of knowledge may justify such inference, as where an accused inducer avoids further confirming what he already believes with good reason to be true. The majority’s decision to expand the statute’s scope appears to depend on the unstated premise that knowledge requires certainty, but the law often permits probabilistic judgments to count as knowledge. Cf. *Connecticut Mut. Life Ins. Co. v. Lathrop*, 111 U.S. 612, 620, 4 S.Ct. 533, 28 L.Ed. 536 (1884) (Harlan, J.) (“[B]eing founded on actual observation, and being consistent with common experience and the ordinary manifestations of the condition of the mind, it is knowledge, so far as the human intellect can acquire knowledge, upon such subjects”).

The instant dispute provides a case in point. Pentalpha copied an innovative fryer. The model it copied bore no U.S. patent markings, but that could not have been a surprise, for Pentalpha knew that a fryer purchased in Hong Kong was unlikely to bear such markings. And Pentalpha failed to tell the lawyer who ran a patent search that it copied the SEB fryer. These facts may suggest knowledge that Pentalpha’s fryers were infringing, and perhaps a jury could so find.

But examining the sufficiency of the evidence presented in the 5–day trial requires careful review of an extensive record. The trial transcript alone spans over 1,000 pages. If

willful blindness is as close to knowledge and as far from the “knew or should have known” jury instruction provided in this case as the Court suggests, then reviewing the record becomes all the more difficult. I would leave that task to the Court of Appeals in the first instance on remand.

For these reasons, and with respect, I dissent.

NOTES ON *GLOBAL-TECH*

1. Willful Blindness as a Substitute for Actual Knowledge: Perhaps, some would say, willful blindness and actual knowledge are equally blameworthy mental states in the criminal context. Criminal law’s retributive purpose justifies substituting one for the other. But patent law has a utilitarian purpose—incentivizing innovation. Justice Kennedy made this distinction in dissent. Do you think the majority willfully blinded itself to this distinction between the purposes of criminal and civil law in general, and patent law in particular? Or do you think they got it right? Was Justice Kennedy overstating the ramifications of deciding this case without hearing from the criminal bar?

2. Strict Liability? The majority opinion notes that, prior to the codification of § 271 in 1952, the courts had given mixed signals about whether contributory infringement required any degree of knowledge that the defendant’s acts constituted infringement. Patent infringement itself requires only that the defendant have undertaken certain acts (perhaps intentionally undertaken those acts) where the acts do constitute infringement (whether or not the defendant knew that they did). Why a different rule for contributory infringement? The Court dodges this issue by relying on its prior decision in *Aro II*, which held that, where liability is sought under § 271(c), the defendant must know “that the combination for which his component was especially designed was both patented and infringing.” 377 U.S. at 488. The Court thought *Aro II*’s conclusion *compels* this same knowledge for liability under § 271(b)? Is that correct? Do subsections (b) and (c) have identical language? Is (b)’s language closer to (a) or to (c)?

3. Right-to-use opinions: A right-to-use opinion is also known as a clearance or freedom-to-operate (FTO) opinion. Such opinions direct companies to the available whitespace between patent thickets. This information can sometimes result in the abandonment of a company’s own patent applications or product lines. Alternatively, companies could initiate licensing agreements with the patentee. A third option, perhaps most desirable from a social welfare standpoint, would involve companies channeling their energies directly into the whitespace revealed by the FTO, or spending resources in “design around” innovation—an important species of inventive activity.

4. And what about the lawyer? If the lawyer had been told about the SEB fryers—a what would his very first research step have been? The Court could not conceive of any reason why Sham did not tell the lawyer about the SEB fryer, other than an effort to manufacture a plausible claim of deniability. Can you?

CHAPTER 10: THE LEGAL PROCESS OF THE PATENT SYSTEM**A.6. PRESUMPTION OF VALIDITY AND COURT REVIEW.**

On page 1080, after the existing note, insert the following case:

MICROSOFT CORP. v. i4i LTD. PARTNERSHIP

131 S. Ct. 2238 (2011)

Justice SOTOMAYOR delivered the opinion of the Court.

Under § 282 of the Patent Act of 1952, “[a] patent shall be presumed valid” and “[t]he burden of establishing in-validity of a patent or any claim thereof shall rest on the party asserting such invalidity.” 35 U.S.C. § 282. We consider whether § 282 requires an invalidity defense to be proved by clear and convincing evidence. We hold that it does.

I

A

Pursuant to its authority under the Patent Clause, U.S. Const., Art. I, § 8, cl. 8, Congress has charged the United States Patent and Trademark Office (PTO) with the task of examining patent applications, 35 U.S.C. § 2(a)(1), and issuing patents if “it appears that the applicant is entitled to a patent under the law,” § 131. Congress has set forth the prerequisites for issuance of a patent, which the PTO must evaluate in the examination process. To receive patent protection a claimed invention must, among other things, fall within one of the express categories of patentable subject matter, § 101, and be novel, § 102, and nonobvious, § 103. Most relevant here, the on-sale bar of § 102(b) precludes patent protection for any “invention” that was “on sale in this country” more than one year prior to the filing of a patent application. See generally *Pfaff v. Wells Electronics, Inc.*, 525 U.S. 55, 67–68 (1998). In evaluating whether these and other statutory conditions have been met, PTO examiners must make various factual determinations—for instance, the state of the prior art in the field and the nature of the advancement embodied in the invention. See *Dickinson v. Zurko*, 527 U.S. 150, 153 (1999).

Once issued, a patent grants certain exclusive rights to its holder, including the exclusive right to use the invention during the patent’s duration. To enforce that right, a patentee can bring a civil action for infringement if another person “without authority makes, uses, offers to sell, or sells any patented invention, within the United States.” § 271(a); see also § 281.

Among other defenses under § 282 of the Patent Act of 1952 (1952 Act), an alleged infringer may assert the invalidity of the patent—that is, he may attempt to prove that the patent never should have issued in the first place. See §§ 282(2), (3). A defendant may argue, for instance, that the claimed invention was obvious at the time and thus that one of the conditions of patentability was lacking. See § 282(2); see also § 103. “While the ultimate question of patent validity is one of law,” *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17, 86 S.Ct. 684, 15 L.Ed.2d 545 (1966) (citing *Great Atlantic & Pacific Tea Co. v. Supermarket Equipment Corp.*, 340 U.S. 147, 155, 71 S.Ct. 127, 95 L.Ed. 162 (1950) (Douglas, J., concurring)); see *post*, at 2253 (BREYER, J., concurring),

the same factual questions underlying the PTO's original examination of a patent application will also bear on an invalidity defense in an infringement action. See, e.g., 383 U.S., at 17, 86 S.Ct. 684 (describing the "basic factual inquiries" that form the "background" for evaluating obviousness); *Pfaff*, 525 U.S., at 67–69, 119 S.Ct. 304 (same, as to the on-sale bar).

In asserting an invalidity defense, an alleged infringer must contend with the first paragraph of § 282, which provides that "[a] patent shall be presumed valid" and "[t]he burden of establishing invalidity ... rest[s] on the party asserting such invalidity." Under the Federal Circuit's reading of § 282, a defendant seeking to overcome this presumption must persuade the factfinder of its in-validity defense by clear and convincing evidence. Judge Rich, a principal drafter of the 1952 Act, articulated this view for the court in *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350 (C.A.Fed.1984). There, the Federal Circuit held that § 282 codified "the existing presumption of validity of patents," *id.*, at 1359 (internal quotation marks omitted)—what, until that point, had been a common-law presumption based on "the basic proposition that a government agency such as the [PTO] was presumed to do its job," *ibid.* Relying on this Court's pre-1952 precedent as to the "force of the presumption," *ibid.* (citing *Radio Corp. of America v. Radio Engineering Laboratories, Inc.*, 293 U.S. 1, 55 S.Ct. 928, 79 L.Ed. 163 (1934) (*RCA*)), Judge Rich concluded:

"[Section] 282 creates a presumption that a patent is valid and imposes the burden of proving invalidity on the attacker. That burden is constant and never changes and is to convince the court of invalidity by clear evidence." 725 F.2d, at 1360.

In the nearly 30 years since *American Hoist*, the Federal Circuit has never wavered in this interpretation of § 282. See, e.g., *Greenwood v. Hattori Seiko Co.*, 900 F.2d 238, 240–241 (C.A.Fed.1990); *Ultra-Tex Surfaces, Inc. v. Hill Bros. Chemical Co.*, 204 F.3d 1360, 1367 (C.A.Fed.2000); *ALZA Corp. v. Andrx Pharmaceuticals, LLC*, 603 F.3d 935, 940 (C.A.Fed.2010).

B

Respondents i4i Limited Partnership and Infrastructures for Information Inc. (collectively, i4i) hold the patent at issue in this suit. The i4i patent claims an improved method for editing computer documents, which stores a document's content separately from the metacodes associated with the document's structure. In 2007, i4i sued petitioner Microsoft Corporation for willful infringement, claiming that Microsoft's manufacture and sale of certain Microsoft Word products infringed i4i's patent. In addition to denying infringement, Microsoft counterclaimed and sought a declaration that i4i's patent was invalid and unenforceable.

Specifically and as relevant here, Microsoft claimed that the on-sale bar of § 102(b) rendered the patent invalid, pointing to i4i's prior sale of a software program known as S4. The parties agreed that, more than one year prior to the filing of the i4i patent application, i4i had sold S4 in the United States. They presented opposing arguments to the jury, however, as to whether that software embodied the invention claimed in i4i's

patent. Because the software's source code had been destroyed years before the commencement of this litigation, the factual dispute turned largely on trial testimony by S4's two inventors—also the named inventors on the i4i patent—both of whom testified that S4 did not practice the key invention disclosed in the patent.

Relying on the undisputed fact that the S4 software was never presented to the PTO examiner, Microsoft objected to i4i's proposed instruction that it was required to prove its invalidity defense by clear and convincing evidence. Instead, "if an instruction on the 'clear and convincing' burden were [to be] given," App. 124a, n. 8, Microsoft requested the following:

" 'Microsoft's burden of proving invalidity and unenforceability is by clear and convincing evidence. However, Microsoft's burden of proof with regard to its defense of invalidity based on prior art that the examiner did not review during the prosecution of the patent-in-suit is by preponderance of the evidence.' " *Ibid.*

Rejecting the hybrid standard of proof that Microsoft advocated, the District Court instructed the jury that "Microsoft has the burden of proving invalidity by clear and convincing evidence." App. to Pet. for Cert. 195a.

The jury found that Microsoft willfully infringed the i4i patent and that Microsoft failed to prove invalidity due to the on-sale bar or otherwise. Denying Microsoft's post-trial motions, the District Court rejected Microsoft's contention that the court improperly instructed the jury on the standard of proof. The Court of Appeals for the Federal Circuit affirmed. 598 F.3d 831, 848 (2010). Relying on its settled interpretation of § 282, the court explained that it could "discern [no] error" in the jury instruction requiring Microsoft to prove its invalidity defense by clear and convincing evidence. *Ibid.* We granted certiorari. 562 U.S. —, 131 S.Ct. 647, 178 L.Ed.2d 476 (2010).

II

According to Microsoft, a defendant in an infringement action need only persuade the jury of an invalidity defense by a preponderance of the evidence. In the alternative, Microsoft insists that a preponderance standard must apply at least when an invalidity defense rests on evidence that was never considered by the PTO in the examination process. We reject both contentions.

A

Where Congress has prescribed the governing standard of proof, its choice controls absent "countervailing constitutional constraints." *Steadman v. SEC*, 450 U.S. 91, 95, 101 S.Ct. 999, 67 L.Ed.2d 69 (1981). The question, then, is whether Congress has made such a choice here.

As stated, the first paragraph of § 282 provides that "[a] patent shall be presumed valid" and "[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." Thus, by its express terms, § 282 establishes a presumption of patent validity, and it provides that a challenger must overcome that presumption to prevail on an invalidity defense. But, while the statute explicitly specifies the burden of proof, it includes no express articulation of the standard of proof.

Our statutory inquiry, however, cannot simply end there. We begin, of course, with “the assumption that the ordinary meaning of the language” chosen by Congress “accurately expresses the legislative purpose.” *Engine Mfrs. Assn. v. South Coast Air Quality Management Dist.*, 541 U.S. 246, 252, 124 S.Ct. 1756, 158 L.Ed.2d 529 (2004) (internal quotation marks omitted). But where Congress uses a common-law term in a statute, we assume the “term ... comes with a common law meaning, absent anything pointing another way.” *Safeco Ins. Co. of America v. Burr*, 551 U.S. 47, 58, 127 S.Ct. 2201, 167 L.Ed.2d 1045 (2007) (citing *Beck v. Prupis*, 529 U.S. 494, 500–501, 120 S.Ct. 1608, 146 L.Ed.2d 561 (2000)). Here, by stating that a patent is “presumed valid,” § 282, Congress used a term with a settled meaning in the common law.

Our decision in *RCA*, 293 U.S. 1, 55 S.Ct. 928, 79 L.Ed. 163, is authoritative. There, tracing nearly a century of case law from this Court and others, Justice Cardozo wrote for a unanimous Court that “there is a presumption of validity, a presumption not to be overthrown except by clear and cogent evidence.” *Id.*, at 2, 55 S.Ct. 928. Although the “force” of the presumption found “varying expression” in this Court and elsewhere, *id.*, at 7, 55 S.Ct. 928, Justice Cardozo explained, one “common core of thought and truth” unified the decisions:

“[O]ne otherwise an infringer who assails the validity of a patent fair upon its face bears a heavy burden of persuasion, and fails unless his evidence has more than a dubious preponderance. If that is true where the assailant connects himself in some way with the title of the true inventor, it is so *a fortiori* where he is a stranger to the invention, without claim of title of his own. If it is true where the assailant launches his attack with evidence different, at least in form, from any theretofore produced in opposition to the patent, it is so a bit more clearly where the evidence is even verbally the same.” *Id.*, at 8, 55 S.Ct. 928 (internal citation omitted).

The common-law presumption, in other words, reflected the universal understanding that a preponderance standard of proof was too “dubious” a basis to deem a patent invalid. *Ibid.*; see also *id.*, at 7, 55 S.Ct. 928 (“[A] patent ... is presumed to be valid until the presumption has been overcome by convincing evidence of error”).

Thus, by the time Congress enacted § 282 and declared that a patent is “presumed valid,” the presumption of patent validity had long been a fixture of the common law. According to its settled meaning, a defendant raising an invalidity defense bore “a heavy burden of persuasion,” requiring proof of the defense by clear and convincing evidence. *Id.*, at 8, 55 S.Ct. 928. That is, the presumption encompassed not only an allocation of the burden of proof but also an imposition of a heightened standard of proof. Under the general rule that a common-law term comes with its common-law meaning, we cannot conclude that Congress intended to “drop” the heightened standard proof from the presumption simply because § 282 fails to reiterate it expressly. *Neder v. United States*, 527 U.S. 1, 23, 119 S.Ct. 1827, 144 L.Ed.2d 35 (1999); see also *id.*, at 21, 119 S.Ct. 1827 (“ ‘Where Congress uses terms that have accumulated settled meaning under ... the common law, [we] must infer, unless the statute otherwise dictates, that Congress means to incorporate the established meaning of those terms.’ ” (quoting *Nationwide Mut. Ins. Co. v. Darden*, 503 U.S. 318, 322, 112 S.Ct. 1344, 117 L.Ed.2d 581 (1992))); *Standard*

Oil Co. of N.J. v. United States, 221 U.S. 1, 59, 31 S.Ct. 502, 55 L.Ed. 619 (1911) (“[W]here words are employed in a statute which had at the time a well-known meaning at common law or in the law of this country they are presumed to have been used in that sense ...”). “On the contrary, we must *presume* that Congress intended to incorporate” the heightened standard of proof, “unless the statute otherwise dictates.” *Neder*, 527 U.S., at 23, 119 S.Ct. 1827 (internal quotation marks omitted).

We recognize that it may be unusual to treat a presumption as alone establishing the governing standard of proof. See, e.g., J. Thayer, *Preliminary Treatise on Evidence at the Common Law* 336–337 (1898) (hereinafter Thayer) (“When ... we read that the contrary of any particular presumption must be proved beyond a reasonable doubt, ... it is to be recognized that we have something superadded to the rule of presumption, namely, another rule as to the amount of evidence which is needed to overcome the presumption”). But given how judges, including Justice Cardozo, repeatedly understood and explained the presumption of patent validity, we cannot accept Microsoft’s argument that Congress used the words “presumed valid” to adopt only a procedural device for “shifting the burden of production,” or for “shifting both the burden of production and the burden of persuasion.” Brief for Petitioner 21–22 (emphasis deleted). Whatever the significance of a presumption in the abstract, basic principles of statutory construction require us to assume that Congress meant to incorporate “the cluster of ideas” attached to the common-law term it adopted. *Beck*, 529 U.S., at 501 (internal quotation marks omitted). And *RCA* leaves no doubt that attached to the common-law presumption of patent validity was an expression as to its “force,” 293 U.S., at 7— that is, the standard of proof required to overcome it.

Resisting the conclusion that Congress adopted the heightened standard of proof reflected in our pre–1952 cases, Microsoft contends that those cases applied a clear-and-convincing standard of proof only in two limited circumstances, not in every case involving an invalidity defense. First, according to Microsoft, the heightened standard of proof applied in cases “involving oral testimony of prior invention,” simply to account for the unreliability of such testimony. Brief for Petitioner 25. Second, Microsoft tells us, the heightened standard of proof applied to “invalidity challenges based on priority of invention,” where that issue had previously been litigated between the parties in PTO proceedings. *Id.*, at 28.

Squint as we may, we fail to see the qualifications that Microsoft purports to identify in our cases. They certainly make no appearance in *RCA*’s explanation of the presumption of patent validity. *RCA* simply said, without qualification, “that one otherwise an infringer who assails the validity of a patent fair upon its face bears a heavy burden of persuasion, and fails unless his evidence has more than a dubious preponderance.” 293 U.S., at 8; see also *id.*, at 7 (“A patent regularly issued, *and even more obviously* a patent issued after a hearing of all the rival claimants, is presumed to be valid until the presumption has been overcome by convincing evidence of error” (emphasis added)). Nor do they appear in any of our cases as express limitations on the application of the heightened standard of proof. Cf., e.g., *Smith v. Hall*, 301 U.S. 216, 233 (1937) (citing *RCA* for the proposition that a “heavy burden of persuasion ... rests upon one who seeks to negative novelty in a patent by showing prior use”); *Mumm v. Jacob E.*

Decker & Sons, 301 U.S. 168, 171 (1937) (“Not only is the burden to make good this defense upon the party setting it up, but his burden is a heavy one, as it has been held that every reasonable doubt should be resolved against him” (internal quotation marks omitted)). In fact, Microsoft itself admits that our cases “could be read as announcing a heightened standard applicable to all invalidity assertions.” Brief for Petitioner 30 (emphasis deleted).

