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Patent Law: An Open-Source Casebook (Chapter 8: Defenses)

Dmitry Karshtedt

Mark D. Janis

Ted M. Sichelman

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Chapter 8: Defenses to Infringement

CHAPTER EDITOR:

Dmitry Karshtedt, Assoc. Professor of Law,
George Washington University School of Law

EDITORS:

Mark D. Janis, Robert A. Lucas Chair of Law,
Indiana University Maurer School of Law (Bloomington)

Ted Sichelman, Professor of Law,
University of San Diego School of Law

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Defenses to Infringement

The previous chapters set forth two general, distinct ways in which accused infringers can defend against patentees' claims in litigation. The first is noninfringement, discussed in Chapter 7. The second is invalidity, which can be brought on the grounds discussed in Chapters 2–6. This Chapter covers additional equitable and legal defenses to patent infringement. The Chapter focuses on inequitable conduct, patent exhaustion (sometimes also called first sale), patent misuse, laches, equitable estoppel, and the so-called "experimental use" defense. Less frequently encountered defenses, which we also address in this Chapter, are spoliation of evidence and unclean hands.

There are significant differences in how these various defenses operate. A judgment of inequitable conduct will render a patent permanently unenforceable against anyone. In contrast, as we will see in Section C, misuse can be "cured." Laches and equitable estoppel can be invoked based on a plaintiff's conduct against a particular defendant, and are defenses personal to that defendant. Thus, they cannot result in general unenforceability of a patent. Experimental use, too, is a personal defense. Finally, the defense of patent exhaustion is different still—it can generally be asserted when the patentee made an authorized sale of a product covered by a patent, and bars lawsuits targeting users (or resellers) of those products. We start with inequitable conduct, which is derived from the equitable defense of unclean hands.

A. INEQUITABLE CONDUCT

Under 37 C.F.R. § 1.56 (Rule 56), the patent applicant and the applicant's attorney or agent owe to the PTO the duty "to disclose information material to patentability." This so-called "duty of candor" includes, for example, the duty to disclose to the PTO the relevant prior art of which the applicant is aware. Rule 56(b) defines materiality as follows:

> Under this section, information is material to patentability when it is not cumulative to information already of record or being made of record in the application, 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.

The following cases explore, among other issues, the relationship between Rule 56 and the doctrine of inequitable conduct.

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

649 F.3d 1276 (Fed. Cir. 2011) (en banc)

RADER, Chief Judge:

The United States District Court for the Northern District of California found U.S. Patent No. 5,820,551 ("the '551 patent") unenforceable due to inequitable conduct. *Therasense, Inc. v. Becton, Dickinson & Co.*, 565 F. Supp. 2d 1088 (N.D. Cal. 2008). Therasense, Inc. (now Abbott Diabetes Care, Inc.) and Abbott Laboratories (collectively, "Abbott") appeal that judgment. This court vacates and remands for further proceedings consistent with this opinion.

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 for testing whole blood without a membrane over the electrode:

> 1. A single use disposable electrode strip for attachment to the signal readout circuitry of a sensor to detect a current representative of the concentration of a compound in a drop of a whole blood sample comprising:
>
> a) an elongated support having a substantially flat, planar surface, adapted for releasable attachment to said readout circuitry;
> b) a first conductor extending along said surface and comprising a conductive element for connection to said readout circuitry;
> c) an active electrode on said strip in electrical contact with said first conductor and positioned to contact said whole blood sample;
> d) a second conductor extending along said surface comprising a conductive element for connection to said read out [sic] circuitry; and

> e) a reference counterelectrode in electrical contact with said second conductor and positioned to contact said whole blood sample,
> *wherein said active electrode is configured to be exposed to said whole blood sample without an intervening membrane or other whole blood filtering member . . . .*

'551 patent col. 13 l. 29–col. 14 l.3 (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.

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] . . . .

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. . . . [T]o 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.*

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*

> *erythrocytes 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.*

II

In March 2004, Becton, Dickinson and Co. ("Becton") sued Abbott in the District of Massachusetts seeking a declaratory judgment of noninfringement of U.S. Patent Nos. 6,143,164 ("the '164 patent") and 6,592,745 ("the '745 patent"). Becton's product was a blood glucose test strip, the BD Test Strip. Abbott countersued Becton in the Northern District of California alleging that Becton's strip infringed the '164, '745, and '551 patents. The District of Massachusetts then transferred its case to the Northern District of California. Abbott then sued Nova Biomedical Corp. ("Nova"), Becton's supplier, alleging infringement of the patents asserted in Abbott's suit against Becton. In August 2005, Abbott also sued Bayer Healthcare LLC ("Bayer"), alleging that its Microfill and Autodisc blood glucose strips infringed the '551 and '745 patents. The Northern District of California consolidated all of the cases.

. . .

Following a bench trial, the district court determined that claims 1–4 of the '551 patent were invalid due to obviousness in light of the '382 patent and U.S. Patent No. 4,225,410 ("the '410 patent"). The central issue for obviousness was whether the prior art would have disclosed a glucose sensor without a membrane for whole blood to a person of ordinary skill in the art. The district court found that the '382 patent disclosed sensors in which "a protective membrane was optional in all cases except the case of live blood, in which case the protective membrane was preferred—but not required." Of primary relevance here, the district court held the '551 patent unenforceable for inequitable conduct because Abbott did not disclose to the PTO its briefs to the EPO filed on January 12, 1994 and May 23, 1995.

Abbott appealed the judgments of invalidity, unenforceability, and noninfringement. . . .

Recognizing the problems created by the expansion and overuse of the inequitable conduct doctrine, this court granted Abbott's petition for rehearing en banc . . . . This court now vacates the district court's inequitable conduct judgment and remands.

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 Instrument 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 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."

Perhaps most importantly, the remedy for inequitable conduct is the "atomic bomb" of patent law. *Aventis Pharma S.A. v. Amphastar Pharm., Inc.*, 525 F.3d 1334, 1349 (Fed. Cir. 2008) (Rader, J., dissenting). 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.

. . .

With these far-reaching consequences, it is no wonder that charging inequitable conduct has become a common litigation tactic. . . . "[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); *see also Abbott Labs. v. Sandoz, Inc.*, 544 F.3d 1341, 1358 (Fed. Cir. 2008); *Multiform Desiccants, Inc. v. Medzam, Ltd.*, 133 F.3d 1473, 1482 (Fed. Cir.1998); *Magnivision, Inc. v. Bonneau Co.*, 115 F.3d 956, 960 (Fed. Cir. 1997); *Allied Colloids Inc. v. Am. Cyanamid Co.*, 64 F.3d 1570, 1578 (Fed. Cir. 1995); *Molins*, 48 F.3d at 1182.

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. . . ." 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. *See Star*, 537 F.3d at 1366 ("the fact that information later found material was not disclosed cannot, by itself, satisfy the deceptive intent element of inequitable conduct").

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. . . .

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. . . . *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. . . .

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 (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. . . . 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. . . . 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.

. . .[T]he 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).

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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.

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VII

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. 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. 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. 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. . . . 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. 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.

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[*Affirmed-in-part, vacated-in-part, and remanded-in-part.*]

[Concurring opinion of O'MALLEY, Circuit Judge, omitted]

BRYSON, Circuit Judge, with whom GAJARSA, DYK, and PROST, Circuit Judges, join, dissenting:

I

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 "overdisclosure" 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 takes the position that nondisclosures should be deemed sufficiently material to trigger the defense of inequitable conduct only if, had the matter in question been disclosed, the applicant would not have obtained a patent. That position, however, marks a significant and, I believe, unwise departure from this court's precedents. Since its first days, this court has looked to the PTO's disclosure rule, Rule 56, 37 C.F.R. § 1.56, as the standard for defining materiality in inequitable conduct cases involving the failure to disclose material information. In its current form, that rule provides that information is material not only if it establishes a prima facie case of unpatentability, but also if it refutes or is inconsistent with a position the applicant takes before the PTO with respect to patentability. I would adhere to the materiality standard set forth in the PTO's disclosure rule for two basic reasons: First, the PTO is in the best position to know what information examiners need to conduct effective and efficient examinations, i.e., what information is material to the examination process. Second, the higher standard of materiality adopted by the majority will not provide appropriate incentives for patent applicants to comply with the disclosure obligations the PTO places upon them.

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[A] five-judge panel opinion in *J.P. Stevens & Co. v. Lex Tex Ltd.*, 747 F.2d 1553 (Fed. Cir. 1984), had addressed the materiality requirement and made the following observations, which have remained the law until today: First, the court endorsed the principle, previously adopted by our predecessor court, that inequitable conduct is broader than common law fraud. *Id.* at 1559 (citing *Norton v. Curtiss*, 433 F.2d 779, 793 (CCPA 1970)). Second, the court explained that inequitable conduct could be based on the failure to disclose material information as well as the submission of false material information. *Id.* Third, the court stated that the disclosure requirement set forth in PTO Rule 56, 37 C.F.R. § 1.56 (1984), established "the appropriate starting point" because that standard "most closely aligns with how one ought to conduct business with the PTO." *J.P. Stevens*, 747 F.2d at 1559. In so doing, the court referred to its earlier opinion in *Driscoll v. Cebalo*, 731 F.2d 878, 884 (Fed. Cir. 1984), where the court had stated that PTO Rule 56 "essentially represents a codification of the 'clean hands' maxim as applied to patent applicants." Moreover, . . . the court in *Gardco Manufacturing, Inc. v. Herst Lighting Co.*, 820 F.2d 1209, 1214 (Fed. Cir.

1987), had reiterated that Rule 56 set forth the appropriate standard for determining the materiality of undisclosed information in an inequitable conduct case.

. . .

The majority, however, has taken a far more radical approach. With respect to the issue of materiality, the majority has adopted a test that has no support in this court's cases and is inconsistent with a long line of precedents dating back to the early years of this court. The effect of the majority's new test, moreover, does not merely reform the doctrine of inequitable conduct, but comes close to abolishing it altogether. I respectfully dissent from that aspect of the court's decision. In my view, what is needed is not to jettison the doctrine of inequitable conduct, but simply to reaffirm the principles set down in the early years of this court in light of the provisions of the current PTO disclosure rule, and require adherence to those principles. As applied to the duty of an applicant or attorney to disclose material information in the course of prosecuting a patent application, those principles can be summarized as follows:

1. Inequitable conduct requires proof, by clear and convincing evidence, that the applicant or attorney intended to mislead the PTO with respect to a material matter.

2. Materiality is measured by what the PTO demands of those who apply for and prosecute patent applications. The disclosure standard that the PTO expects those parties to comply with is set forth in the current version of the PTO's Rule 56. Under that standard, inequitable conduct requires proof that the information at issue either established, by itself or in combination with other information, a prima facie case of unpatentability, or was inconsistent with a position taken by the applicant before the PTO with respect to patentability.

3. Intent to mislead and materiality must be separately proved. There is no "sliding scale" under which the degree of intent that must be proved depends on the strength of the showing as to the materiality of the information at issue. . . .

These principles not only are consistent with our law on inequitable conduct but, if implemented consistently, should be sufficient to address the practical problems that have arisen under the current regime.

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II

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. . . . 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.

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III

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B

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In 1992, the PTO revised Rule 56, adopting what it called a "clearer and more objective definition of what information the Office considers material to patentability." Duty of Disclosure, 57 Fed. Reg. 2021, 2023 (Jan. 17, 1992). As revised in 1992, the current version of Rule 56 imposes a duty on individuals associated with the filing and prosecution of an application to disclose to the Office all information known to be material to patentability as defined in the rule. Rule 56(a). The rule then states that information is "material" if it is "not cumulative to information already of record or being made of record in the application" 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.

. . .

It is the second part of the rule, Rule 56(b)(2), to which the appellants object. That part of the rule requires the applicant to provide information that is inconsistent with or refutes a position taken by the applicant before the office. Rule 56(b)(2) clearly goes beyond a "but for" test and is therefore the focus of the dispute in this case.

At the time it adopted the 1992 revision to Rule 56, the PTO considered the possibility of adopting a "but for" test of materiality of the sort that the majority has adopted today. The Office rejected that test, concluding that adopting such a narrow standard "would not cause the Office to obtain the information it needs to evaluate patentability so that its decisions may be presumed correct by the courts." The PTO added that if it did not have the needed information, "meaningful examination of patent applications will take place for the first time in an infringement case before a district court." Duty of Disclosure, 57 Fed. Reg. at 2023.

. . .

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]

[3] . . . The majority holds that the "but for" test does not apply to "affirmative acts of egregious misconduct." It then adds that neither "nondisclosure of prior art references to the PTO nor failure to mention prior art references in an affidavit constitutes affirmative egregious misconduct" under any circumstances. As this case illustrates, it is often difficult to draw a line between nondisclosure and affirmative misrepresentation. For example, is a submission to the PTO that purports to describe the state of the prior art but knowingly omits the closest prior art an "affirmative act" of misconduct or merely a "non-disclosure of information"? . . . The distinction between "affirmative acts" and "nondisclosure" is thus apt to become fertile ground for litigation in the future, not to mention the distinction between "egregious" misconduct and misconduct that is assertedly less than "egregious." . . .

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C

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Under this court's new rule, an applicant who conceals information with the intent to deceive the PTO will be free to enforce his patent unless it can be proved by clear and convincing evidence that the patent would not have issued but for the fraud. Even though the majority justifies its new rule in part by asserting that it will improve the prosecution of patents before the PTO, I am convinced that the new rule is likely to have an adverse impact on the PTO and the public at large, a view that—significantly—is shared by the PTO itself.

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INTELLECT WIRELESS, INC., v. HTC CORP.

732 F.3d 1339 (Fed. Cir. 2013)

MOORE, Circuit Judge:

Intellect Wireless, Inc. (Intellect) appeals from the district court's judgment that U.S. Patent Nos. 7,266,186 ('186 patent) and 7,310,416 ('416 patent) are unenforceable due to inequitable conduct. We affirm.

BACKGROUND

The technology at issue in this case involves wireless transmission of caller identification (ID) information. The asserted patents share the same specification, which discloses providing caller ID information from a message center to a personal communication device, such as a cell-phone, via a wireless network. '186 patent, at [57]; *id.* col. 4. l. 66–col. 5 l. 4. The specification also teaches displaying the caller ID information on the cell phone's screen. *Id.* col. 15 ll. 20–24. Claim 1 of the '186 patent is representative:

> A wireless portable communication device for use by a message recipient for receiving a picture from a message originator having a telephone number, comprising:
>
> a receiver operably coupled to receive a message from a message center over a wireless connection, the message including a non-facsimile picture supplied by the message originator and a caller ID automatically provided by a communications network that identifies the telephone number of the message originator, the message originator sending the caller ID with the picture to the message center;
> a display; and
> a controller operably coupled to display the picture and caller ID on the display.

'186 patent, claim 1 (emphasis added).

Intellect sued HTC Corporation and HTC America, Inc. (HTC) for patent infringement. After a bench trial, the district court held the asserted patents unenforceable due to inequitable conduct by the sole inventor, Mr. Daniel Henderson. *Intellect Wireless, Inc. v. HTC Corp.*, 910 F. Supp. 2d 1056 (N.D. Ill. 2012).

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DISCUSSION

"To prove inequitable conduct, the challenger must show by clear and convincing evidence that the patent applicant (1) misrepresented or omitted information material to patentability, and (2) did so with specific intent to mislead or deceive" the U.S. Patent and Trademark Office (PTO). *In re Rosuvastatin Calcium Patent Litig.*, 703 F.3d 511, 519 (Fed. Cir. 2012). "When the patentee has engaged in affirmative acts of egregious misconduct, such as the filing of an unmistakably false affidavit, the misconduct is material." *Therasense, Inc v. Becton, Dickinson & Co.*, 649 F.3d 1276, 1292 (Fed. Cir. 2011) (en banc).

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I. Materiality

The district court held that HTC proved the materiality prong of inequitable conduct. The court found that Mr. Henderson submitted to the PTO a declaration under 37 C.F.R. § 1.131 (Rule 131) containing false statements. To overcome a prior art reference during prosecution, Mr. Henderson averred that "the claimed invention was actually reduced to practice and was demonstrated at a meeting . . . in July of 1993." However, the district court found that the claimed subject matter was never actually reduced to practice. *Intellect*, 910 F. Supp. 2d at 1071–72. The court also found "no evidence that any of the false statements in any of the declarations were actually withdrawn, specifically called to the attention of the PTO or fully corrected."

Intellect argues that the district court clearly erred in its materiality finding. Intellect contends that Mr. Henderson's prosecuting attorney quickly corrected the false declaration by filing a revised Rule 131 declaration, which did not include facts supporting actual reduction to practice. It argues that the attorney explained to the Examiner that the applicant was relying on constructive reduction to practice. . . . Intellect lastly argues that the district court discounted evidence that the remaining reference to "actual reduction to practice" in the revised declaration was an inadvertent mistake.

HTC counters that the district court did not clearly err when it found materiality because Mr. Henderson filed multiple unmistakably false declarations during prosecution. Specifically, it argues that Mr. Henderson falsely claimed actual reduction to practice in the original Rule 131 declaration in order to overcome a prior art reference. HTC points out that the revised declaration still referred to "actual reduction to practice." HTC argues that Mr. Henderson made this false assertion during prosecution of other family patents, which suggests that this language was not mere drafting error. HTC contends that neither Mr. Henderson nor his attorney expressly advised the PTO about the misrepresentations during prosecution, as required to cure the misconduct.

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We agree with HTC. It is undisputed that Mr. Henderson's original declaration was unmistakably false. Absent curing, this alone establishes materiality. There is no dispute in this case that Mr. Henderson did not actually reduce the claimed invention to practice—nor did he demonstrate a prototype in July of 1993. Thus, the original declaration contains multiple unmistakably false statements. . . . Intellect argues that Mr. Henderson's revised declaration and subsequent statements to the PTO corrected these misrepresentations. We do not agree.

When an applicant files a false declaration, we require that the applicant "expressly advise the PTO of [the misrepresentation's] existence, stating specifically wherein it resides." *Rohm & Haas Co. v. Crystal Chem. Co.*, 722 F.2d 1556, 1572 (Fed. Cir. 1983). Further, "if the misrepresentation is of one or more facts, the PTO [must] be advised what the actual facts are." *Id.* Finally, the applicant must "take the necessary action . . . openly. It does not suffice that one knowing of misrepresentations in an application or in its prosecution merely supplies the examiner with accurate facts without calling his attention to the untrue or misleading assertions sought to be overcome, leaving him to formulate his own conclusions." *Id.*

The district court did not err in concluding that Mr. Henderson's revised declaration failed to correct the falsehoods in the original declaration under the Rohm & Haas standard. At best, the revised declaration obfuscated the truth. It mentioned "diligence from the date of conception to the effective filing date," implying that Mr. Henderson was now relying upon constructive reduction to practice. But the revised declaration did not cure the misconduct because it never expressly negated the false references to actual reduction to practice in the original declaration. In the original declaration, Mr. Henderson told the PTO that he actually reduced the invention to practice and demonstrated it at a meeting in July of 1993. In the revised declaration, he described a "prototype now in the Smithsonian that was in development for a . . . demonstration" in July of 1993, a statement that could be read to mean that a device embodying the claimed invention was actually built during that month. The revised declaration also described a "product brochure and packing receipt," which further implied the existence of an actual working device. Finally, the revised declaration expressly mentioned "actual reduction to practice" and "bringing the claimed subject matter to commercialization," further obscuring the truth. Most importantly, the declaration nowhere expressly stated the actual facts, which are that "neither [Mr. Henderson] nor Intellect Wireless actually reduced to practice" the inventions claimed in the asserted patents. Nowhere did the declaration openly advise the PTO of Mr. Henderson's misrepresentations, as our precedent clearly requires. *See Rohm & Haas*, 722 F.2d at 1572.

Intellect asserts that Mr. Henderson's attorney "specifically advised the Examiner on multiple occasions of the mistaken claim of actual reduction to practice." But the record contradicts Intellect's position. The prosecution history of the asserted patents is devoid of any statement by Mr. Henderson openly admitting that he did not actually reduce the claimed invention to practice. . . . Neither the PTO nor the public was apprised of the falsehoods in Mr. Henderson's declarations and told the actual facts. Thus, the district court correctly found that "[a] full disclosure or correction of the record was never made." *Intellect*, 910 F. Supp. 2d at 1074. We hold that the district court did not clearly err in concluding that HTC proved materiality by

establishing that Mr. Henderson engaged in affirmative egregious misconduct when he filed a false declaration.

We note that *Therasense* in no way modified *Rohm & Haas*'s holding that the materiality prong of inequitable conduct is met when an applicant files a false affidavit and fails to cure the misconduct. *Therasense* expressly cited *Rohm & Haas* with approval and made clear that filing a false affidavit is exactly the sort of "affirmative act[] of egregious misconduct" that renders the misconduct "material." 649 F.3d at 1292. Indeed, *Therasense* quoted *Rohm & Haas* for the proposition that "there is no room to argue that submission of false affidavits is not material." *Id.* (quoting 722 F.2d at 1571) (internal quotation marks omitted). The district court was faithful to the requirements articulated in *Rohm & Haas*. Given the false statements and the clear failure to do what is necessary according to our precedent to cure the misconduct, the argument that materiality has not been established is entirely without merit.

II. Intent

The district court found that Mr. Henderson acted with specific intent to deceive the PTO. *Intellect*, 910 F. Supp. 2d at 1073–74. The court found that, in addition to misrepresentations during prosecution of the asserted patents, Mr. Henderson made false statements regarding actual reduction to practice during prosecution of related patents in order to overcome prior art. For example, during prosecution of another patent in the family, Mr. Henderson submitted a declaration stating that he had constructed a handheld device that "displayed . . . message information transmitted via the wireless network." However, the court found that no such transmission took place—the device only contained preloaded images for the purpose of demonstration. *Intellect*, 910 F. Supp. 2d at 1071.

During prosecution of still another patent in the family, Mr. Henderson submitted a press release to the PTO stating that the Smithsonian acquired "two prototypes . . .for a pioneering picturephone technology developed in 1993." The district court found that this statement was misleading because Mr. Henderson gave the Smithsonian a device identified as "Intellect prototype" in 2003, and later gave the Smithsonian imitation smartphones made of wood and plastic. *Intellect*, 910 F. Supp. 2d at 1067–68. To be clear, the wood and plastic imitation smartphones were not capable of performing the claimed functions. The court found that, given the pattern of false and misleading statements during prosecution of related patents, Mr. Henderson's explanations for the misrepresentations during prosecution of the asserted patents were not credible. *Id.* at 1073. The court therefore concluded that intent to deceive the PTO was the single most reasonable inference from Mr. Henderson's false assertions.

Intellect argues that there was no specific intent to deceive. It contends that Mr. Henderson's multiple attempts to correct the record demonstrate that intent to deceive is not the most reasonable inference. Intellect argues that Mr. Henderson's attorney explained that he made an inadvertent mistake in the original declaration by including references to actual reduction to practice. Intellect further argues that the court ignored evidence that the Examiner relied on constructive, rather than actual, reduction to practice. It contends that these facts demonstrate that the district

court's finding that Mr. Henderson intended to defraud the PTO was not the most reasonable inference.

Intellect also contends that the court's findings regarding a pattern of deceit are erroneous. Intellect argues that, even though a device that Mr. Henderson used in his demonstration contained only preloaded images, that feature is consistent with the specification's teaching that the device can display a "preselected image, such as an icon." '186 patent, col. 39 ll. 18–19. It argues that the Smithsonian press release is irrelevant because it was submitted after the asserted patents were allowed, during prosecution of a later application. With regard to statements about actual reduction to practice in the revised declaration, Intellect contends that the district court should have drawn the inference that it was a "copy-and-paste" error. It further argues that the court's finding that Mr. Henderson lacked credibility was clear error because HTC failed to prove that deceit was deliberate.

We see no clear error in the district court's fact finding on intent. Submission of an affidavit containing fabricated examples of actual reduction to practice in order to overcome a prior art reference raises a strong inference of intent to deceive. *See Rohm & Haas*, 722 F.2d at 1571. Further, Mr. Henderson engaged in a pattern of deceit, which makes the inference stronger. In order to obtain claims directed to wireless transmission in several related patents, Mr. Henderson told the PTO that he built a device that could receive images via wireless transmission. Nevertheless, the device was, at best, a "simulation"—it contained only preloaded images and was not capable of wireless communication. . . . Intellect's argument that the declaration "satisfies the specification" fails because the patent claims are directed to wireless communication. *See, e.g.*, U.S. Patent No. 7,251,318, claim 1 (reciting a "communications network to wirelessly transmit the caller ID and the picture from the message center to the wireless portable communication device"). While the misleading Smithsonian press release was submitted after the asserted patents were allowed, it reinforces the pattern of deceit.

Moreover, the district court's finding of intent could be affirmed based on the content of the two declarations. The completely false statements in a first declaration were followed by a replacement declaration that, rather than expressly admitting the earlier falsity, dances around the truth. The second declaration, which claims to rely on constructive rather than actual reduction to practice, continues to reference a "prototype" (that was never built), a "product brochure" (even though there was no product), and "commercialization" (that never occurred). As discussed earlier, neither Mr. Henderson nor his attorney told the Examiner the truth. Thus, the district court did not clearly err in concluding that specific intent to deceive the PTO was the most reasonable inference from Mr. Henderson's conduct.

The district court also did not err when it decided not to credit Mr. Henderson's explanations for the repeated submission of false affidavits. "[C]redibility determinations are an aspect of fact-finding that appellate courts should rarely reverse." *Star Scientific, Inc. v. R.J. Reynolds Tobacco Co.*, 537 F.3d 1357, 1368 (Fed. Cir. 2008). The pattern of deceit supports the court's finding that Mr. Henderson's explanations for making false statements during prosecution of the asserted patents are not credible.

[*Affirmed.*]

NOTES AND QUESTIONS

1. *Materiality after* Therasense. In *Powell v. Home Depot U.S.A., Inc.*, 663 F.3d 1221 (Fed. Cir. 2011), the defendant argued that the patentee, Powell, committed inequitable conduct by failing to update the so-called "Petition to Make Special," which refers to requests for accelerated patent examination. The petition was granted based on Powell's contention "that he was obligated to build and supply devices embodying the claims sought." *Id.* at 1235. Although Powell did not turn out to have such an obligation, he never withdrew the Petition. The Federal Circuit concluded that there was no inequitable conduct: "Where, as here, the patent applicant fails to update the record to inform the PTO that the circumstances which support a Petition to Make Special no longer exist—that conduct does not constitute inequitable conduct. That is so because Mr. Powell's conduct obviously fails the but-for materiality standard and is not the type of unequivocal act, 'such as the filing of an unmistakably false affidavit,' that would rise to the level of 'affirmative egregious misconduct.'" *Id.* (quoting *Therasense*). Short of the conduct exhibited in the *HTC* case, what sorts of acts might meet the but-for materiality prong under the affirmative egregious misconduct exception?

In *American Calcar, Inc. v. Honda Motor Co.*, 768 F.3d 1185 (Fed. Cir. 2014), the charge of inequitable conduct was based on the inventor's failure to provide a full disclosure of a prior art navigation system to the PTO. The jury, with the complete picture of the prior art before it, found the asserted claims not invalid for obviousness. But the Federal Circuit nonetheless affirmed the trial judge's finding that the PTO would have rejected the asserted claims as obvious in view of the fully disclosed system, and thus upheld the its conclusion that the defendant proved the but-for materiality prong of inequitable conduct. Although it appears that the trial judge's and the jury's determinations were in conflict, the Federal Circuit emphasized that "[d]istrict courts and the PTO employ different evidentiary standards and rules for claim construction." *Id.* at 1189. Does this approach require the district court to use different claim constructions for the purposes of validity versus inequitable conduct? (Recall that the "broadest reasonable interpretation" standard of claim construction applies during prosecution, but not litigation.) Does it circumvent the presumption of validity?