Furthermore, we cannot agree that Microsoft’s proposed limitations are inherent—even if unexpressed—in our pre-1952 cases. As early as 1874 we explained that the burden of proving prior inventorship “rests upon [the defendant], and every reasonable doubt should be resolved against him,” without tying that rule to the vagaries and manipulability of oral testimony. *Coffin v. Ogden*, 18 Wall. 120, 124, 21 L.Ed. 821 (1874). And, more than 60 years later, we applied that rule where the evidence in support of a prior-use defense included documentary proof—not just oral testimony—in a case presenting no priority issues at all. See *Smith*, 301 U.S., at 221, 233. Thus, even if Congress searched for some unstated limitations on the heightened standard of proof in our cases, it would have found none.

Microsoft also argues that the Federal Circuit’s interpretation of § 282’s statement that “[a] patent shall be presumed valid” must fail because it renders superfluous the statute’s additional statement that “[t]he burden of establishing invalidity of a patent ... shall rest on the party asserting such invalidity.” We agree that if the presumption imposes a heightened standard of proof on the patent challenger, then it alone suffices to establish that the defendant bears the burden of persuasion. Cf. *Director, Office of Workers’ Compensation Programs v. Greenwich Collieries*, 512 U.S. 267 (1994) (“A standard of proof ... can apply only to a burden of persuasion”). Indeed, the Federal Circuit essentially recognized as much in *American Hoist*. See 725 F.2d, at 1359.

But the canon against superfluity assists only where a competing interpretation gives effect “ ‘to every clause and word of a statute.’ ” *Duncan v. Walker*, 533 U.S. 167, 174 (2001) (quoting *United States v. Menasche*, 348 U.S. 528, 538–539 (1955)); see *Bruesewitz v. Wyeth LLC*, 562 U.S. —, —, 131 S.Ct. 1068, 1078, 179 L.Ed.2d 1 (2011). Here, no interpretation of § 282—including the two alternatives advanced by Microsoft—avoids excess language. That is, if the presumption only “allocates the burden of production,” Brief for Petitioner 21, or if it instead “shift[s] both the burden of production and the burden of persuasion,” *id.*, at 22 (emphasis deleted), then *it* would be unnecessary in light of § 282’s statement that the challenger bears the “burden of establishing invalidity.” See 21B Fed. Practice § 5122, at 401 (“[T]he same party who has the burden of persuasion also starts out with the burden of producing evidence”). “There are times when Congress enacts provisions that are superfluous,” *Corley v. United States*, 556 U.S. —, —, 129 S.Ct. 1558, 1572–1573, 173 L.Ed.2d 443 (2009) (ALITO, J., dissenting), and the kind of excess language that Microsoft identifies in § 282 is hardly unusual in comparison to other statutes that set forth a presumption, a burden of persuasion, and a standard of proof. Cf., e.g., 28 U.S.C. § 2254(e)(1).

B

Reprising the more limited argument that it pressed below, Microsoft argues in the

alternative that a preponderance standard must at least apply where the evidence before the factfinder was not before the PTO during the examination process. In particular, it relies on *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398 (2007), where we observed that, in these circumstances, “the rationale underlying the presumption—that the PTO, in its expertise, has approved the claim—seems much diminished.” *Id.*, at 426.

That statement is true enough, although other rationales may animate the presumption in such circumstances. See *The Barbed Wire Patent*, 143 U.S. 275, 292 (1892) (explaining that because the patentee “first published this device; put it upon record; made use of it for a practical purpose; and gave it to the public doubts ... concerning the actual inventor ... should be resolved in favor of the patentee”); cf. Brief for United States as *Amicus Curiae* 33 (arguing that even when the administrative correctness rationale has no relevance, the heightened standard of proof “serves to protect the patent holder’s reliance interests” in disclosing an invention to the public in exchange for patent protection). The question remains, however, whether Congress has specified the applicable standard of proof. As established, Congress did just that by codifying the common-law presumption of patent validity and, implicitly, the heightened standard of proof attached to it.

Our pre-1952 cases never adopted or endorsed the kind of fluctuating standard of proof that Microsoft envisions. And they do not indicate, even in dicta, that anything less than a clear-and-convincing standard would ever apply to an invalidity defense raised in an infringement action. To the contrary, the Court spoke on this issue directly in *RCA*, stating that because the heightened standard of proof applied where the evidence before the court was “different” from that considered by the PTO, it applied even more clearly where the evidence was identical. 293 U.S., at 8. Likewise, the Court’s statement that a “dubious preponderance” will never suffice to sustain an invalidity defense, *ibid.*, admitted of no apparent exceptions. Finally, this Court often applied the heightened standard of proof without any mention of whether the relevant prior-art evidence had been before the PTO examiner, in circumstances strongly suggesting it had not. See, e.g., *Smith*, 301 U.S., at 227, 233.

Nothing in § 282’s text suggests that Congress meant to depart from that understanding to enact a standard of proof that would rise and fall with the facts of each case. Indeed, had Congress intended to drop the heightened standard of proof where the evidence before the jury varied from that before the PTO—and thus to take the unusual and impractical step of enacting a variable standard of proof that must itself be adjudicated in each case, cf. *Santosky v. Kramer*, 455 U.S. 745, 757 (1982) — we assume it would have said so expressly.

To be sure, numerous courts of appeals in the years preceding the 1952 Act observed that the presumption of validity is “weakened” or “dissipated” in the circumstance that the evidence in an infringement action was never considered by the PTO. See *Jacuzzi Bros., Inc. v. Berkeley Pump Co.*, 191 F.2d 632, 634 (C.A.9 1951) (“largely dissipated”); *H. Schindler & Co. v. C. Saladino & Sons*, 81 F.2d 649, 651 (C.A.1 1936) (“weakened”); *Gillette Safety Razor Co. v. Cliff Weil Cigar Co.*, 107 F.2d 105, 107 (C.A.4 1939) (“greatly weakened”); *Butler Mfg. Co. v. Enterprise Cleaning Co.*, 81 F.2d 711, 716

(C.A.8 1936) (“weakened”). But we cannot read these cases to hold or even to suggest that a preponderance standard would apply in such circumstances, and we decline to impute such a reading to Congress. Instead, we understand these cases to reflect the same commonsense principle that the Federal Circuit has recognized throughout its existence—namely, that new evidence supporting an invalidity defense may “carry more weight” in an infringement action than evidence previously considered by the PTO, *American Hoist*, 725 F.2d, at 1360. As Judge Rich explained:

“When new evidence touching validity of the patent not considered by the PTO is relied on, the tribunal considering it is not faced with having to disagree with the PTO or with deferring to its judgment or with taking its expertise into account. The evidence may, therefore, carry more weight and go further toward sustaining the attacker’s unchanging burden.” *Ibid.* (emphasis deleted)

See also *SIBIA Neurosciences, Inc. v. Cadus Pharmaceutical Corp.*, 225 F.3d 1349, 1355–1356 (C.A.Fed.2000) (“[T]he alleged infringer’s burden may be more easily carried because of th[e] additional [evidence]”); *Group One, Ltd. v. Hallmark Cards, Inc.*, 407 F.3d 1297, 1306 (C.A.Fed.2005) (similar).

Simply put, if the PTO did not have all material facts before it, its considered judgment may lose significant force. Cf. *KSR*, 550 U.S., at 427, 127 S.Ct. 1727. And, concomitantly, the challenger’s burden to persuade the jury of its invalidity defense by clear and convincing evidence may be easier to sustain. In this respect, although we have no occasion to endorse any particular formulation, we note that a jury instruction on the effect of new evidence can, and when requested, most often should be given. When warranted, the jury may be instructed to consider that it has heard evidence that the PTO had no opportunity to evaluate before granting the patent. When it is disputed whether the evidence presented to the jury differs from that evaluated by the PTO, the jury may be instructed to consider that question. In either case, the jury may be instructed to evaluate whether the evidence before it is materially new, and if so, to consider that fact when determining whether an invalidity defense has been proved by clear and convincing evidence. Cf., e.g., *Mendenhall v. Cedarapids, Inc.*, 5 F.3d 1557, 1563–1564 (C.A.Fed.1993); see also Brief for International Business Machines Corp. as *Amicus Curiae* 31–37. Although Microsoft emphasized in its argument to the jury that S4 was never considered by the PTO, it failed to request an instruction along these lines from the District Court. Now, in its reply brief in this Court, Microsoft insists that an instruction of this kind was warranted. Reply Brief for Petitioner 22–23. That argument, however, comes far too late, and we therefore refuse to consider it. See *Rent-A-Center, West, Inc. v. Jackson*, 561 U.S. —, —, 130 S.Ct. 2772, 2781, 177 L.Ed.2d 403 (2010); cf. Fed. Rule Civ. Proc. 51(d)(1)(B).

III

The parties and their *amici* have presented opposing views as to the wisdom of the clear-and-convincing-evidence standard that Congress adopted. Microsoft and its *amici* contend that the heightened standard of proof dampens innovation by unduly insulating “bad” patents from invalidity challenges. They point to the high invalidation rate as evidence that the PTO grants patent protection to too many undeserving “inventions.”

They claim that *inter partes* reexamination proceedings before the PTO cannot fix the problem, as some grounds for invalidation (like the on-sale bar at issue here) cannot be raised in such proceedings. They question the deference that the PTO's expert determinations warrant, in light of the agency's resources and procedures, which they deem inadequate. And, they insist that the heightened standard of proof essentially causes juries to abdicate their role in reviewing invalidity claims raised in infringement actions.

For their part, i4i and its *amici*, including the United States, contend that the heightened standard of proof properly limits the circumstances in which a lay jury overturns the considered judgment of an expert agency. They claim that the heightened standard of proof is an essential component of the patent "bargain," see *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 150–151 (1989), and the incentives for inventors to disclose their innovations to the public in exchange for patent protection. They disagree with the notion that the patent issuance rate is above the optimal level. They explain that limits on the reexamination process reflect a judgment by Congress as to the appropriate degree of interference with patentees' reliance interests. Finally, they maintain that juries that are properly instructed as to the application of the clear-and-convincing-evidence standard can, and often do, find an invalidity defense established.

We find ourselves in no position to judge the comparative force of these policy arguments. For nearly 30 years, the Federal Circuit has interpreted § 282 as we do today. During this period, Congress has often amended § 282, see, *e.g.*, Pub.L. 104–141, § 2, 109 Stat. 352; Pub.L. 98–417, § 203, 98 Stat. 1603; not once, so far as we (and Microsoft) are aware, has it even considered a proposal to lower the standard of proof, see Tr. Oral Arg. 10. Moreover, Congress has amended the patent laws to account for concerns about "bad" patents, including by expanding the reexamination process to provide for *inter partes* proceedings. See Optional Inter Partes Reexamination Procedure Act of 1999, 113 Stat. 1501A–567, codified at 35 U.S.C. § 311 *et seq.* Through it all, the evidentiary standard adopted in § 282 has gone untouched. Indeed, Congress has left the Federal Circuit's interpretation of § 282 in place despite ongoing criticism, both from within the Federal Government and without.

Congress specified the applicable standard of proof in 1952 when it codified the common-law presumption of patent validity. Since then, it has allowed the Federal Circuit's correct interpretation of § 282 to stand. Any re-calibration of the standard of proof remains in its hands.

For the reasons stated, the judgment of the Court of Appeals for the Federal Circuit is

Affirmed.

Justice BREYER, with whom Justice SCALIA and Justice ALITO join, concurring.

I join the Court's opinion in full. I write separately because, given the technical but important nature of the invalidity question, I believe it worth emphasizing that in this area of law as in others the evidentiary standard of proof applies to questions of fact and not to questions of law. See, *e.g.*, *Addington v. Texas*, 441 U.S. 418, 423 (1979). Thus a factfinder must use the "clear and convincing" standard where there are disputes about,

say, when a product was first sold or whether a prior art reference had been published.

Many claims of invalidity rest, however, not upon factual disputes, but upon how the law applies to facts as given. Do the given facts show that the product was previously “in public use”? 35 U.S.C. § 102(b). Do they show that the invention was “nove[1]” and that it was “non-obvious”? §§ 102, 103. Do they show that the patent applicant described his claims properly? § 112. Where the ultimate question of patent validity turns on the correct answer to legal questions—what these subsidiary legal standards mean or how they apply to the facts as given—today’s strict standard of proof has no application. See, e.g., *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 17 (1966); *Minnesota Mining & Mfg. Co. v. Chemque, Inc.*, 303 F.3d 1294, 1301 (C.A.Fed.2002); *Transocean Offshore Deepwater Drilling, Inc. v. Maersk Contractors USA, Inc.*, 617 F.3d 1296, 1305 (C.A.Fed.2010); cf. *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996).

Courts can help to keep the application of today’s “clear and convincing” standard within its proper legal bounds by separating factual and legal aspects of an invalidity claim, say, by using instructions based on case-specific circumstances that help the jury make the distinction or by using interrogatories and special verdicts to make clear which specific factual findings underlie the jury’s conclusions. See Fed. Rules Civ. Proc. 49 and 51. By isolating the facts (determined with help of the “clear and convincing” standard), courts can thereby assure the proper interpretation or application of the correct legal standard (without use of the “clear and convincing” standard). By preventing the “clear and convincing” standard from roaming outside its fact-related reservation, courts can increase the likelihood that discoveries or inventions will not receive legal protection where none is due.

Justice THOMAS, concurring in the judgment.

I am not persuaded that Congress codified a standard of proof when it stated in the Patent Act of 1952 that “[a] patent shall be presumed valid.” 35 U.S.C. § 282; see *ante*, at 2245. “[W]here Congress borrows terms of art,” this Court presumes that Congress “knows and adopts the cluster of ideas that were attached to each borrowed word ... and the meaning its use will convey to the judicial mind.” *Morissette v. United States*, 342 U.S. 246, 263, 72 S.Ct. 240, 96 L.Ed. 288 (1952). But I do not think that the words “[a] patent shall be presumed valid” so clearly conveyed a particular standard of proof to the judicial mind in 1952 as to constitute a term of art. See, e.g., *ante*, at 2248, n. 7 (“[S]ome lower courts doubted [the presumption’s] wisdom or even pretended it did not exist”); *Philip A. Hunt Co. v. Mallinckrodt Chemical Works*, 72 F.Supp. 865, 869 (E.D.N.Y.1947) (“[T]he impact upon the presumption of many late decisions seems to have rendered it as attenuated ... as the shadow of a wraith”); *Myers v. Beall Pipe & Tank Corp.*, 90 F.Supp. 265, 268 (D Or.1948) (“[T]he presumption of [patent] validity ... is treated by the appellate courts as evanescent as a cloud”); *American Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1359 (C.A.Fed.1984) (“[I]n 1952, the case law was far from consistent—even contradictory—about the presumption”); cf. *Bruesewitz v. Wyeth LLC*, 562 U.S. —, —, —, 131 S.Ct. 1068, 1076–1077, 179 L.Ed.2d 1 (2011) (Congress’ use of a word that is similar to a term of art does not codify the term of art). Therefore, I would not conclude that Congress’ use of that phrase codified a standard

of proof.

Nevertheless, I reach the same outcome as the Court. Because § 282 is silent as to the standard of proof, it did not alter the common-law rule. See *ante*, at 2245 (“[§ 282] includes no express articulation of the standard of proof”). For that reason, I agree with the Court that the heightened standard of proof set forth in *Radio Corp. of America v. Radio Engineering Laboratories, Inc.*, 293 U.S. 1, 55 S.Ct. 928, 79 L.Ed. 163 (1934)—which has never been overruled by this Court or modified by Congress—applies.

NOTES ON *i4i*

1. Implications of the Preponderance Standard. The Supreme Court did not adopt Microsoft’s suggested preponderance standard to invalidate patents. But what if they had? How would preponderance (as opposed to clear and convincing) impact the economic value of patents? Would it flush away thousands of bad patents and increase the survivors’ value? What impact would it have on innovation? A lower bar would logically make any patent more vulnerable to attack, but how would this increased vulnerability affect innovation in the first place? What about patent prosecution practice? Would patent applicants overburden the PTO with unnecessary disclosure? If an asserted patent was easier to kill, how would that affect settlement prospects? If the litigation bar to invalidate a patent was low, would reexamination lose its allure? Would a preponderance standard tilt the balance of power to patent defendants in a major way? Would juries in certain jurisdictions change their verdicts under a preponderance standard?

2. Microsoft’s Alternative Proposal: The Supreme Court also rejected Microsoft’s alternative proposal that the presumption of validity be *weakened* for validity challenges not considered by the USPTO during prosecution of the application. But they agreed with Judge Rich that “new evidence” of invalidity likely carries more weight than previously-considered-but-rejected evidence by the PTO. Where does that leave us? What jury instructions would an accused infringer pursue post-*i4i* for “new evidence” scenarios? Should the jury be involved at all in validity determinations if such determinations are, as the Supreme Court has previously stated, issues of law?

3. Justice Breyer and Obviousness/Novelty: Justice Breyer indicated that the clear and convincing standard applied to factual but not legal questions. Obviousness is a difficult legal question. Justice Breyer would thus not apply the clear and convincing standard for obviousness. What impact? What about novelty? Is that a legal question as Justice Breyer indicates, or a question of fact? Are all validity matters issues of law?

D. INEQUITABLE CONDUCT

1. Nondisclosure.

On page 1113, replace **J.P. Stevens & Co. v. Lex Tex Ltd.** with the following case:

THERASENSE, INC. v. BECTON, DICKINSON & CO.

2011 U.S. App. LEXIS 10590 (Fed. Cir. May 25, 2011)

Rader, Chief Judge.

[Therasense, a subsidiary of Abbott Laboratories, obtained several patents on disposable glucose test strips for diabetes management. Becton, Dickenson and Co. sued for a declaratory judgment that Abbott’s patents were invalid. Abbott countersued Becton and Bayer Healthcare LLC for infringement. After the cases were consolidated for trial in the Northern District of California, the district court held all of the litigated patent claims either invalid or not infringed. The court also held one of the patents, U.S. Patent No. 5,820,551 (“the ‘551 patent”), unenforceable due to inequitable conduct.

On appeal, a panel of the Federal Circuit unanimously affirmed all of the district court’s holdings of noninfringement and invalidity, including the district court’s ruling that all litigated claims in the ‘551 patent were invalid for obviousness. The panel also affirmed the district court’s holding that the ‘551 patent was unenforceable due to inequitable conduct, but the panel was divided on that issue. The full court granted rehearing en banc solely on the inequitable conduct issue.]

I

The ‘551 patent involves disposable blood glucose test strips for diabetes management. These strips employ electrochemical sensors to measure the level of glucose in a sample of blood. When blood contacts a test strip, glucose in the blood reacts with an enzyme on the strip, resulting in the transfer of electrons from the glucose to the enzyme. A mediator transfers these electrons to an electrode on the strip. Then, the electrons flow from the strip to a glucose meter, which calculates the glucose concentration based on the electrical current.

The ‘551 patent claims a test strip with an electrochemical sensor ... “*configured to be exposed to said whole blood sample without an intervening membrane or other whole blood filtering member . . .*” ‘551 patent [claim 1] (emphasis added). “Whole blood,” an important term in the claim, means blood that contains all of its components, including red blood cells.

In the prior art, some sensors employed diffusion-limiting membranes to control the flow of glucose to the electrode because the slower mediators of the time could not deal with a rapid influx of glucose. Other prior art sensors used protective membranes to prevent “fouling.” Fouling occurs when red blood cells stick to the active electrode and interfere with electron transfer to the electrode. Protective membranes permit glucose molecules to pass, but not red blood cells.

Abbott filed the original application leading to the '551 patent in 1984. Over thirteen years, that original application saw multiple rejections for anticipation and obviousness, including repeated rejections over U.S. Patent No. 4,545,382 ("the '382 patent"), another patent owned by Abbott. The '382 patent specification discussed protective membranes in the following terms: "Optionally, but preferably when being used on live blood, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water and glucose molecules." Col.4 ll.63-66. "Live blood" refers to blood within a body.

In 1997, Lawrence Pope, Abbott's patent attorney, and Dr. Gordon Sanghera, Abbott's Director of Research and Development, studied the novel features of their application and decided to present a new reason for a patent. Pope presented new claims to the examiner based on a new sensor that did not require a protective membrane for whole blood. Pope asserted that this distinction would overcome the prior art '382 patent, whose electrodes allegedly required a protective membrane. The examiner requested an affidavit to show that the prior art required a membrane for whole blood at the time of the invention.

To meet this evidentiary request, Dr. Sanghera submitted a declaration to the U.S. Patent and Trademark Office ("PTO") stating:

[O]ne skilled in the art would have felt that an active electrode comprising an enzyme and a mediator would require a protective membrane if it were to be used with a whole blood sample. . . . [O]ne skilled in the art would not read lines 63 to 65 of column 4 of U.S. Patent No. 4,545,382 to teach that the use of a protective membrane with a whole blood sample is optionally or merely preferred.

J.A. 7637. Pope, in submitting Sanghera's affidavit, represented:

The art continued to believe [following the '382 patent] that a barrier layer for [a] whole blood sample was necessary

One skilled in the art would *not* have read the disclosure of the ['382 patent] as teaching that the use of a protective membrane with whole blood samples was optional. He would not, especially in view of the working examples, have read the "optionally, but preferably" language at line 63 of column [4] as a technical teaching but rather mere patent phraseology.

There is no teaching or suggestion of unprotected active electrodes for use with whole blood specimens in [the '382 patent]

J.A. 7645-46.

Several years earlier, while prosecuting the European counterpart to the '382 patent, European Patent EP 0 078 636 ("EP '636"), Abbott made representations to the European Patent Office ("EPO") regarding the same "optionally, but preferably" language in the European specification. On January 12, 1994, to distinguish a German reference labeled D1, which required a diffusion-limiting membrane, Abbott's European patent counsel argued that their invention did not require a diffusion-limiting membrane:

Contrary to the semipermeable membrane of D1, the protective membrane optionally utilized with the glucose sensor of the patent is [sic] suit is not controlling

the permeability of the substrate Rather, in accordance with column 5, lines 30 to 33 of the patent in suit:

“Optionally, but preferably when being used on live blood, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water and glucose molecules.”

See also claim 10 of the patent in suit as granted according to which the sensor electrode has an outermost protective membrane (11) permeable to water and glucose molecules. . . . Accordingly, *the purpose of the protective membrane of the patent in suit, preferably to be used with in vivo measurements, is a safety measurement to prevent any course [sic] particles coming off during use but not a permeability control for the substrate.*

J.A. 6530-31 (emphases added).

On May 23, 1995, Abbott’s European patent counsel submitted another explanation about the D1 reference and EP ‘636.

“Optionally, but preferably when being used on live blood, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water and glucose molecules.”

It is submitted that this disclosure is unequivocally clear. The protective membrane is optional, however, it is preferred when used on live blood in order to prevent the larger constituents of the blood, in particular [the red blood cells] from interfering with the electrode sensor. Furthermore it is said, that said protective membrane should not prevent the glucose molecules from penetration, the membrane is “permeable” to glucose molecules. This teaches the skilled artisan that, whereas the [D1 membrane] must . . . control the permeability of the glucose . . . the purpose of the protective membrane in the patent in suit is not to control the permeation of the glucose molecules. For this very reason the sensor electrode as claimed does not have (and must not have) a semipermeable membrane in the sense of D1.

J.A. 6585 (first and third emphases added). . . .

III

Inequitable conduct is an equitable defense to patent infringement that, if proved, bars enforcement of a patent. This judge-made doctrine evolved from a trio of Supreme Court cases that applied the doctrine of unclean hands to dismiss patent cases involving egregious misconduct: *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240 (1933), *Hazel-Atlas Glass Co. v. Hartford-Empire Co.*, 322 U.S. 238 (1944), overruled on other grounds by *Standard Oil Co. v. United States*, 429 U.S. 17 (1976), and *Precision Instruments Manufacturing Co. v. Automotive Maintenance Machinery Co.*, 324 U.S. 806 (1945).

Keystone involved the manufacture and suppression of evidence. 290 U.S. at 243. The patentee knew of “a possible prior use” by a third party prior to filing a patent application but did not inform the PTO. *Id.* at 243. After the issuance of the patent, the patentee paid the prior user to sign a false affidavit stating that his use was an abandoned

experiment and bought his agreement to keep secret the details of the prior use and to suppress evidence. *Id.* With these preparations in place, the patentee then asserted this patent, along with two other patents, against Byers Machine Co. (“Byers”). *Keystone Driller Co. v. Byers Mach. Co.*, 4 F. Supp. 159 (N.D. Ohio 1929). Unaware of the prior use and of the cover-up, the court held the patents valid and infringed and granted an injunction. *Id.* at 160.

The patentee then asserted the same patents against General Excavator Co. and Osgood Co. and sought a temporary injunction based on the decree in the previous Byers case. *Keystone*, 290 U.S. at 242. The district court denied the injunctions but made the defendants post bonds. *Id.* The defendants discovered and introduced evidence of the corrupt transaction between the patentee and the prior user. *Id.* at 243-44. The district court declined to dismiss these cases for unclean hands. *Id.* On appeal, the Sixth Circuit reversed and remanded with instructions to dismiss the complaints. *Id.* The Supreme Court affirmed. *Id.* at 247.

The Supreme Court explained that if the corrupt transaction between the patentee and the prior user had been discovered in the previous Byers case, “the court undoubtedly would have been warranted in holding it sufficient to require dismissal of the cause of action.” *Id.* at 246. Because the patentee used the Byers decree to seek an injunction in the cases against General Excavator Co. and Osgood Co., it did not come to the court with clean hands, and dismissal of these cases was appropriate. *Id.* at 247.

Like *Keystone*, *Hazel-Atlas* involved both the manufacture and suppression of evidence. 322 U.S. at 240. Faced with “apparently insurmountable Patent Office opposition,” the patentee’s attorneys wrote an article describing the invention as a remarkable advance in the art and had William Clarke, a well-known expert, sign it as his own and publish it in a trade journal. *Id.* After the patentee submitted the Clarke article to the PTO in support of its application, the PTO allowed a patent to issue. *Id.* at 240-41.

The patentee brought suit against Hazel-Atlas Glass Co. (“Hazel-Atlas”), alleging infringement of this patent. *Id.* at 241. The district court found no infringement. *Id.* On appeal, the patentee’s attorneys emphasized the Clarke article, and the Third Circuit reversed the district court’s judgment, holding the patent valid and infringed. *Id.* The patentee then went to great lengths to conceal the false authorship of the Clarke article, contacting Clarke multiple times, including before and after Hazel-Atlas’s investigators spoke to him. *Id.* at 242-43. After Hazel-Atlas settled with the patentee, the patentee paid Clarke a total of \$8,000. *Id.* These facts surfaced in a later suit, *United States v. Hartford-Empire Co.*, 46 F. Supp. 541 (N.D. Ohio 1942). *Hazel-Atlas*, 322 U.S. at 243.

On the basis of these newly-discovered facts, Hazel-Atlas petitioned the Third Circuit to vacate its judgment, but the court refused. *Id.* at 243-44. The Supreme Court reversed. *Id.* at 251. The Supreme Court explained that if the district court had learned of the patentee’s deception before the PTO, it would have been warranted in dismissing the patentee’s case under the doctrine of unclean hands. *Id.* at 250. Likewise, had the Third Circuit learned of the patentee’s suppression of evidence, it also could have dismissed the appeal. *Id.* Accordingly, the Supreme Court vacated the judgment against Hazel-Atlas and reinstated the original judgment dismissing the patentee’s case. *Id.* at 251.

In *Precision*, the patentee suppressed evidence of perjury before the PTO and attempted to enforce the perjury-tainted patent. 324 U.S. at 816-20. The PTO had declared an interference between two patent applications, one filed by Larson and the other by Zimmerman. *Id.* at 809. Automotive Maintenance Machinery Co. (“Automotive”) owned the Zimmerman application. *Id.* Larson filed his preliminary statement in the PTO proceedings with false dates of conception, disclosure, drawing, description, and reduction to practice. Later, he testified in support of these false dates in an interference proceeding. *Id.* at 809-10.

Automotive discovered this perjury but did not reveal this information to the PTO. *Id.* at 818. Instead, Automotive entered into a private settlement with Larson that gave Automotive the rights to the Larson application and suppressed evidence of Larson’s perjury. *Id.* at 813-14. Automotive eventually received patents on both the Larson and Zimmerman applications. *Id.* at 814. Despite knowing that the Larson patent was tainted with perjury, Automotive sought to enforce it against others. *Id.* at 807.

The district court found that Automotive had unclean hands and dismissed the suit. *Id.* at 808. The Seventh Circuit reversed. *Id.* The Supreme Court reversed the Seventh Circuit’s decision, explaining that dismissal was warranted because not only had the patentee failed to disclose its knowledge of perjury to the PTO, it had actively suppressed evidence of the perjury and magnified its effects. *Id.* at 818-19.

IV

The unclean hands cases of *Keystone*, *Hazel-Atlas*, and *Precision* formed the basis for a new doctrine of inequitable conduct that developed and evolved over time. Each of these unclean hands cases before the Supreme Court dealt with particularly egregious misconduct, including perjury, the manufacture of false evidence, and the suppression of evidence. *See Precision*, 324 U.S. at 816-20; *Hazel-Atlas*, 322 U.S. at 240; *Keystone*, 290 U.S. at 243. Moreover, they all involved “deliberately planned and carefully executed scheme[s] to defraud” not only the PTO but also the courts. *Hazel-Atlas*, 322 U.S. at 245. As the inequitable conduct doctrine evolved from these unclean hands cases, it came to embrace a broader scope of misconduct, including not only egregious affirmative acts of misconduct intended to deceive both the PTO and the courts but also the mere nondisclosure of information to the PTO. Inequitable conduct also diverged from the doctrine of unclean hands by adopting a different and more potent remedy—unenforceability of the entire patent rather than mere dismissal of the instant suit. *See Precision*, 324 U.S. at 819 (dismissing suit); *Hazel-Atlas*, 322 U.S. at 251 (noting that the remedy was limited to dismissal and did not render the patent unenforceable); *Keystone*, 290 U.S. at 247 (affirming dismissal of suit).

In line with this wider scope and stronger remedy, inequitable conduct came to require a finding of both intent to deceive and materiality. *Star Scientific Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1365 (Fed. Cir. 2008). To prevail on the defense of inequitable conduct, the accused infringer must prove that the applicant misrepresented or omitted material information with the specific intent to deceive the PTO. *Id.* The accused infringer must prove both elements—intent and materiality—by clear and convincing evidence. *Id.* If the accused infringer meets its burden, then the district court

must weigh the equities to determine whether the applicant's conduct before the PTO warrants rendering the entire patent unenforceable. *Id.*

This court recognizes that the early unclean hands cases do not present any standard for materiality. Needless to say, this court's development of a materiality requirement for inequitable conduct does not (and cannot) supplant Supreme Court precedent. Though inequitable conduct developed from these cases, the unclean hands doctrine remains available to supply a remedy for egregious misconduct like that in the Supreme Court cases.

As inequitable conduct emerged from unclean hands, the standards for intent to deceive and materiality have fluctuated over time. In the past, this court has espoused low standards for meeting the intent requirement, finding it satisfied based on gross negligence or even negligence. ... This court has also previously adopted a broad view of materiality, using a "reasonable examiner" standard based on the PTO's 1977 amendment to Rule 56. *See Am. Hoist & Derrick Co. v. Sowa & Sons, Inc.*, 725 F.2d 1350, 1362 (Fed. Cir. 1984); *see also* 37 C.F.R. § 1.56 (1977) (a reference is material if "there is a substantial likelihood that a reasonable examiner would consider it important in deciding whether to allow the application to issue as a patent"). Further weakening the showing needed to establish inequitable conduct, this court then placed intent and materiality together on a "sliding scale." *Am. Hoist*, 725 F.2d at 1362. This modification to the inequitable conduct doctrine held patents unenforceable based on a reduced showing of intent if the record contained a strong showing of materiality, and vice versa. In effect, this change conflated, and diluted, the standards for both intent and materiality.

This court embraced these reduced standards for intent and materiality to foster full disclosure to the PTO. *See id.* at 1363. This new focus on encouraging disclosure has had numerous unforeseen and unintended consequences. Most prominently, inequitable conduct has become a significant litigation strategy. A charge of inequitable conduct conveniently expands discovery into corporate practices before patent filing and disqualifies the prosecuting attorney from the patentee's litigation team. *See* Stephen A. Merrill et al., Nat'l Research Council of the Nat'l Academies, *A Patent System for the 21st Century* 122 (2004). Moreover, inequitable conduct charges cast a dark cloud over the patent's validity and paint the patentee as a bad actor. Because the doctrine focuses on the moral turpitude of the patentee with ruinous consequences for the reputation of his patent attorney, it discourages settlement and deflects attention from the merits of validity and infringement issues. Committee Position Paper, *The Doctrine of Inequitable Conduct and the Duty of Candor in Patent Prosecution: Its Current Adverse Impact on the Operation of the United States Patent System*, 16 AIPLA Q.J. 74, 75 (1988). Inequitable conduct disputes also "increas[e] the complexity, duration and cost of patent infringement litigation that is already notorious for its complexity and high cost." Brief and Appendix of the American Bar Ass'n as Amicus Curiae at 9.

Perhaps most importantly, the remedy for inequitable conduct is the "atomic bomb" of patent law. *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting). Unlike validity defenses, which are claim specific, *see* 35 U.S.C. § 288, inequitable conduct regarding any single claim renders the

entire patent unenforceable. *Kingsdown Med. Consultants, Ltd. v. Hollister Inc.*, 863 F.2d 867, 877 (Fed. Cir. 1988). Unlike other deficiencies, inequitable conduct cannot be cured by reissue, *Aventis*, 525 F.3d at 1341, n.6, or reexamination, *Molins PLC v. Textron, Inc.*, 48 F.3d 1172, 1182 (Fed. Cir. 1995). Moreover, the taint of a finding of inequitable conduct can spread from a single patent to render unenforceable other related patents and applications in the same technology family. *See, e.g., Consol. Aluminum Corp. v. Foseco Int'l Ltd.*, 910 F.2d 804, 808-12 (Fed. Cir. 1990). Thus, a finding of inequitable conduct may endanger a substantial portion of a company's patent portfolio.

A finding of inequitable conduct may also spawn anti-trust and unfair competition claims[,] often makes a case "exceptional," leading potentially to an award of attorneys' fees under 35 U.S.C. § 285[, and] may also prove the crime or fraud exception to the attorney-client privilege.

With these far-reaching consequences, it is no wonder that charging inequitable conduct has become a common litigation tactic. One study estimated that eighty percent of patent infringement cases included allegations of inequitable conduct. Committee Position Paper at 75; *see also* Christian Mammen, *Controlling the "Plague": Reforming the Doctrine of Inequitable Conduct*, 24 Berkeley Tech. L.J. 1329, 1358 (2009). Inequitable conduct "has been overplayed, is appearing in nearly every patent suit, and is cluttering up the patent system." *Kimberly-Clark Corp. v. Johnson & Johnson*, 745 F.2d 1437, 1454 (Fed. Cir. 1984). "[T]he habit of charging inequitable conduct in almost every major patent case has become an absolute plague. Reputable lawyers seem to feel compelled to make the charge against other reputable lawyers on the slenderest grounds, to represent their client's interests adequately, perhaps." *Burlington Indus., Inc. v. Dayco Corp.*, 849 F.2d 1418, 1422 (Fed. Cir. 1988)

Left unfettered, the inequitable conduct doctrine has plagued not only the courts but also the entire patent system. Because allegations of inequitable conduct are routinely brought on "the slenderest grounds," *Burlington Indus.*, 849 F.2d at 1422, patent prosecutors constantly confront the specter of inequitable conduct charges. With inequitable conduct casting the shadow of a hangman's noose, it is unsurprising that patent prosecutors regularly bury PTO examiners with a deluge of prior art references, most of which have marginal value. *See* Brief for the United States as Amicus Curiae at 17 (submission of nine hundred references without any indication which ones were most relevant); Brief of the Biotechnology Industry Organization as Amicus Curiae at 7 (submission of eighteen pages of cited references, including five pages listing references to claims, office actions, declarations, amendments, interview summaries, and other communications in related applications). "Applicants disclose too much prior art for the PTO to meaningfully consider, and do not explain its significance, all out of fear that to do otherwise risks a claim of inequitable conduct." ABA Section of Intellectual Property Law, *A Section White Paper: Agenda for 21st Century Patent Reform 2* (2009). This tidal wave of disclosure makes identifying the most relevant prior art more difficult. *See* Brief for the United States as Amicus Curiae at 1 (submission of "large numbers of prior art references of questionable materiality . . . harms the effectiveness of the examination process"). "This flood of information strains the agency's examining resources and directly contributes to the backlog." *Id.* at 17-18.