2. *Intent after* Therasense. *Therasense* held that, to establish intent to deceive the PTO, "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" and that "specific intent to deceive must be the single most reasonable inference able to be drawn from the evidence." 649 F.3d at 1290 (citations omitted). How can a defendant meet this high burden? In *American Calcar*, the Federal Circuit concluded that the district court did not clearly err in its finding of intent:

> The district court expressly rejected Calcar's suggestion that it would have been equally reasonable for the district court to infer that [the inventor's] actions were merely negligent or grossly negligent. In Calcar's view, [the inventor's] inexperience may have contributed to a mistaken or accidental failure to disclose. The district court found, however, that any such suggestion was unsupported by the evidence. It found that the evidence showed that Mr. [the inventor] had "ample time and opportunity" for a comprehensive disclosure, and yet he only disclosed the mere existence of the [prior art] system without providing its operational details. It concluded, therefore, that his failure to disclose other information that would have prevented his patent application from succeeding "demonstrates a deliberative process, not an accident or mistake."

768 F.3d at 1191 (citations omitted).

3. *The end of the sliding scale?* An important aspect of *Therasense* is its command that "[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." 649 F.3d at 1290. In his dissent, Judge Bryson agreed with this part of the majority's holding. *Id.* at 1304 (Bryson, J., dissenting). In a concurrence, however, Judge O'Malley sounded a cautionary note, joining the part of the opinion in which this rule appears "with the understanding that the majority does not hold that it is impermissible for a court to consider the level of materiality as circumstantial evidence in its intent analysis." *Id.* at 1297 n.1 (O'Malley, J., concurring). She explained: "As in all other inquiries involving multiple elements, the district court may rely on the same items of evidence in both its materiality and intent inquiries. A district court must, however, reach separate conclusions of intent and materiality and may not base a finding of specific intent to deceive on materiality alone, regardless of the level of materiality." *Id.*

4. *Eviscerating inequitable conduct?* Judge Bryson's dissent maintains that the majority's but-for materiality test might mean that patent applicants and their attorneys and agents have "little to lose" by lying to the PTO, arguing that "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." *Therasense*, 649 F.3d at 1306 (Bryson, J., dissenting). Judge Bryson concludes that the majority has ushered in "a regime that ensures that a dishonest but potentially profitable course of action can be pursued with essentially no marginal added risk." *Id.* Is this correct? Conversely, given the but-for materiality standard, do accused infringers have anything to gain by alleging inequitable conduct in litigation—doesn't proving but-for materiality mean that the claims would be held invalid anyway?

Note 1 shows that the answer to this last question is no: but-for materiality is measured based on the PTO's patentability standards, not on district court validity standards. *See Therasense*, 649 F.3d at 1291–92 ("In making this [but-for] patentability determination, the court should apply the preponderance of the evidence

standard and give claims their broadest reasonable construction. . . . [E]ven 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."). In addition, under the affirmative egregious misconduct exception explored in *Intellect Wireless*, the but-for materiality prong of inequitable conduct could be deemed proven without an actual showing that the PTO would not have rejected the claims if it had the relevant information before it.

Moreover, a holding of inequitable conduct may have many other negative consequences for the losing patent owner and the attorneys or patent agents involved. First, while invalidity is claim-by-claim, a finding of inequitable conduct renders the entire patent, and sometimes multiple related patents, unenforceable. *Therasense*, 649 F.3d at 1288–89. Second, inequitable conduct can serve as a basis for an exceptional case determination under § 285, resulting in an order to the losing patentee to pay the defendant's attorney's fees. *See Ohio Willow Wood Co. v. Alps South, LLC*, 2014 WL 4775374 (S.D. Ohio 2014), *aff'd*, 813 F.3d 1350 (Fed. Cir. 2016). Third, a claim of inequitable conduct can give the defendant access to additional discovery, especially from the attorney or agent who prosecuted the patent—and if the trial judge allows the jury to see this information as part of his or her request for an advisory verdict whether inequitable conduct occurred, it may view the patentee in a very negative light. Fourth, there could be professional consequences for the patent attorney or agent involved in committing inequitable conduct. Fifth, the inequitable conduct allegation can drive a wedge between the patent owner and his or her litigation counsel, with negative consequences for the infringement case. *Cf. Regeneron Pharm., Inc. v. Merus NV*, 864 F.3d 1343 (Fed. Cir. 2017) (deeming the intent prong of inequitable conduct proven based on plaintiff's litigation misconduct, which included failure to timely disclose evidence probative of intent to deceive the PTO).

5. *Curing the misconduct?* In addition to the *Rohm & Haas* approach to curing inequitable conduct during prosecution, discussed in *Intellect Wireless*, the Patent Act (after the AIA) provides an additional, post-issuance route. *See* 35 U.S.C. § 257 ("Supplemental examinations to consider, reconsider, or correct information.") Section 257(a) states: "A patent owner may request supplemental examination of a patent in the Office to consider, reconsider, or correct information believed to be relevant to the patent . . . [T]he Director shall conduct the supplemental examination and shall conclude such examination by issuing a certificate indicating whether the information presented in the request raises a substantial new question of patentability."

If the PTO concludes that a substantial new question of patentability has been presented in view of the new information, it would conduct a reexamination of the patent. Section 257(c)(1) states that "a patent shall not be held unenforceable on the basis of conduct relating to information that had not been considered, was inadequately considered, or was incorrect in a prior examination of the patent if the information was considered, reconsidered, or corrected during a supplemental examination of the patent." This procedure, however, is not available if inequitable conduct has already been alleged in a patent infringement action. *Id.* § 257(c)(2). Moreover, "[i]f the Director becomes aware, during the course of a supplemental

examination or reexamination proceeding ordered under this section, that a material fraud on the Office may have been committed in connection with the patent that is the subject of the supplemental examination, then in addition to any other actions the Director is authorized to take, including the cancellation of any claims found to be invalid under section 307 as a result of a reexamination ordered under this section, the Director shall also refer the matter to the Attorney General for such further action as the Attorney General may deem appropriate . . . ." *Id.* § 257(e). For a critique of § 257(e), see Jason Rantanen, Lee Petherbridge & Jay P. Kesan, *America Invents, More or Less?*, 160 U. PA. L. REV. PENNUMBRA 229, 231, 244 (2012), http://www.pennumbra.com/debates/pdfs/AmericaInvents.pdf.

6. *The pleading standard for inequitable conduct.* Recall that allegations of fraud must be pled with particularity. See Fed. R. Civ. P. 9(b). Applying this principle to inequitable conduct pleadings, the Federal Circuit held: "[T]o plead the 'circumstances' of inequitable conduct with the requisite 'particularity' under Rule 9(b), the pleading must identify the specific who, what, when, where, and how of the material misrepresentation or omission committed before the PTO. Moreover, although 'knowledge' and 'intent' may be averred generally, a pleading of inequitable conduct under Rule 9(b) must include sufficient allegations of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1328 (Fed. Cir. 2009). For an empirical take on inequitable conduct, see Robert D. Swanson, Comment, *The* Exergen *and* Therasense *Effects*, 66 STAN. L. REV. 695, 724 (2014) ("This Comment finds that *Exergen* and *Therasense* have had a substantial impact upon patent litigation. The prevalence of inequitable conduct claims has decreased from 17% to 8% of patent cases. Most of this drop occurred after *Therasense*, but it is likely that the decline is due to a combination of heightened pleading and proof standards.").

7. *Is the PTO equipped to investigate and adjudicate inequitable conduct issues?* In the early 1980s, the PTO decided to take on that responsibility, authorizing examiners to suspend examination and refer the application to an internal PTO body (which informally came to be known as the "fraud squad") upon detecting apparent inequitable conduct. This proved to be a failure, and the PTO discontinued the practice in 1988. See Harry F. Manbeck, Jr., *The Evolution and Issue of New Rule 56*, 20 AIPLA Q.J. 136 (1992) (detailing the history). Should the PTO revisit this issue?

8. *Grounds for inequitable conduct other than attempts to overcome prior art.* Scenarios that end up leading to inequitable conduct allegations most often involve intentionally withholding material prior art. The *Powell* case, discussed in Note 1, explores (and rejects) a potential ground for inequitable conduct that does not involve an attempt to overcome an anticipation or obviousness challenge. In *PerSeptive Biosystems, Inc. v. Pharmacia Biotech, Inc.*, 225 F.3d 1315 (Fed. Cir. 2000), inequitable conduct was found when the patentee intentionally failed to identify the proper inventors. Would the but-for materiality prong of *Therasense* be met in this scenario and, if so, why? *See* 35 U.S.C. § 116. Can you think of other grounds for inequitable conduct not involving patentees' attempts to meet novelty and

nonobviousness requirements? How would you articulate the precise misconduct committed in *Therasense*? Note that, on remand, the district court upheld the finding of inequitable conduct under the new standard. *Therasense, Inc. v. Becton, Dickinson & Co.*, 864 F. Supp. 2d 856 (N.D. Cal. 2012).

B. PATENT EXHAUSTION

IMPRESSION PRODS., INC. v. LEXMARK INT'L, INC.
137 S.Ct. 1523 (2017)

Chief Justice ROBERTS delivered the opinion of the Court.

A United States patent entitles the patent holder (the "patentee"), for a period of 20 years, to "exclude others from making, using, offering for sale, or selling [its] invention throughout the United States or importing the invention into the United States." 35 U.S.C. § 154(a). Whoever engages in one of these acts "without authority" from the patentee may face liability for patent infringement. § 271(a).

When a patentee sells one of its products, however, the patentee can no longer control that item through the patent laws—its patent rights are said to "exhaust." The purchaser and all subsequent owners are free to use or resell the product just like any other item of personal property, without fear of an infringement lawsuit.

This case presents two questions about the scope of the patent exhaustion doctrine: First, whether a patentee that sells an item under an express restriction on the purchaser's right to reuse or resell the product may enforce that restriction through an infringement lawsuit. And second, whether a patentee exhausts its patent rights by selling its product outside the United States, where American patent laws do not apply. We conclude that a patentee's decision to sell a product exhausts all of its patent rights in that item, regardless of any restrictions the patentee purports to impose or the location of the sale.

I

The underlying dispute in this case is about laser printers—or, more specifically, the cartridges that contain the powdery substance, known as toner, that laser printers use to make an image appear on paper. Respondent Lexmark International, Inc. designs, manufactures, and sells toner cartridges to consumers in the United States and around the globe. It owns a number of patents that cover components of those cartridges and the manner in which they are used.

When toner cartridges run out of toner they can be refilled and used again. This creates an opportunity for other companies—known as remanufacturers—to acquire empty Lexmark cartridges from purchasers in the United States and abroad, refill them with toner, and then resell them at a lower price than the new ones Lexmark puts on the shelves.

Not blind to this business problem, Lexmark structures its sales in a way that encourages customers to return spent cartridges. It gives purchasers two options: One

is to buy a toner cartridge at full price, with no strings attached. The other is to buy a cartridge at roughly 20-percent off through Lexmark's "Return Program." A customer who buys through the Return Program still owns the cartridge but, in exchange for the lower price, signs a contract agreeing to use it only once and to refrain from transferring the empty cartridge to anyone but Lexmark. To enforce this single-use/no-resale restriction, Lexmark installs a microchip on each Return Program cartridge that prevents reuse once the toner in the cartridge runs out.

Lexmark's strategy just spurred remanufacturers to get more creative. Many kept acquiring empty Return Program cartridges and developed methods to counteract the effect of the microchips. With that technological obstacle out of the way, there was little to prevent the remanufacturers from using the Return Program cartridges in their resale business. After all, Lexmark's contractual single-use/no-resale agreements were with the initial customers, not with downstream purchasers like the remanufacturers.

Lexmark, however, was not so ready to concede that its plan had been foiled. In 2010, it sued a number of remanufacturers, including petitioner Impression Products, Inc., for patent infringement with respect to two groups of cartridges. One group consists of Return Program cartridges that Lexmark sold within the United States. Lexmark argued that, because it expressly prohibited reuse and resale of these cartridges, the remanufacturers infringed the Lexmark patents when they refurbished and resold them. The other group consists of all toner cartridges that Lexmark sold abroad and that remanufacturers imported into the country. Lexmark claimed that it never gave anyone authority to import these cartridges, so the remanufacturers ran afoul of its patent rights by doing just that.

Eventually, the lawsuit was whittled down to one defendant, Impression Products, and one defense: that Lexmark's sales, both in the United States and abroad, exhausted its patent rights in the cartridges, so Impression Products was free to refurbish and resell them, and to import them if acquired abroad. Impression Products filed separate motions to dismiss with respect to both groups of cartridges. The District Court granted the motion as to the domestic Return Program cartridges, but denied the motion as to the cartridges Lexmark sold abroad. Both parties appealed.

The Federal Circuit considered the appeals en banc and ruled for Lexmark with respect to both groups of cartridges. The court began with the Return Program cartridges that Lexmark sold in the United States. Relying on its decision in *Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700 (1992), the Federal Circuit held that a patentee may sell an item and retain the right to enforce, through patent infringement lawsuits, "clearly communicated, . . . lawful restriction[s] as to post-sale use or resale." 816 F.3d 721, 735 (2016). The exhaustion doctrine, the court reasoned, derives from the prohibition on making, using, selling, or importing items "without authority." *Id.*, at 734 (quoting 35 U.S.C. § 271(a)). When you purchase an item you presumptively also acquire the authority to use or resell the item freely, but that is just a presumption; the same authority does not run with the item when the seller restricts post-sale use or resale. 816 F.3d, at 742. Because the parties agreed that Impression Products knew about Lexmark's restrictions and that those restrictions did not violate any laws, the Federal Circuit concluded that Lexmark's sales had not

exhausted all of its patent rights, and that the company could sue for infringement when Impression Products refurbished and resold Return Program cartridges.

As for the cartridges that Lexmark sold abroad, the Federal Circuit once again looked to its precedent. In *Jazz Photo Corp. v. International Trade Commission*, 264 F.3d 1094 (2001), the court had held that a patentee's decision to sell a product abroad did not terminate its ability to bring an infringement suit against a buyer that "import[ed] the article and [sold] . . . it in the United States." 816 F.3d, at 726–727. That rule, the court concluded, makes good sense: Exhaustion is justified when a patentee receives "the reward available from [selling in] American markets," which does not occur when the patentee sells overseas, where the American patent offers no protection and therefore cannot bolster the price of the patentee's goods. *Id.*, at 760–761. As a result, Lexmark was free to exercise its patent rights to sue Impression Products for bringing the foreign-sold cartridges to market in the United States.

Judge Dyk, joined by Judge Hughes, dissented. In their view, selling the Return Program cartridges in the United States exhausted Lexmark's patent rights in those items because any "authorized sale of a patented article . . . free[s] the article from any restrictions on use or sale based on the patent laws." *Id.*, at 775–776. As for the foreign cartridges, the dissenters would have held that a sale abroad also results in exhaustion, unless the seller "explicitly reserve[s] [its] United States patent rights" at the time of sale. *Id.*, at 774, 788. Because Lexmark failed to make such an express reservation, its foreign sales exhausted its patent rights.

We granted certiorari to consider the Federal Circuit's decisions with respect to both domestic and international exhaustion, . . . and now reverse.

II

A

First up are the Return Program cartridges that Lexmark sold in the United States. We conclude that Lexmark exhausted its patent rights in these cartridges the moment it sold them. The single-use/no-resale restrictions in Lexmark's contracts with customers may have been clear and enforceable under contract law, but they do not entitle Lexmark to retain patent rights in an item that it has elected to sell.

The Patent Act grants patentees the "right to exclude others from making, using, offering for sale, or selling [their] invention[s]." 35 U.S.C. § 154(a). For over 160 years, the doctrine of patent exhaustion has imposed a limit on that right to exclude. See *Bloomer v. McQuewan*, 14 How. 539 (1853). The limit functions automatically: When a patentee chooses to sell an item, that product "is no longer within the limits of the monopoly" and instead becomes the "private, individual property" of the purchaser, with the rights and benefits that come along with ownership. *Id.*, at 549–550. A patentee is free to set the price and negotiate contracts with purchasers, but may not, "*by virtue of his patent*, control the use or disposition" of the product after ownership passes to the purchaser. *United States v. Univis Lens Co.*, 316 U.S. 241, 250 (1942) (emphasis added). The sale "terminates all patent rights to that item." *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U.S. 617, 625 (2008).

This well-established exhaustion rule marks the point where patent rights yield to the common law principle against restraints on alienation. The Patent Act "promote[s] the progress of science and the useful arts by granting to [inventors] a limited monopoly" that allows them to "secure the financial rewards" for their inventions. *Univis*, 316 U.S., at 250. But once a patentee sells an item, it has "enjoyed all the rights secured" by that limited monopoly. *Keeler v. Standard Folding Bed Co.*, 157 U.S. 659, 661 (1895). Because "the purpose of the patent law is fulfilled . . . when the patentee has received his reward for the use of his invention," that law furnishes "no basis for restraining the use and enjoyment of the thing sold." *Univis*, 316 U.S., at 251.

We have explained in the context of copyright law that exhaustion has "an impeccable historic pedigree," tracing its lineage back to the "common law's refusal to permit restraints on the alienation of chattels." *Kirtsaeng v. John Wiley & Sons, Inc.*, 568 U.S. 519, 538 (2013). As Lord Coke put it in the 17th century, if an owner restricts the resale or use of an item after selling it, that restriction "is voide, because . . . it is against Trade and Traffique, and bargaining and contracting betweene man and man." 1 E. Coke, Institutes of the Laws of England § 360, p. 223 (1628); see J. Gray, Restraints on the Alienation of Property § 27, p. 18 (2d ed. 1895) ("A condition or conditional limitation on alienation attached to a transfer of the entire interest in personalty is as void as if attached to a fee simple in land").

This venerable principle is not, as the Federal Circuit dismissively viewed it, merely "one common-law jurisdiction's general judicial policy at one time toward anti-alienation restrictions." 816 F.3d, at 750. Congress enacted and has repeatedly revised the Patent Act against the backdrop of the hostility toward restraints on alienation. That enmity is reflected in the exhaustion doctrine. The patent laws do not include the right to "restrain [ ] . . . further alienation" after an initial sale; such conditions have been "hateful to the law from Lord Coke's day to ours" and are "obnoxious to the public interest." *Straus v. Victor Talking Machine Co.*, 243 U.S. 490, 501 (1917). "The inconvenience and annoyance to the public that an opposite conclusion would occasion are too obvious to require illustration." *Keeler*, 157 U.S., at 667.

But an illustration never hurts. Take a shop that restores and sells used cars. The business works because the shop can rest assured that, so long as those bringing in the cars own them, the shop is free to repair and resell those vehicles. That smooth flow of commerce would sputter if companies that make the thousands of parts that go into a vehicle could keep their patent rights after the first sale. Those companies might, for instance, restrict resale rights and sue the shop owner for patent infringement. And even if they refrained from imposing such restrictions, the very threat of patent liability would force the shop to invest in efforts to protect itself from hidden lawsuits. Either way, extending the patent rights beyond the first sale would clog the channels of commerce, with little benefit from the extra control that the patentees retain. And advances in technology, along with increasingly complex supply chains, magnify the problem. See Brief for Costco Wholesale Corp. et al. as *Amici Curiae* 7–9; Brief for Intel Corp. et al. as *Amici Curiae* 17, n. 5 ("A generic smartphone assembled from various high-tech components could practice an estimated 250,000 patents").

This Court accordingly has long held that, even when a patentee sells an item under an express restriction, the patentee does not retain patent rights in that product. In *Boston Store of Chicago v. American Graphophone Co.*, for example, a manufacturer sold graphophones—one of the earliest devices for recording and reproducing sounds—to retailers under contracts requiring those stores to resell at a specific price. 246 U.S. 8, 17–18 (1918). When the manufacturer brought a patent infringement suit against a retailer who sold for less, we concluded that there was "no room for controversy" about the result: By selling the item, the manufacturer placed it "beyond the confines of the patent law, [and] could not, by qualifying restrictions as to use, keep [it] under the patent monopoly." *Id.*, at 20, 25.

Two decades later, we confronted a similar arrangement in *United States v. Univis Lens Co*. There, a company that made eyeglass lenses authorized an agent to sell its products to wholesalers and retailers only if they promised to market the lenses at fixed prices. The Government filed an antitrust lawsuit, and the company defended its arrangement on the ground that it was exercising authority under the Patent Act. We held that the initial sales "relinquish [ed] . . . the patent monopoly with respect to the article[s] sold," so the "stipulation . . . fixing resale prices derive[d] no support from the patent and must stand on the same footing" as restrictions on unpatented goods. 316 U.S., at 249–251.

It is true that *Boston Store* and *Univis* involved resale price restrictions that, at the time of those decisions, violated the antitrust laws. But in both cases it was the sale of the items, rather than the illegality of the restrictions, that prevented the patentees from enforcing those resale price agreements through patent infringement suits. And if there were any lingering doubt that patent exhaustion applies even when a sale is subject to an express, otherwise lawful restriction, our recent decision in *Quanta Computer, Inc. v. LG Electronics, Inc.* settled the matter. In that case, a technology company—with authorization from the patentee—sold microprocessors under contracts requiring purchasers to use those processors with other parts that the company manufactured. One buyer disregarded the restriction, and the patentee sued for infringement. Without so much as mentioning the lawfulness of the contract, we held that the patentee could not bring an infringement suit because the "authorized sale . . . took its products outside the scope of the patent monopoly." 553 U.S., at 638.

Turning to the case at hand, we conclude that this well-settled line of precedent allows for only one answer: Lexmark cannot bring a patent infringement suit against Impression Products to enforce the single-use/no-resale provision accompanying its Return Program cartridges. Once sold, the Return Program cartridges passed outside of the patent monopoly, and whatever rights Lexmark retained are a matter of the contracts with its purchasers, not the patent law.

B

The Federal Circuit reached a different result largely because it got off on the wrong foot. The "exhaustion doctrine," the court believed, "must be understood as an interpretation of" the infringement statute, which prohibits anyone from using or selling a patented article "without authority" from the patentee. 816 F.3d, at 734 (quoting 35 U.S.C. § 271(a)). Exhaustion reflects a default rule that a patentee's decision to sell an item "*presumptively* grant[s] 'authority' to the purchaser to use it

and resell it." 816 F.3d, at 742. But, the Federal Circuit explained, the patentee does not have to hand over the full "bundle of rights" every time. *Id.*, at 741 (internal quotation marks omitted). If the patentee expressly withholds a stick from the bundle—perhaps by restricting the purchaser's resale rights—the buyer never acquires that withheld authority, and the patentee may continue to enforce its right to exclude that practice under the patent laws.

The misstep in this logic is that the exhaustion doctrine is not a presumption about the authority that comes along with a sale; it is instead a limit on "the scope of the *patentee's rights*." *United States v. General Elec. Co.*, 272 U.S. 476, 489 (1926) (emphasis added). The right to use, sell, or import an item exists independently of the Patent Act. What a patent adds—and grants exclusively to the patentee—is a limited right to prevent others from engaging in those practices. See *Crown Die & Tool Co. v. Nye Tool & Machine Works*, 261 U.S. 24, 35 (1923). Exhaustion extinguishes that exclusionary power. See *Bloomer*, 14 How., at 549 (the purchaser "exercises no rights created by the act of Congress, nor does he derive title to [the item] by virtue of the . . . exclusive privilege granted to the patentee"). As a result, the sale transfers the right to use, sell, or import because those are the rights that come along with ownership, and the buyer is free and clear of an infringement lawsuit because there is no exclusionary right left to enforce.

The Federal Circuit also expressed concern that preventing patentees from reserving patent rights when they sell goods would create an artificial distinction between such sales and sales by licensees. Patentees, the court explained, often license others to make and sell their products, and may place restrictions on those licenses. A computer developer could, for instance, license a manufacturer to make its patented devices and sell them only for non-commercial use by individuals. If a licensee breaches the license by selling a computer for commercial use, the patentee can sue the licensee for infringement. And, in the Federal Circuit's view, our decision in *General Talking Pictures Corp. v. Western Elec. Co.*, 304 U.S. 175, aff'd on reh'g, 305 U.S. 124 (1938), established that—when a patentee grants a license "under clearly stated restrictions on post-sale activities" of those who purchase products from the licensee—the patentee can *also* sue for infringement those purchasers who knowingly violate the restrictions. 816 F.3d, at 743–744. If patentees can employ licenses to impose post-sale restrictions on purchasers that are enforceable through infringement suits, the court concluded, it would make little sense to prevent patentees from doing so when they sell directly to consumers.

The Federal Circuit's concern is misplaced. A patentee can impose restrictions on licensees because a license does not implicate the same concerns about restraints on alienation as a sale. Patent exhaustion reflects the principle that, when an item passes into commerce, it should not be shaded by a legal cloud on title as it moves through the marketplace. But a license is not about passing title to a product, it is about changing the contours of the patentee's monopoly: The patentee agrees not to exclude a licensee from making or selling the patented invention, expanding the club of authorized producers and sellers. See *General Elec. Co.*, 272 U.S., at 489–490. Because the patentee is exchanging rights, not goods, it is free to relinquish only a portion of its bundle of patent protections.

A patentee's authority to limit *licensees* does not, as the Federal Circuit thought, mean that patentees can use licenses to impose post-sale restrictions on *purchasers* that are enforceable through the patent laws. So long as a licensee complies with the license when selling an item, the patentee has, in effect, authorized the sale. That licensee's sale is treated, for purposes of patent exhaustion, as if the patentee made the sale itself. The result: The sale exhausts the patentee's rights in that item. See *Hobbie v. Jennison*, 149 U.S. 355, 362–363 (1893). A license may require the licensee to impose a restriction on purchasers, like the license limiting the computer manufacturer to selling for non-commercial use by individuals. But if the licensee does so—by, perhaps, having each customer sign a contract promising not to use the computers in business—the sale nonetheless exhausts all patent rights in the item sold. See *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 506–507, 516 (1917). The purchasers might not comply with the restriction, but the only recourse for the licensee is through contract law, just as if the patentee itself sold the item with a restriction.

General Talking Pictures involved a fundamentally different situation: There, a licensee "knowingly ma[de] . . . sales . . . *outside* the scope of its license." 304 U.S., at 181–182 (emphasis added). We treated the sale "as if no license whatsoever had been granted" by the patentee, which meant that the patentee could sue both the licensee and the purchaser—who knew about the breach—for infringement. *General Talking Pictures Corp. v. Western Elec. Co.*, 305 U.S. 124, 127 (1938). This does not mean that patentees can use licenses to impose post-sale restraints on purchasers. Quite the contrary: The licensee infringed the patentee's rights because it did *not* comply with the terms of its license, and the patentee could bring a patent suit against the purchaser only because the purchaser participated in the licensee's infringement. *General Talking Pictures*, then, stands for the modest principle that, if a patentee has not given authority for a licensee to make a sale, that sale cannot exhaust the patentee's rights.

In sum, patent exhaustion is uniform and automatic. Once a patentee decides to sell—whether on its own or through a licensee—that sale exhausts its patent rights, regardless of any post-sale restrictions the patentee purports to impose, either directly or through a license.