While honesty at the PTO is essential, low standards for intent and materiality have inadvertently led to many unintended consequences, among them, increased adjudication cost and complexity, reduced likelihood of settlement, burdened courts, strained PTO resources, increased PTO backlog, and impaired patent quality. This court now tightens the standards for finding both intent and materiality in order to redirect a doctrine that has been overused to the detriment of the public.

V

To prevail on a claim of inequitable conduct, the accused infringer must prove that the patentee acted with the specific intent to deceive the PTO. *Star*, 537 F.3d at 1366 (citing *Kingsdown*, 863 F.2d at 876). A finding that the misrepresentation or omission amounts to gross negligence or negligence under a “should have known” standard does not satisfy this intent requirement. *Kingsdown*, 863 F.2d at 876. “In a case involving nondisclosure of information, clear and convincing evidence must show that the applicant *made a deliberate decision* to withhold a *known* material reference.” *Molins*, 48 F.3d at 1181 (emphases added). In other words, the accused infringer must prove 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.

This requirement of knowledge and deliberate action has origins in the trio of Supreme Court cases that set in motion the development of the inequitable conduct doctrine. In each of those cases, the patentee acted knowingly and deliberately with the purpose of defrauding the PTO and the courts. See *Precision*, 324 U.S. at 815-16 (assertion of patent known to be tainted by perjury); *Hazel-Atlas*, 322 U.S. at 245 (a “deliberately planned and carefully executed scheme to defraud” the PTO involving both bribery and perjury); *Keystone*, 290 U.S. at 246-47 (bribery and suppression of evidence).

Intent and materiality are separate requirements. *Hoffmann-La Roche, Inc. v. Promega Corp.*, 323 F.3d 1354, 1359 (Fed. Cir. 2003). A district court should not use a “sliding scale,” where a weak showing of intent may be found sufficient based on a strong showing of materiality, and vice versa. Moreover, a district court may not infer intent solely from materiality. Instead, a court must weigh the evidence of intent to deceive independent of its analysis of materiality. Proving that the applicant knew of a reference, should have known of its materiality, and decided not to submit it to the PTO does not prove specific intent to deceive.

Because direct evidence of deceptive intent is rare, a district court may infer intent from indirect and circumstantial evidence. *Larson Mfg. Co. of S.D., Inc. v. Aluminart Prods. Ltd.*, 559 F.3d 1317, 1340 (Fed. Cir. 2009). However, 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.” *Star*, 537 F.3d at 1366. Indeed, the evidence “must be sufficient to *require* a finding of deceitful intent in the light of all the circumstances.” *Kingsdown*, 863 F.2d at 873 (emphasis added). Hence, when there are multiple reasonable inferences that may be drawn, intent to deceive cannot be found. See *Scanner Techs. Corp. v. ICOS Vision Sys. Corp.*, 528 F.3d 1365, 1376 (Fed. Cir. 2008) (“Whenever evidence proffered to show either materiality or intent is susceptible of multiple reasonable inferences, a district court clearly errs in overlooking one

inference in favor of another equally reasonable inference.”). This court reviews the district court’s factual findings regarding what reasonable inferences may be drawn from the evidence for clear error. *See Star*, 537 F.3d at 1365.

Because the party alleging inequitable conduct bears the burden of proof, the “patentee need not offer any good faith explanation unless the accused infringer first . . . prove[s] a threshold level of intent to deceive by clear and convincing evidence.” *Star*, 537 F.3d at 1368. The absence of a good faith explanation for withholding a material reference does not, by itself, prove intent to deceive.

VI

In the past, this court has tried to address the proliferation of inequitable conduct charges by raising the intent standard alone. In *Kingsdown*, this court made clear that gross negligence alone was not enough to justify an inference of intent to deceive. 863 F.2d at 876. *Kingsdown* established that “the involved conduct . . . must indicate sufficient culpability to *require* a finding of intent to deceive.” *Id.* (emphasis added). This higher intent standard, standing alone, did not reduce the number of inequitable conduct cases before the courts and did not cure the problem of overdisclosure of marginally relevant prior art to the PTO. To address these concerns, this court adjusts as well the standard for materiality.

In *Corona Cord Tire Co. v. Dovan Chemical Corp.*, the Supreme Court considered the materiality of a patentee’s misrepresentation to the PTO. 276 U.S. 358, 373-74 (1928). The patentee had submitted two affidavits, falsely claiming that the invention had been used in the production of rubber goods when in fact only test slabs of rubber had been produced. *Id.* Because the misrepresentation was not the but-for cause of the patent’s issuance, the Court held that it was immaterial and refused to extinguish the patent’s presumption of validity:

Production of rubber goods for use or sale was not indispensable to the granting of the patent. Hence the affidavits, though perhaps reckless, were not the basis for it or essentially material to its issue. The reasonable presumption of validity furnished by the grant of the patent, therefore, would not seem to be destroyed.

Id. at 374. Although *Corona Cord* does not address unclean hands, the precursor to inequitable conduct, it demonstrates the Court’s unwillingness to extinguish the statutory presumption of validity where the patentee made a misrepresentation to the PTO that did not affect the issuance of the patent. *Corona Cord* thus supports a but-for materiality standard for inequitable conduct, particularly given that the severe remedy of unenforceability for inequitable conduct far exceeds the mere removal of a presumption of validity.

This court holds that, as a general matter, the materiality required to establish inequitable conduct is but-for materiality. When an applicant fails to disclose prior art to the PTO, that prior art is but-for material if the PTO would not have allowed a claim had it been aware of the undisclosed prior art. Hence, in assessing the materiality of a withheld reference, the court must determine whether the PTO would have allowed the claim if it had been aware of the undisclosed reference. In making this patentability

determination, the court should apply the preponderance of the evidence standard and give claims their broadest reasonable construction. *See* Manual of Patent Examining Procedure (“MPEP”) §§ 706, 2111 (8th ed. Rev. 8, July 2010). Often the patentability of a claim will be congruent with the validity determination—if a claim is properly invalidated in district court based on the deliberately withheld reference, then that reference is necessarily material because a finding of invalidity in a district court requires clear and convincing evidence, a higher evidentiary burden than that used in prosecution at the PTO. However, even if a district court does not invalidate a claim based on a deliberately withheld reference, the reference may be material if it would have blocked patent issuance under the PTO’s different evidentiary standards. *See* MPEP §§ 706 (preponderance of the evidence), 2111 (broadest reasonable construction).

As an equitable doctrine, inequitable conduct hinges on basic fairness. “[T]he remedy imposed by a court of equity should be commensurate with the violation.” *Columbus Bd. of Educ. v. Penick*, 443 U.S. 449, 465, 99 S. Ct. 2941, 61 L. Ed. 2d 666 (1979). Because inequitable conduct renders an entire patent (or even a patent family) unenforceable, as a general rule, this doctrine should only be applied in instances where the patentee’s misconduct resulted in the unfair benefit of receiving an unwarranted claim. *See Star*, 537 F.3d at 1366 (“[j]ust as it is inequitable to permit a patentee who obtained his patent through deliberate misrepresentations or omissions of material information to enforce the patent against others, it is also inequitable to strike down an entire patent where the patentee committed only minor missteps or acted with minimal culpability”). After all, the patentee obtains no advantage from misconduct if the patent would have issued anyway. *See Keystone*, 290 U.S. at 245 (“The equitable powers of the court can never be exerted in behalf of one . . . who by deceit or any unfair means has *gained an advantage.*”) (emphasis added) (internal citations omitted). Moreover, enforcement of an otherwise valid patent does not injure the public merely because of misconduct, lurking somewhere in patent prosecution, that was immaterial to the patent’s issuance.

Although but-for materiality generally must be proved to satisfy the materiality prong of inequitable conduct, this court recognizes an exception in cases of affirmative egregious misconduct. This exception to the general rule requiring but-for proof incorporates elements of the early unclean hands cases before the Supreme Court, which dealt with “deliberately planned and carefully executed scheme[s]” to defraud the PTO and the courts. *Hazel-Atlas*, 322 U.S. at 245. When the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit, the misconduct is material. *See Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1571 (Fed. Cir. 1983) (“there is no room to argue that submission of false affidavits is not material”); *see also Refac Int’l, Ltd. v. Lotus Dev. Corp.*, 81 F.3d 1576, 1583 (Fed. Cir. 1996) (finding the intentional omission of declarant’s employment with inventor’s company rendered the affidavit false and that “[a]ffidavits are inherently material”). After all, a patentee is unlikely to go to great lengths to deceive the PTO with a falsehood unless it believes that the falsehood will affect issuance of the patent. *See id.* at 247 (pointing out that patentee’s lawyers “went to considerable trouble and expense” to manufacture false evidence because they believed it was needed to obtain issuance of

the patent). Because neither mere nondisclosure of prior art references to the PTO nor failure to mention prior art references in an affidavit constitutes affirmative egregious misconduct, claims of inequitable conduct that are based on such omissions require proof of but-for materiality. By 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.

The concurrence mischaracterizes this exception for affirmative egregious acts by limiting it to the example provided—the filing of an unmistakably false affidavit. Based on this misunderstanding, the concurrence asserts that this court’s test for materiality is unduly rigid and contrary to Supreme Court precedent. In actuality, however, the materiality standard set forth in this opinion includes an exception for affirmative acts of egregious misconduct, not just the filing of false affidavits. Accordingly, the general rule requiring but-for materiality provides clear guidance to patent practitioners and courts, while the egregious misconduct exception gives the test sufficient flexibility to capture extraordinary circumstances. Thus, not only is this court’s approach sensitive to varied facts and equitable considerations, it is also consistent with the early unclean hands cases—all of which dealt with egregious misconduct. *See Precision*, 324 U.S. at 816-20 (perjury and suppression of evidence); *Hazel-Atlas*, 322 U.S. at 240 (manufacture and suppression of evidence); *Keystone*, 290 U.S. at 243 (bribery and suppression of evidence).

The concurrence appears to eschew the use of *any* test because, by definition, under any test for materiality, a district court could not find inequitable conduct in cases “where the conduct in question would not be defined as such [under the test].” Although equitable doctrines require some measure of flexibility, abandoning the use of tests entirely is contrary to both longstanding practice and Supreme Court precedent. Courts have long applied rules and tests in determining whether a particular factual situation falls within the scope of an equitable doctrine. *See, e.g., Winter v. NRDC, Inc.*, 555 U.S. 7 (2008) (four-factor test for preliminary injunctions); *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 391 (2006) (four-factor test for permanent injunctions); *Gutierrez v. Waterman S.S. Corp.*, 373 U.S. 206, 215 (1963) (“the test of laches” requires both unreasonable delay and consequent prejudice). Moreover, the Supreme Court has made clear that such tests serve an important purpose in limiting the discretion of district courts.

[C]ourts of equity must be governed by rules and precedents no less than the courts of law . . . [because] the alternative is to use each equity chancellor’s conscience as a measure of equity, which alternative would be as arbitrary and uncertain as measuring distance by the length of each chancellor’s foot. . . .

After all, equitable rules that guide lower courts reduce uncertainty, avoid unfair surprise, minimize disparate treatment of similar cases, and thereby help all litigants.

Lonchar v. Thomas, 517 U.S. 314, 323 (1996) (internal quotations omitted). This court therefore rejects the view that its test—albeit flexible enough to capture varying

manifestations of egregious and abusive conduct—is inappropriate in the context of the way inequitable conduct has metastasized.

This court does not adopt the definition of materiality in PTO Rule 56. As an initial matter, this court is not bound by the definition of materiality in PTO rules. *See Merck & Co., Inc. v. Kessler*, 80 F.3d 1543, 1549-50 (Fed. Cir. 1996) (“[T]he broadest of the PTO’s rulemaking powers . . . does NOT grant the Commissioner the authority to issue substantive rules.”); *see also* 57 Fed. Reg. 2021 (Jan. 17, 1992) (The PTO stated that Rule 56 “do[es] not define fraud or inequitable conduct.”). While this court respects the PTO’s knowledge in its area of expertise, the routine invocation of inequitable conduct in patent litigation has had adverse ramifications beyond its effect on the PTO. As discussed above, patent prosecutors, inventors, courts, and the public at large have an interest in reining in inequitable conduct. Notably, both the American Bar Association and the American Intellectual Property Law Association, which represent a wide spectrum of interests, support requiring but-for materiality (which is absent from Rule 56).

This court has looked to the PTO’s Rule 56 in the past as a starting point for determining materiality. *See Am. Hoist*, 725 F.2d at 1363. Rule 56 has gone through several revisions, from the “fraud” standard in its original promulgation in 1949 to the “reasonable examiner” standard in 1977 to the current version, which includes any information that “refutes or is inconsistent with” any position the applicant took regarding patentability. *See* 37 C.F.R. § 1.56 (1950); 37 C.F.R. § 1.56 (1977); 37 C.F.R. § 1.56 (1992). Tying the materiality standard for inequitable conduct to PTO rules, which understandably change from time to time, has led to uncertainty and inconsistency in the development of the inequitable conduct doctrine. Experience thus counsels against this court abdicating its responsibility to determine the boundaries for inequitable conduct.

This court declines to adopt the current version of Rule 56 in defining inequitable conduct because reliance on this standard has resulted in the very problems this court sought to address by taking this case en banc. Rule 56 provides that information is material if it is not cumulative and:

- (1) It establishes, by itself or in combination with other information, a prima facie case of unpatentability of a claim; or
- (2) It refutes, or is inconsistent with, a position the applicant takes in:
 - (i) Opposing an argument of unpatentability relied on by the Office, or
 - (ii) Asserting an argument of patentability.

37 C.F.R. § 1.56. Rule 56 further provides that a “prima facie case of unpatentability is established when the information compels a conclusion that a claim is unpatentable . . . before any consideration is given to evidence which may be submitted in an attempt to establish a contrary conclusion of patentability.” *Id.* (emphasis added). The first prong of Rule 56 is overly broad because information is considered material even if the information would be rendered irrelevant in light of subsequent argument or explanation by the patentee. Under this standard, inequitable conduct could be found based on an applicant’s failure to disclose information that a patent examiner would readily agree was

not relevant to the prosecution after considering the patentee's argument. Likewise, the second prong of Rule 56 broadly encompasses anything that could be considered marginally relevant to patentability. If an applicant were to assert that his invention would have been non-obvious, for example, anything bearing any relation to obviousness could be found material under the second prong of Rule 56. Because Rule 56 sets such a low bar for materiality, adopting this standard would inevitably result in patent prosecutors continuing the existing practice of disclosing too much prior art of marginal relevance and patent litigators continuing to charge inequitable conduct in nearly every case as a litigation strategy.

The dissent's critique of but-for materiality relies heavily on definitions of materiality in other contexts. Contrary to the implication made in the dissent, however, but-for proof is required to establish common law fraud. Common law fraud requires proof of reliance, which is equivalent to the but-for test for materiality set forth in this opinion. *See* 37 C.J.S. *Fraud* § 51 ("the reliance element of a fraud claim requires that the misrepresentation actually induced the injured party to change its course of action"); *Restatement (Second) of Torts* § 525 (1977) (fraud requires that the party "relies on the misrepresentation in acting or refraining from action"); The remaining examples in the dissent, where but-for materiality is not required, have limited relevance to inequitable conduct. While but-for materiality may not be required in every context, it is appropriate for inequitable conduct in light of the numerous adverse consequences of a looser standard.

Moreover, if this court were to consider standards of materiality in other contexts, the most analogous area of law is copyright. *See Sony Corp. of Am. v. Univ. City Studios, Inc.*, 464 U.S. 417, 439 (1984) (finding it appropriate to draw an analogy between copyrights and patents "because of the historic kinship between patent law and copyright law"). But-for proof is required to invalidate both copyrights and trademarks based on applicant misconduct. *See* 17 U.S.C. § 411(b)(1) (copyright); *Citibank, N.A. v. Citibanc Group, Inc.*, 724 F.2d 1540, 1544 (11th Cir. 1984) (trademarks). The dissent concedes that "but for" materiality is required to cancel a trademark but contends that it is not required to invalidate federal registration of a copyright. Various courts have held otherwise. *See* 2 Melville B. Nimmer & David Nimmer, *Nimmer on Copyright* § 7.20[B][1] (rev. ed. 2010) ("plaintiff's failure to inform the Copyright Office of given facts is without substance, to the extent that the Office would have registered the subject work even had it known those facts"). Moreover, the Copyright Act has codified this "but for" requirement, making clear that copyright registration is sufficient to permit an infringement suit, even if the certificate of registration contains inaccurate information, unless "the inaccuracy of the information, if known, would have caused the Register of Copyrights to refuse registration." 17 U.S.C. § 411(b)(1); *see also* 2 *Nimmer on Copyright* § 7.20[B][2] (explaining that the materiality "standard [set forth in the 2008 amendment to the Copyright Act] is well in line with the construction of the Act prior to this amendment").

In this case, the district court held the ‘551 patent unenforceable for inequitable conduct because Abbott did not disclose briefs it submitted to the EPO regarding the European counterpart of the ‘382 patent. *Trial Opinion* at 1127. Because the district court found statements made in the EPO briefs material under the PTO’s Rule 56 materiality standard, not under the but-for materiality standard set forth in this opinion, this court vacates the district court’s findings of materiality. *Id.* at 1113, 1115. On remand, the district court should determine whether the PTO would not have granted the patent but for Abbott’s failure to disclose the EPO briefs. In particular, the district court must determine whether the PTO would have found Sanghera’s declaration and Pope’s accompanying submission unpersuasive in overcoming the obviousness rejection over the ‘382 patent if Abbott had disclosed the EPO briefs.

The district court found intent to deceive based on the absence of a good faith explanation for failing to disclose the EPO briefs. *Id.* at 1113-16. However, a “patentee need not offer any good faith explanation unless the accused infringer first . . . prove[s] a threshold level of intent to deceive by clear and convincing evidence.” *Star*, 537 F.3d at 1368. The district court also relied upon the “should have known” negligence standard in reaching its finding of intent. *See Trial Opinion* at 1113 (“Attorney Pope knew or should have known that the withheld information would have been highly material to the examiner”). Because the district court did not find intent to deceive under the knowing and deliberate standard set forth in this opinion, this court vacates the district court’s findings of intent. *Id.* at 1113-16. On remand, the district court should determine whether there is clear and convincing evidence demonstrating that Sanghera or Pope knew of the EPO briefs, knew of their materiality, and made the conscious decision not to disclose them in order to deceive the PTO.

For the foregoing reasons, this court vacates the district court’s finding of inequitable conduct and remands for further proceedings consistent with this opinion. This court also reinstates [those portions of the panel decision] affirming the district court’s judgment of obviousness, noninfringement, and anticipation, respectively. The judgment below is

AFFIRMED-IN-PART, VACATED-IN-PART, and REMANDED-IN-PART.

O’Malley, *Circuit Judge*, concurring in part and dissenting in part.

Patent practitioners regularly call on this court to provide clear guidelines. They seek to know under precisely what circumstances governing principles will be applied, and precisely how they will be applied. While precision may be in the nature of what patent practitioners do, and the desire for defining rules in the scientific world understandable, the law does not always lend itself to such precision. Indeed, when dealing with the application of equitable principles and remedies, the law is imprecise by design.

I understand and admire the majority’s desire to respond to practitioners’ calls for precision and clarity. I also understand its concern with perceived litigation abuses surrounding assertions of inequitable conduct. I believe, however, that the majority responds to that call and addresses those concerns in ways that fail to acknowledge and remain true to the equitable nature of the doctrine it seeks to cabin. . . .

“The essence of equity jurisdiction has been the power of the Chancellor to do equity and to mould each decree to the necessities of the particular case.” *Weinberger v. Romero-Barcelo*, 456 U.S. 305, 312 (1982) (quoting *Hecht Co. v. Bowles*, 321 U.S. 321, 329 (1944)). While courts of equity “must be governed by rules and precedents no less than the courts of law,” *Lonchar v. Thomas*, 517 U.S. 314, 323 (1996), “[f]lexibility rather than rigidity has distinguished” equitable jurisdiction, *Weinberger*, 456 U.S. at 312. “Equity eschews mechanical rules; it depends on flexibility.” *Holmberg v. Armbrecht*, 327 U.S. 392, 396 (1946).

Traditional notions of equitable relief apply with equal force in the context of patents. *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 393-94 (2006) (holding that a categorical rule of granting an injunction to a prevailing patent holder abrogates a district court’s discretion in granting equitable relief and runs afoul of traditional principles of equity). We have long recognized that the doctrine of inequitable conduct is based in equity. Despite this longstanding principle, both the majority and dissenting opinions eschew flexibility in favor of rigidity. Both opinions suggest tests for materiality to apply in all cases. Their respective materiality inquiries are black or white, while equity requires judicial consideration of shades of gray. ...

To provide guidance to district courts to aid in the exercise of their discretion in inequitable conduct inquiries—beyond the Supreme Court’s direction that “any willful act concerning the cause of action which rightfully can be said to transgress equitable standards of conduct is sufficient cause for the invocation of the maxim by the chancellor,” *Precision Instrument Mfg. Co. v. Auto. Maint. Mach. Co.*, 324 U.S. 806, 814-16 (1945)—I believe such guidance should reflect the concerns expressed by the Supreme Court in the case trilogy from which the doctrine emerged. As the Court said in *Precision*, at minimum, equity requires that, when seeking the public benefit of a government sponsored monopoly, applicants must act “fairly and without fraud or deceit.” *Id.* ...

With this general guidance in mind, I believe conduct should be deemed material where: (1) but for the conduct (whether it be in the form of an affirmative act or intentional non-disclosure), the patent would not have issued (as Chief Judge Rader explains that concept in the majority opinion); (2) the conduct constitutes a false or misleading representation of fact (rendered so either because the statement made is false on its face or information is omitted which, if known, would render the representation false or misleading); or (3) the district court finds that the behavior is so offensive that the court is left with a firm conviction that the integrity of the PTO process as to the application at issue was wholly undermined. In adopting such a test, I also believe we should confirm, as explained above, that the equitable nature of the doctrine demands that this test provide guidance only—albeit firm guidance—to district courts with respect to the exercise of their discretion in the face of inequitable conduct claims. ...

Applying the test I propose, or any reasonable test for materiality that comports with Supreme Court precedent, I would affirm the district court’s finding that the nondisclosure of information in this case was material. Indeed, I believe the omissions here qualify as material under the majority’s “but-for plus” standard and that, even

accepting that test as the governing standard, a remand on the issue of materiality is neither necessary nor appropriate.

As the other dissenters note, whether the prior art taught that glucose sensors could be used to test whole blood without a protective membrane was a key focus of the PTO examiner's patentability inquiry. After requesting permission to submit extrinsic evidence in response to a rejection from the PTO, Abbott submitted a sworn declaration from its expert Dr. Gordon Sanghera accompanied by statements from its counsel Lawrence Pope. Both contained representations to the examiner regarding what they alleged to be the appropriate understanding of the critical prior art reference with which the examiner was concerned. Among other things, they asserted unequivocally that one skilled in the art would not have read the prior art to say that use of a protective membrane with whole blood samples was optional. Omitted from these declarations was the fact that Abbott had made contrary representations on this same matter to the European Patent Office ("EPO") in connection with the earlier prosecution of a European patent application. There, Abbott represented that it was "unequivocally clear" that the same prior art language meant that the protective membrane was, in fact, optional.

The district court concluded that these non-disclosures were "highly material" because "they centered on the precise sentence in question [in the prior art reference], its meaning and what it taught." *Therasense, Inc. v. Becton, Dickson & Co.*, 565 F. Supp. 2d 1088, 1112 (N.D. Cal. 2008). [Judge O'Malley concluded that the district court's materiality conclusions should be affirmed.]

I do not weigh in on the policy debate between the majority and the dissenters. There are merits to the concerns expressed by each, and they may be relevant, in varying degrees, to the exercise of a court's discretion in a particular case. Policy concerns cannot, however, justify adopting broad legal standards that diverge from doctrines explicated by the Supreme Court. A desire to provide immutable guidance to lower courts and parties similarly is not sufficient to justify the court's attempt to corral an equitable doctrine with neat tests.

To the extent there are concerns with litigation abuses surrounding the improper use of this otherwise important doctrine, there are vehicles available to the district court to address those concerns. Careful application of the pleading requirements set forth in *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312 (Fed. Cir. 2009), early case management techniques designed to ferret out and test unsupported inequitable conduct claims, orders to stay discovery or consideration of such claims pending all other determinations in the case, or even sanctions, are all tools district courts can employ where appropriate.

For these reasons, I concur in part in and dissent in part from the decision the majority announces today. I would leave to district courts the discretion to apply this equitable doctrine to the unique circumstances with which they are presented, while encouraging them to keep in sight their obligation to guard against abuses of it.

Bryson, *Circuit Judge*, with whom Gajarsa, Dyk, and Prost, *Circuit Judges*, join, dissenting.

There is broad consensus that the law of inequitable conduct is in an unsatisfactory state and needs adjustment. In recent years, differing standards have been applied in determining whether particular conduct rises to the level of inequitable conduct sufficient to render a patent unenforceable. That doctrinal uncertainty has had adverse consequences both for patent litigation and for the PTO. In litigation, counterclaims of inequitable conduct have been raised in too many cases and have proved difficult to resolve. In the PTO, the lack of a clear and uniform standard for inequitable conduct has led some patent prosecutors to err on the side of “over-disclosure” in order to avoid the risk of rendering all claims of an otherwise valid patent unenforceable because of the omission of some marginally relevant reference. As a result, examiners have frequently been swamped with an excess of prior art references having little relevance to the applications before them.

These problems can be traced, at least in part, to doctrinal uncertainty on three points: First, what standard of intent should be applied in assessing an allegation that an applicant has made false representations or failed to disclose material facts to the PTO. Second, what standard of materiality should be applied to such misrepresentations or nondisclosures. Third, whether there should be a “sliding scale” under which a strong showing of either materiality or intent should be able to make up for a weaker showing on the other element.

There is substantial agreement as to the proper resolution of two of those three issues. First, the parties to this case and most of the amici agree that proof of inequitable conduct should require a showing of specific intent to deceive the PTO; negligence, or even gross negligence, should not be enough. Second, the parties and most of the amici agree that a party invoking the defense of inequitable conduct should be required to prove both specific intent and materiality by clear and convincing evidence; there should be no “sliding scale” whereby a strong showing as to one element can make up for weaker proof as to the other.

However, on the remaining issue—the proper standard to apply in determining whether the conduct at issue is sufficiently material to render the patent in suit unenforceable—there is sharp disagreement. That disagreement is what divides the court in this case. ...

The majority holds that a failure to disclose information is “material” for purposes of inequitable conduct only if it satisfies the “but for” test; i.e., the conduct must be such that, but for the conduct, the claims would have been found unpatentable. This is not a tweak to the doctrine of inequitable conduct; it is fundamental change that would have the effect of eliminating the independent role of the doctrine of inequitable conduct as to disclosure obligations except in limited circumstances. This court has repeatedly rejected the “but for” test as too restrictive in light of the policies served by the inequitable conduct doctrine. [Citing Federal Circuit cases.] Those policies dictate that it should continue to do so.

As the PTO persuasively argues in its amicus brief, the “but for” standard for materiality is too restrictive to serve the purposes that the doctrine of inequitable conduct was designed to promote. If a failure to disclose constitutes inequitable conduct only

when a proper disclosure would result in rejection of a claim, there will be little incentive for applicants to be candid with the PTO, because in most instances the sanction of inequitable conduct will apply only if the claims that issue are invalid anyway. For example, under the “but for” test of materiality, an applicant considering whether to disclose facts about a possible prior use of the invention would have little reason to disclose those facts to the PTO. If the applicant remained silent about the prior use, the patent issued, and the prior use was never discovered, the applicant would benefit from the nondisclosure. But even if the prior use was discovered during litigation, the failure to disclose would be held to constitute inequitable conduct only if the prior use otherwise rendered the relevant claims invalid. The applicant would thus lose nothing by concealing the prior use from the PTO, because he would not be at risk of losing the right to enforce an otherwise valid patent.

In that situation, particularly if the opportunity to obtain a valuable patent is at stake, there will be no inducement for the applicant to be forthcoming. If the applicant withholds prior art or misleadingly discloses particular matters and succeeds, he obtains a patent that would not have issued otherwise. Even if the nondisclosure or misleading disclosure is later discovered, under the majority’s rule the applicant is no worse off, as the patent will be lost only if the claims would otherwise be held invalid. So there is little to lose by following a course of deceit. It is no indictment of the uprightness and professionalism of patent applicants and prosecutors as a group to say that they should not be subjected to an incentive system such as that. After all, it has long been recognized that “an open door may tempt a saint.” Given the large stakes sometimes at issue in patent prosecutions, a regime that ensures that a dishonest but potentially profitable course of action can be pursued with essentially no marginal added risk is an unwise regime no matter how virtuous its subjects.

It is unrealistic to expect that other means will provide an effective deterrent to ensure that material information will not be withheld during patent prosecutions. The PTO advises us that the prospect of enforcing the duty of disclosure other than through the threat of inequitable conduct claims is not possible or practical. The prospect of agency disciplinary action for disclosure violations is unrealistic, the PTO explains, because the Office is required by statute to file any charges within five years, see 28 U.S.C. § 2462, and it seldom learns of inequitable conduct within that period of time. In addition, the PTO explains that it rarely has access to relevant facts regarding inequitable conduct, because it lacks investigative resources. As a result, the PTO has concluded that a court is the best forum in which to consider alleged breaches of the disclosure duty in the context of an inequitable conduct defense. *See* Patent and Trademark Office Implementation of 37 C.F.R. § 1.56, 1095 Off. Gaz. Pat. & Trademark Office 16 (Oct. 11, 1988). ...

The PTO has defined the disclosure obligation for those involved in patent prosecutions in its Rule 56, which the PTO has promulgated under its statutory authority to establish regulations that “govern the conduct of proceedings in the Office.” 35 U.S.C. § 2(b). [The dissent traces the history of Rule 56, which was first promulgated in 1949, was amended to state a more expansive disclosure duty in 1977, and was revised in 1992 to impose a slightly less expansive duty of disclosure.]

Because the PTO is the best judge of what information its examiners need to conduct effective examinations, the PTO's definition of materiality is entitled to deference in determining whether the failure to disclose particular information during patent prosecution constitutes inequitable conduct. Moreover, because the PTO has refined the materiality standard in setting forth what it expects of applicants and their representatives, there is no need for courts to apply a broader test of materiality in adjudicating inequitable conduct claims, as doing so could at least theoretically result in the imposition of sanctions for a failure to disclose matters that the PTO does not require to be disclosed.³ This is not to suggest that any disclosure requirement that the PTO might have devised would serve as a predicate for an inequitable conduct charge. Because inequitable conduct is an equitable doctrine applied by courts, and not simply a mechanism for judicial enforcement of PTO rules, the scope of the court-made doctrine is not inseparably tied to the breadth of the PTO's disclosure rules. However, the basic purposes of both the inequitable conduct doctrine and Rule 56 are the same, and the disclosure duties that the PTO imposes on applicants, which are defined by Rule 56, are reasonably calculated to produce the disclosure necessary to promote efficient conduct of examinations and to discourage the types of omissions and misrepresentations that (if made intentionally) raise equitable concerns. In these circumstances, considerations of efficiency and economy encourage us to embrace the PTO's approach. So long as it reasonably aligns with our own equitable calculus, we should defer to the PTO's assessment of its needs and treat intentional breaches of the PTO's disclosure rules as providing a basis for a finding of inequitable conduct. *See Bruno Indep. Living*, 394 F.3d at 1353. ...

The facts of this case, as found by the district court, illustrate why the materiality standard of Rule 56 is a suitable test for inequitable conduct claims based on disclosure violations. A central issue during the examination that led to the issuance of the '551 patent was whether the prior art had taught that glucose sensors could be used to test whole blood without a protective membrane. The examiner focused on whether the prior art '382 patent taught the use of sensors without membranes. On its face, the '382 patent seemed to teach that sensors could be used without membranes when testing whole blood because the specification of the '382 patent, when discussing the use of sensors with whole blood, stated the following:

Optionally, but preferably when being used on live blood, a protective membrane surrounds both the enzyme and the mediator layers, permeable to water and glucose molecules.

'382 patent, col. 4, ll. 63-66. A central issue before the examiner was whether the use of the term "optionally" in that passage indicated that it was possible to use the sensors in whole (or live) blood without a protective membrane.

The district court found that the persons involved in prosecuting the '551 application, Abbott's attorney Lawrence Pope and its expert, Dr. Gordon Sanghera, made representations to the examiner that the pertinent passage in the '382 patent should not be taken at face value. In particular, Dr. Sanghera submitted a declaration in which he stated that even though the '382 patent referred to the use of a protective membrane surrounding

the enzyme and mediator layers of the glucose meter as “optionally, but preferably” present, “one skilled in the art would have felt that an active electrode comprising an enzyme and a mediator would require a protective membrane if it were to be used with a whole blood sample.” For that reason, he stated, he was “sure that one skilled in the art would not read [the ‘382 patent] to teach that the use of a protective membrane with a whole blood sample is optionally or merely preferred.” Mr. Pope, the prosecuting attorney, added his own remarks when submitting Dr. Sanghera’s declaration. He stated: “One skilled in the art would not have read the disclosure of the [‘382 patent] as teaching that the use of a protective membrane with whole blood samples was optional. He would not, especially in view of the working examples, have read the optionally, but preferably language . . . as a technical teaching but rather mere patent phraseology.” Mr. Pope added: “There is no teaching or suggestion of unprotected active electrodes for use with whole blood specimens in [the ‘382] patent or the other prior art of record in this application.” Shortly after those submissions were made, the examiner allowed the claims for a membraneless sensor.

The problem, the district court found, is that Abbott had made directly contradictory representations to the European Patent Office (“EPO”) concerning the teaching of the ‘382 patent in connection with the prosecution of a European patent application and had not disclosed those contradictory representations to the PTO. Before the EPO, Abbott represented that the European counterpart to the ‘382 patent referred to a “protective membrane optionally utilized with the glucose sensor of the patent,” and that the membrane was “preferably to be used with in vivo measurements.” With specific reference to the language from the patent reciting the use of the protective membrane “optionally, but preferably when being used on live blood,” Abbott told the EPO: “It is submitted that this disclosure is unequivocally clear. The protective membrane is optional, however, it is preferred when used on live blood in order to prevent the larger constituents of the blood, in particular [the red blood cells] from interfering with the electrode sensor.”

The district court found that Abbott’s representations to the EPO contradicted its representations to the PTO, made through Dr. Sanghera and Mr. Pope. The court’s finding on that issue, made after a detailed analysis of the representations to the two bodies, cannot be held to be clearly erroneous. The district court also found that Abbott’s failure to disclose to the examiner that it had made inconsistent statements to the EPO regarding the teaching of the ‘382 patent was highly material. In particular, the court found that the failure to disclose the inconsistency in those statements was the kind of nondisclosure covered by PTO Rule 56, as being nondisclosure of information “inconsistent with a position the applicant takes in . . . [a]sserting an argument of patentability.” That finding, too, cannot be regarded as clearly erroneous in light of the central role of the pertinent portion of the ‘382 patent in the examination of the application that led to the issuance of the ‘551 patent.

Turning to the issue of intent, the district court found that Abbott’s failure to disclose material information was intentional, i.e., it was made with the specific intent to deceive the PTO. The district court heard live testimony from Mr. Pope and Dr. Sanghera and conducted a detailed analysis of their testimony in light of the record. Based on that

analysis, the court concluded that their efforts to justify their conduct were unpersuasive. The court found that Mr. Pope and Dr. Sanghera were aware of the contrary representations made to the EPO and consciously chose to withhold them from the PTO. The court carefully considered their explanations for their failure to disclose the references and found each witness's explanation to be lacking. The court discredited Mr. Pope's explanation that he understood the term "unequivocally clear" in the EPO submission to relate to the permeability of the membrane, not to the text immediately following the words "unequivocally clear," where it is plainly stated that the membrane is optional. The court was not persuaded by Mr. Pope's statement that he believed "optionally, but preferably" meant, in the context of patents, "optionally, but always."

The court then considered possible alternative reasons for Mr. Pope's decision not to disclose the contradictory EPO statements, such as the possibility that Mr. Pope had misunderstood the meaning of the terms "whole blood" and "live blood." Ultimately, however, the district court could identify no plausible reason for the non-disclosure and therefore found that Mr. Pope had acted with deceptive intent. That finding, based on the court's consideration of Mr. Pope's demeanor and overall credibility, as well as the court's analysis of the record as a whole, cannot be said to be clearly erroneous.