III

Our conclusion that Lexmark exhausted its patent rights when it sold the domestic Return Program cartridges goes only halfway to resolving this case. Lexmark also sold toner cartridges abroad and sued Impression Products for patent infringement for "importing [Lexmark's] invention into the United States." 35 U.S.C. § 154(a). Lexmark contends that it may sue for infringement with respect to all of the imported cartridges—not just those in the Return Program—because a foreign sale does not trigger patent exhaustion unless the patentee "expressly or implicitly transfer[s] or license[s]" its rights. Brief for Respondent 36–37. The Federal Circuit agreed, but we do not. An authorized sale outside the United States, just as one within the United States, exhausts all rights under the Patent Act.

This question about international exhaustion of intellectual property rights has also arisen in the context of copyright law. Under the "first sale doctrine," which is codified

at 17 U.S.C. § 109(a), when a copyright owner sells a lawfully made copy of its work, it loses the power to restrict the purchaser's freedom "to sell or otherwise dispose of . . . that copy." In *Kirtsaeng v. John Wiley & Sons, Inc.*, we held that this " 'first sale' [rule] applies to copies of a copyrighted work lawfully made [and sold] abroad." 568 U.S., at 525. We began with the text of § 109(a), but it was not decisive: The language neither "restrict[s] the scope of [the] 'first sale' doctrine geographically," nor clearly embraces international exhaustion. *Id.*, at 528–533. What helped tip the scales for global exhaustion was the fact that the first sale doctrine originated in "the common law's refusal to permit restraints on the alienation of chattels." *Id.*, at 538. That "common-law doctrine makes no geographical distinctions." *Id.*, at 539. The lack of any textual basis for distinguishing between domestic and international sales meant that "a straightforward application" of the first sale doctrine required the conclusion that it applies overseas. *Id.*, at 540 (internal quotation marks omitted).

Applying patent exhaustion to foreign sales is just as straightforward. Patent exhaustion, too, has its roots in the antipathy toward restraints on alienation, see *supra*, and nothing in the text or history of the Patent Act shows that Congress intended to confine that borderless common law principle to domestic sales. In fact, Congress has not altered patent exhaustion at all; it remains an unwritten limit on the scope of the patentee's monopoly. See *Astoria Fed. Sav. & Loan Assn. v. Solimino*, 501 U.S. 104, 108 (1991) ("[W]here a common-law principle is well established, . . . courts may take it as given that Congress has legislated with an expectation that the principle will apply except when a statutory purpose to the contrary is evident" (internal quotation marks omitted)). And differentiating the patent exhaustion and copyright first sale doctrines would make little theoretical or practical sense: The two share a "strong similarity . . . and identity of purpose," *Bauer & Cie v. O'Donnell*, 229 U.S. 1, 13 (1913), and many everyday products—"automobiles, microwaves, calculators, mobile phones, tablets, and personal computers"—are subject to both patent and copyright protections, see *Kirtsaeng*, 568 U.S., at 545; Brief for Costco Wholesale Corp. et al. as *Amici Curiae* 14–15. There is a "historic kinship between patent law and copyright law," *Sony Corp. of America v. Universal City Studios, Inc.*, 464 U.S. 417, 439 (1984), and the bond between the two leaves no room for a rift on the question of international exhaustion.

Lexmark sees the matter differently. The Patent Act, it points out, limits the patentee's "right to exclude others" from making, using, selling, or importing its products to acts that occur in the United States. 35 U.S.C. § 154(a). A domestic sale, it argues, triggers exhaustion because the sale compensates the patentee for "surrendering [those] *U.S.* rights." Brief for Respondent 38. A foreign sale is different: The Patent Act does not give patentees exclusionary powers abroad. Without those powers, a patentee selling in a foreign market may not be able to sell its product for the same price that it could in the United States, and therefore is not sure to receive "the reward guaranteed by U.S. patent law." *Id.*, at 39 (internal quotation marks omitted). Absent that reward, says Lexmark, there should be no exhaustion. In short, there is no patent exhaustion from sales abroad because there are no patent rights abroad to exhaust.

The territorial limit on patent rights is, however, no basis for distinguishing copyright protections; those protections "do not have any extraterritorial operation" either. 5 M.

Nimmer & D. Nimmer, Copyright § 17.02, p. 17–26 (2017). Nor does the territorial limit support the premise of Lexmark's argument. Exhaustion is a separate limit on the patent grant, and does not depend on the patentee receiving some undefined premium for selling the right to access the American market. A purchaser buys an item, not patent rights. And exhaustion is triggered by the patentee's decision to give that item up and receive whatever fee it decides is appropriate "for the article and the invention which it embodies." *Univis*, 316 U.S., at 251. The patentee may not be able to command the same amount for its products abroad as it does in the United States. But the Patent Act does not guarantee a particular price, much less the price from selling to American consumers. Instead, the right to exclude just ensures that the patentee receives one reward—of whatever amount the patentee deems to be "satisfactory compensation," *Keeler*, 157 U.S., at 661—for every item that passes outside the scope of the patent monopoly.

This Court has addressed international patent exhaustion in only one case, *Boesch v. Graff*, decided over 125 years ago. All that case illustrates is that a sale abroad does not exhaust a patentee's rights when the patentee had nothing to do with the transaction. *Boesch*—from the days before the widespread adoption of electrical lighting—involved a retailer who purchased lamp burners from a manufacturer in Germany, with plans to sell them in the United States. The manufacturer had authority to make the burners under German law, but there was a hitch: Two individuals with no ties to the German manufacturer held the American patent to that invention. These patentees sued the retailer for infringement when the retailer imported the lamp burners into the United States, and we rejected the argument that the German manufacturer's sale had exhausted the American patentees' rights. The German manufacturer had no permission to sell in the United States from the American patentees, and the American patentees had not exhausted their patent rights in the products because they had not sold them to anyone, so "purchasers from [the German manufacturer] could not be thereby authorized to sell the articles in the United States." 133 U.S. 697, 703 (1890).

Our decision did not, as Lexmark contends, exempt all foreign sales from patent exhaustion. See Brief for Respondent 44–45. Rather, it reaffirmed the basic premise that only the patentee can decide whether to make a sale that exhausts its patent rights in an item. The American patentees did not do so with respect to the German products, so the German sales did not exhaust their rights.

Finally, the United States, as an *amicus*, advocates what it views as a middle-ground position: that "a foreign sale authorized by the U.S. patentee exhausts U.S. patent rights unless those rights are expressly reserved." Brief for United States 7–8. Its position is largely based on policy rather than principle. The Government thinks that an overseas "buyer's legitimate expectation" is that a "sale conveys all of the seller's interest in the patented article," so the presumption should be that a foreign sale triggers exhaustion. *Id.*, at 32–33. But, at the same time, "lower courts long ago coalesced around" the rule that "a patentee's express reservation of U.S. patent rights at the time of a foreign sale will be given effect," so that option should remain open to the patentee. *Id.*, at 22 (emphasis deleted).

The Government has little more than "long ago" on its side. In the 1890s, two circuit courts—in cases involving the same company—did hold that patentees may use express restrictions to reserve their patent rights in connection with foreign sales. See *Dickerson v. Tinling*, 84 F. 192, 194–195 (C.A.8 1897); *Dickerson v. Matheson*, 57 F. 524, 527 (C.A.2 1893). But no "coalesc[ing]" ever took place: Over the following hundred-plus years, only a smattering of lower court decisions mentioned this express-reservation rule for foreign sales. See, *e.g.*, *Sanofi, S.A. v. Med-Tech Veterinarian Prods., Inc.*, 565 F. Supp. 931, 938 (D.N.J. 1983). And in 2001, the Federal Circuit adopted its blanket rule that foreign sales do not trigger exhaustion, even if the patentee fails to expressly reserve its rights. *Jazz Photo*, 264 F.3d, at 1105. These sparse and inconsistent decisions provide no basis for any expectation, let alone a settled one, that patentees can reserve patent rights when they sell abroad.

The theory behind the Government's express-reservation rule also wrongly focuses on the likely expectations of the patentee and purchaser during a sale. Exhaustion does not arise because of the parties' expectations about how sales transfer patent rights. More is at stake when it comes to patents than simply the dealings between the parties, which can be addressed through contract law. Instead, exhaustion occurs because, in a sale, the patentee elects to give up title to an item in exchange for payment. Allowing patent rights to stick remora-like to that item as it flows through the market would violate the principle against restraints on alienation. Exhaustion does not depend on whether the patentee receives a premium for selling in the United States, or the type of rights that buyers expect to receive. As a result, restrictions and location are irrelevant; what matters is the patentee's decision to make a sale.

The judgment of the United States Court of Appeals for the Federal Circuit is reversed, and the case is remanded for further proceedings consistent with this opinion.

It is so ordered.

Justice GORSUCH took no part in the consideration or decision of this case.

Justice GINSBURG, concurring in part and dissenting in part.

I concur in the Court's holding regarding domestic exhaustion—a patentee who sells a product with an express restriction on reuse or resale may not enforce that restriction through an infringement lawsuit, because the U.S. sale exhausts the U.S. patent rights in the product sold. I dissent, however, from the Court's holding on international exhaustion. A foreign sale, I would hold, does not exhaust a U.S. inventor's U.S. patent rights.

Patent law is territorial. When an inventor receives a U.S. patent, that patent provides no protection abroad. See *Deepsouth Packing Co. v. Laitram Corp.*, 406 U.S. 518, 531 (1972) ("Our patent system makes no claim to extraterritorial effect."). See also 35 U.S.C. § 271(a) (establishing liability for acts of patent infringement "within the United States" and for "import[ation] into the United States [of] any patented invention"). A U.S. patentee must apply to each country in which she seeks the exclusive right to sell her invention. *Microsoft Corp. v. AT & T Corp.*, 550 U.S. 437, 456 (2007) ("[F]oreign law alone, not United States law, currently governs the

manufacture and sale of components of patented inventions in foreign countries."). See also Convention at Brussels, An Additional Act Modifying the Paris Convention for the Protection of Industrial Property of Mar. 20, 1883, Dec. 14, 1900, Art. I, 32 Stat. 1940 ("Patents applied for in the different contracting States . . . shall be independent of the patents obtained for the same invention in the other States."). And patent laws vary by country; each country's laws "may embody different policy judgments about the relative rights of inventors, competitors, and the public in patented inventions." *Microsoft*, 550 U.S., at 455 (internal quotation marks omitted).

Because a sale abroad operates independently of the U.S. patent system, it makes little sense to say that such a sale exhausts an inventor's U.S. patent rights. U.S. patent protection accompanies none of a U.S. patentee's sales abroad—a competitor could sell the same patented product abroad with no U.S.-patent-law consequence. Accordingly, the foreign sale should not diminish the protections of U.S. law in the United States.

The majority disagrees, in part because this Court decided, in *Kirtsaeng v. John Wiley & Sons, Inc.*, 568 U.S. 519, 525 (2013), that a foreign sale exhausts U.S. *copyright* protections. Copyright and patent exhaustion, the majority states, "share a strong similarity." I dissented from our decision in *Kirtsaeng* and adhere to the view that a foreign sale should not exhaust U.S. copyright protections. See 568 U.S., at 557.

But even if I subscribed to *Kirtsaeng*'s reasoning with respect to copyright, that decision should bear little weight in the patent context. Although there may be a "historical kinship" between patent law and copyright law, *Sony Corp. of America v. Universal City Studios, Inc.*, 464 U.S. 417, 439 (1984), the two "are not identical twins," *id.*, at 439, n. 19. The Patent Act contains no analogue to 17 U.S.C. § 109(a), the Copyright Act first-sale provision analyzed in *Kirtsaeng*. More importantly, copyright protections, unlike patent protections, are harmonized across countries. Under the Berne Convention, which 174 countries have joined,* members "agree to treat authors from other member countries as well as they treat their own." *Golan v. Holder*, 565 U.S. 302, 308 (2012) (citing Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, as revised at Stockholm on July 14, 1967, Arts. 1, 5(1), 828 U.N.T.S. 225, 231–233). The copyright protections one receives abroad are thus likely to be similar to those received at home, even if provided under each country's separate copyright regime.

For these reasons, I would affirm the Federal Circuit's judgment with respect to foreign exhaustion.

NOTES AND QUESTIONS

1. *The limits of exhaustion.* In *Bowman v. Monsanto Co.*, 569 U.S. 278 (2013), Monsanto sued a farmer, Bowman, for infringing its patents by using genetically modified ROUNDUP READY® soybean seeds that grow into herbicide-resistant soybean plants. Bowman had purchased from a grain elevator, and planted,

* See WIPO–Administered Treaties: Contracting Parties: Berne Convention, www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_id=5 (as last visited May 25, 2017).

"commodity soybeans" intended for human and animal consumption rather than for growing new crops. He treated the soybean plants that grew from these seeds with herbicide until only the surviving plans yielding ROUNDUP READY® seeds remained. Then, he planted the ROUNDUP READY® seeds thus produced.

Bowman asserted exhaustion, "arguing that Monsanto could not control his use of the soybeans because they were the subject of a prior authorized sale (from local farmers to the grain elevator)." *Id.* at 283. The Supreme Court disagreed: "Under the patent exhaustion doctrine, Bowman could resell the patented soybeans he purchased from the grain elevator; so too he could consume the beans himself or feed them to his animals. . . . . But the exhaustion doctrine does not enable Bowman to make *additional* patented soybeans without Monsanto's permission (either express or implied)." *Id.* at 284–85 (emphasis in the original). The Court explained that "the doctrine restricts a patentee's rights only as to the 'particular article' sold." *Id.* at 284 (quoting *United States v. Univis Lens Co.*, 316 U.S. 241, 251 (1942)). It then rejected Bowman's attempt to carve out "an unprecedented exception" to this rule for self-replicating technologies, like seeds. *Id.* at 284. The Court also disagreed on factual grounds with Bowman's argument that seeds grew without a voluntary act on his part: "Bowman was not a passive observer of his soybeans' multiplication; or put another way, the seeds he purchased . . . did not spontaneously create eight successive soybean crops. . . . . [I]t was Bowman, and not the bean, who controlled the reproduction . . . of Monsanto's patented invention." *Id.* at 288–89.

Would the voluntary act defense apply if the seeds were blown onto Bowman's land and then grew into herbicide-resistant crops? It seems that, in the course of litigating *Organic Seed Growers & Trade Association v. Monsanto Co.*, 718 F.3d 1350 (Fed. Cir. 2013), Monsanto obviated this issue by making representations that would preclude a suit for infringement in these circumstances, at least when the number of infringing seeds that accidentally ended up on an accused farmer's land is less than one percent of the total number of seeds in use by the farmer. *Id.* at 1358 ("We conclude that Monsanto has disclaimed any intent to sue inadvertent users or sellers of seeds that are inadvertently contaminated with up to one percent of seeds carrying Monsanto's patented traits."). Nonetheless, the court noted that "we cannot conclude that Monsanto has disclaimed any intent to sue a conventional grower who never buys modified seed, but accumulates greater than trace amounts of modified seed by using or selling contaminated seed from his fields." *Id.* at 1359. After noting that the doctrine of judicial estoppel would bar Monsanto's suit against inadvertent farming of trace amounts of ROUNDUP READY® seeds, the Federal Circuit affirmed the dismissal of the farmers' declaratory judgment suit against Monsanto for lack of justiciable case or controversy. *Id.* at 1358–61.

In their attempt to establish standing, declaratory judgment plaintiffs in *Organic Farmers* argued that Monsanto has, in fact, sued allegedly involuntary infringers in the past. Thus, Monsanto engaged in long-running litigation in Canada against a farmer who claimed that the presence of Monsanto's patented trait in his canola field was the result of windblown seed. The evidence in support of that claim was less than definitive. See Mark D. Janis *et al.*, INTELLECTUAL PROPERTY LAW OF PLANTS 8.209-8.228 (Oxford 2014) (summarizing the *Schmeiser* case).

2. Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U.S. 617 (2008)*. Prior to *Impression Products*, *Quanta* was the Supreme Court's most recent decision dealing with patent exhaustion. LGE, the plaintiff, "licensed Intel to practice any of its patents and to sell products practicing those patents." *Id.* at 638. In a separate agreement, the Master Agreement, "Intel agreed to give written notice to its own customers informing them that . . . the license 'does not extend, expressly or by implication, to any product that you make by combining an Intel product with any non-Intel product.'" *Id.* at 623–24. Quanta, one of Intel's customers, bought Intel microprocessors and chipsets covered by the licensed LGE patents and combined them with non-Intel products. LGE sued Quanta for patent infringement. The Court held that "[b]ecause Intel was authorized to sell its products to Quanta, the doctrine of patent exhaustion prevents LGE from further asserting its patent rights with respect to the patents substantially embodied in those products." *Id.* at 637. It explained that the notice required by the Master Agreement was irrelevant to exhaustion, emphasizing instead that "[n]othing in the *License* Agreement restricts Intel's right to sell its microprocessors and chipsets to purchasers who intend to combine them with non-Intel parts." *Id.* at 636. Accordingly, Intel's sale to Quanta was "authorized" and the exhaustion doctrine applied. *Id.* at 637–38. How do the facts of *Quanta* differ from those of *Impression Products*? Has *Quanta* truly "settled the matter" at issue in *Impression Products*, as the Supreme Court noted? *Impression Prods.*, 137 S. Ct. at 1533. In the opinion that the Court reversed in *Impression Products*, a 10-2 majority of the judges on the Federal Circuit did not think so because "[t]he facts defining the issues for decision, and the issues decided, were at least two steps removed from the present case. There were no patentee sales, and there were no restrictions on the sales made by the licensee." *Lexmark Int'l, Inc. v. Impression Prods., Inc.*, 816 F.3d 721, 737–38 (Fed. Cir. 2016) (en banc).

One of the issues in *Quanta* was whether method claims, as opposed to apparatus or product claims, could be subject to the exhaustion doctrine. The Supreme Court answered that question in the affirmative, explaining that while "[i]t is true that a patented method may not be sold in the same way as an article or device, but methods nonetheless may be 'embodied' in a product, the sale of which exhausts patent rights." *Quanta*, 553 U.S. at 628. The Court voiced suspicion of patent drafters, noting that "[b]y characterizing their claims as method instead of apparatus claims, or including a method claim for the machine's patented method of performing its task, a patent drafter could shield practically any patented item from exhaustion." *Id.* at 629–30. It then determined that LGE's claims were exhausted because "Intel all but practiced the patent itself by designing its products to practice [LGE's] patents, lacking only the addition of standard parts. . . . [T]he final step to practice the patent is common and noninventive." *Id.* at 634. Elaborating on this standard, the Court concluded that "Intel's microprocessors and chipsets substantially embodied the LGE Patents because they had no reasonable noninfringing use and included all the inventive aspects of the patented methods." *Id.* at 638. What does it mean for a product to "substantially embody" a claimed method? Can a patentee win an infringement suit by arguing that the defendant product "substantially embodies" the claims? *Cf. Carnegie Mellon Univ. v. Marvell Tech. Grp., Ltd.*, 807 F.3d 1283, 1305–07 (Fed. Cir. 2015) (grappling with a related issue in the context of measuring damages).

3. *Exhaustion and contributory infringement.* In *Lifescan Scotland Ltd. v. Shasta Technologies LLC*, 734 F.3d 1361 (Fed. Cir. 2013), the patentee, Lifescan, asserted claims directed to a method of measuring the concentration of substances in a liquid. One application of the method is the measurement of a user's blood glucose level, and practicing the method for this purpose requires disposable test strips and a blood glucose meter. Lifescan adopted the following business model: it sold meters below cost or gave them away to health care providers, but charged the health care providers for test strips. Shasta competed with Lifescan in the market for test strips, and Lifescan sued Shasta on indirect infringement theories. Shasta argued that the sales and giveaways of the meters exhausted Lifescan's patent. Lifescan countered that, among other things, the meters could be used for purposes other than the practice of the patented method and contended that "the sale of a component does not result in exhaustion where the component has reasonable noninfringing uses." *Id.* at 1368. The Federal Circuit nonetheless concluded that the meter sales and giveaways exhaust the patent, noting that "a potential non-infringing use" does not vitiate the exhaustion defense "where the use in question is the very use contemplated by the patented invention itself." *Id.* at 1369 (citing *Keurig, Inc. v. Sturm Foods, Inc.*, 732 F.3d 1370, 1373 (Fed. Cir. 2013)). The court explained that "alternative uses are relevant to the exhaustion inquiry under *Quanta* only if they are both 'reasonable and *intended*' by the patentee or its authorized licensee." *Id.* (quoting *Quanta*, 553 U.S. at 631) (emphasis added by the Federal Circuit). *See also Helferich Patent Licensing v. New York Times Co.*, 778 F.3d 1293, 1309 (Fed. Cir. 2015) (distinguishing *Quanta* and *Lifescan* on the basis of the "reasonable and intended" language).

Lifescan also argued that the meters do not "substantially embody" the asserted claims within the meaning of *Quanta* because *the test strips*, which work with the meters in the execution of the claimed method, are not "standard parts" under the reasoning of *Quanta*. The Federal Circuit rejected this argument as well, noting that "*Quanta* does not suggest that only standard parts can be viewed as noninventive." *Lifescan*, 734 F.3d at 1372. The court also noted that "[r]ejecting a claim of exhaustion in this case would be particularly problematic because LifeScan would be permitted to eliminate competition in the sale of the strips even though the strips do not embody the claimed invention are themselves not patentable." *Id.* at 1373. Although, as noted above, Lifescan proceeded on indirect infringement theories, the court did not address the question "whether there would be any impact on exhaustion principles if a strip were '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 within the meaning of 35 U.S.C. § 271(c)'" because the parties did not raise this issue. *Id.* at 1372 n.7. What if they did? *See Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176, 197 (1980) ("[A]n inevitable concomitant of the right to enjoin another from contributory infringement is the capacity to suppress competition in an unpatented article of commerce.").

4. *The repair-reconstruction doctrine.* Behind the patent exhaustion doctrine is the intuitive notion that when a patentee sells a patented article, the buyer should be free to use the article or dispose of it without fear of an infringement suit from the patentee. In these circumstances, the value of the underlying patent should be "priced

in," or accounted for in the price of the article. The doctrine of implied license likewise reflects this notion: as the Supreme Court explained in *Aro Manufacturing Co. v. Convertible Top Replacement Co.*, "it is fundamental that a sale of a patented article by the patentee or under his authority carries with it an 'implied license to use.'" 377 U.S 476, 848 (1964) (quoting *Adams v. Burke*, 84 U.S. (17 Wall.) 453, 456 (1873)). One consequence of these intuitions is that the patentee cannot prevent buyers from "reconditioning articles worn by use, unless they in fact make a new article." *Aro Mfg. Co. v. Convertible Top Replacement Co.*, 365 U.S. 336, 344 (1961) (quoting *United States v. Aluminum Co. of Am.*, 148 F.2d 416, 425 (2d Cir. 1945 (Learned Hand, J.)). Under this principle, which has come to be known as the repair-reconstruction doctrine, courts must draw the line between "permissible 'repair' or infringing 'reconstruction.'" *Id.* at 342.

Two cases provide examples on either side of that line. In *Hewlett-Packard Co. v. Repeat-O-Type Stencil Mfg. Corp.*, the defendant (ROT) purchased HP's printer ink cartridges that were intended to be single-use only and modified them to enable refilling—a familiar scenario in patent exhaustion cases. 123 F.3d 1445, 1449 (Fed. Cir. 1997). The Federal Circuit held that "[t]he modification made by ROT, essentially replacing the type of seal holding the cap onto an unused cartridge, is not a 'second creation of the patented entity' so as to constitute an infringement of HP's ink jet pen patents." *Id.* at 1454 (citing *Aro*, 365 U.S. at 346). The court continued: "Were we to rule in HP's favor in this case, we would be depriving ROT of the right to use and resell its own property . . . ." *Id.* In contrast, in *Sandvik Aktiebolag v. E.J. Co.*, the Federal Circuit concluded that re-tipping of worn-down drills was an infringing reconstruction. 121 F.3d 669 (Fed. Cir. 1997). The court explained:

> [T]he nature of the work done by E.J. shows that retipping is more like reconstruction than repair. E.J. does not just attach a new part for a worn part, but rather must go through several steps to replace, configure and integrate the tip onto the shank. It has to break the worn or damaged tip from the shank by heating it to 1300 degrees Fahrenheit. It brazes to the shank a new rectangular block of carbide and grinds and machines it to the proper diameter and creates the point. Thereafter, the tip is honed and sharpened, grinding the rake surfaces and the center of the point and honing the edges. These actions are effectively a re-creation of the patented invention after it is spent.

Id. at 673. *Sandvik* was not cited in *Hewlett-Packard*. HP filed a petition suggesting rehearing in banc in which it argued that the court's conclusion that ROT performed a permissible repair was inconsistent with *Sandvik*, 1997 WL 34722638 (Sept. 11, 1997). Per its usual practice, however, the Federal Circuit denied the petition without opinion.

Are "methods to counteract the effect of the microchips" that the remanufacturers of Lexmark's cartridges employed to get around the single-use restriction a repair or a reconstruction?

5. *Can patentees get around* Impression Products *by structuring transactions as licenses or leases rather than sales?* After all, *Impression Products* makes clear that

the nature of the transfer is significant, noting that "license does not implicate the same concerns about restraints on alienation as a sale" and that "exhaustion occurs because, in a sale, the patentee elects to give up title to an item in exchange for payment." 137 S. Ct. at 1534, 1538. Software, for example, is often licensed, not sold—and might Lexmark, in view of the outcome of *Impression Products*, now wish to lease its cartridges rather than sell them and maintain the single-use restriction in this manner? *See generally* Samuel F. Ernst, *Patent Exhaustion for the Exhausted Defendant: Should Parties Be Able to Contract Afround Exhaustion in Settling Patent Litigation?*, 2014 U. ILL. J.L. TECH. & POL'Y 445 (2014).

It appears that, after *Impression Products*, contract-based (as opposed to patent-based) claims remain available against buyers who breach a restriction accompanying a sale. The Court, for example, observes that "[a] patentee is free to set a price and negotiate contracts with purchasers." *Id.* at 1531. But is this approach consistent with the law's aversion toward restraints on alienation of chattels? Note the Court's reliance on Lord Coke's observation that "if an owner restricts the resale or use of an item after selling it, that restriction 'is voide, because . . . it is against Trade and Traffique, and bargaining and contracting betweene man and man.'" *Id.* at 1526 (quoting 1 E. Coke, Institutes of the Laws of England § 360, p. 223 (1628)). Assuming contracts restricting post-sale uses of chattels remain valid, what is the proper remedy when such contracts are breached? Why didn't Lexmark seek contractual remedies in *Impression Products*?

C. PATENT MISUSE

Patent misuse is a defense to infringement that has seen better days (from a defendant's point of view!)—it can be difficult to succeed on misuse. The Federal Circuit, for example, recently observed that "[b]ecause patent misuse is a judge-made doctrine that is in derogation of statutory patent rights against infringement, this court has not applied the doctrine of patent misuse expansively." *Princo Corp. v. Int'l Trade Comm'n*, 616 F.3d 1318, 1321 (Fed. Cir. 2010) (en banc). Like inequitable conduct, misuse is related to the equitable doctrine of unclean hands, which is covered below in the Chapter. But there are important differences between inequitable conduct and patent misuse. First, while inequitable conduct relates to wrongful behavior during *procurement* of the patent, misuse typically relates to wrongful patent enforcement or licensing—as the term "misuse" suggests, the problem lies in a disfavored "use" of a patent. Second, while inequitable conduct, once established, permanently renders the affected patents unenforceable, misuse can in theory be "cured" or purged. In other words, once its owner stopped engaging in the misusing conduct, the patent would once again become enforceable. *See B.B. Chemical Co. v. Ellis*, 314 U.S. 495, 498 (1942).