For similar reasons, the court found that Dr. Sanghera also acted with intent to deceive the PTO. The court considered and rejected the possibility that Dr. Sanghera believed that Mr. Pope, Abbott's counsel before the PTO, would disclose the material information. The court began by finding that Dr. Sanghera's declaration before the PTO contained representations that were misleading by omission. The court explained that finding as follows:

He did not have to take this extra step. Having done so, he was obligated to avoid intentional deception. His sworn statements to the PTO about the meaning of the "optionally but preferably" sentence were known by him to be inconsistent with his own company's statements to the EPO— statements he had himself helped craft.

As to Dr. Sanghera's testimony that he believed that statements he made to the PTO did not contradict the statements made to the EPO, the court found that Dr. Sanghera knew that a representation had been made to the EPO that the '326 patent did not require a membrane when used with whole blood. Noting that Dr. Sanghera's trial testimony had been impeached by his prior inconsistent statements on certain points, and finding that Dr. Sanghera exhibited an "unconvincing trial demeanor," the district court found that he acted with the requisite intent to deceive. As in the case of Mr. Pope, the district court's findings as to Dr. Sanghera are not clearly erroneous.

Viewed in light of the district court's findings, this case is a compelling one for applying the principles of inequitable conduct. The district court found that Abbott's representatives deliberately withheld material from the PTO that directly refuted Abbott's contention that one skilled in the art would have believed that the '382 patent taught that a membrane was required for whole blood analysis. Abbott's inconsistent position on the teachings of this critical reference falls squarely within the scope of information of the sort referred to in PTO Rule 56(b)(2), i.e., information that "refutes, or is inconsistent with, a position the applicant takes in . . . [a]sserting an argument of patentability." Given

the examiner's focus on the issue of whether the protective membrane in the prior art patent was optional or not, the issue was of critical importance in the prosecution of the application that issued as the '551 patent, even though the undisclosed information, if revealed, may not have resulted in the rejection of the claims at issue. Accordingly, the district court made all the findings necessary to support its holding that the '551 patent was unenforceable for inequitable conduct. Because the district court's factual findings are not clearly erroneous and because its legal analysis comports with the proper role of the doctrine of inequitable conduct in patent law, the district court's judgment that the '551 patent is unenforceable for inequitable conduct should be affirmed.

I respectfully dissent.

NOTES ON THERASENSE

1. The Inequities of Inequitable Conduct. Despite the close vote in the case—6 to 1 to 4, with the opinion of the court holding only the minimum number of judges necessary to achieve a majority—almost all of the judges agree that the prior law on inequitable conduct was, as the dissent states, “in an unsatisfactory state.” The majority opinion goes a bit further, stating the pre-existing inequitable conduct doctrine “has plagued not only the courts but also the entire patent system.” This agreement arises from a consensus that inequitable conduct doctrine has at least two negative aspects.

First, because a finding of inequitable conduct leads to the strong remedy of unenforceability of the whole patent, patent infringement defendants have powerful incentives to litigate the issue in almost every case. As a consequence, patent infringement litigation is no longer focused on technological issues alone but is also very much a trial about the manner in which the patentee's attorneys prosecuted the application. That expansion of the trial issues also increases the cost of pre-trial discovery because many more issues are capable of being investigated. Moreover, inequitable conduct turns on the subjective intent of individuals involved in prosecution, so live testimony (in contrast to documentary evidence about a technology) is typically necessary to resolve the litigation.

Second, inequitable conduct doctrine also has negative effects on patent prosecutions. As both the majority and dissent note, fear of inequitable conduct doctrine could lead to overdisclosure, with prosecuting attorneys submitting everything imaginable to the examiner. The additional disclosure might not be so bad if the attorneys could at least inform the examiner which documents they consider highly relevant and which they have submitted merely to satisfy the disclosure requirement. Unfortunately, however, any such statements by the attorneys would be extremely risky because, after the patent has issued, infringement defendants could challenge *those statements*—those prioritizing documents for the examiner's attention—as being designed to deceive or mislead the PTO. Indeed, infringement defendants might have an even easier time proving inequitable conduct because opinions about the degree of relevance might vary more from person to person.

In addition to these recognized problems associated with inequitable conduct doctrine, there is another basic problem with the remedy imposed: The doctrine's most

controversial applications occur when it renders unenforceable *valid* patent claims. Everyone can agree that patent applicants who commit fraud *in order to obtain a patent* should be punished harshly, and there are several remedies that do punish such bad actors (including criminal penalties). But if the fraud were necessary to obtain the patent—in other words the patent would be invalid if the true facts were known—then the remedy of unenforceability provides no *additional* punishment. Thus, unenforceability provides the least punishment to the worst actors (whose patents are not valid anyway) and the most punishment to the least culpable actors (those who failed to disclose marginally material information that would not have prevented the patent from issuing). This fundamental mismatch between conduct and punishment is at the root of the controversy surrounding inequitable conduct's unenforceability remedy.

2. Thin Supreme Court Precedent. The Federal Circuit opinion recounts the extremely thin Supreme Court precedent on inequitable conduct. There are only three potentially relevant cases, and two of those involved different legal issues. *Keystone Driller* involved fraud committed before a court, and the legal issue was whether the prior misconduct justified vacating the judgment of infringement in the earlier court proceeding. *Hazel-Atlas* also involved fraud before the courts, and the issue was whether the courts had power to dismiss the lawsuit in which the misconduct occurred. The course of misconduct in *Hazel-Atlas*, while extending into the courts, did start with evidence fabricated in the Patent Office, and the Supreme Court stated that “[h]ad the District Court learned of the fraud on the Patent Office at the original infringement trial, it would have been warranted in dismissing Hartford’s case.” That statement was, however, pure dicta.

Judicial remedies for misconduct before the courts might be fundamentally different from judicial remedies for administrative misconduct. Administrative agencies are, after all, part of a different constitutional branch of government, and recent Supreme Court precedent suggests that courts cannot hold administrative orders unenforceable due to misconduct before the agency at least in circumstances where the agency knew of misconduct and decided not to withhold favorable administrative action. *See ABF Freight System, Inc. v. NLRB*, 510 US 317 (1994) (unanimously holding that the courts may not hold unenforceable an NLRB order issued in favor of an employee who perjured himself before the agency).

Of the three Supreme Court cases, only *Precision Instrument* squarely involve the issue of the proper remedy for misconduct at the Patent Office, although even in that case the course of fraud extended into the courts because the patentee had tried to keep the evidence of the fraud suppressed. *Precision Instrument* involved highly unusual facts where the firm that ultimately became the assignee of the tainted patent had originally been involved in an interference with a competing inventor, who was fraudulently trying to claim more than he had invented. Once it discovered the other inventor’s fraud, the firm blackmailed the inventor not only into conceding defeat in the interference, but also into assigning to the firm other patent claims that were not fraudulent. The patent rights had been *obtained* through misconduct, but the misconduct (blackmail) had nothing to do with the validity of the patents. In those unusual circumstances, the remedy of holding

unenforceable otherwise valid patent claims seems appropriate since the assignee's property interest in the claims had been obtained through blackmail.

Should the absence of additional Supreme Court precedent make the Federal Circuit wary of extending the inequitable conduct doctrine too far? Or should the relatively few Supreme Court decisions be viewed as an invitation for the Federal Circuit to fill in the details of the doctrine?

3. The End of the “Sliding Scale”? Prior to *Therasense*, several Federal Circuit precedents had endorsed a so-called “sliding scale” approach that allowed a strong showing of materiality to reduce somewhat the evidentiary showing needed to prove deceptive intent. See, e.g., *Aventis Pharma S.A. v. Amphastar Pharms., Inc.*, 525 F.3d 1334, 1344 (Fed. Cir. 2008) (holding that “[t]he more material the omission or misrepresentations, the less intent that must be shown to elicit a finding of inequitable conduct”). (In theory, the sliding scale could also work the other way, with strong evidence of an intent to deceive making up for a weaker showing of materiality, the that fact pattern was not common because proof of intent is typically hard to find.)

In *Therasense*, all of the circuit judges reject the “sliding scale” approach, but how reliable is that unanimity? Consider two cases, both of which involve a material document that was known to the prosecuting attorney but not disclosed to the PTO. In both cases, the attorney testifies before the district judge that he did not disclose the document because he did not believe it to be material. In one case, however, the district judge believes the document to be so highly relevant that no trained attorney could possibly think otherwise. In the other case the district judge believes that, while the document is clearly material, at least some attorneys might erroneously, but honestly, think otherwise. Isn't it reasonable for the district judge to conclude in the first case, but not the second, that the attorney is lying and therefore must be trying to cover up an intent to deceive the agency? After *Therasense*, must the district judge now treat the two cases the same? Or can the district judge still use the perceived degree of materiality in judging the credibility of an explanation for nondisclosure?

4. The Majority's “But-For” Standard of Materiality. The *Therasense* court's new standard for materiality sounds extremely difficult for parties to meet: the withheld information will be viewed as material only if, but for the nondisclosure, the PTO would not have granted the patent rights. This new rule may seem to eliminate the most controversial applications of the inequitable conduct doctrine—i.e., cases where the doctrine renders unenforceable otherwise valid patent rights—but it does not in fact eliminate such situations.

Consider two patents, each with ten claims. For the first patent, a single claim would have been rejected had the PTO reviewed certain withheld information. For the second patent, all ten claims would have been rejected. Even under *Therasense*, each patent can be held unenforceable in its entirety. Thus, valid patent rights can still be held unenforceable because of nondisclosure, and the unenforceability remedy still punishes the less culpable party more severely than the more culpable party (because the less culpable party loses enforceability of nine otherwise valid patent claims; the more culpable party loses enforceability of no valid claims).

Note that valuable patents often have dozens of claims, not all of which need to be asserted in any particular infringement case. Will *Therasense*'s new standard of materiality lead to a great deal of litigation about unasserted patent claims that would otherwise be irrelevant to the infringement litigation?

5. A Victory for the Patentee? What is likely to happen on remand in this case? Will the undisclosed documents still meet the “but-for” materiality standard (as Judge O’Malley believes)? Did the patentee really make contradictory representations to the EPO and the PTO? In considering these questions, focus carefully on the distinction between a *protective* membrane (which restricts the flow of red blood cells to the sensor) and a *semipermeable* or *diffusion-limitation* membrane (which restricts the flow of some of the glucose to the sensor).

6. Judge O’Malley’s Flexible Approach. In isolation, Judge O’Malley’s approach to materiality—which would extend to any “misleading representation of fact”—appears to be the broadest approach to inequitable conduct. Yet to temper her capacious view of the materiality, Judge O’Malley would grant district courts flexibility to tailor more limited remedies for inequitable conduct. In one portion of her opinion (not within the excerpt above), Judge O’Malley writes:

While we have held previously that a finding of inequitable conduct renders unenforceable all claims of the wrongly procured patent and, in certain circumstances, related patents, this singular remedy is neither compelled by statute, nor consistent with the equitable nature of the doctrine. Accordingly, I would overrule those cases and hold that, in the exercise of its discretion, a district court may choose to render fewer than all claims unenforceable, may simply dismiss the action before it, or may fashion some other reasonable remedy, so long as the remedy imposed by the court is “commensurate with the violation.” *Columbus Bd. of Educ. v. Penick*, 443 U.S. 449, 465 (1979). Allowing for flexibility in the remedy would reduce the incentive to use inequitable conduct as a litigation tactic and address many of the concerns that trouble my colleagues and were expressed by Abbott and certain amici in these *en banc* proceedings.

What other remedies might be “reasonable”? Consider these possibilities:

(1) *Removing the presumption of validity.* In cases where a patentee has not been fully candid with the PTO, but in which the court is not certain that the withheld information would render some or all of the patent claims invalid, should the court merely refuse to afford the statutory presumption of validity to the patent? The patentee would then bear the burden of proving validity. This remedy would be a significant penalty on the patentee, but patent claims capable of being shown to be valid would still get enforced. Note that the defendants in *Corona Cord Tire Co. v. Donovan Chemical Corp.*, 276 U.S. 358 (1928), were seeking this remedy for the patentee’s misconduct. While the Court in *Corona Cord Tire* rejected imposition of such a penalty in that case, it did so because it held the conduct to be not “essentially material” to the issuance of the patent. In cases where the conduct is more material, however, shouldn’t the first remedy be loss of the presumption of validity, with the “atomic bomb” of unenforceability saved for truly egregious situations?

(2) *Requiring reexamination.* In many cases where a party has withheld information from the PTO, the newly revealed information could be used as the basis for administrative reexamination at the PTO. Should the courts require the patentee to seek reexamination if that is possible? Note that reexamination would give the PTO the power to decide whether it would have granted the patent if it had known about the withheld information.

(3) *Awarding attorney's fees.* In many situations, awarding the accused infringer attorney's fees might also be an appropriate remedy, with or without other remedies. Indeed, in the *Therasense* case itself, most of what was at stake with the inequitable conduct issue was an award of attorney's fees because all of the litigated patent claims had been held invalid.

7. The Dissent's Materiality Rule: Follow the Agency. The dissent proposed to have the materiality standard for inequitable conduct be defined by what the agency considers to be material information. Superficially, this proposal sounds eminently reasonable. After all, isn't the agency in the best position to know what information it needs? Indeed, as the dissent suggests, the PTO's statutory rulemaking power appears to confer full authority to regulate the amount of information that should be disclosed during "the conduct of proceedings in the Office." 35 U.S.C. § 2(b).

Two points about the dissent's proposal are worth noting. First, a follow-the-agency rule would itself have been a change in the law, for the Federal Circuit had previously held that it would not necessarily follow the definition of materiality set forth in the PTO's rules. See *Digital Control, Inc. v. Charles Mach. Works*, 437 F.3d 1309 (Fed. Cir. 2006).

Second, even if the agency's rule were to govern the standard of materiality, the agency would still lack a fundamental degree of control over inequitable conduct doctrine. For example, the courts—not the PTO—would still decide in any particular case which information meets the materiality standard. Patentees would therefore still need to worry about *both* administrative *and* judicial views about materiality. Also, the agency would lack power to decide the remedy for any nondisclosure. As previously mentioned, other administrative agencies have power even to grant relief to parties who perjured themselves in administrative proceedings. See *ABF Freight System, Inc. v. NLRB*, 510 US 317 (1994). The PTO would lack that discretion. Do such limitations on the agency's power undermine the dissent's proposal? Does the majority's rule mean that the agency will need to find some other mechanism(s) to punish beaches of the agency's disclosure rules?

8. The Agency's Power to Punish Administrative Misconduct. As stated in the dissenting opinion, "[t]he prospect of agency disciplinary action for disclosure violations is unrealistic, the PTO explains, because the Office is required by statute to file any charges within five years, see 28 U.S.C. § 2462, and it seldom learns of inequitable conduct within that period of time." The dissent is correct that the PTO made that argument, and it included no caveats on the argument (we've checked the government's brief, which is available at <http://www.patentlyo.com/ts.enbanc.uspto.pdf>).

That's a highly surprising argument for the government to make, given that the government has argued to other circuit courts—successfully!!!—that, in cases of fraud or misleading statements, the five-year statute of limitations in 28 U.S.C. § 2462 begins to run only upon *discovery* of the fraud or misrepresentation. *See, e.g.*, SEC v. Koenig, 557 F.3d 736, 739-40 (7th Cir. 2009); *see also* SEC v. Gabelli, 2011 U.S. App. LEXIS 15810, at *21-*25 (2nd Cir. Aug. 1, 2011) (same). Might the government have omitted some material information in making its arguments to the Federal Circuit?

9. Other Remedies for Nondisclosure. The dissenting judges are worried that, under the majority's "but-for" materiality standard, "an applicant considering whether to disclose facts about a possible prior use of the invention would have little reason to disclose those facts to the PTO." As articulated by the dissent, the concern is that the applicant has much to gain but nothing to lose from the nondisclosure because the applicant "would not be at risk of losing the right to enforce an otherwise valid patent." Does the applicant really have nothing to lose by concealing such information?

In deciding whether withholding information from the PTO is a good idea after *Therasense*, one should consider the other possible remedies for misconduct:

(a) *Disbarment from the PTO.* The PTO clearly has the power to disbar attorneys who commit misconduct in administrative proceedings, including violations of the disclosure obligation in Rule 56. While the PTO represented to the court in *Therasense* that 28 U.S.C. § 2462's five year statute of limitations would make such sanctions practically difficult, the PTO's representation may not have been an accurate statement of the law (as noted above). Moreover, would you want to bet your livelihood on the hope that the agency won't discover your misconduct within five years?

(b) *Criminal Liability for Concealing Material Facts.* 18 U.S.C. § 1001(a) provides in relevant part:

[W]hoever, in any matter within the jurisdiction of the executive, legislative, or judicial branch of the Government of the United States, knowingly and willfully—

(1) falsifies, conceals, or covers up by any trick, scheme, or device a material fact; ...

shall be fined under this title, imprisoned not more than 5 years

(c) *Antitrust Liability.* Under *Walker Process Equipment, Inc. v. Food Machinery & Chemical Corp.*, 382 U.S. 172 (1965), the fraudulent procurement of a patent can generate liability under federal antitrust statutes, and the Federal Circuit has held that liability under *Walker Process* can be triggered from omissions. *See Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1070 (Fed. Cir. 1998) (holding that, "if the evidence shows that the asserted patent was acquired by means of either a fraudulent misrepresentation or a fraudulent omission and that the party asserting the patent was aware of the fraud when bringing suit, such conduct can expose a patentee to liability under the antitrust laws"). Federal antitrust laws authorize harsh penalties such as treble damages, and they are criminal statutes, so imprisonment is also a possibility.

In sum, before anyone decides to withhold evidence from the PTO to get an invalid patent, some consideration should be afforded to the rather severe possible consequences—disbarment, treble damages and prison—that could result from succeeding in obtaining such a patent.

CHAPTER 11: INVENTORS AND OWNERS**B. ASSIGNMENT AND OWNERSHIP****Add to page 1198, after note 5:**

As suggested in the text of the main book, a significant weakness in the position advocated by Stanford and the Solicitor General is that the entire Bayh-Dole scheme applies only where the invention is a “subject invention,” which the Act defines to be “any invention of *the contractor* conceived or first actually reduced to practice in the performance of work under a funding agreement.” 35 U.S.C. § 201(e) (emphasis added). That difficulty proved fatal to the arguments of Stanford and the Government. The case is set forth below. In addition to providing a good introduction to the Bayh-Dole Act, the decision also underscores some basic traditions governing the ownership of patent rights:

LELAND STANFORD JUNIOR UNIV. v. ROCHE MOLECULAR SYS, INC.

131 S. Ct. 2188 (2011)

Chief Justice ROBERTS delivered the opinion of the Court.

Since 1790, the patent law has operated on the premise that rights in an invention belong to the inventor. The question here is whether the University and Small Business Patent Procedures Act of 1980—commonly referred to as the Bayh–Dole Act—displaces that norm and automatically vests title to federally funded inventions in federal contractors. We hold that it does not.

I**A**

In 1985, a small California research company called Cetus began to develop methods for quantifying blood-borne levels of human immunodeficiency virus (HIV), the virus that causes AIDS. A Nobel Prize winning technique developed at Cetus—polymerase chain reaction, or PCR—was an integral part of these efforts. PCR allows billions of copies of DNA sequences to be made from a small initial blood sample.

In 1988, Cetus began to collaborate with scientists at Stanford University’s Department of Infectious Diseases to test the efficacy of new AIDS drugs. Dr. Mark Holodniy joined Stanford as a research fellow in the department around that time. When he did so, he signed a Copyright and Patent Agreement (CPA) stating that he “agree[d] to assign” to Stanford his “right, title and interest in” inventions resulting from his employment at the University. App. to Pet. for Cert. 118a–119a.

At Stanford Holodniy undertook to develop an improved method for quantifying HIV levels in patient blood samples, using PCR. Because Holodniy was largely unfamiliar with PCR, his supervisor arranged for him to conduct research at Cetus. As a condition of gaining access to Cetus, Holodniy signed a Visitor’s Confidentiality Agreement (VCA). That agreement stated that Holodniy “will assign and do[es] hereby

assign” to Cetus his “right, title and interest in each of the ideas, inventions and improvements” made “as a consequence of [his] access” to Cetus. *Id.*, at 122a–124a.

For the next nine months, Holodniy conducted research at Cetus. Working with Cetus employees, Holodniy devised a PCR-based procedure for calculating the amount of HIV in a patient’s blood. That technique allowed doctors to determine whether a patient was benefiting from HIV therapy.

Holodniy then returned to Stanford where he and other University employees tested the HIV measurement technique. Over the next few years, Stanford obtained written assignments of rights from the Stanford employees involved in refinement of the technique, including Holodniy, and filed several patent applications related to the procedure. Stanford secured three patents to the HIV measurement process.

In 1991, Roche Molecular Systems, a company that specializes in diagnostic blood screening, acquired Cetus’s PCR-related assets, including all rights Cetus had obtained through agreements like the VCA signed by Holodniy. After conducting clinical trials on the HIV quantification method developed at Cetus, Roche commercialized the procedure. Today, Roche’s HIV test “kits are used in hospitals and AIDS clinics worldwide.” Brief for Respondents 10–11.

B

In 1980, Congress passed the Bayh–Dole Act to “promote the utilization of inventions arising from federally supported research,” “promote collaboration between commercial concerns and nonprofit organizations,” and “ensure that the Government obtains sufficient rights in federally supported inventions.” 35 U.S.C. § 200. To achieve these aims, the Act allocates rights in federally funded “subject invention[s]” between the Federal Government and federal contractors (“any person, small business firm, or nonprofit organization that is a party to a funding agreement”). §§ 201(e), (c), 202(a). The Act defines “subject invention” as “any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement.” § 201(e).

The Bayh–Dole Act provides that contractors may “elect to retain title to any subject invention.” § 202(a). To be able to retain title, a contractor must fulfill a number of obligations imposed by the statute. The contractor must “disclose each subject invention to the [relevant] Federal agency within a reasonable time”; it must “make a written election within two years after disclosure” stating that the contractor opts to retain title to the invention; and the contractor must “file a patent application prior to any statutory bar date.” §§ 202(c)(1)–(3). The “Federal Government may receive title” to a subject invention if a contractor fails to comply with any of these obligations. *Ibid.*

The Government has several rights in federally funded subject inventions under the Bayh–Dole Act. The agency that granted the federal funds receives from the contractor “a nonexclusive, nontransferrable, irrevocable, paid-up license to practice ... [the] subject invention.” § 202(c)(4). The agency also possesses “[m]arch-in rights,” which permit the agency to grant a license to a responsible third party under certain circumstances, such as when the contractor fails to take “effective steps to achieve practical application” of the

invention. § 203. The Act further provides that when the contractor does not elect to retain title to a subject invention, the Government “may consider and after consultation with the contractor grant requests for retention of rights by the inventor.” § 202(d).

Some of Stanford’s research related to the HIV measurement technique was funded by the National Institutes of Health (NIH), thereby subjecting the invention to the Bayh–Dole Act. Accordingly, Stanford disclosed the invention, conferred on the Government a nonexclusive, nontransferable, paid-up license to use the patented procedure, and formally notified NIH that it elected to retain title to the invention.

C

In 2005, the Board of Trustees of Stanford University filed suit against Roche Molecular Systems, Inc., Roche Diagnostics Corporation, and Roche Diagnostics Operations, Inc. (collectively Roche), contending that Roche’s HIV test kits infringed Stanford’s patents. As relevant here, Roche responded by asserting that it was a co-owner of the HIV quantification procedure, based on Holodniy’s assignment of his rights in the Visitor’s Confidentiality Agreement. As a result, Roche argued, Stanford lacked standing to sue it for patent infringement. 487 F.Supp.2d 1099, 1111, 1115 (N.D.Cal.2007). Stanford claimed that Holodniy had no rights to assign because the University’s HIV research was federally funded, giving the school superior rights in the invention under the Bayh–Dole Act. *Ibid.*

The District Court held that the “VCA effectively assigned any rights that Holodniy had in the patented invention to Cetus,” and thus to Roche. *Id.*, at 1117. But because of the operation of the Bayh–Dole Act, “Holodniy had no interest to assign.” *Id.*, at 1117, 1119. The court concluded that the Bayh–Dole Act “provides that the individual inventor may obtain title” to a federally funded invention “only after the government and the contracting party have declined to do so.” *Id.*, at 1118.

The Court of Appeals for the Federal Circuit disagreed. First, the court concluded that Holodniy’s initial agreement with Stanford in the Copyright and Patent Agreement constituted a mere promise to assign rights in the future, unlike Holodniy’s agreement with Cetus in the Visitor’s Confidentiality Agreement, which itself assigned Holodniy’s rights in the invention to Cetus. See 583 F.3d 832, 841–842 (2009). Therefore, as a matter of contract law, Cetus obtained Holodniy’s rights in the HIV quantification technique through the VCA. Next, the court explained that the Bayh–Dole Act “does not automatically void ab initio the inventors’ rights in government-funded inventions” and that the “statutory scheme did not automatically void the patent rights that Cetus received from Holodniy.” *Id.*, at 844–845. The court held that “Roche possess[e]d an ownership interest in the patents-in-suit” that was not extinguished by the Bayh–Dole Act, “depriv[ing] Stanford of standing.” *Id.*, at 836–837. The Court of Appeals then remanded the case with instructions to dismiss Stanford’s infringement claim. *Id.*, at 849.

We granted certiorari. 562 U.S. —, 131 S.Ct. 502, 178 L.Ed.2d 368 (2010).

II

A

Congress has the authority “[t]o promote the Progress of Science and useful Arts, by securing ... to Authors and Inventors the exclusive Right to their respective Writings and Discoveries.” U.S. Const. Art. I, § 8, cl. 8. The first Congress put that power to use by enacting the Patent Act of 1790. That Act provided “[t]hat upon the petition of any person or persons ... setting forth, that he, she, or they, hath or have invented or discovered” an invention, a patent could be granted to “such petitioner or petitioners” or “their heirs, administrators or assigns.” Act of Apr. 10, 1790, § 1, 1 Stat. 109–110. Under that law, the first patent was granted in 1790 to Samuel Hopkins, who had devised an improved method for making potash, America’s first industrial chemical. U.S. Patent No. 1 (issued July 31, 1790).

Although much in intellectual property law has changed in the 220 years since the first Patent Act, the basic idea that inventors have the right to patent their inventions has not. Under the law in its current form, “[w]hoever invents or discovers any new and useful process, machine, manufacture, or composition of matter ... may obtain a patent therefor.” 35 U.S.C. § 101. The inventor must attest that “he believes himself to be the original and first inventor of the [invention] for which he solicits a patent.” § 115. In most cases, a patent may be issued only to an applying inventor, or—because an inventor’s interest in his invention is “assignable in law by an instrument in writing”—an inventor’s assignee. §§ 151, 152, 261.

Our precedents confirm the general rule that rights in an invention belong to the inventor. See, e.g., *Gayler v. Wilder*, 51 U.S.(10 How. 477), 493, 13 L.Ed. 504 (1851) (“the discoverer of a new and useful improvement is vested by law with an inchoate right to its exclusive use, which he may perfect and make absolute by proceeding in the manner which the law requires”); *Solomons v. United States*, 137 U.S. 342, 346, 26 Ct.Cl. 620, 11 S.Ct. 88, 34 L.Ed. 667 (1890) (“whatever invention [an inventor] may thus conceive and perfect is his individual property”); *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 188, 53 S.Ct. 554, 77 L.Ed. 1114 (1933) (an inventor owns “the product of [his] original thought”). The treatises are to the same effect. See, e.g., 8 Chisum on Patents § 22.01, p. 22–2 (2011) (“The presumptive owner of the property right in a patentable invention is the single human inventor”).

It is equally well established that an inventor can assign his rights in an invention to a third party. See *Dubilier Condenser Corp.*, *supra*, at 187, 53 S.Ct. 554 (“A patent is property and title to it can pass only by assignment”); 8 Chisum on Patents, *supra*, § 22.01, at 22–2 (“The inventor ... [may] transfer ownership interests by written assignment to anyone”). Thus, although others may acquire an interest in an invention, any such interest—as a general rule—must trace back to the inventor.

In accordance with these principles, we have recognized that unless there is an agreement to the contrary, an employer does not have rights in an invention “which is the original conception of the employee alone.” *Dubilier Condenser Corp.*, 289 U.S., at 189,

53 S.Ct. 554. Such an invention “remains the property of him who conceived it.” *Ibid.* In most circumstances, an inventor must expressly grant his rights in an invention to his employer if the employer is to obtain those rights. See *id.*, at 187, 53 S.Ct. 554 (“The respective rights and obligations of employer and employee, touching an invention conceived by the latter, spring from the contract of employment”).

B

Stanford and the United States as *amicus curiae* contend that the Bayh–Dole Act reorders the normal priority of rights in an invention when the invention is conceived or first reduced to practice with the support of federal funds. In their view, the Act moves inventors from the front of the line to the back by vesting title to federally funded inventions in the inventor’s employer—the federal contractor. See Brief for Petitioner 26–27; Brief for United States as *Amicus Curiae* 6.

Congress has in the past divested inventors of their rights in inventions by providing unambiguously that inventions created pursuant to specified federal contracts become the property of the United States. For example, with respect to certain contracts dealing with nuclear material and atomic energy, Congress provided that title to such inventions “shall be vested in, and be the property of, the [Atomic Energy] Commission.” 42 U.S.C. § 2182. Congress has also enacted laws requiring that title to certain inventions made pursuant to contracts with the National Aeronautics and Space Administration “shall be the exclusive property of the United States,” Pub.L. 111–314, § 3, 124 Stat. 3339, 51 U.S.C. § 20135(b)(1), and that title to certain inventions under contracts with the Department of Energy “shall vest in the United States.” 42 U.S.C. § 5908.

Such language is notably absent from the Bayh–Dole Act. Nowhere in the Act is title expressly vested in contractors or anyone else; nowhere in the Act are inventors expressly deprived of their interest in federally funded inventions. Instead, the Act provides that contractors may “elect to retain title to any subject invention.” 35 U.S.C. § 202(a). A “subject invention” is defined as “any invention of the contractor conceived or first actually reduced to practice in the performance of work under a funding agreement.” § 201(e).

Stanford asserts that the phrase “invention of the contractor” in this provision “is naturally read to include all inventions made by the contractor’s employees with the aid of federal funding.” Brief for Petitioner 32 (footnote omitted). That reading assumes that Congress subtly set aside two centuries of patent law in a statutory definition. It also renders the phrase “of the contractor” superfluous. If the phrase “of the contractor” were deleted from the definition of “subject invention,” the definition would cover “any invention ... conceived or first actually reduced to practice in the performance of work under a funding agreement.” Reading “of the contractor” to mean “all inventions made by the contractor’s employees with the aid of federal funding,” as Stanford would, adds nothing that is not already in the definition, since the definition already covers inventions made under the funding agreement. That is contrary to our general “reluctan[ce] to treat statutory terms as surplusage.” *Duncan v. Walker*, 533 U.S. 167, 174, 121 S.Ct. 2120, 150 L.Ed.2d 251 (2001) (internal quotation marks omitted).

Construing the phrase to refer instead to a particular category of inventions conceived or reduced to practice under a funding agreement—inventions “of the contractor,” that is, those owned by or belonging to the contractor—makes the phrase meaningful in the statutory definition. And “invention owned by the contractor” or “invention belonging to the contractor” are natural readings of the phrase “invention of the contractor.” As we have explained, “[t]he use of the word ‘of’ denotes ownership.” *Poe v. Seaborn*, 282 U.S. 101, 109, 51 S.Ct. 58, 75 L.Ed. 239 (1930); see *Flores-Figueroa v. United States*, 556 U.S. —, —, —, 129 S.Ct. 1886, 1889, 1894, 173 L.Ed.2d 853 (2009) (treating the phrase “identification [papers] of another person” as meaning such items belonging to another person (internal quotation marks omitted)); *Ellis v. United States*, 206 U.S. 246, 259, 27 S.Ct. 600, 51 L.Ed. 1047 (1907) (interpreting the phrase “works of the United States” to mean “works belonging to the United States” (internal quotation marks omitted)).

That reading follows from a common definition of the word “of.” See Webster’s Third New International Dictionary 1565 (2002) (“of” can be “used as a function word indicating a possessive relationship”); New Oxford American Dictionary 1180 (2d ed.2005) (defining “of” as “indicating an association between two entities, typically one of belonging”); Webster’s New Twentieth Century Dictionary 1241 (2d ed.1979) (defining “of” as “belonging to”).

Stanford’s reading of the phrase “invention of the contractor” to mean “all inventions made by the contractor’s employees” is plausible enough in the abstract; it is often the case that whatever an employee produces in the course of his employment belongs to his employer. No one would claim that an autoworker who builds a car while working in a factory owns that car. But, as noted, patent law has always been different: We have rejected the idea that mere employment is sufficient to vest title to an employee’s invention in the employer. Against this background, a contractor’s invention—an “invention of the contractor” —does not automatically include inventions made by the contractor’s employees.

The Bayh–Dole Act’s provision stating that contractors may “elect to *retain* title” confirms that the Act does not *vest* title. 35 U.S.C. § 202(a) (emphasis added). Stanford reaches the opposite conclusion, but only because it reads “retain” to mean “acquire” and “receive.” Brief for Petitioner 36 (internal quotation marks omitted). That is certainly not the common meaning of “retain.” “[R]etain” means “to hold or continue to hold in possession or use.” Webster’s Third, *supra*, at 1938; see Webster’s New Collegiate Dictionary 980 (1980) (“to keep in possession or use”); American Heritage Dictionary 1109 (1969) (“[t]o keep or hold in one’s possession”). You cannot retain something unless you already have it. See *Alaska v. United States*, 545 U.S. 75, 104, 125 S.Ct. 2137, 162 L.Ed.2d 57 (2005) (interpreting the phrase “the United States shall retain title to all property” to mean that “[t]he United States ... retained title to *its* property located within Alaska’s borders”) (emphasis added). The Bayh–Dole Act does not confer title to federally funded inventions on contractors or authorize contractors to unilaterally take title to those inventions; it simply assures contractors that they may keep title to whatever it is they already have. Such a provision makes sense in a statute specifying the respective rights and responsibilities of federal contractors and the Government.

The Bayh–Dole Act states that it “take[s] precedence over any other Act which would require a disposition of rights in subject inventions ... that is inconsistent with” the Act. 35 U.S.C. § 210(a). The United States as *amicus curiae* argues that this provision operates to displace the basic principle, codified in the Patent Act, that an inventor owns the rights to his invention. See Brief for United States 21. But because the Bayh–Dole Act, including § 210(a), applies only to “subject inventions”—“inventions of the contractor”—it does not displace an inventor’s antecedent title to his invention. Only when an invention belongs to the contractor does the Bayh–Dole Act come into play. The Act’s disposition of rights—like much of the rest of the Bayh–Dole Act—serves to clarify the order of priority of rights between the Federal Government and a federal contractor in a federally funded invention that already belongs to the contractor. Nothing more.

The isolated provisions of the Bayh–Dole Act dealing with inventors’ rights in subject inventions are consistent with our construction of the Act. Under the Act, a federal agency may “grant requests for retention of rights by the inventor ... [i]f a contractor does not elect to retain title to a subject invention.” § 202(d). If an employee inventor never had title to his invention because title vested in the contractor by operation of law—as Stanford submits—it would be odd to allow the Government to grant “requests for retention of rights by the inventor.” By using the word “retention,” § 202(d) assumes that the inventor had rights in the subject invention at some point, undermining the notion that the Act automatically vests title to federally funded inventions in federal contractors.

The limited scope of the Act’s procedural protections also bolsters our conclusion. The Bayh–Dole Act expressly confers on contractors the right to challenge a Government-imposed impediment to retaining title to a subject invention. § 202(b)(4). As Roche correctly notes, however, “the Act contains not a single procedural protection for third parties that have neither sought nor received federal funds,” such as cooperating private research institutions. Brief for Respondents 29. Nor does the Bayh–Dole Act allow inventors employed by federal contractors to contest their employer’s claim to a subject invention. The Act, for example, does not expressly permit an interested third party or an inventor to challenge a claim that a particular invention was supported by federal funding. In a world in which there is frequent collaboration between private entities, inventors, and federal contractors, see Brief for Pharmaceutical Research and Manufacturers of America as *Amicus Curiae* 22–23, that absence would be deeply troubling. But the lack of procedures protecting inventor and third-party rights makes perfect sense if the Act applies only when a federal contractor has already acquired title to an inventor’s interest. In that case, there is no need to protect inventor or third-party rights, because the only rights at issue are those of the contractor and the Government.

The Bayh–Dole Act applies to subject inventions “conceived *or* first actually reduced to practice in the performance of work” “funded in whole *or in part* by the Federal Government.” 35 U.S.C. §§ 201(e), 201(b) (emphasis added). Under Stanford’s construction of the Act, title to one of its employee’s inventions could vest in the University even if the invention was conceived before the inventor became a University employee, so long as the invention’s reduction to practice was supported by federal

funding. What is more, Stanford's reading suggests that the school would obtain title to one of its employee's inventions even if only one dollar of federal funding was applied toward the invention's conception or reduction to practice.