As noted, patent misuse claims have often revolved around allegedly questionable patent licensing practices. In particular, courts have found misuse when the patentee has made a so-called "tying" arrangement—a contract requiring, for example, the licensee to use unpatented, staple articles provided by the patentee along with the

objects that are patented. *See Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488 (1942) (finding misuse where the license required use of unpatented salt tablets sold by the patentee along with the patented machine for depositing the salt tablets). Since *Morton Salt*, the availability of the misuse defense has been sharply circumscribed by statute. For example, a tying arrangement does not constitute misuse unless "the patent owner has market power for the patent or patented product on which the license or sale is conditioned." 35 U.S.C. § 271(d)(5). And merely having a patent does not confer market power on the patentee. *Illinois Tool Works Inc. v. Independent Ink, Inc.*, 547 U.S. 28 (2006). Finally, it is not misuse for the patentee to take advantage of its rights granted by 35 U.S.C. § 271(c), the contributory infringement subsection, *id.* § 271(d)(1)–(3); *see Dawson Chem. Co. v. Rohm & Haas Co.*, 448 U.S. 176 (1980), or to refuse to license its patents, 35 U.S.C. § 271(d)(4).

Patent misuse has also been limited by case law. One opinion dealt with the genetic engineering technology we already encountered in the section on patent exhaustion, in the *Bowman* case. In *Monsanto Co. v. McFarling*, 363 F.3d 1336, 1341 (Fed. Cir. 2004), the Federal Circuit considered a license under which Monsanto provided to farmers its patented genetically-modified ROUNDUP READY® seeds, which grow into soybean plants that survive Monsanto's ROUNDUP® herbicide. The license prohibited the farmers from saving the second-generation seeds and replanting them. The Federal Circuit noted that "[i]n the cases in which the [contractual] restriction is reasonably within the patent grant, the patent misuse defense can never succeed" and concluded that no patent misuse occurred. The court explained that "given that we must presume that Monsanto's . . . patent reads on the first-generation seeds, it also reads on the second-generation seeds." *Id.* at 1343 (footnote omitted).

The following case captures the prevailing attitude toward the patent misuse defense, and the notes that follow include examples of some the limited circumstances in which it remains viable.

C.R. BARD, INC. v. M3 SYSTEMS, INC.

157 F.3d 1340 (Fed. Cir. 1998)

NEWMAN, Circuit Judge:

In suit are United States Patent No. 4,944,308 issued July 31, 1990 (the '308 patent) and United States Reissue Patent No. RE 34,056 issued September 8, 1992 (the '056 patent), both entitled "Tissue Sampling Device." . . .

The patented inventions are devices for taking samples of body tissue for biopsy purposes, wherein a biopsy needle firing device or "gun" mechanically injects a biopsy needle assembly into the core body tissue. These devices are described as improving the speed, accuracy, ease, and patient comfort of tissue sampling, compared with manually inserted biopsy needles. They are said to be particularly advantageous for sampling small or movable lesions and fibrous or firm tissues, because the rapidly and firmly fired needles can penetrate even fibrotic lesions before the lesions can slip aside. The patented guns and needles have achieved commercial success.

. . .

MISUSE

. . .

The defense of patent misuse arises from the equitable doctrine of unclean hands, and relates generally to the use of patent rights to obtain or to coerce an unfair commercial advantage. Patent misuse relates primarily to a patentee's actions that affect competition in unpatented goods or that otherwise extend the economic effect beyond the scope of the patent grant. *See Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 703–04 (Fed. Cir. 1992) ("The concept of patent misuse arose to restrain practices that did not in themselves violate any law, but that draw anticompetitive strength from the patent right, and thus were deemed to be contrary to public policy.")

Patent misuse is viewed as a broader wrong than antitrust violation because of the economic power that may be derived from the patentee's right to exclude. Thus misuse may arise when the conditions of antitrust violation are not met. *See Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 140–41 (1969). The key inquiry is whether, by imposing conditions that derive their force from the patent, the patentee has impermissibly broadened the scope of the patent grant with anticompetitive effect. *See Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 868 (Fed. Cir. 1997); *B. Braun Medical, Inc. v. Abbott Labs.*, 124 F.3d 1419, 1426 (Fed. Cir. 1997); *Mallinckrodt*, 976 F.2d at 704.

The jury returned special verdicts that Bard had misused both the '056 and '308 patents. Patent misuse arises in equity, and a holding of misuse renders the patent unenforceable until the misuse is purged; it does not, of itself, invalidate the patent. *See Morton Salt Co. v. G.S. Suppiger Co.*, 314 U.S. 488, (1942); *Senza-Gel Corp. v. Seiffhart*, 803 F.2d 661, 668 n.10 (Fed. Cir. 1986). When a jury has determined that patent misuse occurred we review the underlying findings of fact for support by substantial evidence, presuming that the jury resolved any factual disputes in favor of the verdict winner. We then determine whether, on the found or presumed facts, the conclusion on the issue of misuse is correct. *See Virginia Panel*, 133 F.3d at 868.

The jury instruction on patent misuse was focused primarily on the charge that Bard was attempting to enforce the patents against goods known not to be infringing, the court explaining that antitrust violation is not necessary to find misuse if patents have been used "wrongfully" to exclude competitors:

> A patent is unenforceable for misuse if the patent owner attempts to exclude products from the marketplace which do not infringe the claims of the patent and the patent owner has actual knowledge that those products do not infringe any claim of the patents. The patent is also unenforceable for misuse when a patent owner attempts to use the patent to exclude competitors from their marketplace knowing that the patent was invalid or unenforceable.

> A patent will not be rendered unenforceable for misuse if the patent owner has enforced the patent in the good faith belief that the accused products infringed the patent's claims.
>
> You may consider all aspects of the conduct of the patent owner in deciding whether a patent has been misused. In order to find misuse, you may not determine that—you need not determine that an antitrust violation has been proved. Even if an antitrust violation has not been proven, you may still find that the patents have been misused if you conclude that the patents have been used wrongfully.

This instruction calls to mind the view expressed in *USM Corp. v. SPS Techs., Inc.*, 694 F.2d 505, 510 (7th Cir. 1982) that the misuse doctrine is "too vague a formulation to be useful." Although the defense of patent misuse indeed evolved to protect against "wrongful" use of patents, the catalog of practices labelled "patent misuse" does not include a general notion of "wrongful" use. *See id.* ("in application, the doctrine has largely been confined to a handful of specific practices").

M3 Systems did not propose any of the classic grounds of patent misuse, such as tying or enforced package licensing or price restraints or extended royalty terms, see Chisum [on Patents] § 19.04[3], but generally urged the view that Bard's actions, even if not illegal, were an improper use of patents. Although the law should not condone wrongful commercial activity, the body of misuse law and precedent need not be enlarged into an open-ended pitfall for patent-supported commerce.

There was no evidence that Bard's competitive activities were either per se patent misuse or that they were not "reasonably within the patent grant." *See Mallinckrodt*, 976 F.2d at 708 . . . . M3 Systems adduced no evidence of patent misuse other than was presented for its antitrust claims. It is not patent misuse to bring suit to enforce patent rights not fraudulently obtained, nor is otherwise legal competition such behavior as to warrant creation of a new class of prohibited commercial conduct when patents are involved.

The verdicts of patent misuse are not supported by evidence or correct legal theory. The judgment on these verdicts is reversed.

. . .

[*Affirmed-in-part, reversed-in-part, vacated-in-part, and remanded.*]

NOTES AND QUESTIONS

1. *The relationship between the patent misuse defense and antitrust counterclaims in patent cases.* The Federal Circuit stated in *Bard* that "[p]atent misuse is viewed as a broader wrong than antitrust violation because of the economic power that may be derived from the patentee's right to exclude." *Bard,* 157 F.3d at 1372. It is also a *different* wrong, both as a matter of substance, procedure, and remedies. Patent misuse is an equitable doctrine internal to patent law that is tied to competition concerns, while antitrust law is an external mechanism that can be used to enforce

competition concerns that some forms of patent exploitation might raise. As an internal doctrine, patent misuse operates as a defense to infringement, while antitrust provides independent causes of action that may lead to civil liability that includes an award of treble damages, or even criminal liability. Needless to say, an adjudicated antitrust violation cannot be "purged" in the way that misuse can be.

In patent cases, antitrust counterclaims are frequently based on allegations of "sham litigation" by the patentee. The Federal Circuit recently explained:

> A party is ordinarily exempt from antitrust liability for bringing a lawsuit against a competitor. That principle is known as "*Noerr-Pennington* immunity," because it originated with the Supreme Court's decisions in *Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc.*, 365 U.S. 127 (1961), and *United Mine Workers of Am. v. Pennington*, 381 U.S. 657 (1965). There is a recognized exception to *Noerr-Pennington* immunity for "sham litigation," which the Supreme Court has defined as litigation that (1) is "objectively baseless in the sense that no reasonable litigant could realistically expect success on the merits" (the objective element), and (2) is motivated by a desire "to interfere directly with the business relationships of a competitor" (the subjective element). *Prof'l Real Estate Investors, Inc. v. Columbia Pictures Indus., Inc.*, 508 U.S. 49, 60–61 (1993).

Tyco Healthcare Grp. LP v. Mut. Pharm. Co., 762 F.3d 1338, 1343 (Fed. Cir. 2014). The Federal Circuit held that these stringent requirements may be satisfied if the patentee brings suit "with knowledge that the patent is invalid or not infringed." *Id.* at 1346 (citation omitted). As the Supreme Court explained, "[w]e crafted the *Noerr-Pennington* doctrine—an carved out only a narrow exception for 'sham' litigation—to avoid chilling the exercise of the First Amendmnt right to petition the government for the redress of grievances." *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. 545, 556 (2014).

The fact "that the asserted patent was obtained through knowing and willful fraud" can also serve as a predicate for an antitrust claim. *Nobelpharma AB v. Implant Innovations, Inc.*, 141 F.3d 1059, 1068 (Fed. Cir. 1998) (citing *Walker Process Equip., Inc. v. Food Mach. & Chem. Corp.*, 382 U.S. 172 (1965)). This formulation calls to mind the elements of inequitable conduct, and the Federal Circuit recently opined on the resemblance between inequitable conduct and the so-called "*Walker Process* fraud" underlying antitrust liability. *See Transweb, LLC v. 3M Innovative Props. Co.*, 812 F.3d 1295, 1307 (Fed. Cir. 2016) ("After *Therasense,* the showing required for proving inequitable conduct and the showing required for proving the fraud component of *Walker Process* liability may be nearly identical.") (citing Gideon Mark & T. Leigh Anenson, *Inequitable Conduct and* Walker Process *Claims After* Therasense *and the America Invents Act*, 16 U. PENN. J. BUS. L. 361, 402 n.258 (2014)). But that is not all. The defendant must also prove the key element of Section 2 of the Sherman Act, which is that the patentee has monopoly power in the relevant market—and market power cannot be presumed from the mere existence of the patent. *See Abbott Labs. v.*

Brennan, 952 F.2d 1346, 1354 (Fed. Cir. 1991); *see also Illinois Tool Works*, 547 U.S. 28.

Thus, while the patent misuse defense is foundationally concerned about extension of patent rights as such beyond their lawful scope, antitrust claims in patent cases focus on the abuse of patent law in order to achieve a market monopoly. To be clear, as we will see in Note 4, a showing of anticompetitive effect can be critical to the success of the misuse defense. At the same time, though, some patent misuse theories—see, for example, Note 2—require no showing of market power or anticompetitive effect. Finally, as *Bard* suggests, conduct that would support an antitrust claim, such as enforcement of a fraudulently obtained patent, can also constitute patent misuse.

2. *Post-expiration royalties as per se misuse.* In *Kimble v. Marvel Entertainment, LLC*, 576 U.S. 446 (2015), the Supreme Court reaffirmed its earlier decision, *Brulotte v. Thys Co.*, 379 U.S. 29 (1964), which concluded that "a patent holder cannot charge royalties for the use of the invention after its patent term has expired." *Kimble*, 576 U.S. at 449. In other words, the Court determined that the patentee engaged in the "misuse of the patents through extension of the license agreement beyond the expiration date of the patents." *Brulotte*, 379 U.S. at 30. The petitioner in *Kimble* argued that enforceability of such agreements should be evaluated under antitrust-style "rule of reason" analysis, which would take into account the patentee's market power and other factors. The *Kimble* Court acknowledged that "[a] broad scholarly consensus supports Kimble's view of the competitive effects of post-expiration royalties," but adhered to *Brulotte*'s rule that post-expiration royalties always constitute misuse mainly on stare decisis grounds. *Kimble*, 576 U.S. at 461–63. What might be some *pro*-competitive effects of post-expiration royalties?

3. *Reach-through royalties.* The patent misuse defense was raised in an interesting scenario in *Bayer AG v. Housey Pharm., Inc.*, 228 F. Supp. 2d 467 (D. Del. 2002). Bayer, the declaratory judgment plaintiff, asserted a patent misuse defense against "a running royalty license that requires the licensee to pay a royalty for sales of pharmaceutical products discovered using the subject invention," a screening method for drug discovery. *Id.* at 468. The essence of the defense was that the pharmaceutical products themselves were not covered by the patent on the drug discovery method. The district court rejected the defense because Bayer, the licensee, did not actually propose a licensing arrangement committing it to pay the for actual use of the method—instead, it was fully onboard with a royalty agreement based on drug sales. This fact foreclosed the conclusion that Housey, the patentee, impermissibly conditioned "the grant of a patent license upon payment of royalties on products which do not use the teaching of the patent." *Id.* at 470 (quoting *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 135 (1969)). In addition, Housey "indicate[d] a willingness to consider other licensing terms." *Id.* at 471. Does this analysis suggest that patent misuse would have been found if Housey insisted on a royalty based on drug sales even in the face of counterproposals to the contrary? For an analysis of this case and a broader discussion of the effects of these so-called "reach-through royalties," see Robin C. Feldman, *The Insufficiency of Antitrust Analysis for Patent Misuse*, 55 HASTINGS L.J. 399 (2003).

4. Princo Corp. v. International Trade Comm'n, *616 F.3d 1318 (Fed. Cir. 2010) (en banc) and the test for patent misuse*. *Princo*, mentioned in the introduction to this Section, reinforces the point that the patent misuse defense is sharply circumscribed. Thus, "[w]here the patentee has not leveraged its patent beyond the scope of rights granted by the Patent Act, misuse has not been found." *Id.* at 1328 (citing *Monsanto*, 363 F.3d at 1341), and "the defense of patent misuse is not available to a presumptive infringer simply because a patentee engages in some kind of wrongful commercial conduct, *id.* at 1329 (citing *Bard*, 157 F.3d at 1373). Conduct alleged to constitute misuse in *Princo* included the following actions: Philips and Sony jointly developed a certain aspect of the technology underlying recordable and rewritable CDs (CD-R/RW) and each obtained patents on that technology. The two companies decided that Phillips's approach worked better, and Phillips's patented invention became a part of "technical standards to ensure that discs made by different manufacturers would be compatible and playable on machines that were designed to read the earlier generations compact discs." *Id.* at 1322. Philips and Sony jointly offered package licenses to compact disc manufacturers on CD-R/RW patents from both companies, but restricted the licenses in such a way that the manufacturers could not develop a competing standard. In particular, the licensees were prohibited from using the invention claimed in Sony's patent, which did not become a part of the standard, in pursuit of the competing standard.

Princo, one of the licensees, stopped paying the licensee fees and asserted misuse. The Federal Circuit, however, held that this defense was dead on arrival because "Philips is not imposing restrictive conditions on the use of [its] patents to enlarge the physical or temporal scope of those patents," but rather "restrict[ing] the availability of . . . an entirely different patent that was never asserted in the infringement action." *Id.* at 1331. *Princo* explained that, assuming that Sony and Philips did engage in anticompetitive conduct not involving the asserted patent, "[t]hat is a different issue altogether"—remediable if at all only via antitrust law, and not via the patent misuse defense. *Id.* at 1332. Notably, *Princo* was an appeal from a decision of the International Trade Commission, which lacks jurisdiction to entertain antitrust counterclaims.

Moreover, "[a]part from Princo's failure to show that Philips unlawfully leveraged its . . . patents, a finding of patent misuse is unwarranted in this case because Princo failed to establish that the [license] had anticompetitive effects." *Id.* at 1334. The Federal Circuit declined to eliminate this antitrust-derived requirement to show misuse in certain circumstances. The court explained that "[t]o sustain a misuse defense involving a licensing arrangement not held to have been per se anticompetitive by the Supreme Court, a factual determination must reveal that the overall effect of the license tends to restrain competition unlawfully in an appropriately defined relevant market." *Id.* at 1334 (quoting *Windsurfing Int'l, Inc. v. AMF, Inc.*, 782 F.2d 995, 1001–02 (Fed. Cir. 1986)). Applying the "rule of reason" approach, also borrowed from antitrust law, that calls on courts to evaluate the costs and benefits of allegedly wrongful forms of competition, the Federal Circuit determined that Princo failed to show that the license "had an actual adverse effect on the competition in the relevant market." *Id.* at 1335, 1338. The court observed that "research joint ventures that seek to develop industry-wide standards for new

technology can have decidedly procompetitive effects," and concluded that even if "Philips and Sony engaged in an agreement" to restrict the license Sony's patent, misuse was not established given the lack of anticompetitive effect. *Id*. at 1335, 1340.

Princo delineates a three-pronged approach to patent misuse developed by the Federal Circuit. *See Virginia Panel Corp. v. MAC Panel Co.*, 133 F.3d 860, 868–71 (Fed. Cir. 1997). At one extreme is per se misuse, such as the practice of charging post-expiration royalties discussed in Note 2. (Another example of per se misuse is so-called "product-to-patent tying," which was mentioned in the Introduction to this section. This practice requires patent licensees to also use products not covered by the licensed patent. *See Senza-Gel Corp. v. Seiffhart*, 803 F.2d 661, 668–69 (Fed. Cir. 1986.).) At the other extreme, some activities cannot be misuse because they are excluded from the scope of the misuse defense by 35 U.S.C. § 271(d), because "the restriction is reasonably within the patent grant," *Monsanto*, 363 F.3d at 1341, or because, as in the licensing scheme in *Princo*, the patentee is not actually "leveraging" the asserted patent at all. Between these extremes are activities analyzed under the rule of reason, applied in the section of *Princo* discussed at the end of the previous paragraph. *See also Mallinckrodt, Inc. v. Medipart, Inc.*, 976 F.2d 700, 708–09 (Fed. Cir. 1992), *abrogated on other grounds by Impression Prods., Inc. v. Lexmark Int'l, Inc.*, 137 S. Ct. 1523 (2017). Could certain post-sale restrictions or limits imposed on uses of patented products through leases or licenses be a form of patent misuse? *Cf. Illinois Tool Works*, 547 U.S. at 38–40.

D. LACHES AND EQUITABLE ESTOPPEL

SCA HYGIENE PRODS. AKTIEBOLAG

v.

FIRST QUALITY BABY PRODS., LLC
137 S.Ct. 954 (2017)

Justice ALITO delivered the opinion of the Court.

We return to a subject that we addressed in *Petrella v. Metro-Goldwyn-Mayer, Inc.*, 134 S. Ct. 1962 (2014): the relationship between the equitable defense of laches and claims for damages that are brought within the time allowed by a statute of limitations. In *Petrella*, we held that laches cannot preclude a claim for damages incurred within the Copyright Act's 3-year limitations period. *Id.* at 1967. "[L]aches," we explained, "cannot be invoked to bar legal relief" "[i]n the face of a statute of limitations enacted by Congress." *Id.*, at 1974. The question in this case is whether *Petrella*'s reasoning applies to a similar provision of the Patent Act, 35 U.S.C. § 286. We hold that it does.

I

Petitioners SCA Hygiene Products Aktiebolag and SCA Personal Care, Inc.

(collectively, SCA), manufacture and sell adult incontinence products. In October 2003, SCA sent a letter to respondents (collectively, First Quality), alleging that First Quality was making and selling products that infringed SCA's rights under U.S. Patent No. 6,375,646 B1 ('646 patent). First Quality responded that one of *its* patents—U.S. Patent No. 5,415,649 (Watanabe patent)—antedated the '646 patent and revealed "the same diaper construction." As a result, First Quality maintained, the '646 patent was invalid and could not support an infringement claim. SCA sent First Quality no further correspondence regarding the '646 patent, and First Quality proceeded to develop and market its products.

In July 2004, without notifying First Quality, SCA asked the Patent and Trademark Office (PTO) to initiate a reexamination proceeding to determine whether the '646 patent was valid in light of the Watanabe patent. Three years later, in March 2007, the PTO issued a certificate confirming the validity of the '646 patent.

In August 2010, SCA filed this patent infringement action against First Quality. First Quality moved for summary judgment based on laches and equitable estoppel, and the District Court granted that motion on both grounds.

SCA appealed to the Federal Circuit, but before the Federal Circuit panel issued its decision, this Court decided *Petrella.* The panel nevertheless held, based on a Federal Circuit precedent, *A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020 (1992) (en banc), that SCA's claims were barred by laches.[1]

The Federal Circuit then reheard the case en banc in order to reconsider *Aukerman* in light of *Petrella.* But in a 6–to–5 decision, the en banc court reaffirmed *Aukerman*'s holding that laches can be asserted to defeat a claim for damages incurred within the 6–year period set out in the Patent Act. As it had in *Aukerman*, the en banc court concluded that Congress, in enacting the Patent Act, had "codified a laches defense" that "barred recovery of legal remedies." 807 F.3d 1311, 1323–1329 (2015). Judge Hughes, joined by four other judges, dissented.[2] *Id.*, at 1337–1342 (opinion concurring in part and dissenting in part). We granted certiorari.

II

Laches is "a defense developed by courts of equity" to protect defendants against "unreasonable, prejudicial delay in commencing suit." *Petrella*, 134 S. Ct., at 1967, 1973. See also 1 D. Dobbs, Law of Remedies § 2.3(5), p. 89 (2d ed. 1993) (Dobbs) ("The equitable doctrine of laches bars the plaintiff whose unreasonable delay in prosecuting a claim or protecting a right has worked a prejudice to the defendant"). Before the

[1] The panel reversed the District Court's holding on equitable estoppel, concluding that there are genuine disputes of material fact relating to that defense. 767 F.3d 1339, 1351 (C.A. Fed. 2014).

[2] The dissenting judges concurred in the portion of the majority opinion relating to the application of laches to equitable relief. 807 F.3d, at 1333, n. 1 (opinion of Hughes, J.); see also *id.,* at 1331–1333 (majority opinion). We do not address that aspect of the Federal Circuit's judgment. Nor do we address the Federal Circuit's reversal of the District Court's equitable estoppel holding. *Id.,* at 1333 (reinstating original panel holding on equitable estoppel).

separate systems of law and equity were merged in 1938, the ordinary rule was that laches was available only in equity courts. See *County of Oneida v. Oneida Indian Nation of N. Y.*, 470 U.S. 226, 244, n. 16 (1985). This case turns on the application of the defense to a claim for damages, a quintessential legal remedy. We discussed this subject at length in *Petrella*.

Petrella arose out of a copyright dispute relating to the film Raging Bull. 134 S.Ct., at 1971. The Copyright Act's statute of limitations requires a copyright holder claiming infringement to file suit "within three years after the claim accrued." 17 U.S.C. § 507(b). In *Petrella*, the plaintiff sought relief for alleged acts of infringement that accrued within that 3–year period, but the lower courts nevertheless held that laches barred her claims. We reversed, holding that laches cannot defeat a damages claim brought within the period prescribed by the Copyright Act's statute of limitations. *Petrella*, 134 S. Ct., at 1972–1975. And in so holding, we spoke in broad terms. See 134 S. Ct., at 1974 ("[I]n the face of a statute of limitations enacted by Congress, laches cannot be invoked to bar legal relief").

Petrella's holding rested on both separation-of-powers principles and the traditional role of laches in equity. Laches provides a shield against untimely claims, 134 S. Ct., at 1977, and statutes of limitations serve a similar function. When Congress enacts a statute of limitations, it speaks directly to the issue of timeliness and provides a rule for determining whether a claim is timely enough to permit relief. 134 S. Ct., at 1972–1973. The enactment of a statute of limitations necessarily reflects a congressional decision that the timeliness of covered claims is better judged on the basis of a generally hard and fast rule rather than the sort of case-specific judicial determination that occurs when a laches defense is asserted. Therefore, applying laches within a limitations period specified by Congress would give judges a "legislation-overriding" role that is beyond the Judiciary's power. 134 S. Ct., at 1974. As we stressed in *Petrella*, "courts are not at liberty to jettison Congress' judgment on the timeliness of suit." 134 S. Ct., at 1967.

Applying laches within the limitations period would also clash with the purpose for which the defense developed in the equity courts. As *Petrella* recounted, the "principal application" of laches "was, and remains, to claims of an equitable cast for which the Legislature has provided no fixed time limitation." 134 S. Ct., at 1973; see also R. Weaver, E. Shoben, & M. Kelly, Principles of Remedies Law 21 (2d ed. 2011); 1 Dobbs § 2.4(4), at 104; 1 J. Story, Commentaries on Equity Jurisprudence § 55(*a*), p. 73 (2d ed. 1839). Laches is a gap-filling doctrine, and where there is a statute of limitations, there is no gap to fill. *Petrella*, 134 S. Ct., at 1974–1975; see also 1 Dobbs § 2.4(4), at 108 ("[I]f the plaintiff has done only what she is permitted to do by statute, and has not misled the defendant [so as to trigger equitable estoppel], the basis for barring the plaintiff seems to have disappeared").

With *Petrella*'s principles in mind, we turn to the present dispute.

III

A

Although the relevant statutory provisions in *Petrella* and this case are worded differently, *Petrella*'s reasoning easily fits the provision at issue here. As noted, the statute in *Petrella* precludes a civil action for copyright infringement "unless it is commenced within three years after the claim accrued." 17 U.S.C. § 507(b). We saw in this language a congressional judgment that a claim filed within three years of accrual cannot be dismissed on timeliness grounds. 134 S. Ct., at 1972–1973; see also *id.*, at 1974–1975.

The same reasoning applies in this case. Section 286 of the Patent Act provides: "Except as otherwise provided by law, no recovery shall be had for any infringement committed more than six years prior to the filing of the complaint or counterclaim for infringement in the action." By the logic of *Petrella*, we infer that this provision represents a judgment by Congress that a patentee may recover damages for any infringement committed within six years of the filing of the claim.

B

First Quality contends that this case differs from *Petrella* because § 286 of the Patent Act is not a *true* statute of limitations. A true statute of limitations, we are told, "runs forward from the date a cause of action accrues," but § 286 "runs backward from the time of suit." Brief for Respondents 41.

Petrella cannot reasonably be distinguished on this ground. First Quality thinks it critical that § 286 "runs backward from the time of suit," but *Petrella* described the Copyright Act's statute of limitations in almost identical terms. We said that this provision "allows plaintiffs . . . to gain retrospective relief *running only three years back from the date the complaint was filed*." 134 S. Ct., at 1970 (emphasis added). See also *id.*, at 1973 ("[A] successful plaintiff can gain retrospective relief only three years back from the time of suit"). And we described the Copyright Act's statute of limitations as "a three-year look-back limitations period." *Id.*, at 1968.