It would be noteworthy enough for Congress to supplant one of the fundamental precepts of patent law and deprive inventors of rights in their own inventions. To do so under such unusual terms would be truly surprising. We are confident that if Congress had intended such a sea change in intellectual property rights it would have said so clearly—not obliquely through an ambiguous definition of “subject invention” and an idiosyncratic use of the word “retain.” Cf. *Whitman v. American Trucking Assns., Inc.*, 531 U.S. 457, 468, 121 S.Ct. 903, 149 L.Ed.2d 1 (2001) (“Congress ... does not alter the fundamental details of a regulatory scheme in vague terms or ancillary provisions”).

Though unnecessary to our conclusion, it is worth noting that our construction of the Bayh–Dole Act is reflected in the common practice among parties operating under the Act. Contractors generally institute policies to obtain assignments from their employees. See Brief for Respondents 34; Brief for Pharmaceutical Research and Manufacturers of America as *Amicus Curiae* 13–18. Agencies that grant funds to federal contractors typically expect those contractors to obtain assignments. So it is with NIH, the agency that granted the federal funds at issue in this case. In guidance documents made available to contractors, NIH has made clear that “[b]y law, an inventor has initial ownership of an invention” and that contractors should therefore “have in place employee agreements requiring an inventor to ‘assign’ or give ownership of an invention to the organization upon acceptance of Federal funds.” NIH Policies, Procedures, and Forms, A “20–20” View of Invention Reporting to the National Institutes of Health (Sept. 22, 1995). Such guidance would be unnecessary if Stanford's reading of the statute were correct.

Stanford contends that reading the Bayh–Dole Act as not vesting title to federally funded inventions in federal contractors “fundamentally undermin [es]” the Act's framework and severely threatens its continued “successful application.” Brief for Petitioner 45. We do not agree. As just noted, universities typically enter into agreements with their employees requiring the assignment to the university of rights in inventions. With an effective assignment, those inventions—if federally funded—become “subject inventions” under the Act, and the statute as a practical matter works pretty much the way Stanford says it should. The only significant difference is that it does so without violence to the basic principle of patent law that inventors own their inventions.

The judgment of the Court of Appeals for the Federal Circuit is affirmed.

It is so ordered.

Justice SOTOMAYOR, concurring.

I agree with the Court's resolution of this case and with its reasoning. I write separately to note that I share JUSTICE BREYER's concerns as to the principles adopted by the Court of Appeals for the Federal Circuit in *FilmTec Corp. v. Allied–Signal, Inc.*, 939 F.2d 1568 (1991), and the application of those principles to agreements that

implicate the Bayh–Dole Act. See *post*, at 2202 – 2205 (dissenting opinion). Because Stanford failed to challenge the decision below on these grounds, I agree that the appropriate disposition is to affirm. Like the dissent, however, I understand the majority opinion to permit consideration of these arguments in a future case. See *ante*, at 2194, n. 2.

Justice BREYER, with whom Justice GINSBURG joins, dissenting.

The question presented in this case is:

“Whether a federal contractor university’s statutory right under the Bayh–Dole Act, 35 U.S.C. §§ 200–212, in inventions arising from federally funded research can be terminated unilaterally by an individual inventor through a separate agreement purporting to assign the inventor’s rights to a third party.” Brief for Petitioner i.

In my view, the answer to this question is likely no. But because that answer turns on matters that have not been fully briefed (and are not resolved by the opinion of the Court), I would return this case to the Federal Circuit for further argument.

I

The Bayh–Dole Act creates a three-tier system for patent rights ownership applicable to federally funded research conducted by nonprofit organizations, such as universities, and small businesses. It sets forth conditions that mean (1) the funded firm; (2) failing that, the United States Government; and (3) failing that, the employee who made the invention, will likely obtain (or retain) any resulting patent rights (normally in that just-listed order). 35 U.S.C. §§ 202–203. The statute applies to “subject invention[s]” defined as “any *invention of the contractor* conceived or first actually reduced to practice in the performance of work under a funding agreement.” § 201(e) (emphasis added). Since the “contractor” (*e.g.*, a university or small business) is unlikely to “conceiv[e]” of an idea or “reduc[e]” it “to practice” *other than* through its employees, the term “invention of the contractor” must refer to the work and ideas of those employees. We all agree that the term covers those employee inventions that the employee properly assigns to the contractor, *i.e.*, his or her employer. But does the term “subject invention” also include inventions that the employee fails to assign properly?

II

Congress enacted this statute against a background norm that often, but not always, denies individual inventors patent rights growing out of research for which the public has already paid. This legal norm reflects the fact that patents themselves have both benefits and costs. Patents, for example, help to elicit useful inventions and research and to assure public disclosure of technological advances. See, *e.g.*, *Mazer v. Stein*, 347 U.S. 201, 219, 74 S.Ct. 460, 98 L.Ed. 630 (1954); *Bilski v. Kappos*, 561 U.S. —, —, 130 S.Ct. 3218, 3225, 177 L.Ed.2d 792 (2010); *id.*, at —, 130 S.Ct., at 3228 (Stevens, J., concurring in judgment). But patents sometimes mean unnecessarily high prices or restricted dissemination; and they sometimes discourage further innovation and competition by requiring costly searches for earlier, related patents or by tying up ideas, which, were they free, would more effectively spur research and development. See, *e.g.*,

Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc., 548 U.S. 124, 128, 126 S.Ct. 2921, 165 L.Ed.2d 399 (2006) (BREYER, J., dissenting from dismissal of certiorari as improvidently granted); Heller & Eisenberg, Can Patents Deter Innovation? The Anticommons in Biomedical Research, 280 Science 698 (1998).

Thus, Thomas Jefferson wrote of “the difficulty of drawing a line between the things which are worth to the public the embarrassment of an exclusive patent, and those which are not.” Letter to Isaac McPherson (Aug. 13, 1813), in 6 Writings of Thomas Jefferson 181 (H. Washington ed. 1854). And James Madison favored the patent monopoly because it amounted to “compensation for” a community “benefit.” Monopolies. Perpetuities. Corporations. Ecclesiastical Endowments., in J. Madison, Writings 756 (J. Rakove ed.1999).

The importance of assuring this community “benefit” is reflected in legal rules that may deny or limit the award of patent rights where the public has already paid to produce an invention, lest the public bear the potential costs of patent protection where there is no offsetting need for such protection to elicit that invention. Why should the public have to pay twice for the same invention?

Legal rules of this kind include an Executive Order that ordinarily gives to the Government “the entire right, title and interest” to inventions made by Government employees who “conduct or perform research, development work, or both.” 37 CFR § 501.6 (2010) (codifying, as amended, Exec. Order 10096, 3 CFR 292 (1949–1953 Comp.)). See also *Heinemann v. United States*, 796 F.2d 451, 455–456 (C.A.Fed.1986) (holding Executive Order constitutional and finding “no ‘taking’ because the invention was not the property of Heinemann”). They also include statutes, which, in specific research areas, give the Government title to inventions made pursuant to Government contracts. See Atomic Energy Act of 1954, § 152, 68 Stat. 944 (codified as amended at 42 U.S.C. § 2182); National Aeronautics and Space Act of 1958, § 305, 72 Stat. 435 (codified at 42 U.S.C. § 2457), repealed by § 6, 124 Stat. 3444; Federal Nonnuclear Energy Research and Development Act of 1974, § 9, 88 Stat. 1887 (codified as amended at 42 U.S.C. § 5908(a)). And they have included Government regulations, established prior to the Bayh–Dole Act’s enactment, that work in roughly similar ways. See, e.g., 45 CFR § 650.4(b) (1977) (National Science Foundation regulations providing that Foundation would “determine the disposition of the invention [made under the grant] and title to and rights under any patent application”); §§ 8.1(a), 8.2(d) (Department of Health, Education, and Welfare regulations providing that inventions made under department grants “shall be subject to determination” by the agency and that the department may “require that all domestic rights in the invention shall be assigned to the United States”).

These legal rules provide the basic background against which Congress passed the Bayh–Dole Act. And the Act’s provisions reflect a related effort to assure that rights to inventions arising out of research for which the public has paid are distributed and used in ways that further specific important public interests. I agree with the majority that the Act does not simply take the individual inventors’ rights and grant them to the Government. Rather, it assumes that the federal funds’ recipient, say a university or small business, will possess those rights. The Act leaves those rights in the hands of that

recipient, not because it seeks to make the public pay twice for the same invention, but for a special public policy reason. In doing so, it seeks to encourage those institutions *to commercialize* inventions that otherwise might not realize their potentially beneficial public use. 35 U.S.C. § 200. The Act helps assure that commercialization (while “promot[ing] free competition” and “protect[ing] the public,” *ibid.*) by imposing a set of conditions upon the federal funds recipient, by providing that sometimes the Government will take direct control of the patent rights, and by adding that on occasion the Government will permit the individual inventor to retain those rights. §§ 202–203.

Given this basic statutory objective, I cannot so easily accept the majority’s conclusion—that the individual inventor can lawfully assign an invention (produced by public funds) to a third party, thereby taking that invention out from under the Bayh–Dole Act’s restrictions, conditions, and allocation rules. That conclusion, in my view, is inconsistent with the Act’s basic purposes. It may significantly undercut the Act’s ability to achieve its objectives. It allows individual inventors, for whose invention the public has paid, to avoid the Act’s corresponding restrictions and conditions. And it makes the commercialization and marketing of such an invention more difficult: A potential purchaser of rights from the contractor, say a university, will not know if the university itself possesses the patent right in question or whether, as here, the individual, inadvertently or deliberately, has previously assigned the title to a third party.

Moreover, I do not agree that the language to which the majority points—the words “invention of the contractor” and “retain”—requires its result. As the majority concedes, Stanford’s alternative reading of the phrase “ ‘invention of the contractor’ ” is “plausible enough in the abstract.” *Ante*, at 2196. Nor do I agree that the Act’s lack of an explicit provision for “an interested third party” to claim that an invention was not the result of federal funding “bolsters” the majority’s interpretation. *Ante*, at 2198. In any event, universities and businesses have worked out ways to protect the various participants to research. See Brief for Association of American Universities et al. as *Amici Curiae* 22–24 (hereinafter AAU Brief); App. 118–124 (Materials Transfer Agreement between Cetus and Stanford University).

Ultimately, the majority rejects Stanford’s reading (and the Government’s reading) of the Act because it believes that it is inconsistent with certain background norms of patent law, norms that ordinarily provide an individual inventor with full patent rights. *Ante*, at 2196 – 2197. But in my view, the competing norms governing rights in inventions for which the public has already paid, along with the Bayh–Dole Act’s objectives, suggest a different result.

III

There are two different legal routes to what I consider an interpretation more consistent with the statute’s objectives. First, we could set aside the Federal Circuit’s interpretation of the licensing agreements and its related licensing doctrine. That doctrine governs interpretation of licensing agreements made *before* an invention is conceived or reduced to practice. Here, there are two such agreements. In the earlier agreement—that between Dr. Holodniy and Stanford University—Dr. Holodniy said, “I *agree to assign ... to Stanford ... that right, title and interest in and to ... such inventions as required by*

Contracts and Grants.” App. to Pet. for Cert. 119a (emphasis added). In the later agreement—that between Dr. Holodniy and the private research firm Cetus—Dr. Holodniy said, “I will assign and *do hereby assign* to Cetus, my right, title, and interest in” here relevant “ideas” and “inventions.” *Id.*, at 123a (emphasis added; capitalization omitted).

The Federal Circuit held that the earlier Stanford agreement’s use of the words “agree to assign,” when compared with the later Cetus agreement’s use of the words “do hereby assign,” made all the difference. It concluded that, once the invention came into existence, the latter words meant that the Cetus agreement trumped the earlier, Stanford agreement. 583 F.3d 832, 841–842 (C.A.Fed.2009). That, in the Circuit’s view, is because the latter words operated upon the invention automatically, while the former did not. Quoting its 1991 opinion in *FilmTec Corp. v. Allied-Signal, Inc.*, 939 F.2d 1568, 1572, the Circuit declared that “ [o]nce the invention is made and [the] application for [a] patent is filed, ... legal title to the rights accruing thereunder would be in the assignee [*i.e.*, Cetus] ..., and the assignor-inventor would have nothing remaining to assign.” 583 F.3d, at 842.

Given what seem only slight linguistic differences in the contractual language, this reasoning seems to make too much of too little. Dr. Holodniy executed his agreement with Stanford in 1988. At that time, patent law appears to have long specified that a present assignment of future inventions (as in both contracts here) conveyed equitable, but not legal, title. See, *e.g.*, G. Curtis, *A Treatise on the Law of Patents for Useful Inventions* § 170, p. 155 (3d ed. 1867) (“A contract to convey a future invention ... cannot alone authorize a patent to be taken by the party in whose favor such a contract was intended to operate”); Comment, *Contract Rights as Commercial Security: Present and Future Intangibles*, 67 *Yale L.J.* 847, 854, n. 27 (1958) (“The rule generally applicable grants equitable enforcement to an assignment of an expectancy but demands a further act, either reduction to possession or further assignment of the right when it comes into existence”).

Under this rule, both the initial Stanford and later Cetus agreements would have given rise only to equitable interests in Dr. Holodniy’s invention. And as between these two claims in equity, the facts that Stanford’s contract came first and that Stanford subsequently obtained a postinvention assignment as well should have meant that Stanford, not Cetus, would receive the rights its contract conveyed.

In 1991, however, the Federal Circuit, in *FilmTec*, adopted the new rule quoted above—a rule that distinguishes between these equitable claims and, in effect, says that Cetus must win. The Federal Circuit provided no explanation for what seems a significant change in the law. See 939 F.2d, at 1572. Nor did it give any explanation for that change in its opinion in this case. See 583 F.3d, at 841–842. The Federal Circuit’s *FilmTec* rule undercuts the objectives of the Bayh–Dole Act. While the cognoscenti may be able to meet the *FilmTec* rule in future contracts simply by copying the precise words blessed by the Federal Circuit, the rule nonetheless remains a technical drafting trap for the unwary. See AAU Brief 35–36. But cf. *ante*, at 2199 (assuming ease of obtaining effective assignments). It is unclear to me why, where the Bayh–Dole Act is at issue, we should

prefer the Federal Circuit's *FilmTec* rule to the rule, of apparently much longer vintage, that would treat both agreements in this case as creating merely equitable rights.

At the same time, the Federal Circuit's reasoning brings about an interpretation contrary to the intention of the parties to the earlier, Stanford, contract. See App. to Pet. for Cert. 120a (provision in Stanford contract promising that Dr. Holodniy "will not enter into any agreement creating copyright or patent obligations in conflict with this agreement"). And it runs counter to what may well have been the drafters' reasonable expectations of how courts would interpret the relevant language.

Second, we could interpret the Bayh–Dole Act as ordinarily assuming, and thereby ordinarily requiring, an assignment of patent rights by the federally funded employee to the federally funded employer. I concede that this interpretation would treat federally funded employees of contractors (subject to the Act) differently than the law ordinarily treats private sector employees. The Court long ago described the latter, private sector principles. In *United States v. Dubilier Condenser Corp.*, 289 U.S. 178, 53 S.Ct. 554, 77 L.Ed. 1114 (1933), the Court explained that a "patent is property, and title to it can pass only by assignment." *Id.*, at 187, 53 S.Ct. 554. It then described two categories of private sector employee-to-employer assignments as follows: First, a person who is

"employed to make an invention, who succeeds, during his term of service, in accomplishing that task, is bound to assign to his employer any patent obtained." *Ibid.*

But, second,

"if the employment be general, albeit it cover a field of labor and effort in the performance of which the employee conceived the invention for which he obtained a patent, the contract is not so broadly construed as to require an assignment of the patent." *Ibid.*

The Court added that, because of "the peculiar nature of the act of invention," courts are "reluctan[t] ... to imply or infer an agreement by the employee to assign his patent." *Id.*, at 188, 53 S.Ct. 554. And it applied these same principles governing assignment to inventions made by employees of the United States. *Id.*, at 189–190, 53 S.Ct. 554.

Subsequently, however, the President promulgated Executive Order 10096. Courts have since found that this Executive Order, not *Dubilier*, governs Federal Government employee-to-employer patent right assignments. See, e.g., *Kaplan v. Corcoran*, 545 F.2d 1073, 1076–1077 (C.A.7 1976); *Heinemann*, 796 F.2d, at 455–456; *Wright v. United States*, 164 F.3d 267, 269 (C.A.5 1999); *Halas v. United States*, 28 Fed.Cl. 354, 364 (1993). The Bayh–Dole Act seeks objectives roughly analogous to the objectives of the Executive Order. At least one agency has promulgated regulations that require Bayh–Dole contractors to insist upon similar assignments. See NIH Policies, Procedures, and Forms, A "20–20" View of Invention Reporting to the National Institutes of Health (Sept. 22, 1995) (available in the Clerk of Court's case file) (requiring a Government contractor, such as Stanford University, to "have in place employee agreements requiring an inventor to 'assign' or give ownership of an invention to the organization upon acceptance of Federal funds," as the Bayh–Dole Act "require[s]"). And an *amicus* brief, filed by major associations of universities, scientists, medical researchers, and others, argues that we

should interpret the rules governing assignments of the employees at issue here (and consequently the Act's reference to "inventions of the contractor") in a similar way. AAU Brief 5–14.

The District Court in this case adopted roughly this approach. 487 F.Supp.2d 1099, 1118 (N.D.Cal.2007) (“[A]lthough title still vests in the named inventor, the inventor remains under a legal obligation to assign his interest either to the government or the nonprofit contractor unless the inventor acts within the statutory framework to retain title”). And since a university often enters into a grant agreement with the Government for a researcher's benefit and at his request, see J. Hall, *Grant Management* 205 (2010), implying such a presumption in favor of compliance with the grant agreement, and thus with the Bayh–Dole Act, would ordinarily be equitable.

IV

As I have suggested, these views are tentative. That is because the parties have not fully argued these matters (though one *amicus* brief raises the license interpretation question, see Brief for Alexander M. Shukh as *Amicus Curiae* 18–24, and at least one other can be read as supporting something like the equitable presumption I have described, see AAU Brief 5–14). Cf. *ante*, at 2194, n. 2. While I do not understand the majority to have foreclosed a similarly situated party from raising these matters in a future case, see *ibid.*, I believe them relevant to our efforts to answer the question presented here. Consequently, I would vacate the judgment of the Federal Circuit and remand this case to provide the parties with an opportunity to argue these, or related, matters more fully.

Because the Court decides otherwise, with respect, I dissent.