First Quality contends that the application of a true statute of limitations, like the defense of laches (but unlike § 286), takes into account the fairness of permitting the adjudication of a *particular* plaintiff's claim. First Quality argues as follows: "When Congress enacts [a true statute of limitations], it can be viewed as having made a considered judgment about how much delay may occur after a plaintiff knows of a cause of action (*i.e.*, after accrual) before the plaintiff must bring suit—thus potentially leaving no room for judges to evaluate the reasonableness of a plaintiff's delay on a case-by-case basis under laches." Brief for Respondents 42. According to First Quality, § 286 of the Patent Act is different because it "turns only on when the infringer is sued, regardless of when the patentee learned of the infringement." *Ibid.*

This argument misunderstands the way in which statutes of limitations generally work. First Quality says that the accrual of a claim, the event that triggers the running of a statute of limitations, occurs when "a plaintiff knows of a cause of action," *ibid.*, but that is not ordinarily true. As we wrote in *Petrella*, "[a] claim ordinarily

accrues 'when [a] plaintiff has a complete and present cause of action.' " 134 S. Ct., at 1969; see *Graham County Soil & Water Conservation Dist. v. United States ex rel. Wilson*, 545 U.S. 409, 418–419 (2005). While some claims are subject to a "discovery rule" under which the limitations period begins when the plaintiff discovers or should have discovered the injury giving rise to the claim, that is not a universal feature of statutes of limitations. See, *e.g.*, *ibid.* (limitations period in 31 U.S.C. § 3731(b)(1) begins to run when the cause of action accrues); *TRW Inc. v. Andrews*, 534 U.S. 19, 28 (2001) (same with regard to 15 U.S.C. § 1681p). And in *Petrella*, we specifically noted that "we have not passed on the question" whether the Copyright Act's statute of limitations is governed by such a rule. 134 S. Ct., at 1969, n. 4.

For these reasons, *Petrella* cannot be dismissed as applicable only to what First Quality regards as true statutes of limitations. At least for present purposes, nothing depends on this debatable taxonomy. Compare *Automobile Workers v. Hoosier Cardinal Corp.*, 383 U.S. 696, 704 (1966) (describing § 286 as "enacting a uniform period of limitations"); 1 Dobbs § 2.4(4), at 107, and n. 33 (same), with *A. Stucki Co. v. Buckeye Steel Castings Co.*, 963 F.2d 360, 363, n. 3 (C.A. Fed. 1992) (Section 286 "is not, strictly speaking, a statute of limitations"); *Standard Oil Co. v. Nippon Shokubai Kagaku Co., Ltd.*, 754 F.2d 345, 348 (C.A.Fed. 1985) ("[Section] 286 cannot properly be called a 'statute of limitations' in the sense that it defeats the right to bring suit").

C

The Federal Circuit based its decision on a different footing. Section 286 of the Patent Act begins with the phrase "[e]xcept as otherwise provided by law," and according to the Federal Circuit, § 282 of the Act is a provision that provides otherwise. In its view, § 282 creates an exception to § 286 by codifying laches as a defense to all patent infringement claims, including claims for damages suffered within § 286's 6–year period. 807 F.3d, at 1329–1330. Section 282(b), which does not specifically mention laches, provides in relevant part as follows:

> "The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded:
>
> "(1) Noninfringement, absence of liability for infringement or unenforceability."

The en banc majority below never identified which word or phrase in § 282 codifies laches as a defense, but First Quality argues that laches falls within § 282(b)(1) because laches is a defense based on "unenforceability." Brief for Respondents 28–33.

SCA disputes this interpretation of § 282(b)(1), arguing that laches does not make a patent categorically unenforceable. Reply Brief 6–8; see *Aukerman*, 960 F.2d, at 1030 ("Recognition of laches as a defense ... does not affect the general enforceability of the patent against others"). We need not decide this question. Even if we assume for the sake of argument that § 282(b)(1) incorporates a laches defense *of some dimension*, it does not necessarily follow that this defense may be invoked to bar a claim for damages incurred within the period set out in § 286. Indeed, it would be exceedingly unusual, if not unprecedented, if Congress chose to include in the Patent Act both a statute of limitations for damages and a laches provision applicable to a damages

claim. Neither the Federal Circuit, nor First Quality, nor any of First Quality's *amici* has identified a single federal statute that provides such dual protection against untimely claims.

D

In holding that Congress codified a damages-limiting laches defense, the Federal Circuit relied on patent cases decided by the lower courts prior to the enactment of the Patent Act. After surveying these cases, the Federal Circuit concluded that by 1952 there was a well-established practice of applying laches to such damages claims and that Congress, in adopting § 282, must have chosen to codify such a defense in § 282(b)(1). 807 F.3d, at 1321–1329. First Quality now presses a similar argument. We have closely examined the cases on which the Federal Circuit and First Quality rely, and we find that they are insufficient to support the suggested interpretation of the Patent Act. The most prominent feature of the relevant legal landscape at the time of enactment of the Patent Act was the well-established general rule, often repeated by this Court, that laches cannot be invoked to bar a claim for damages incurred within a limitations period specified by Congress. See *Holmberg v. Armbrecht*, 327 U.S. 392, 395 (1946) ("If Congress explicitly puts a limit upon the time for enforcing a right which it created, there is an end of the matter"); *United States v. Mack*, 295 U.S. 480 (1935) ("Laches within the term of the statute of limitations is no defense at law"); *Wehrman v. Conklin*, 155 U.S. 314, 326 (1894) ("Though a good defense in equity, laches is no defense at law. If the plaintiff at law has brought his action within the period fixed by the statute of limitations, no court can deprive him of his right to proceed"); *Cross v. Allen*, 141 U.S. 528, 537 (1891) ("So long as the demands secured were not barred by the statute of limitations, there could be no laches in prosecuting a suit"). *Petrella* confirmed and restated this long-standing rule. 134 S. Ct., at 1973 ("[T]his Court has cautioned against invoking laches to bar legal relief"). If Congress examined the relevant legal landscape when it adopted 35 U.S.C. § 282, it could not have missed our cases endorsing this general rule.

The Federal Circuit and First Quality dismiss the significance of this Court's many reiterations of the general rule because they were not made in patent cases. But as the dissenters below noted, "[p]atent law is governed by the same common-law principles, methods of statutory interpretation, and procedural rules as other areas of civil litigation." 807 F.3d, at 1333 (opinion of Hughes, J.).

In light of the general rule regarding the relationship between laches and statutes of limitations, nothing less than a broad and unambiguous consensus of lower court decisions could support the inference that § 282(b)(1) codifies a very different patent-law-specific rule. No such consensus is to be found.

IV

The pre–1952 cases on which First Quality relies fall into three groups: (1) cases

decided by equity courts before 1938; (2) cases decided by law courts before 1938; and (3) cases decided after the merger of equity and law in 1938. We will discuss each group separately.

A

Pre–1938 equity cases

The pre–1938 equity cases are unpersuasive for several, often overlapping reasons. Many do not even reveal whether the plaintiff asked for damages. Indeed, some say nothing at all about the form of relief that was sought, see, *e.g.*, *Cummings v. Wilson & Willard Mfg. Co.*, 4 F.2d 453 (C.A.9 1925), and others state only that the plaintiff wanted an accounting of profits, *e.g.*, *Westco–Chippewa Pump Co. v. Delaware Elec. & Supply Co.*, 64 F.2d 185, 186 (C.A.3 1933); *Wolf Mineral Process Corp. v. Minerals Separation North Am. Corp.*, 18 F.2d 483, 484 (C.A.4 1927). The equitable remedy of an accounting, however, was not the same as damages. The remedy of damages seeks to compensate the victim for its loss, whereas the remedy of an accounting, which Congress abolished in the patent context in 1946, sought disgorgement of ill-gotten profits. See *Birdsall v. Coolidge*, 93 U.S. 64 (1876); 1 Dobbs § 4.3(5), at 611 ("Accounting holds the defendant liable for his profits, not for damages"); A. Walker, Patent Laws § 573, p. 401 (1886) (distinguishing between the two remedies); G. Curtis, Law of Patents § 341(*a*), p. 461 (4th ed. 1873); 2 J. Pomeroy, Treatise on Equitable Remedies § 568, p. 977 (1905).

First Quality argues that courts sometimes used the term "accounting" imprecisely to refer to both an accounting of profits and a calculation of damages, Brief for Respondents 19–20, but even if that is true, this loose usage shows only that a reference to "accounting" *might* refer to damages. For that reason, the Federal Circuit did not rely on cases seeking only an accounting, 807 F.3d, at 1326, n. 7, and we likewise exclude such cases from our analysis.

Turning to the cases that actually refer to damages, we note that many of the cases merely suggest in dicta that laches might limit recovery of damages. See, *e.g.*, *Hartford–Empire Co. v. Swindell Bros.*, 96 F.2d 227, 233, modified on reh'g, 99 F.2d 61 (C.A.4 1938). Such dicta "settles nothing." *Jama v. Immigration and Customs Enforcement*, 543 U.S. 335, 351, n. 12, 125 S.Ct. 694, 160 L.Ed.2d 708 (2005). See also *Hartford Underwriters Ins. Co. v. Union Planters Bank, N. A.*, 530 U.S. 1, 9–10 (2000); *Metropolitan Stevedore Co. v. Rambo*, 515 U.S. 291, 300 (1995).

As for the cases in which laches was actually held to bar a claim for damages, *e.g.*, *Wolf, Sayer & Heller v. United States Slicing Mach. Co.*, 261 F. 195, 197–198 (C.A.7 1919); *A.R. Mosler & Co. v. Lurie*, 209 F. 364, 369–370 (C.A.2 1913), these cases are too few to establish a settled, national consensus. See *Hartford Underwriters*, *supra*, at 10.

Moreover, the most that can possibly be gathered from a pre–1938 equity case is that laches could defeat a damages claim *in an equity court*, not that the defense could entirely prevent a patentee from recovering damages. Before 1870, a patentee wishing

to obtain both an injunction against future infringement and damages for past infringement was required to bring two suits, one in an equity court (where injunctive relief but not damages was available), and one in a court of law (where damages but not injunctive relief could be sought). See Beauchamp, The First Patent Litigation Explosion, 125 Yale L.J. 848, 913–914 (2016). To rectify this situation, Congress enacted a law in 1870 authorizing equity courts to award damages in patent-infringement actions. Rev. Stat. § 4921. And although statutes of limitations did not generally apply in equity, Congress in 1897 enacted a statute that, like the current § 286, imposed a 6–year limitations period for damages claims and made that statute applicable in both law and equity. § 6, 29 Stat. 694. Pointing to cases decided between 1897 and 1938 in which an equity court permitted a defendant in an infringement case to invoke the defense of laches, First Quality contends that Congress, aware of these cases, assumed that the 1952 Act would likewise allow a defendant in an infringement case to claim laches with respect to a claim for damages occurring within a limitations period.

This argument overlooks the fact that a patentee, during the period in question, could always sue for damages in law, where the equitable doctrine of laches did not apply, and could thus avoid any possible laches defense. Thus, accepting First Quality's argument would not return patentees to the position they held from 1897 to 1938. Instead, it would go much further and permit laches entirely to defeat claims like SCA's.

B

Pre–1938 claims at law

First Quality cites three Court of Appeals cases in which laches was raised in a proceeding at law and in which, according to First Quality, the defense was held to bar a damages claim. See *Universal Coin Lock Co. v. American Sanitary Lock Co.*, 104 F.2d 781 (C.A.7 1939); *Banker v. Ford Motor Co.*, 69 F.2d 665 (C.A.3 1934); *Ford v. Huff*, 296 F. 652 (C.A.5 1924). But even if all of these cases squarely held that laches could be applied to a damages claim at law within the limitations period, they would still constitute only a handful of decisions out of the corpus of pre–1952 patent cases, and that would not be enough to overcome the presumption that Congress legislates against the background of general common-law principles. See H. McClintock, Handbook of the Principles of Equity § 28, p. 75 (2d ed. 1948) ("The majority of the courts which have considered the question have refused to enjoin an action at law on the ground of the laches of the plaintiff at law").

In any event, these cases, like the equity cases, offer minimal support for First Quality's position. Not one of these cases even mentions the statute of limitations. One of the three, *Ford*, is not even a patent infringement case; it is a breach-of-contract case arising out of a patent dispute, 296 F., at 654, and it is unclear whether the ground for decision was laches or equitable estoppel. See 807 F.3d, at 1340 (opinion of Hughes, J.). Another, *Universal Coin*, applied laches to a legal damages claim without any analysis of the propriety of doing so. 104 F.2d, at 783.

First Quality protests that the paucity of supporting cases at law should not count against its argument since very few patent-infringement cases were brought at law after 1870. Brief for Respondents 25–26. But the fact remains that it is First Quality's burden to show that Congress departed from the traditional common-law rule highlighted in our cases.

C

Post-merger cases

First Quality claims that courts continued to apply laches to damages claims after the merger of law and equity in 1938, but First Quality's evidence is scant. During this period, two Courts of Appeals stated in dicta that laches could bar legal damages claims. See *Chicago Pneumatic Tool Co. v. Hughes Tool Co.*, 192 F.2d 620, 625 (C.A.10 1951); *Shaffer v. Rector Well Equip. Co.*, 155 F.2d 344, 347 (C.A.5 1946). And two others actually held that laches could bar a damages claim. See, *e.g.*, *Brennan v. Hawley Prods. Co.*, 182 F.2d 945, 948 (C.A.7 1950); *Lukens Steel Co. v. American Locomotive Co.*, 197 F.2d 939, 941 (C.A.2 1952) (alternative holding). This does not constitute a settled, uniform practice of applying laches to damages claims.

After surveying the pre–1952 case law, we are not convinced that Congress, in enacting § 282 of the Patent Act, departed from the general rule regarding the application of laches to damages suffered within the time for filing suit set out in a statute of limitations.

V

First Quality's additional arguments do not require extended discussion. First Quality points to post–1952 Court of Appeals decisions holding that laches can be invoked as a defense against a damages claim. Noting that Congress has amended § 282 without altering the " 'unenforceability' " language that is said to incorporate a laches defense, First Quality contends that Congress has implicitly ratified these decisions. Brief for Respondents 35–36.

We reject this argument. Nothing that Congress has done since 1952 has altered the meaning of § 282. See *Central Bank of Denver, N.A. v. First Interstate Bank of Denver, N. A.*, 511 U.S. 164, 186(1994); *West Virginia Univ. Hospitals, Inc. v. Casey*, 499 U.S. 83, 100, 101, and n. 7 (1991).

First Quality and its supporting *amici* also make various policy arguments, but we cannot overrule Congress's judgment based on our own policy views. We note, however, as we did in *Petrella*, that the doctrine of equitable estoppel provides protection against some of the problems that First Quality highlights, namely, unscrupulous patentees inducing potential targets of infringement suits to invest in the production of arguably infringing products. 134 S. Ct., at 1972. Indeed, the Federal Circuit held that there are genuine disputes of material fact as to whether equitable

estoppel bars First Quality's claims in this very case. See 807 F.3d, at 1333.

* * *

Laches cannot be interposed as a defense against damages where the infringement occurred within the period prescribed by § 286. The judgment of the Court of Appeals is vacated in part, and the case is remanded for further proceedings consistent with this opinion.

It is so ordered.

Justice BREYER, dissenting.

Laches is a doctrine that bars a plaintiff's claim when there has been unreasonable, prejudicial delay in commencing suit. See 1 D. Dobbs, Law of Remedies § 2.3(5), p. 89 (2d ed. 1993). The question before us is whether a court can apply this doctrine in a patent infringement action for damages brought within the statute of limitations. The Court holds that a court cannot. Laches, it says, is a "gap-filling doctrine," generally applicable where there is no statute of limitations. But the 1952 Patent Act contains a statute of limitations. Hence there is "no gap to fill." *Ante*, at 961.

In my view, however, the majority has ignored the fact that, despite the 1952 Act's statute of limitations, there remains a "gap" to fill. See *infra*, at 968. Laches fills this gap. And for more than a century courts with virtual unanimity have applied laches in patent damages cases. Congress, when it wrote the 1952 statute, was aware of and intended to codify that judicial practice. I fear that the majority, in ignoring this legal history, opens a new "gap" in the patent law, threatening harmful and unfair legal consequences.

I

Consider the relevant statutory language. Section 286 of the Patent Act says: "*Except as otherwise provided by law*, no recovery shall be had for any infringement committed more than six years prior to the filing of the complaint or counterclaim for infringement in the action." 35 U.S.C. § 286 (emphasis added). Section 282 says what the word "otherwise" means. It tells us that "unenforceability" shall be a defense "in *any* action involving the validity or infringement of a patent." § 282(b) (emphasis added).

Two features of this statutory language are important. First, the limitations provision, unlike those in many other statutes, does *not* set forth a period of time in which to sue, beginning when a claim accrues and then expiring some time later. (The False Claims Act, for example, gives a plaintiff six years from the date of the violation or three years from the date of discovery to file his suit, 31 U.S.C. § 3731(b).) Rather, it permits a patentee to sue at any time after an infringement takes place. It simply limits damages to those caused within the preceding six years. That means that a patentee, after learning of a possible infringement in year 1, might wait until year 10

or year 15 or year 20 to bring a lawsuit. And if he wins, he can collect damages for the preceding six years of infringement.

This fact creates a gap. Why? Because a patentee might wait for a decade or more while the infringer (who perhaps does not know or believe he is an infringer) invests heavily in the development of the infringing product (of which the patentee's invention could be only a small component), while evidence that the infringer might use to, say, show the patent is invalid disappears with time. Then, if the product is a success, the patentee can bring his lawsuit, hoping to collect a significant recovery. And if business-related circumstances make it difficult or impossible for the infringer to abandon its use of the patented invention (*i.e.*, if the infringer is "locked in"), then the patentee can keep bringing lawsuits, say, in year 10 (collecting damages from years 4 through 10), in year 16 (collecting damages from years 10 through 16), and in year 20 (collecting any remaining damages). The possibility of this type of outcome reveals a "gap." Laches works to fill the gap by barring recovery when the patentee unreasonably and prejudicially delays suit.

Second, the Patent Act's language strongly suggests that Congress, when writing the statutory provisions before us, intended to permit courts to continue to use laches to fill this gap. The statute says that there are "except[ions]" to its 6–year damages limitation rule. It lists "unenforceability" as one of those exceptions. At common law, the word "unenforceability" had a meaning that encompassed laches. See, *e.g.*, *United States v. New Orleans Pacific R. Co.*, 248 U.S. 507, 511 (1919) (considering whether an agreement "had become unenforceable by reason of inexcusable laches"). We often read statutes as incorporating common-law meanings. See *Neder v. United States*, 527 U.S. 1, 21 (1999). And here there are good reasons for doing so. For one thing, the principal technical drafter of the Patent Act (in a commentary upon which this Court has previously relied, *e.g.*, *Warner–Jenkinson Co. v. Hilton Davis Chemical Co.*, 520 U.S. 17, 28 (1997)) stated that § 282 was meant to codify "equitable defenses such as laches." P. Federico, Commentary on the New Patent Act, 35 U.S.C.A. 1, 55 (West 1954). For another thing, there is a long history of prior case law that shows with crystal clarity that Congress intended the statute to keep laches as a defense.

II

The pre–1952 case law that I shall discuss is directly relevant because, as this Court has recognized, the 1952 Patent Act was primarily intended to codify existing law. See *Halo Electronics v. Pulse Electronics, Inc.*, 136 S. Ct. 1923, 1929–1930 (2016); accord, H.R. Rep. No. 1923, 82d Cong., 2d Sess., 3 (1952) (stating that the "main purpose" of the Patent Act was "codification and enactment" of existing law); 98 Cong. Rec. 9323 (1952) (drafter of the Act stating that it was generally intended to "codif[y] the present patent laws").

Now consider the existing law that the Patent Act's drafters intended the Act to reflect. The decisions that find or say or hold that laches can bar monetary relief in patent infringement actions stretch in a virtually unbroken chain from the late 19th century through the Patent Act's enactment in 1952. They number in the dozens and include every federal appeals court to have considered the matter. (We have found

only two contrary decisions, both from the same District Court: *Thorpe v. Wm. Filene's Sons Co.*, 40 F.2d 269 (D.Mass. 1930); and *Concord v. Norton*, 16 F. 477 (C.C.Mass. 1883).)

Here are the cases from the Federal Courts of Appeals alone: [citing 24 cases]

The majority replies that this list proves nothing. After all, it says, nearly all of these decisions come from courts of equity. Courts of equity ordinarily applied laches " 'to claims of an equitable cast for which the Legislature ha[d] provided no fixed time limitation,' " *ante*, at 961 (quoting *Petrella v. Metro–Goldwyn–Mayer, Inc.*, 134 S.C t. 1962, 1973 (2014)), not to requests for damages, "a quintessential legal remedy," *ante*, at 960. Since "laches is a gap-filling doctrine," the fact that it was applied to equitable claims without statutes of limitations says little about whether it should apply to legal damages claims when "there is a statute of limitations," and therefore "no gap to fill." *Ante*, at 961.

Good reply. But no cigar. Why not? (1) Because in 1897 Congress *enacted a statute of limitations*—very much like the one before us now—for patent claims *brought in courts of equity*. Ch. 391, § 6, 29 Stat. 694 ("[I]n any suit or action . . . there shall be no recovery of profits or damages for any infringement committed more than six years before" filing). Thus, after 1897, *there was no statute of limitations gap for equity courts to fill*, and yet they continued to hold that laches applied. See, *e.g.*, *France Mfg. Co. v. Jefferson Elec. Co.*, 106 F.2d 605, 609 (C.A.6 1939) ("[N]otwithstanding the statute of limitations, relief may be denied on the ground of laches . . ."); *Sintering Co. v. Greenawalt*, 27 F.2d 823, 827 (C.A.2 1928) (Hand, J.) (explaining how laches operates in conjunction with the statute of limitations to allow an infringer to "garne[r] the harvest of even the earliest of the 6 years to which recovery is in any event limited, with just confidence that he will not be disturbed").

(2) Because in 1870 Congress enacted a statute that gave courts of equity the power to award legal relief, namely, damages, in patent cases. Act of July 8, 1870, § 55, 16 Stat. 206. Congress did not give law courts an equivalent power to grant injunctive relief in patent suits. As a result, from the late 19th century until the merger of law and equity in 1938, nearly all patent litigation—including suits for damages—took place in courts of equity that were applying laches in conjunction with a statute of limitations. See Lemley, Why Do Juries Decide If Patents Are Valid? 99 Va. L. Rev. 1673, 1704 (2013) (discussing the predominance of equity litigation).

(3) Because Congress recognized that damages suits for patent infringement took place almost exclusively in equity courts, not law courts. Whenever Congress wished to modify patent damages law, it rewrote the statutory provisions governing damages in equity, not law. See, *e.g.*, § 8, 42 Stat. 392 (modifying the equity damages statute to allow equity courts to award a "reasonable sum" even if a patentee had difficulty proving actual damages, but making no change to the legal damages provision). The 1952 Congress, seeking to understand whether, or how, laches applied in patent damages cases, would almost certainly have looked to equity practice.

(4) Because, in any event, in those few pre-law/equity-merger cases in which courts of

law considered whether laches could bar a patent damages action, they, like their equity counterparts, held that it could. See *Universal Coin Lock Co. v. American Sanitary Lock Co.*, 104 F.2d 781, 781–783 (C.A.7 1939); *Banker v. Ford Motor Co.*, 69 F.2d 665, 666 (C.A.3 1934); *Ford v. Huff*, 296 F. 652, 658 (C.A.5 1924). As the majority points out, these cases brought in law courts constitute "only a handful of decisions." *Ante*, at 966. But that is simply because, as I just noted, almost all patent damages litigation took place in courts of equity. Regardless, before the merger of law and equity both law courts and equity courts recognized laches as a defense. And, after the merger of law and equity in 1938, federal courts *still* applied laches to patent damages claims. *E.g.*, *Brennan v. Hawley Prods. Co.*, 182 F.2d 945, 948 (C.A.7 1950) (holding that "laches on the part of the plaintiff" can "bar his right to recover damages"). This, of course, would make no sense if laches for patent damages was really an equity-only rule.

Does the majority have any other good reason to ignore the mountain of authority recognizing laches as a defense? It refers to many general statements in opinions and treatises that say that laches is "no defense at law." *United States v. Mack*, 295 U.S. 480, 489 (1935). But these statements are not about patent damages cases. They do not claim to encompass the problem at issue here. And they do not prevent Congress from enacting a statute that, recognizing patent litigation's history, combines a statute of limitations with a laches defense. And that is what Congress has done in the Patent Act.

The majority also tries to discredit the persuasiveness of the pre-Patent Act case law authority. It goes through the lengthy list of decisions, finding some judicial statements too vague, others just dicta, and still others having confused an equitable claim for "accounting" with a legal claim for "damages." I agree that it has found weaknesses in the reasoning of some individual cases. But those weaknesses were not sufficient to prevent a 1951 treatise writer from concluding, on the basis of the great weight of authority, that in patent cases, "[l]aches . . . may be interposed in an action at law." 3 A. Deller, Walker on Patents 106 (Cum. Supp. 1951).

In any event, with all its efforts, the majority is unable to identify a single case—not one—from any court of appeals sitting in law or in equity before the merger, or sitting after the merger but before 1952, holding that laches could *not* bar a patent claim for damages. Furthermore, the majority concedes that it is unable to distinguish, by my count, at least six Court of Appeals cases directly holding that laches *could* bar a patent claim for damages. See *Wolf, Sayer & Heller, Inc. v. United States Slicing Mach. Co.*, 261 F. 195 (C.A.7 1919); *A.R. Mosler & Co. v. Lurie*, 209 F. 364, (C.A.2 1913); *Universal Coin*, *supra*; *Banker*, 69 F.2d 665; *Brennan*, *supra*; *Lukens Steel Co. v. American Locomotive Co.*, 197 F.2d 939, 941 (C.A.2 1952). And that is the case law situation that Congress faced when it wrote a statute that, as we have said, sought primarily to codify existing patent law. See *supra*, at 959–960.

The majority tries to minimize the overall thrust of this case law by dividing the cases into subgroups and then concluding that the number of undistinguishable precedents in each subgroup is "too few to establish a settled, national consensus." *Ante*, at 965. The problem with this approach is that, once we look at the body of case law as a

whole, rather than in subgroups, we find what I have said and repeated, namely, that *all the cases say the same thing*: Laches applies. The majority's insistence on subdivision makes it sound a little like a Phillies fan who announces that a 9–0 loss to the Red Sox was a "close one." Why close? Because, says the fan, the Phillies lost each inning by only one run.

For the sake of completeness I add that, since 1952, every Federal Court of Appeals to consider the question has held that laches remains available for damages claims brought under the Patent Act. See *A.C. Aukerman Co. v. R.L. Chaides Constr. Co.*, 960 F.2d 1020, 1030 (C.A.Fed. 1992) (en banc). Yet, Congress has repeatedly reenacted 35 U.S.C. § 282's "unenforceability" language without material change. See, *e.g.*, §§ 15(a), 20(g)(2)(B), 125 Stat. 328, 334. See also *Texas Dept. of Housing and Community Affairs v. Inclusive Communities Project, Inc.*, 135 S. Ct. 2507, 2520 (2015) (holding that congressional reenactment provides "convincing support for the conclusion that Congress accepted and ratified the unanimous holdings of the Courts of Appeals"); *Microsoft Corp. v. i4i Ltd. Partnership*, 564 U.S. 91, 113–114 (2011) (when Congress has "often amended § 282" while "le[aving] the Federal Circuit's interpretation of § 282 in place," any further "recalibration" should be left to the Legislature).

III

The majority's strongest argument is *Petrella*. There, the Court held that laches could not bar a damages claim brought within the Copyright Act's limitations period. The present case holds roughly the same in respect to the Patent Act, providing a degree of consistency.

There are relevant differences, however, between patent law and copyright law. For one thing, copyright law, unlike patent law, does not contain a century and a half of history during which courts held that laches and a statute of limitations could coexist. When Congress enacted the Patent Act in 1952, patent statutes had already contained a 6–year statute of limitations for 55 years (since 1897), during which time courts had continued to apply laches to patent damages cases. Copyright law, on the other hand, contained no federal statute of limitations until 1957. See *Petrella*, 134 S. Ct., at 1968.

For another thing, the Copyright Act, unlike the Patent Act, has express provisions that mitigate the unfairness of a copyright holder waiting for decades to bring his lawsuit. A copyright holder who tries to lie in wait to see if a defendant's investment will prove successful will discover that the Copyright Act allows that defendant to "prove and offset against . . . profits 'deductible expenses' incurred in generating those profits." *Id.*, at 1973 (quoting 17 U.S.C. § 504(b)). Thus, if the defendant invests say $50 million in a film, a copyright holder who waits until year 15 (when the film begins to earn a profit) to bring a lawsuit may be limited to recovering the defendant's profits less an apportioned amount of the defendant's initial $50 million investment. But the Patent Act has no such deduction provision.

Further, the Court, in *Petrella*, pointed out that the evidentiary loss that occurs while a copyright holder waits to bring suit is "at least as likely to affect plaintiffs as it is to

disadvantage defendants." 134 S. Ct., at 1977. But that symmetry does not exist to the same degree in patent law. To win a copyright suit the copyright holder must show that the defendant copied his work. The death of witnesses and loss of documents from the time of the alleged infringement can therefore significantly impair the copyright holder's ability to prove his case. There is no such requirement in a patent suit. Patent infringement is a strict-liability offense: There need not be any copying, only an end product (or process) that invades the area the patentee has carved out in his patent.

At the same time, the passage of time may well harm patent *defendants* who wish to show a patent invalid by raising defenses of anticipation, obviousness, or insufficiency. These kinds of defenses can depend upon contemporaneous evidence that may be lost over time, and they arise far more frequently in patent cases than any of their counterparts do in copyright cases. See Brief for Electronic Frontier Foundation et al. as *Amici Curiae* 23 (reporting that of all copyright cases pending as of January 2009, only 2.7% of judgment events resulted in a finding of a lack of ownership or validity of the copyright at issue); Allison, Lemley, & Schwartz, Understanding the Realities of Modern Patent Litigation, 92 Texas L. Rev. 1769, 1778, 1784–1785 (2014) (finding that 70% of summary judgment motions in patent cases filed in 2008–2009 related to anticipation or obviousness). The upshot is an absence here of the symmetrical effect of delay upon which the Court relied in *Petrella*.

Finally, there is a "lock-in" problem that is likely to be more serious where patents are at issue. Once a business chooses to rely on a particular technology, it can become expensive to switch, even if it would have been cheap to do so earlier. See Lee & Melamed, Breaking the Vicious Cycle of Patent Damages, 101 Cornell L. Rev. 385, 409–410 (2016). As a result, a patentee has considerable incentive to delay suit until the costs of switching—and accordingly the settlement value of a claim—are high. The practical consequences of such delay can be significant, as the facts of this case illustrate: First Quality invested hundreds of millions of dollars in its allegedly infringing technologies during the years that SCA waited to bring its suit. And *amici* have provided numerous other examples that suggest this fact pattern is far from uncommon. See Brief for Dell et al. 11–19.

I recognize the Majority's suggestion that the doctrine of "equitable estoppel" might help alleviate some of these problems. See *ante*, at 967. I certainly hope so. But I would be more "cautious before adopting changes that disrupt the settled expectations of the inventing community." *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, 535 U.S. 722, 739 (2002).

I add or confess that I believe that *Petrella* too was wrongly decided. Today's case helps illustrate why I think that *Petrella* started this Court down the wrong track. I would stop, finding adequate grounds to distinguish *Petrella*. But the majority remains "determined to stay the course and continue on, travelling even further away," *Mathis v. United States*, 136 S. Ct. 2243, 2271 (2016) (ALITO, J., dissenting), from Congress' efforts, in the Patent Act, to promote the "Progress of Science and useful Arts," U.S. Const. Art. I, § 8, cl. 8. Trite but true: Two wrongs don't make a right.

With respect, I dissent.

NOTES AND QUESTIONS

1. *The holding of* SCA. Understanding the holding of *SCA* requires appreciation of the "separate-accrual rule" for patent and copyright infringement actions. A car accident, for example, is a one-time event. After it occurs, the claim has "accrued" and the injured party may bring suit within a certain amount of time specified in the relevant jurisdiction's statute of limitations. Copyright and patent cases are typically different in that defendants often commit multiple acts of infringement over time, often up until and through the time of the suit. In a copyright case, a defendant might repeatedly engage in copying (as when continuing to market a film based on an infringing screenplay), while in a patent case, a defendant might continuously sell a product incorporating an infringing feature. Indeed, as Justice Breyer explains in his dissent, a defendant in a patent case might become "locked in" after adopting that feature, but lock-in does not change the rule that each act of selling a product that includes it (or each act of making or using the patented invention in some way) is a separate, new violation. As the Court in explained in *Petrella*, this aspect of infringement actions has a critical effect on the operation of the limitation of damages section in the Copyright Act (and, by extension, on its analog in the Patent Act, 35 U.S.C. § 286):

> It is widely recognized that the separate-accrual rule attends the copyright statute of limitations. Under that rule, when a defendant commits successive violations, the statute of limitations runs separately from each violation. Each time an infringing work is reproduced or distributed, the infringer commits a new wrong. Each wrong gives rise to a discrete "claim" that "accrue[s]" at the time the wrong occurs. In short, each infringing act starts a new limitations period.

134 S. Ct. at 1969. Accordingly, while § 286 relieves the infringer from damages for any acts of infringement committed more than six years prior to the infringement suit, any act of infringement within the six-year period, even if "continuing" from beyond the six years, is still actionable and remediable with damages. Prior to *SCA*, however, the doctrine of laches could *bar the entire suit*. For an illuminating treatment of this problem in various areas of law, see Kyle Graham, *The Continuing Violations Doctrine*, 43 GONZAGA L. REV. 271 (2007).

Is there anything left of laches in patent infringement cases after *SCA*? What sorts of remedies, if any, are still subject to the laches defense?

2. *Equitable estoppel.* The doctrine of equitable estoppel does bar the patentee's entire suit, including prospective and retrospective relief. As *SCA* explains, this defense is unaffected by § 286. Equitable estoppel is established upon showing that "(1) the patentee, through misleading conduct (or silence), leads the alleged infringer to reasonably infer that the patentee does not intend to enforce its patent against the alleged infringer; (2) the alleged infringer relies on that conduct; and (3) the alleged infringer will be materially prejudiced if the patentee is allowed to proceed with its

claim." *Radio Sys. Corp. v. Lalor*, 709 F.3d 1124, 1130 (Fed. Cir. 2013). How do these elements differ from the elements of laches?

In *Radio Systems*, the Federal Circuit affirmed a finding of equitable estoppel with respect to one of the asserted patents where the patentee misled the accused infringer's predecessor-in-interest through a "demand letter and subsequent silence for over four and a half years." *Id.* at 1130. The accused infringer "relied on this silence by significantly expanding its product line" and made an "investment in new products [that] constituted economic prejudice." *Id.* Nonetheless, the Federal Circuit reversed the finding of inequitable estoppel with respect to another asserted patent, a continuation-in-part of the first, because the second patent had not yet issued when the demand letter was sent. The dissent concluded instead that equitable estoppel applied to both patents, suggesting the patentee was obligated to tell the accused infringer that it had related pending patent applications that might cover the technology at issue. But would the infringer have been able to discover this information anyway? For an interesting case involving similar issues in the context of a related doctrine of legal estoppel, see *Endo Pharmaceuticals Inc. v. Actavis, Inc.*, 746 F.3d 1371 (Fed. Cir. 2014).

3. *General rules versus patent-specific rules*. One point of disagreement between the majority and dissent in *SCA* is the question whether a doctrine like laches, which is not limited to patent cases, should nonetheless follow patent-specific rules. The majority cites a number of its non-patent cases to derive "the well-established general rule . . . that laches cannot be invoked to bar a claim for damages incurred within a limitations period specified by Congress," 137 S. Ct. at 963, and also relies heavily on *Petrella,* a copyright case. Moreover, the majority endorses the proposition from Judge Hughes's Federal Circuit dissent that "[p]atent law is governed by the same common-law principles, methods of statutory interpretation, and procedural rules as other areas of civil litigation." *Id.* at 964. In contrast, Justice Breyer focuses on patent cases supporting the application of the laches defense to claims of past damages. As a matter of statutory interpretation, which approach is more defensible? Does the Supreme Court consistently favor generally applicable rules over patent-specific ones? For two examples of scholarly work addressing these issues, see Peter Lee, *The Supreme Assimilation of Patent Law*, 114 MICH. L. REV. 1413 (2016); Tejas N. Narechania, *Certiorari, Universality, and a Patent Puzzle*, 116 MICH. L. REV. 1345 (2018).

E. EXPERIMENTAL USE

MADEY v. DUKE UNIVERSITY

307 F.3d 1351 (Fed. Cir. 2002)

GAJARSA, Circuit Judge:

Dr. John M.J. Madey ("Madey") appeals from a judgment of the United States District Court for the Middle District of North Carolina. Madey sued Duke University ("Duke"), bringing claims of patent infringement and various other federal and state

law claims. . . . [T]he district court granted summary judgment in favor of Duke on the [relevant patent infringement] claims. . . . [I]t held that the experimental use defense applied to Duke's use of Madey's patented laser technology. . . . The district court . . . erred in applying the experimental use defense . . . . Accordingly, we reverse-in-part, affirm-in-part, and remand.

BACKGROUND

In the mid-1980s Madey was a tenured research professor at Stanford University. At Stanford, he had an innovative laser research program, which was highly regarded in the scientific community. An opportunity arose for Madey to consider leaving Stanford and take a tenured position at Duke. Duke recruited Madey, and in 1988 he left Stanford for a position in Duke's physics department. In 1989 Madey moved his free electron laser ("FEL") research lab from Stanford to Duke. The FEL lab contained substantial equipment, requiring Duke to build an addition to its physics building to house the lab. In addition, during his time at Stanford, Madey had obtained sole ownership of two patents practiced by some of the equipment in the FEL lab.

At Duke, Madey served for almost a decade as director of the FEL lab. . . . Duke eventually . . . remove[d] Madey as director of the lab in 1997. The removal is not at issue in this appeal, however, it is the genesis of this unique patent infringement case. As a result of the removal, Madey resigned from Duke in 1998. Duke, however, continued to operate some of the equipment in the lab. Madey then sued Duke for patent infringement of his two patents, and brought a variety of other claims.

A. The Patents and Infringing Equipment

One of Madey's patents, U.S. Patent No. 4,641,103 ("the '103 patent"), covers a "Microwave Electron Gun" used in connection with free electron lasers. The other patent, U.S. Patent No. 5,130,994 ("the '994 patent"), is titled "Free-Electron Laser Oscillator For Simultaneous Narrow Spectral Resolution And Fast Time Resolution Spectroscopy." The details of these two patents are not material to the issues on appeal. Their use in the lab, however, as embodied in certain equipment, is central to this appeal.

. . .

The three alleged infringing devices are the Mark III FEL, the Storage Ring FEL, and the Microwave Gun Test Stand. Although it is not clear from the record, perhaps because Duke defended by asserting experimental use and government license defenses, Duke seems to concede that the alleged infringing devices and methods read on the claims of the patents.

. . .

D. The District Court's Summary Judgment Opinion

Among Duke's motions [was a motion for summary judgment of noninfringement under the experimental use defense].

. . .

Experimental Use Defense

The district court acknowledged a common law "exception" for patent infringement liability for uses that, in the district court's words, are "solely for research, academic or experimental purposes." *Summary Judgment Opinion* at 9 (citing *Deuterium Corp. v. United States*, 19 Cl. Ct. 624, 631 (1990); *Whittemore v. Cutter*, 29 F. Cas. 1120 (C.C.D. Mass. 1813) (No. 17,600); and citing two commentators).[2] The district court recognized the debate over the scope of the experimental use defense, but cited this court's opinion in *Embrex, Inc. v. Service Engineering Corp.*, 216 F.3d 1343, 1349 (Fed. Cir. 2000) to hold that the defense was viable for experimental, non-profit purposes."

. . .

After having recognized the experimental use defense, the district court then fashioned the defense for application to Madey in the passage set forth below.

Given this standard [for experimental use], for [Madey] to overcome his burden of establishing actionable infringement in this case, he must establish that [Duke] has not used the equipment at issue "solely for an experimental or other non-profit purpose." 5 Donald S. Chisum, *Chisum on Patents* § 16.03[1] (2000). More specifically, [Madey] must sufficiently establish that [Duke's] use of the patent had "definite, cognizable, and not insubstantial commercial purposes." *Roche Prods., Inc. v. Bolar Pharm. Co.*, 733 F.2d 858, 863 (Fed. Cir. 1984), *cert. denied*, 469 U.S. 856 (1984).

On appeal, Madey attacks this passage as improperly shifting the burden to the plaintiff to allege and prove that the defendant's use was not experimental.

Before the district court, Madey argued that Duke's research in its FEL lab was commercial in character and intent. *Id.* Madey relied on *Pitcairn v. United States,* 547 F.2d 1106 (Ct. Cl. 1976), where the government used patented rotor structures and control systems for a helicopter to test the "lifting ability" and other attributes of the patented technology. *Pitcairn*, 547 F.2d at 1125–26. The *Pitcairn* court held that the helicopters were not built solely for experimental purposes because they were also built to benefit the government in its legitimate business. *Id.* Based on language in Duke's patent policy, Madey argues that Duke is in the business of "obtaining grants and developing possible commercial applications for the fruits of its "academic research."

The district court rejected Madey's argument, relying on another statement in the preamble of the Duke patent policy which stated that Duke was "dedicated to teaching, research, and the expansion of knowledge . . . [and] does not undertake research or development work principally for the purpose of developing patents and commercial applications." The district court reasoned that these statements from the patent policy refute any contention that Duke is "in the business" of developing technology for commercial applications. According to the district court, Madey's "evidence" was mere speculation,[4] and thus Madey did not meet his burden of proof to

[2] Janice M. Mueller, *No "Dilettante Affair": Rethinking the Experimental Use Exception to Patent Infringement for Biomedical Research Tools,* 76 Wash. L. Rev. 1, 17 (2001); 5 *Chisum on Patents* § 16.03[1] (2000).

[4] Madey also argued that Duke's acceptance of funding from the government and private foundations was evidence of developing patented devices with commercial intent. The district court also rejected this proposition. . . .

create a genuine issue of material fact.[5] The court went on to state that "[w]ithout more concrete evidence to rebut [Duke's] stated purpose with respect to its research in the FEL lab, Plaintiff has failed to meet its burden of establishing patent infringement by a preponderance of the evidence."

. . .

II. DISCUSSION

A. Standard of Review

. . .

Review of the district court's interpretation of the experimental use defense and its proper scope are questions of law and statutory interpretation that are reviewed *de novo. Vectra Fitness, Inc. v. TNWK Corp.*, 162 F.3d 1379, 1381 (Fed. Cir. 1998).

. . .

C. The District Court's Application of Experimental Use

On appeal, Madey asserts three primary errors related to experimental use. First, Madey claims that the district court improperly shifted the burden to Madey to prove that Duke's use was not experimental. Second, Madey argues that the district court applied an overly broad version of the very narrow experimental use defense inconsistent with our precedent. Third, Madey attacks the supporting evidence relied on by the district court as overly general and not indicative of the specific propositions and findings required by the experimental use defense, and further argues that there is no support in the record before us to allow any court to apply the very narrow experimental use defense to Duke's ongoing FEL lab operation. We substantially agree with Madey on all three points. In addition, Madey makes a threshold argument concerning the continued existence of the experimental use doctrine in any form, which we turn to first. Our precedent, to which we are bound, continues to recognize the judicially created experimental use defense, however, in a very limited form.

The Experimental Use Defense

Citing the concurring opinion in *Embrex,* Madey contends that the Supreme Court's opinion in *Warner-Jenkinson Co. v. Hilton Davis Chem. Co.*, 520 U.S. 17, (1997) eliminates the experimental use defense. *Embrex,* 216 F.3d at 1352–53 (Rader, J., concurring). The Supreme Court held in *Warner-Jenkinson* that intent plays no role in the application of the doctrine of equivalents. *Warner-Jenkinson*, 520 U.S. at 36. Madey implicitly argues that the experimental use defense necessarily incorporates an intent inquiry, and thus is inconsistent with *Warner-Jenkinson*. Like the majority in *Embrex*, we do not view such an inconsistency as inescapable, and conclude the experimental use defense persists albeit in the very narrow form articulated by this court in *Embrex*, 216 F.3d at 1349, and in *Roche*, 733 F.2d at 863.

The District Court Improperly Shifted the Burden to Madey

[5] The district court discussed and dismissed in a footnote other evidence suggested by Madey, including the fact that Duke had established (but not yet applied) an hourly fee for industrial users wishing to use the FEL lab's resources, and statements from Duke's website for the FEL lab indicating an interest in corporate partnerships.

As a precursor to the burden-shifting issue, Madey argues that the experimental use defense is an affirmative defense that Duke must plead or lose. We disagree. Madey points to no source of authority for its assertion that experimental use is an affirmative defense. Indeed, we have referred to the defense in a variety of ways. *See Roche*, 733 F.2d at 862 (referring to experimental use as both an exception and a defense). Given this lack of precise treatment in the precedent, Madey has no basis to support its affirmative defense argument. The district court and the parties in the present case joined the issue during the summary judgment briefing. We see no mandate from our precedent, nor any compelling reason from other considerations, why the opportunity to raise the defense if not raised in the responsive pleading should not also be available at the later stages of a case, within the procedural discretion typically afforded the trial court judge.

The district court held that in order for Madey to overcome his burden to establish actionable infringement, he must establish that Duke did not use the patent-covered free electron laser equipment solely for experimental or other non-profit purposes. Madey argues that this improperly shifts the burden to the patentee and conflates the experimental use defense with the initial infringement inquiry.

We agree with Madey that the district court improperly shifted the burden to him. The district court folded the experimental use defense into the baseline assessment as to whether Duke infringed the patents. Duke characterizes the district court's holding as expressing the following sequence: first, the court recognized that Madey carried his burden of proof on infringement; second, the court held that Duke carried its burden of proof on the experimental use defense; and third, the court held that Madey was unable to marshal sufficient evidence to rebut Duke's shifting of the burden. We disagree with Duke's reading of the district court's opinion. The district court explicitly contradicts Duke's argument by stating that Madey failed to "meet its burden to establish patent infringement by a preponderance of the evidence." This statement is an assessment of whether Madey supported his initial infringement claim. It is not an assessment of which party carried or shifted the burden of evidence related to the experimental use defense. Thus, the district court did not conclude that Madey failed to rebut Duke's assertion of the experimental use defense. Instead, it erroneously required Madey to show as a part of his initial claim that Duke's use was not experimental. The defense, if available at all, must be established by Duke.

The District Court's Overly Broad Conception of Experimental Use

Madey argues, and we agree, that the district court had an overly broad conception of the very narrow and strictly limited experimental use defense. The district court stated that the experimental use defense inoculated uses that "were solely for research, academic, or experimental purposes," and that the defense covered use that "is made for experimental, non-profit purposes only." Both formulations are too broad and stand in sharp contrast to our admonitions in *Embrex* and *Roche* that the experimental use defense is very narrow and strictly limited. In *Embrex,* we followed the teachings of *Roche* and *Pitcairn* to hold that the defense was very narrow and limited to actions performed "for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry." *Embrex*, 216 F.3d at 1349. Further, use does not qualify for the

experimental use defense when it is undertaken in the "guise of scientific inquiry" but has "definite, cognizable, and not insubstantial commercial purposes." *Id.* The concurring opinion in *Embrex* expresses a similar view: use is disqualified from the defense if it has the "slightest commercial implication." *Id.* at 1353. Moreover, use in keeping with the legitimate business of the alleged infringer does not qualify for the experimental use defense. *See Pitcairn*, 547 F.2d at 1125–26. The district court supported its conclusion with a citation to *Ruth v. Stearns-Roger Mfg. Co.*, 13 F. Supp. 697, 713 (D. Colo. 1935), a case that is not binding precedent for this court.

The *Ruth* case represents the conceptual dilemma that may have led the district court astray. Cases evaluating the experimental use defense are few, and those involving non-profit, educational alleged infringers are even fewer. In *Ruth,* the court concluded that a manufacturer of equipment covered by patents was not liable for contributory infringement because the end-user purchaser was the Colorado School of Mines, which used the equipment in furtherance of its educational purpose. Thus, the combination of apparent lack of commerciality, with the non-profit status of an educational institution, prompted the court in *Ruth*, without any detailed analysis of the character, nature and effect of the use, to hold that the experimental use defense applied. This is not consistent with the binding precedent of our case law postulated by *Embrex, Roche* and *Pitcairn.*

Our precedent clearly does not immunize use that is in any way commercial in nature. Similarly, our precedent does not immunize any conduct that is in keeping with the alleged infringer's legitimate business, regardless of commercial implications. For example, major research universities, such as Duke, often sanction and fund research projects with arguably no commercial application whatsoever. However, these projects unmistakably further the institution's legitimate business objectives, including educating and enlightening students and faculty participating in these projects. These projects also serve, for example, to increase the status of the institution and lure lucrative research grants, students and faculty.

In short, regardless of whether a particular institution or entity is engaged in an endeavor for commercial gain, so long as the act is in furtherance of the alleged infringer's legitimate business and is not solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry, the act does not qualify for the very narrow and strictly limited experimental use defense. Moreover, the profit or non-profit status of the user is not determinative.

In the present case, the district court attached too great a weight to the nonprofit, educational status of Duke, effectively suppressing the fact that Duke's acts appear to be in accordance with any reasonable interpretation of Duke's legitimate business objectives.[7] On remand, the district court will have to significantly narrow and limit its conception of the experimental use defense. The correct focus should not be on the

[7] Duke's patent and licensing policy may support its primary function as an educational institution. *See Duke University Policy on Inventions, Patents, and Technology Transfer* (1996), *available at http://www.ors.duke.edu/policies/patpol.htm* (last visited Oct. 3, 2002). Duke, however, like other major research institutions of higher learning, is not shy in pursuing an aggressive patent licensing program from which it derives a not insubstantial revenue stream. *See id.*

non-profit status of Duke but on the legitimate business Duke is involved in and whether or not the use was solely for amusement, to satisfy idle curiosity, or for strictly philosophical inquiry.

. . .

[*Affirmed-in-part, reversed-in-part, and remanded.*]

MERCK KGAA v. INTEGRA LIFESCIENCES I, LTD.

545 U.S. 193 (2005)

Justice SCALIA delivered the opinion of the Court.

This case presents the question whether uses of patented inventions in preclinical research, the results of which are not ultimately included in a submission to the Food and Drug Administration (FDA), are exempted from infringement by 35 U. S. C. § 271(e)(1).

I

It is generally an act of patent infringement to "mak[e], us[e], offe[r] to sell, or sel[l] any patented invention . . . during the term of the patent therefor." § 271(a). In 1984, Congress enacted an exemption to this general rule, see Drug Price Competition and Patent Term Restoration Act of 1984, § 202, 98 Stat. 1585, as amended, 35 U. S. C. §271(e)(1), which provides:

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs. . . .

The Federal Food, Drug, and Cosmetic Act (FDCA), ch. 675, 52 Stat. 1040, as amended, 21 U. S. C. § 301 *et seq.*, is "a Federal law which regulates the manufacture, use, or sale of drugs." See § 355(a); *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U. S. 661, 665–66, 674 (1990). Under the FDCA, a drugmaker must submit research data to the FDA at two general stages of new-drug development.[1] First, a drugmaker must gain authorization to conduct clinical trials (tests on humans) by submitting an investigational new drug application (IND). *See* 21 U. S. C. § 355(i) . . . The IND must describe "preclinical tests (including tests on animals) of [the] drug adequate to justify the proposed clinical testing." 21 U. S. C. § 355(i)(1)(A); *see* 21 CFR §§312.23(a)(5) and (a)(8) (specifying necessary information from preclinical tests). Second, to obtain

[1] Drugmakers that desire to market a generic drug (a drug containing the same active ingredients as a drug already approved for the market) may file an abbreviated new drug application (ANDA) with the FDA. See 21 U. S. C. § 355(j). The sponsor of a generic drug does not have to make an independent showing that the drug is safe and effective, either in preclinical or clinical studies. See § 355(j)(2)(A). It need only show that the drug includes the same active ingredients as, and is bioequivalent to, the drug that it is mimicking. See §§ 355(j)(2)(A)(ii) and (iv); § 355(j)(8)(B).

authorization to market a new drug, a drugmaker must submit a new drug application (NDA), containing "full reports of investigations which have been made to show whether or not [the] drug is safe for use and whether [the] drug is effective in use." 21 U. S. C. § 355(b)(1). Pursuant to FDA regulations, the NDA must include all clinical studies, as well as preclinical studies related to a drug's efficacy, toxicity, and pharmacological properties. See 21 CFR §§ 314.50(d)(2) (preclinical studies) and (d)(5) (clinical studies).

II

A

Respondents, Integra Lifesciences I, Ltd., and the Burnham Institute, own five patents related to the tripeptide sequence Arg-Gly-Asp, known in single-letter notation as the "RGD peptide." U. S. Patent Nos. 4,988,621, 4,792,525, 5,695,997, 4,879,237, and 4,789,734. The RGD peptide promotes cell adhesion by attaching to αvβ3 integrins, receptors commonly located on the outer surface of certain endothelial cells. 331 F.3d 860, 862–863 (CA Fed. 2003).

Beginning in 1988, petitioner Merck KGAA provided funding for angiogenesis research conducted by Dr. David Cheresh at the Scripps Research Institute (Scripps). . . . Angiogenesis is the process by which new blood vessels sprout from existing vessels; it plays a critical role in many diseases, including solid tumor cancers, diabetic retinopathy, and rheumatoid arthritis. 331 F.3d, at 863. In the course of his research, Dr. Cheresh discovered that it was possible to inhibit angiogenesis by blocking the αvβ3 integrins on proliferating endothelial cells. In 1994, Dr. Cheresh succeeded in reversing tumor growth in chicken embryos, first using a monoclonal antibody (LM609) he developed himself and later using a cyclic RGD peptide (EMD 66203) provided by petitioner.[3]

. . .

With petitioner's agreement to fund research at Scripps due to expire in July 1995, Dr. Cheresh submitted a detailed proposal for expanded collaboration between Scripps and petitioner on February 1, 1995. The proposal set forth a 3-year timetable in which to develop "integrin antagonists as angiogenesis inhibitors," beginning with *in vitro* and *in vivo* testing of RGD peptides at Scripps in year one and culminating with the submission of an IND to the FDA in year three. [Petitioner] specified that Scripps would be responsible for testing RGD peptides produced by petitioner as potential drug candidates but that, once a primary candidate for clinical testing was in "the pipeline," petitioner would perform the toxicology tests necessary for FDA approval to proceed to clinical trials. . . . Scripps and petitioner concluded an agreement of continued collaboration in September 1995.

Pursuant to the agreement, Dr. Cheresh directed *in vitro* and *in vivo* experiments on RGD peptides provided by petitioner from 1995 to 1998. These experiments focused on EMD 66203 and two closely related derivatives, EMD 85189 and EMD 121974, and were designed to evaluate the suitability of each of the peptides as potential drug

[3] In the proceedings below, the Court of Appeals held that respondents' patents covered the cyclic RGD peptides developed by petitioner. 331 F. 3d 860, 869 (CA Fed. 2003). Petitioner does not contest that ruling here.

candidates. 331 F.3d, at 863. Accordingly, the tests measured the efficacy, specificity, and toxicity of the particular peptides as angiogenesis inhibitors, and evaluated their mechanism of action and pharmacokinetics in animals. Based on the test results, Scripps decided in 1997 that EMD 121974 was the most promising candidate for testing in humans. . . . Scripps also conducted more basic research on organic mimetics designed to block αvβ3 integrins in a manner similar to the RGD peptides; it appears that Scripps used the RGD peptides in these tests as "positive controls" against which to measure the efficacy of the mimetics.

In November 1996, petitioner initiated a formal project to guide one of its RGD peptides through the regulatory approval process in the United States and Europe. Petitioner originally directed its efforts at EMD 85189, but switched focus in April 1997 to EMD 121974. Petitioner subsequently discussed EMD 121974 with officials at the FDA. In October 1998, petitioner shared its research on RGD peptides with the National Cancer Institute (NCI), which agreed to sponsor clinical trials.

. . .

B

On July 18, 1996, respondents filed a patent-infringement suit against petitioner, Scripps, and Dr. Cheresh in the District Court for the Southern District of California. Respondents' complaint alleged that petitioner willfully infringed and induced others to infringe respondents' patents by supplying the RGD peptide to Scripps, and that Dr. Cheresh and Scripps infringed the same patents by using the RGD peptide in experiments related to angiogenesis. Respondents sought damages from petitioner and a declaratory judgment against Dr. Cheresh and Scripps. Petitioner answered that its actions involving the RGD peptides did not infringe respondents' patents, and that in any event they were protected by the common-law research exemption and 35 U. S. C. §271(e)(1). 331 F.3d, at 863.

At the conclusion of trial, the District Court held that, with one exception, petitioner's pre-1995 actions related to the RGD peptides were protected by the common-law research exemption, but that a question of fact remained as to whether petitioner's use of the RGD peptides after 1995 fell within the § 271(e)(1) safe harbor. With the consent of the parties, the District Court gave the following instruction regarding the § 271(e)(1) exemption:

> To prevail on this defense, [petitioner] must prove by a preponderance of the evidence that it would be objectively reasonable for a party in [petitioner's] and Scripps' situation to believe that there was a decent prospect that the accused activities would contribute, relatively directly, to the generation of the kinds of information that are likely to be relevant in the processes by which the FDA would decide whether to approve the product in question.
>
> Each of the accused activities must be evaluated separately to determine whether the exemption applies.
>
> [Petitioner] does not need to show that the information gathered from a particular activity was actually submitted to the FDA.

The jury found that petitioner, Dr. Cheresh, and Scripps infringed respondents' patents and that petitioner had failed to show that its activities were protected by § 271(e)(1). It awarded damages of $15 million.

In response to post-trial motions, the District Court . . . denied petitioner's motion for judgment as a matter of law. . . . [T]he District Court explained that the evidence was sufficient to show that "any connection between the infringing Scripps experiments and FDA review was insufficiently direct to qualify for the [§271(e)(1) exemption]."

A divided panel of the Court of Appeals for the Federal Circuit affirmed in part and reversed in part. The panel majority affirmed the denial of judgment as a matter of law to petitioner, on the ground that §271(e)(1)'s safe harbor did not apply because "the Scripps work sponsored by [petitioner] was not clinical testing to supply information to the FDA, but only general biomedical research to identify new pharmaceutical compounds." 331 F.3d, at 866. . . . We granted certiorari to review the Court of Appeals' construction of § 271(e)(1).

III

As described earlier, 35 U. S. C. § 271(e)(1) provides that "[i]t shall not be an act of infringement to . . . use . . . or import into the United States a patented invention . . . solely for uses reasonably related to the development and submission of information under a Federal law which regulates the . . . use . . . of drugs." Though the contours of this provision are not exact in every respect, the statutory text makes clear that it provides a wide berth for the use of patented drugs in activities related to the federal regulatory process.

As an initial matter, we think it apparent from the statutory text that § 271(e)(1)'s exemption from infringement extends to all uses of patented inventions that are reasonably related to the development and submission of *any* information under the FDCA. Cf. *Eli Lilly*, 496 U. S., at 665–69 (declining to limit § 271(e)(1)'s exemption from infringement to submissions under particular statutory provisions that regulate drugs). This necessarily includes preclinical studies of patented compounds that are appropriate for submission to the FDA in the regulatory process. There is simply no room in the statute for excluding certain information from the exemption on the basis of the phase of research in which it is developed or the particular submission in which it could be included.[6]

Respondents concede the breadth of § 271(e)(1) in this regard, but argue that the only preclinical data of interest to the FDA is that which pertains to the safety of the drug in humans. In respondents' view, preclinical studies related to a drug's efficacy, mechanism of action, pharmacokinetics, and pharmacology are not reasonably included in an IND or an NDA, and are therefore outside the scope of the exemption.

[6] Although the Court of Appeals' opinion suggests in places that § 271(e)(1)'s exemption from infringement is limited to research conducted in *clinical* trials, see 331 F.3d, at 866, we do not understand it to have adopted that position. The Court of Appeals recognized that information included in an IND would come within § 271(e)(1)'s safe harbor. Because an IND must be filed *before* clinical trials may begin, such information would necessarily be developed in preclinical studies.

We do not understand the FDA's interest in information gathered in preclinical studies to be so constrained. To be sure, its regulations provide that the agency's "primary objectives in reviewing an IND are . . . to assure the safety and rights of subjects," 21 CFR § 312.22(a) (2005), but it does not follow that the FDA is not interested in reviewing information related to other characteristics of a drug. To the contrary, the FDA requires that applicants include in an IND summaries of the pharmacological, toxicological, pharmacokinetic, and biological qualities of the drug in animals. See § 312.23(a)(5); U. S. Dept. of Health and Human Services, Guidance for Industry, Good Clinical Practice: Consolidated Guidance 45 (Apr. 1996) ("The results of all relevant nonclinical pharmacology, toxicology, pharmacokinetic, and investigational product metabolism studies should be provided in summary form. This summary should address the methodology used, the results, and a discussion of the relevance of the findings to the investigated therapeutic and the possible unfavorable and unintended effects in humans"). The primary (and, in some cases, only) way in which a drugmaker may obtain such information is through preclinical *in vitro* and *in vivo* studies.

Moreover, the FDA does not evaluate the safety of proposed clinical experiments in a vacuum; rather, as the statute and regulations reflect, it asks whether the proposed clinical trial poses an "unreasonable risk." 21 U.S.C. § 355(i)(3)(B)(i); see also 21 CFR § 312.23(a)(8) (2005) (requiring applicants to include pharmacological and toxicological studies that serve as the basis of their conclusion that clinical testing would be "reasonably safe"); § 56.111(a)(2) (2004) (providing that the Institutional Review Boards that oversee clinical trials must consider whether the "[r]isks to subjects are reasonable in relation to anticipated benefits"). This assessment involves a comparison of the risks and the benefits associated with the proposed clinical trials. As the Government's brief, filed on behalf of the FDA, explains, the "FDA might allow clinical testing of a drug that posed significant safety concerns if the drug had a sufficiently positive potential to address a serious disease, although the agency would not accept similar risks for a drug that was less likely to succeed or that would treat a less serious medical condition." Accordingly, the FDA directs that an IND must provide sufficient information for the investigator to "make his/her own unbiased risk-benefit assessment of the appropriateness of the proposed trial." Such information necessarily includes preclinical studies of a drug's efficacy in achieving particular results.

Respondents contend that, even accepting that the FDA is interested in preclinical research concerning drug characteristics other than safety, the experiments in question here are necessarily disqualified because they were not conducted in conformity with the FDA's good laboratory practices regulations. This argument fails for at least two reasons. First, the FDA's requirement that preclinical studies be conducted under "good laboratory practices" applies only to experiments on drugs "to determine their safety," 21 CFR § 58.3(d) (2004). See § 58.1(a); § 312.23(a)(8)(iii) (2005) (only "nonclinical laboratory study subject to the good laboratory practice regulations under part 58" must certify compliance with good laboratory practice regulations). The good laboratory practice regulations do not apply to preclinical studies of a drug's efficacy, mechanism of action, pharmacology, or pharmacokinetics. Second, FDA regulations do not provide that even safety-related experiments not conducted in compliance with good laboratory practices regulations are not suitable

for submission in an IND. Rather, such studies must include "a brief statement of the reason for the noncompliance."

The Court of Appeals' conclusion that § 271(e)(1) did not protect petitioner's provision of the patented RGD peptides for research at Scripps appeared to rest on two somewhat related propositions. First, the court credited the fact that the "Scripps-Merck experiments did not supply information for submission to the [FDA], but instead identified the best drug candidate to subject to future clinical testing under the FDA processes." 331 F.3d, at 865; see also *id.*, at 866 (similar). The court explained:

> The FDA has no interest in the hunt for drugs that may or may not later undergo clinical testing for FDA approval. For instance, the FDA does not require information about drugs other than the compound featured in an [IND] application. Thus, the Scripps work sponsored by [petitioner] was not "solely for uses reasonably related" to clinical testing for FDA.

Ibid.

Second, the court concluded that the exemption "does not globally embrace all experimental activity that at some point, however attenuated, may lead to an FDA approval process." *Id.*, at 867.[7]

We do not quibble with the latter statement. Basic scientific research on a particular compound, performed without the intent to develop a particular drug or a reasonable belief that the compound will cause the sort of physiological effect the researcher intends to induce, is surely not "reasonably related to the development and submission of information" to the FDA. It does not follow from this, however, that § 271(e)(1)'s exemption from infringement categorically excludes either (1) experimentation on drugs that are not ultimately the subject of an FDA submission or (2) use of patented compounds in experiments that are not ultimately submitted to the FDA. Under certain conditions, we think the exemption is sufficiently broad to protect the use of patented compounds in both situations.

As to the first proposition, it disregards the reality that, even at late stages in the development of a new drug, scientific testing is a process of trial and error. In the vast majority of cases, neither the drugmaker nor its scientists have any way of knowing whether an initially promising candidate will prove successful over a battery of experiments. That is the reason they conduct the experiments. Thus, to construe § 271(e)(1), as the Court of Appeals did, not to protect research conducted on patented compounds for which an IND is not ultimately filed is effectively to limit assurance of

[7] The Court of Appeals also suggested that a limited construction of § 271(e)(1) is necessary to avoid depriving so-called "research tools" of the complete value of their patents. Respondents have never argued the RGD peptides were used at Scripps as research tools, and it is apparent from the record that they were not. See 331 F.3d, at 878 (Newman, J., dissenting) ("Use of an existing tool in one's research is quite different from study of the tool itself"). We therefore need not and do not express a view about whether, or to what extent, § 271(e)(1) exempts from infringement the use of "research tools" in the development of information for the regulatory process.

exemption to the activities necessary to seek approval of a generic drug: One can know at the outset that a particular compound will be the subject of an eventual application to the FDA only if the active ingredient in the drug being tested is identical to that in a drug that has already been approved.

The statutory text does not require such a result. Congress did not limit § 271(e)(1)'s safe harbor to the development of information for inclusion in a submission to the FDA; nor did it create an exemption applicable only to the research relevant to filing an ANDA for approval of a generic drug. Rather, it exempted from infringement *all* uses of patented compounds "reasonably related" to the process of developing information for submission under *any* federal law regulating the manufacture, use, or distribution of drugs. *See Eli Lilly,* 496 U. S., at 674. We decline to read the "reasonable relation" requirement so narrowly as to render § 271(e)(1)'s stated protection of activities leading to FDA approval for all drugs illusory. Properly construed, § 271(e)(1) leaves adequate space for experimentation and failure on the road to regulatory approval: At least where a drugmaker has a reasonable basis for believing that a patented compound may work, through a particular biological process, to produce a particular physiological effect, and uses the compound in research that, if successful, would be appropriate to include in a submission to the FDA, that use is "reasonably related" to the "development and submission of information under . . . Federal law." § 271(e)(1).

For similar reasons, the use of a patented compound in experiments that are not themselves included in a "submission of information" to the FDA does not, standing alone, render the use infringing. The relationship of the use of a patented compound in a particular experiment to the "development and submission of information" to the FDA does not become more attenuated (or less reasonable) simply because the data from that experiment are left out of the submission that is ultimately passed along to the FDA. Moreover, many of the uncertainties that exist with respect to the selection of a specific drug exist as well with respect to the decision of what research to include in an IND or NDA. As a District Court has observed, "[I]t will not always be clear to parties setting out to seek FDA approval for their new product exactly which kinds of information, and in what quantities, it will take to win that agency's approval." *Intermedics, Inc. v. Ventritex, Inc.,* 775 F. Supp. 1269, 1280 (N.D. Cal. 1991), *aff'd*, 991 F.2d 808 (Fed. Cir. 1993). This is especially true at the preclinical stage of drug approval. FDA regulations provide only that "[t]he amount of information on a particular drug that must be submitted in an IND . . . depends upon such factors as the novelty of the drug, the extent to which it has been studied previously, the known or suspected risks, and the developmental phase of the drug." 21 CFR § 312.22(b). We thus agree with the Government that the use of patented compounds in preclinical studies is protected under § 271(e)(1) as long as there is a reasonable basis for believing that the experiments will produce "the types of information that are relevant to an IND or NDA."

. . .

Before the Court of Appeals, petitioner challenged the sufficiency of the evidence supporting the jury's finding that it failed to show that "all of the accused activities are covered by [§271(e)(1)]." That court rejected the challenge on the basis of a construction of § 271(e)(1) that was not consistent with the text of that provision or

the relevant jury instruction.[8] Thus, the evidence presented at trial has yet to be reviewed under the standards set forth in the jury instruction, which we believe to be consistent with, if less detailed than, the construction of § 271(e)(1) that we adopt today. We decline to undertake a review of the sufficiency of the evidence under a proper construction of § 271(e)(1) for the first time here. Accordingly, we vacate the judgment of the Court of Appeals and remand the case for proceedings consistent with this opinion.

. . .

[*Vacated and remanded*.]

NOTES AND QUESTIONS

1. *Common-law and statutory experimental use.* *Madey*, the first principal case, holds that the common-law experimental use defense is extremely narrow in scope. One of the cases that *Madey* relied on, *Roche Products, Inc. v. Bolar Pharmaceutical Co.*, 733 F.2d 858 (Fed. Cir. 1984), was overruled in part by 35 U.S.C. § 271(e)(1)—the provision interpreted in *Merck*, the second principal case—but the parts of *Roche* concerning non-statutory experimental use defenses remain good law. Although, procedurally, all the Federal Circuit did in *Madey* was vacate the grant of summary judgment to the defendant, the court's expansive conception of what constitutes a commercial purpose in the academic context certainly put a thumb on the scale in favor of Madey. Indeed, the district court on remand made clear that Duke was unlikely to succeed on the experimental use defense at trial under the Federal Circuit's reasoning. *Madey v. Duke Univ.*, 336 F. Supp. 2d 583, 592 (M.D.N.C. 2004) ("Given the Federal Circuit's extremely narrow conception of the experimental use defense and the total lack of evidence currently in the record, the Court has doubts about whether Duke will be able to provide any evidence in support of its experimental use defense.").

Madey's limiting of the experimental use defense has come under a great deal of academic criticism. *See, e.g.*, Katherine J. Strandburg, *What Does the Public Get? Experimental Use and the Patent Bargain*, 2004 WIS. L. REV. 81, 85 (2004) ("Because *Madey* contradicted a belief widespread in the research community—whether or not justified by earlier law—that all nonprofit research was exempt from infringement liability, many commentators fear that the decision may have a significant chilling effect on university research."); *see also id.* at 99 ("[T]he 'legitimate business' concept can (and inevitably will) be expanded to cover almost any conceivable use that could cut into the patentee's potential market for the invention."). It does not seem, however, that universities often face lawsuits from patent owners for activities of academic researchers they employ. Indeed, *Madey* had relatively unusual facts for a patent

[8] The relevant jury instruction provided only that there must be a "decent prospect that the accused activities would contribute, relatively directly, to the generation of the kinds of information that are likely to be relevant in the processes by which the FDA would decide whether to approve the product in question." It did not say that, to fall within § 271(e)(1)'s exemption from infringement, the patented compound used in experimentation must be the subject of an eventual application to the FDA. And it expressly rejected the notion that the exemption only included experiments that produced information included in an IND or NDA.

case—a former professor, holding patents in his own name (rather than assigned to the university), and suing an institution from which he resigned.

One explanation for the rarity of lawsuits against academic institutions might be sovereign immunity available to public universities, which function as "an arm of the State." *See Florida Prepaid Postsecondary Educ. Expense Bd. v. College Sav. Bank*, 527 U.S. 627, 633 n.3 (1999). But this cannot be the whole story given the number of private universities, like Duke. Why is it that universities rarely find themselves on the receiving end of a patent infringement complaint? What would be the optics of such a suit for the private sector plaintiff? What sorts of remedies would be available? For a further exploration of these issues, see Rebecca S. Eisenberg, *Noncompliance, Nonenforcement, Nonproblem? Rethinking the Anticommons in Biomedical Research*, 45 HOUS. L. REV. 1059 (2008).

2. *Fair use for patents?* The virtual absence of an experimental use exception, other than the § 271(e)(1) carve-out, in patent law can be contrasted with the "fair use" defense in copyright law. This defense is a creation of the common law that was codified in the Copyright Act of 1976 under 17 U.S.C. § 107. This section exempts from copyright infringement "the fair use of a copyrighted work . . . for purposes such as criticism, comment, news reporting, teaching . . . , scholarship, or research." Its provides four factors for courts to consider in making this determination: "(1) the purpose and character of the use, including whether such use is of a commercial nature or is for nonprofit educational purposes; (2) the nature of the copyrighted work; (3) the amount and substantiality of the portion used in relation to the copyrighted work as a whole; and (4) the effect of the use upon the potential market for or value of the copyrighted work." This defense may, for example, protect the uses of copyrighted works that have First Amendment value, such as parodies. *See Campbell v. Acuff-Rose Music, Inc*, 510 U.S. 569 (1994). Should there be a general defense to patent infringement similar to fair use in copyright law? For a proposal, see Maureen A. O'Rourke, *Toward a Doctrine of Fair Use in Patent Law*, 100 COLUM. L. REV. 1177 (2000).

3. *Statutory experimental use: a legislative proposal.* Although proposals for a general fair use defense to patent infringement have not gained a great deal of traction, more limited "experimental use" legislation has been introduced. A bill from 1990, for example, distinguished between experimenting *on* a patented invention (*e.g.*, to figure out if it actually works) and conducting experiments *using* a patented invention, such as a research tool. The bill would have shielded the former types of acts, but not the latter, from claims of infringement. Why did the proponent of the bill make this distinction? The proposal would have protected the following "experimenting on" activities:

> (1) testing an invention to determine its sufficiency or to compare it to prior art;
> (2) tests to determine how the patented invention works;
> (3) experimentation on a patented invention for the purpose of improving on it or developing a further patentable invention;

(4) experimentation for the purpose of "designing around" a patented invention;
(5) testing to determine whether the invention meets the tester's purposes in anticipation of requesting a license; and
(6) academic instructional experimentation with the invention.

H.R. Rep. No. 010-960, Pt. I, at 144 (1990). What are the pros and cons of this proposal? For analysis, see Harold C. Wegner, *Post*-Merck *Experimental Use and the "Safe Harbor,"* 15 FED. CIR. B.J. 1, 34–35 (2005). For a criticism of the proposal, see Jordan P. Karp, Note, *Experimental Use as Patent Infringement: The Impropriety of a Broad Exception*, 100 YALE L.J. 2169 (1991).

4. *Subject matter-specific defenses: a representative proposal.* A bill titled Genomic Research and Diagnostic Accessibility Act of 2002 included the following language:

> It shall not be an act of infringement for any individual or entity to use any patent for or patented use of genetic sequence information for purposes of research. This paragraph shall not apply to any individual or entity that is directly engaged in the commercial manufacture, commercial sale, or commercial offer for sale of a drug, medical device, process, or other product using such patent for or patented use of genetic sequence information.

H.R. 3967, 107th Cong. (2002). Why does the bill single out patents on "genetic sequence information?" Recall the controversy over the patenting of ESTs in the 1990s and early 2000, discussed in Chapter 3, and see Molly A. Holman & Stephen R. Munzer, *Intellectual Property Rights in Genes and Gene Fragments: A Registration Solution for Expressed Sequence Tags*, 85 IOWA L. REV. 7353 (2000).

Does the outcome in *In re Fisher*, 421 F.3d 1365 (Fed. Cir. 2005), obviate the concerns behind the Genomic Research and Diagnostic Accessibility Act of 2002? How about the outcome in *Association for Molecular Pathology v. Myriad*, 569 U.S. 576 (2013)? For an analysis connecting the Supreme Court's increasingly vigorous enforcement of the patentable subject matter requirement to the Federal Circuit's limits on the experimental use defense, see Harold C. Wegner, *Whatever Happened to* Alice*?*, Letter to the Hon. Joseph D. Matal, Performing the Functions and Duties of the Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office (July 3, 2017), *available at* http://www.laipla.net/wp-content/uploads/2017/07/MatalLetterJuly3.pdf.

5. *The current statutory carve-out.* In the wake of *Merck*, § 271(e)(1)'s "solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products" provision continued to present interpretive challenges. In particular, the courts have struggled with the question whether this section provides a safe harbor only to activities preceding FDA approval, or whether it may also cover post-approval activities. In *Classen Immunotherapies, Inc. v. Biogen IDEC*, 659 F.3d

1057 (Fed. Cir. 2011), the accused infringer performed a patented method for improving the safety of immunization schedules of already-approved vaccines. The majority opinion in *Classen* concluded that this activity was outside the safe harbor, noting that "every decision examining the statute has appreciated that § 271(e)(1) is directed to premarketing approval of generic counterparts before patent expiration" and found in favor of the patentee." *Id.* at 1071. The dissent countered that the safe harbor applied, noting that the Supreme Court in *Merck* repeatedly underscored the breadth of the statute's text" and concluding that "the safe harbor extends to *all* uses that are reasonably related to submitting *any* information under the [Federal Food Drug and Cosmetic Act], including information regarding post-approval uses." *Id.* at 1083 (Moore, J., dissenting) (emphasis in original).

In *Momenta Pharmaceuticals, Inc. v. Teva Pharmaceuticals USA Inc.*, 809 F.3d 610 (Fed. Cir. 2015), the accused infringer performed a patented process for analyzing a composition of an FDA-approved drug as a means of quality control. Relying on *Classen*'s language that "the statute does not apply to information that may be routinely reported to the FDA, long after marketing approval has been obtained," the Federal Circuit concluded that this activity was not covered by the safe harbor. *Id.* at 620 (quoting *Classen*, 659 F.3d at 1070). The court noted that the defendant, Amphastar, was engaged in "routine record retention requirements associated with testing and other aspects of the commercial production process," *id.*, abandoning its earlier conclusion in the same case, at the stage of a preliminary injunction appeal, that Amphastar's submissions were "anything but 'routine.'" *Momenta Pharm., Inc. v. Amphastar Pharm. Inc.*, 686 F.3d 1348, 1358 (Fed. Cir. 2012). But even in its 2015 opinion, the Federal Circuit remained open to the possibility that non-routine post-approval submissions may qualify for the safe harbor. *Momenta*, 809 F.3d at 620. What would be an example of a non-routine post-approval submission?

6. *What about research tools? Merck*'s footnote 7 explicitly reserves the question whether "research tools" can fall under the § 271(e)(1) safe harbor. In *Proveris Scientific Corp. v. Innovasystems, Inc.*, 536 F.3d 1256 (Fed. Cir. 2008), the Federal Circuit appeared to answer this question in the negative. It concluded that the accused device, a so-called Optical Spray Analyzer, did not qualify for the safe harbor because it was not itself subject to an FDA approval process. *See id.* at 1265–66.

7. *Immunities for certain classes of defendants.* Recall from Note 4 that the infringement shield against patents on genetic sequences proposed as part of the Genomic Research and Diagnostic Accessibility Act of 2002 "shall not apply to any individual or entity that is directly engaged in the commercial manufacture, commercial sale, or commercial offer for sale of a drug, medical device, process, or other product using such patent for or patented use of genetic sequence information." Thus, only some defendants would have qualified for this defense. An example of a successful proposal for limiting patent infringement liability against a specific class of defendant has been codified in 35 U.S.C. § 287(c), which relieves liability for "a medical practitioner's performance of a medical activity that constitutes an infringement," where "medical activity" is defined as "a medical or surgical procedure on a body." The statute also makes clear uses of medical devices or drugs by medical practitioners are still actionable. *Id.* § 287(c)(2)(A). This subsection does not apply

retroactively, having been limited to patents filed on or after Sept. 30, 1996. *Id.* § 287(c)(4). The case that spurred this legislation is *Pallin v. Singer*, 36 U.S.P.Q.2d 1050 (D. Vt. 1995), *further proceedings*, 1996 WL 274407 (Mar. 28, 1996) (holding that all the asserted claims on a technique for performing cataract surgery are invalid and not infringed).

Another example of a defense that applies only to some defendants concerns prior user rights, discussed in Chapter 4. *See* 35 U.S.C. § 273.

F. SPOLIATION OF EVIDENCE AND UNCLEAN HANDS

MICRON TECHNOLOGY, INC. V. RAMBUS, INC.
645 F.3d 1311 (Fed. Cir. 2011)

LINN, Circuit Judge:

I. BACKGROUND

This case and the companion case of *Hynix Semiconductor Inc. v. Rambus Inc.,* 645 F.3d 1336 (Fed. Cir. 2011) ("*Hynix II*") (decided contemporaneously herewith), concern a group of U.S. patents issued to Rambus covering various aspects of dynamic random access memory ("DRAM"). Although semiconductor memory chips have been used in computers for decades, advances in other aspects of computer technology by the early 1990s created a bottleneck in the ability of computers to process growing amounts of data through the memory. At least two related methods were discovered of building memory chips (and the interfaces between memory chips and computer processors) in a way that eliminated or minimized this bottleneck. The founders of Rambus, Mike Farmwald and Mark Horowitz, developed one of these methods, which Rambus later commercialized as Rambus DRAM, or RDRAM. The original Rambus applications claim the inventions included in RDRAM. Rambus believed that Farmwald's and Horowitz's invention was broad enough to encompass synchronous dynamic random access memory, or SDRAM, the other type of new memory technology.

Farmwald and Horowitz did not initially file patent applications with claims explicitly directed at SDRAM. However, after Rambus's tenure and resignation as a member of the standard setting Joint Electron Devices Engineering Council ("JEDEC"), Rambus amended its claims to cover the SDRAM technology adopted as the standard by JEDEC. *See generally Rambus Inc. v. Infineon Techs. AG*, 318 F.3d 1081 (Fed. Cir. 2003) ("*Infineon*") (discussing Rambus's participation in JEDEC). The patents at issue here and their enforceability against SDRAM products have been the subject of numerous suits in district courts, the Federal Trade Commission, the International Trade Commission, and this court. However, this court has never finally and definitively resolved the question of whether Rambus engaged in spoliation in connection with this litigation.

The present appeal began when Micron filed a declaratory judgment action against

Rambus, asserting that Micron's production of SDRAM products do not infringe Rambus's patents and that Rambus's patents are invalid, unenforceable, and violate antitrust laws. The district court separated the case into three proceedings: (1) unenforceability due to spoliation, (2) invalidity, and (3) infringement. The court held a bench trial on the spoliation issue, and concluded that the patents in suit were unenforceable against Micron because Rambus had engaged in spoliation by intentionally destroying relevant, discoverable documents in derogation of a duty to preserve them. The district court thus did not reach the validity or infringement issues. On appeal, Rambus argues that the trial court clearly erred in determining that Rambus spoliated documents, acted in bad faith, and prejudiced Micron. Rambus also argues that the district court abused its discretion by dismissing the case as a sanction for the spoliation. Rambus also puts forth two procedural arguments: (1) that the district court erred by requiring the production of documents allegedly subject to attorney-client privilege; and (2) that the district court erred by denying Rambus's motion to transfer the litigation to the Northern District of California.

The record is lengthy but uncomplicated. In 1990, Farmwald and Horowitz filed their first patent application directed to improving the speed with which computer memory can function. Rambus was founded the same year to commercialize this invention. Rambus developed its proprietary RDRAM technology, and licensed chip makers to manufacture memory chips incorporating this technology. Around this time, JEDEC was working to develop industry standard specifications for memory chips and the interfaces between memory chips and computer processor chips, eventually adopting its first SDRAM standard in 1993. In approximately 1992, Rambus learned of SDRAM and came to believe that the Farmwald and Horowitz invention encompassed SDRAM. Rambus continued prosecuting multiple patent applications in the Farmwald/Horowitz family, intending to obtain issued patent claims that covered SDRAM. Rambus thereafter pursued a two-prong business strategy: it licensed chip makers to manufacture chips that complied with Rambus's proprietary RDRAM standards, and prepared to demand license fees and to potentially bring infringement suits against those manufacturers who insisted on adopting the competing SDRAM standard instead.

The first prong of Rambus's strategy went smoothly for some time. In 1996, Intel licensed the RDRAM technology and adopted it as the memory interface technology for its next generation microprocessors. Rambus negotiated licenses with eleven DRAM manufacturers to produce RDRAM-compliant chips for Intel's use. By the fall of 1999, though, these manufacturers had failed to deliver the promised manufacturing capacity, and Intel was therefore beginning to rethink its adoption of RDRAM. Rambus contends that only after RDRAM failed to become a market leader in late 1999 did it to put into action the second prong of its business strategy, to seek licensing revenue (and litigation damages) from those manufacturers adopting SDRAM.

Micron disagrees, arguing that Rambus was planning litigation against SDRAM manufacturers at the same time it was seeking to license RDRAM manufacturers.

In 1997, Rambus hired Joel Karp as its vice-president in charge of intellectual property, and on January 7, 1998, Karp was directed by Rambus's CEO Tate to

develop a strategy for licensing and litigation. Karp then met with several transactional attorneys at Cooley Godward. Because they were not litigation specialists, they referred Karp to Dan Johnson, a litigation partner at Cooley Godward. Karp met Johnson on February 12, 1998. At the meeting with Johnson, Karp discussed licensing accused infringers, mentioning royalty rates that were so high that Johnson said "you're not going to have a licensing program, you're going to have a lawsuit on your hands." Karp said Rambus needed to get "battle-ready," by which he meant that Rambus needed to be ready for litigation. Johnson also advised putting into place a document-retention policy. In March 1998, Karp presented his proposal for a licensing and litigation strategy to the Rambus board of directors. He proposed a 5% royalty on SDRAM, a rate within the range that had prompted Johnson to say that litigation would inevitably follow. In the course of presenting the litigation strategy, Karp recommended implementing a document-retention policy.

In August or September 1998, Rambus hired outside counsel to perform licensing and patent prosecution work as well as to begin preparing for litigation against SDRAM manufacturers. In October 1998, Karp advised Rambus executives that he was planning to assert Rambus's patents against SDRAM manufacturers in the first quarter of 2000, explaining that there were good business reasons for the delay in bringing suit, particularly Rambus's interest in getting licensing revenues from RDRAM manufacturers, who would be the same parties it would seek to license for the production of SDRAM. In November 1998, Rambus executives held an offsite strategy meeting. The meeting notes show that Rambus planned to eventually assert its patents against SDRAM, even if the RDRAM adoption strategy succeeded. In approximately December 1998, Karp drafted a memo describing a possible "nuclear winter" scenario under which Intel moved away from RDRAM. The memo outlined plans for suing Intel and SDRAM manufacturers, saying that "by the time we do this, the proper litigants will be obvious." The memo also noted that infringement claim charts for Micron devices had already been completed by December 1998. On April 15, 1999, Karp met with Rambus's outside counsel at Fenwick & West to "discuss [Rambus's] patent portfolio and potential litigation."

Thereafter, in 1998, Rambus also began implementing the portion of Karp's litigation strategy that required the institution of a document-retention policy. In the second quarter of 1998, Rambus established "Top Level Goals" for "IP Litigation Activity." These goals included "[p]ropos[ing] [a] policy for document retention." In the third quarter of 1998, Rambus established "Key Goals" for "IP Litigation Activity." These goals included "[i]mplement[ing] [a] document retention action plan." On July 22, 1998, Karp presented the finished document retention policy to Rambus employees. The slides used for this presentation were titled "BEFORE LITIGATION: A Document Retention/Destruction Policy." The policy explicitly stated that destruction of relevant and discoverable evidence did not need to stop until the commencement of litigation. Despite the policy's stated goal of destroying all documents once they were old enough, Karp instructed employees to look for helpful documents to keep, including documents that would "help establish conception and prove that [Rambus had] IP."

The document destruction policy extended to the destruction of backups of Rambus's internal email. On March 16, 1998, an internal Rambus email discussed the "growing worry" that email backup tapes were "discoverable information," and discussions

began regarding how long to keep these backup tapes. On May 14, 1998, Rambus implemented a new policy of keeping email backup tapes for only 3 months. Karp said that keeping tapes for any longer period of time was shot down by "Rambus'[s] litigation counsel." Consistent with this policy, in July 1998, Rambus magnetically erased all but 1 of the 1,269 tapes storing its email backups from the previous several years. The one exempted was a document that helped Rambus establish a priority date, and, as discussed below, Rambus went through great lengths to restore that document from the backup tapes.

In addition to destroying the email backup tapes, Rambus began destroying paper documents in accordance with its newly-adopted document-retention policy. On September 3–4, 1998, Rambus held its first "shred day" to implement the policy. In April 1999, Karp instructed Lester Vincent, Rambus's outside patent prosecution counsel at Blakeley Sokoloff, to implement the Rambus document-retention policy with respect to Rambus documents in Vincent's possession. Vincent complied, discarding material from his patent prosecution files. Vincent continued discarding material through at least July 1999. He discarded draft patent applications, draft patent claims, draft patent amendments, attorney notes, and correspondence with Rambus.

In June 1999, the first patent in suit issued. On June 24, 1999, Karp was instructed by the Rambus CEO to "hammer out ... our strategy for the battle with the first target that we will launch in October [1999]." In June 27, 1999, Rambus established its "IP 3Q '99 Goals," including goals for "Licensing/Litigation Readiness." These goals included "[p]repar[ing] litigation strategy against 1 of the 3 manufacturers," being "[r]eady for litigation with 30 days notice," and "[o]rganiz[ing] [the] 1999 shredding party at Rambus." Planning for litigation continued when, on July 8, 1999, Fenwick & West prepared a timeline for the proposed patent infringement suits showing that Rambus planned to file a patent infringement complaint on October 1, 1999.

On August 26, 1999, Rambus held the "shredding party" it had planned as part of its third-quarter intellectual property litigation readiness goals. Rambus destroyed between 9,000 and 18,000 pounds of documents in 300 boxes.

Litigation did not ultimately start as planned on October 1, 1999. Still, conditions eventually deteriorated to the point that Rambus felt it could no longer delay the litigation it had started planning in early 1998. As noted above, in the fall of 1999, several RDRAM manufacturers failed to deliver on their promised production of RDRAM chips, causing Intel to rethink its commitment to RDRAM. On September 24, 1999, Karp spoke to Rambus executives, telling them that the industry did not respect Rambus's intellectual property and that Rambus would "have to ultimately pursue remedies in court." Karp asked the board to approve his licensing and litigation strategy, and the board did so. In October 1999, Rambus approached Hitachi, seeking license payments for Hitachi's manufacture of SDRAM. In November 1999, negotiations with Hitachi broke down. Rambus instituted a litigation hold in December 1999, and Rambus sued Hitachi on January 18, 2000. The suit against Hitachi was settled on June 22, 2000. In the meantime, Rambus negotiated SDRAM licenses with Toshiba, Oki, and NEC. Rambus continued to litigate against the members of the chip-making industry by bringing suit against Infineon on August 8,

2000. *Rambus, Inc. v. Infineon AG,* 155 F.Supp.2d 668, 671 (E.D. Va. 2001). Before that litigation began, Rambus's in-house counsel reminded Rambus executives on July 17, 2000, to continue destroying drafts and other materials related to license negotiations.

On August 18, 2000, Rambus approached Micron about the possibility of Micron taking a license for its SDRAM production. Micron filed a declaratory judgment action against Rambus in the District of Delaware on August 28, 2000, asserting invalidity, non-infringement, and unenforceability. The following day, Hynix Semiconductor filed a similar declaratory judgment suit against Rambus in the Northern District of California. *Hynix Semiconductor, Inc. v. Rambus, Inc.,* 591 F. Supp. 2d 1038 (N.D. Cal. 2006) ("*Hynix I*"). The issue of whether Rambus had destroyed relevant documents after it had a duty to begin preserving documents was litigated in both suits. The Northern District of California reached the issue first. Following a bench trial, that court ruled in January 2006 that "Rambus did not actively contemplate litigation or believe litigation against any particular DRAM manufacturer to be necessary or wise before its negotiation with Hitachi failed, namely in [November] 1999." *Id.* at 1064. The Northern District of California ruled that this made Rambus's adoption of its document-retention policy in mid–1998 a permissible business decision, and the destruction of documents pursuant to that policy did not constitute spoliation. *Id.* The appeal of that decision is the subject of the companion *Hynix* case decided herewith. *Hynix II*, 645 F.3d 1336.

Meanwhile, in the Micron litigation in the District of Delaware, Micron sought access to communications between Rambus and its attorneys relating to the adoption of Rambus's document-retention policy. Courts in *Hynix* and *Infineon* had previously required production of these documents, and in February 2006, the District of Delaware agreed after finding that the adoption of the policy on the advice of counsel raised the likelihood that Delaware and California criminal statutes prohibiting destruction of evidence had been violated. The court held that the attorney-client privilege could be breached under the crime-fraud exception because Rambus and its counsel had possibly committed a crime. Following this decision and the favorable ruling of the Northern District of California on the spoliation issue, Rambus sought on February 14, 2006, to have the Micron case transferred to the Northern District of California. The District of Delaware denied the motion to transfer.

In November 2007, the District of Delaware held a bench trial on the unclean-hands issue asserted by Micron. Stopping short of reaching the unclean-hands claim, the district court found that Rambus had engaged in spoliation; the court accordingly entered judgment in Micron's favor as a spoliation sanction. The court found that litigation was reasonably foreseeable to Rambus "no later than December 1998, when Karp had articulated a time frame and a motive for implementation of the Rambus litigation strategy." The district court thus ruled that documents destroyed after December 1998 were intentionally destroyed in bad faith. The district court concluded that the only reasonable sanction for the intentional destruction of documents was to hold Rambus's patents in suit unenforceable against Micron. Rambus timely appealed.

II. DISCUSSION

A. Spoliation

As the Supreme Court has noted, "[d]ocument retention policies, which are created in part to keep certain information from getting into the hands of others, including the Government, are common in business. It is, of course, not wrongful for a manager to instruct his employees to comply with a valid document retention policy under ordinary circumstances." *Arthur Andersen LLP v. United States,* 544 U.S. 696, 704, 125 S.Ct. 2129, 161 L.Ed.2d 1008 (2005) (internal citation and quotation marks omitted). Thus, "a party can only be sanctioned for destroying evidence if it had a duty to preserve it." *Zubulake v. UBS Warburg LLC,* 220 F.R.D. 212, 216 (S.D.N.Y. 2003). The duty to preserve evidence begins when litigation is "pending or reasonably foreseeable." *Silvestri v. General Motors Corp.,* 271 F.3d 583, 590 (4th Cir. 2001). *See also West v. Goodyear Tire & Rubber Co.,* 167 F.3d 776, 779 (2d Cir. 1999) (applying the same standard). Thus, "[s]poliation refers to the destruction or material alteration of evidence or to the failure to preserve property for another's use as evidence in pending or reasonably foreseeable litigation." *Silvestri*, 271 F.3d at 590. This is an objective standard, asking not whether the party in fact reasonably foresaw litigation, but whether a reasonable party in the same factual circumstances would have reasonably foreseen litigation.

When litigation is "reasonably foreseeable" is a flexible fact-specific standard that allows a district court to exercise the discretion necessary to confront the myriad factual situations inherent in the spoliation inquiry. *Fujitsu Ltd. v. Fed. Express Corp.*, 247 F.3d 423, 436 (2d Cir. 2001). This standard does not trigger the duty to preserve documents from the mere existence of a potential claim or the distant possibility of litigation. *See, e.g., Trask–Morton v. Motel 6 Operating L.P.,* 534 F.3d 672, 681–82 (7th Cir. 2008). However, it is not so inflexible as to require that litigation be "imminent, or probable without significant contingencies," as Rambus suggests. Reply Br. of Rambus at 4. Rambus's proposed gloss on the "reasonably foreseeable" standard comes from an overly generous reading of several cases. *See Burlington N. & Santa Fe Ry. Co. v. Grant,* 505 F.3d 1013, 1032 (10th Cir. 2007) (noting that "[a] spoliation sanction is proper where (1) a party has a duty to preserve evidence because it knew, or should have known, that litigation was *imminent,* and (2) the adverse party was prejudiced by the destruction of the evidence" (emphasis added); *Trask–Morton,* 534 F.3d at 681 (citing *Burlington* for the proposition that "courts have found a spoliation sanction to be proper only where a party has a duty to preserve evidence because it knew, or should known, that litigation was *imminent,*" but holding that "Motel 6 had no reason to *suspect litigation* until—at the earliest—Morton's attorney sent Motel 6 a demand letter" after the alleged spoliation (emphases added)). *Burlington* merely noted that imminent litigation was sufficient, not that it was necessary for spoliation, and on the easy facts of *Trask–Morton,* it was decided that the alleged spoliator did not even "suspect" litigation. This court declines to sully the flexible reasonably foreseeable standard with the restrictive gloss proposed by Rambus in light of the weight of contrary authority and the unnecessary generosity that such a gloss would extend to alleged spoliators. *See Silvestri,* 271 F.3d at 591;

West, 167 F.3d at 779 ("Spoliation is the destruction or significant alteration of evidence, or the failure to preserve property for another's use as evidence in pending or reasonably foreseeable litigation."); *Kronisch v. United States,* 150 F.3d 112, 126 (2d Cir. 1998) ("This obligation to preserve evidence arises when the party has notice that the evidence is relevant to litigation ... as for example when a party should have known that the evidence may be relevant to future litigation."); *MOSAID Techs. Inc. v. Samsung Elecs. Co.,* 348 F.Supp.2d 332, 336 (D.N.J. 2004) (noting that a litigant "is under a duty to preserve what it knows, or reasonably should know, will likely be requested in reasonably foreseeable litigation"); *Scott v. IBM Corp.,* 196 F.R.D. 233, 249 (D.N.J.2000) (same). *See also United States v. Rockwell Int'l,* 897 F.2d 1255, 1266 (3rd Cir. 1990) (holding that for attorney work product to be shielded by the work product privilege, "[l]itigation need not be imminent ... as long as the primary motivating purpose behind the creation of the document was to aid in possible future litigation.") (internal citations omitted)). Moreover, it would make little sense to enjoin document destruction only when the party clears all the hurdles on the litigation track, but endorse it when the party begins the race under the reasonable expectation of clearing those same hurdles. Thus, the proper standard for determining when the duty to preserve documents attaches is the flexible one of reasonably foreseeable litigation, without any additional gloss.

After carefully reviewing the record, the district court determined that "litigation was reasonably foreseeable no later than December 1998, when Karp had articulated a time frame and a motive for implementation of the Rambus litigation strategy." *Decision,* 255 F.R.D. at 150. In coming to this conclusion, the district court applied the correct standard, noting that "[a] duty to preserve evidence arises when.... litigation is pending or imminent, or when there is a reasonable belief that litigation is foreseeable." *Id.* at 148.

This court reviews the district court's factual findings, such as the date at which litigation was reasonably foreseeable, for clear error. *Citizens Fed. Bank v. United States,* 474 F.3d 1314, 1321 (Fed. Cir. 2007); *Port Auth. of N.Y. & N.J. v. Arcadian Corp.,* 189 F.3d 305, 315 (3d Cir. 1999); *Brewer v. Quaker State Oil Ref. Corp.,* 72 F.3d 326, 334 (3d Cir. 1995). Rambus argues that when litigation was reasonably foreseeable is a "mixed question of law and fact reviewed de novo." However, the cases it cites do not support such a standard in this context. For example, *Travelers Indemnity v. Ewing, Cole, Erdman & Eubank,* 711 F.2d 14 (3d Cir. 1983), addressed the "issue of whether the level of care exercised by the defendant measured up to the standard expected of reasonably prudent architects" as a mixed question of law and fact. *Id.* at 17. However, that question is more about whether a duty is breached than when the duty commenced. Similarly inapposite, *Pell v. E.I. DuPont de Nemours,* 539 F.3d 292 (3d Cir. 2008), concluded that "the District Court's determination that 1972 is the appropriate adjusted service date is a mixed conclusion of law and fact," and that this question is broken down into its "components and [the appeals court applies] the appropriate standard of review to each component." *Id.* at 305. *Pell* does not specify whether the date at which the duty arises is a law component or a fact component, and thus does not persuade this court to review the issue de novo. In a variety of contexts, foreseeability of an event is a traditional issue of fact, and is reviewed with deference to the district court. *Cates v. Dillard Dep't Stores, Inc.,* 624 F.3d 695, 697

(5th Cir .2010) (noting that whether a risk of harm was reasonably foreseeable is a question of fact); *Citizens Fed. Bank v. United States,* 474 F.3d 1314, 1321 (Fed.Cir. 2007) (noting that "[f]oreseeability is a question of fact reviewed for clear error" in the damages context); *United States v. Cover,* 199 F.3d 1270, 1274 (11th Cir. 2000) (reasonable foreseeability of a co-conspirators actions is a question of fact). This court likewise applies a clear error standard of review.

The district court found that Rambus destroyed relevant, discoverable documents beginning in July 1998, with the first major shred day occurring in September 1998. The court found that the destruction continued at least through November 1999, with another major shred day occurring in August 1999. In addition, the district court found that Rambus ordered its outside patent prosecution counsel to purge his files relating to the prosecution of the prospective patents in suit in April 1999. There is ample evidence to support all these findings, and they are not seriously disputed even by Rambus. The exact date at which litigation was reasonably foreseeable is not critical to this decision; the real question is binary: was litigation reasonably foreseeable before the second shred day or after? Therefore, the question this court must answer is whether the district court clearly erred when it determined that, at some time before the second shred day in August of 1999, litigation was reasonably foreseeable. This court cannot conclude that the district court clearly erred for at least the following five reasons.

First, it is certainly true that most document retention policies are adopted with benign business purposes, reflecting the fact that "litigation is an ever-present possibility in American life." *Nat'l Union Fire Ins. v. Murray Sheet Metal Co.,* 967 F.2d 980, 984 (4th Cir. 1992). In addition, there is the innocent purpose of simply limiting the volume of a party's files and retaining only that which is of continuing value. One might call it the "good housekeeping" purpose. Thus, where a party has a long-standing policy of destruction of documents on a regular schedule, with that policy motivated by general business needs, which may include a general concern for the possibility of litigation, destruction that occurs in line with the policy is relatively unlikely to be seen as spoliation. Here, however, it was not clear error for the district court to conclude that the raison d'être for Rambus's document retention policy was to further Rambus's litigation strategy by frustrating the fact-finding efforts of parties adverse to Rambus. This is a natural reading of getting "[b]attle ready." The preparation of the document retention policy was one of Rambus's "IP Litigation Activity" goals in the second and third quarters of 1998. When the finished document retention policy was presented to Rambus employees, the presentation slides used were titled "BEFORE LITIGATION: A Document Retention/Destruction Policy." The policy explicitly stated that destruction of relevant and discoverable evidence did not need to stop until the actual commencement of litigation. Despite the policy's stated goal of destroying all documents once they were old enough, employees were instructed to look for helpful documents to keep, including documents that would "help establish conception and prove that [Rambus had] IP," and they did keep these documents. Moreover, on March 16, 1998, an internal Rambus e-mail noted a "growing worry" that email backup tapes were "discoverable information," and discussions began regarding how long to keep these backup tapes. On May 14, 1998, Rambus implemented a new policy of keeping email backup tapes for only 3 months. Karp said that keeping tapes for any longer period of time was shot down by "Rambus'[s]

litigation counsel." Karp also noted that if anyone had questions about the document retention policy, they could contact him, but that he "would prefer to discuss [the] issue face to face," and that if they did send e-mails, to "keep them brief, and keep the distribution narrow." Shortly after the email backup destruction policy was instituted, all of Rambus's old backup tapes were destroyed. Taken together, the implementation of a document retention policy as an important component of a litigation strategy makes it more likely that litigation was reasonably foreseeable. *Cf. United States v. Adlman,* 134 F.3d 1194, 1203 (2d Cir. 1998) (adopting a test for work product immunity where a document is prepared in anticipation of litigation where the document "can fairly be said to have been prepared or obtained *because of* the prospect of litigation") (emphasis added) (citing 8 Charles Alan Wright, Arthur R. Miller, and Richard L. Marcus, Federal Practice and Procedure § 2024, at 343 (1994)).

Second, Rambus was on notice of potentially infringing activities by particular manufacturers. Once the patent issued, the gun was loaded; when the targets were acquired, it was cocked; all that was left was to pull the trigger by filing a complaint. While it may not be enough to have a target in sight that the patentee believes may infringe, the knowledge of likely infringing activity by particular parties makes litigation more objectively likely to occur because the patentee is then more likely to bring suit. Here, numerous internal documents manifest Rambus's plan "to play [its] IP card with the DRAM companies" against SDRAM products, either through a patent infringement or a breach of contract suit. *See Decision*, 255 F.R.D. at 138–48 (noting that even in the early 1990s, Rambus was already "concerned that DRAM manufacturers were using Rambus'[s] technology to develop their own competing DRAMs," and detailing Rambus's campaign to capitalize on non-compliant products' infringement); *id.* at 144 ("The [Nuclear Winter Memorandum] indicated specifically that Rambus already had claim charts showing that Micron infringed one of the Rambus patents."). *See also* Br. of Rambus's at 34 ("Rambus therefore feared that demanding licenses on non-compatible products (let alone initiating litigation) would risk undermining its relationships with the very DRAM manufacturers its business strategy depended upon."). In addition, the bulk of the discussions between CEO Tate, Karp, and Rambus's attorneys related to SDRAM and Rambus's licensing (as Rambus argues) or litigation (as Micron argues) plans. Either way, Rambus was on notice of activities it believed were infringing. *Cf. Schmid v. Milwaukee Elec. Tool Corp.*, 13 F.3d 76, 81 (3d Cir. 1994) (overturning a district court spoliation sanction in part because the plaintiff's expert's destruction of evidence occurred when "no suit had been filed and Schmid did not know whether he had a basis for instituting suit."). Indeed, Rambus was more than on notice because, by its own admission, it actively broadened its claims to cover JEDEC standard-compliant products, and, according to the testimony of CEO Tate, it knew that those products would infringe its claims.

Third, Rambus took several steps in furtherance of litigation prior to its second shredding party on August 26, 1999. Karp had already concluded that Rambus would "need to litigate against someone to establish [a] royalty rate and have [the] court declare [the Rambus] patent[s] valid," had prioritized defendants and forums, had created claim charts and determined an expected timeline for litigation that it would "launch in October [1999]," and had as its goal to "be ready for litigation with 30 days notice" "against 1 of the 3 manufacturers" by the third quarter of 1999. On June 24, 1999, Karp was instructed by CEO Tate to "hammer out ... our strategy for the battle

with the first target that we will launch in October [1999]." The first steps toward this litigation were spelled out on June 27, 1999, when Rambus established "IP 3Q '99 Goals," including goals for "Licensing/Litigation Readiness." These goals included "[p]repar[ing] litigation strategy against 1 of the 3 manufacturers," being "[r]eady for litigation with 30 days notice," and "[o]rganiz[ing] [the] 1999 shredding party at Rambus." Planning for litigation continued when, on July 8, 1999, Rambus's outside litigation counsel, Fenwick & West, prepared a timeline for the proposed patent infringement suits showing that Rambus planned to file complaints on October 1, 1999. Indeed, the second shredding party was itself part of Rambus's third-quarter intellectual property litigation readiness goals.

Rambus strongly argues that the steps it did *not* yet take in furtherance of litigation, i.e. the contingencies, compel a finding that litigation was not reasonably foreseeable. Rambus cites the contingencies accepted by Judge Whyte in the companion *Hynix* case as precluding Rambus from reasonably foreseeing litigation:

> (1) the direct RDRAM ramp had to be sufficiently developed so as not to jeopardize RDRAM production; (2) Rambus's patents covering non-RDRAM technology had to issue; (3) product samples from potentially infringing DRAM manufacturers had to be available in the market; (4) the noncompatible products had to be reverse engineered and claim charts made showing coverage of the actual products; (5) Rambus's board had to approve commencement of negotiations with a DRAM manufacturer; and (6) the targeted DRAM manufacturer had to reject Rambus's licensing terms.

Hynix, 591 F.Supp.2d at 1062. It is of course true that had these contingencies been cleared, litigation would have been more foreseeable. However, it was not clear error to conclude that overcoming the contingencies was reasonably foreseeable. For example, Rambus makes much of the inadvisability of jeopardizing its relationship with the manufacturers through litigation over SDRAM, because those same manufacturers were producing RDRAM, which Rambus hoped would become the market leader. However, as was made clear in the Nuclear Winter Memorandum, if RDRAM did not become a market leader, Rambus would go after the manufacturers of SDRAM and if RDRAM did become a market leader, and the RDRAM ramp "reache[d] a point of no return," then Rambus could come out from "stealth mode," and could then "ROCK THE DIRECT BOAT" because the manufacturers would be locked in to the RDRAM standard. Hence the use of definitive language of future intention, such as asking "WHAT'S THE RUSH [to assert patents against RDRAM partners]?" and noting that it should "not asserts patents against Direct [RDRAM] partners *until* ramp reaches a point of no return (TBD)." (emphasis added). Similarly, obtaining product samples would certainly be a reasonably foreseeable event, particularly because Rambus had explicitly broadened its claim coverage in prosecution to cover standard-compliant products, which, by the terms of the standard, all the manufacturers would meet. It was also reasonably foreseeable that the manufacturers would reject Rambus's licensing terms, because Karp proposed a five percent royalty rate to the board in March 1998 that attorney Johnson had called "ridiculous," and that the Cooley attorneys informed him would result in a lawsuit. In December 1998 or January 1999, Karp opined that in situations where Rambus was "not interested

in settling," they should propose a royalty rate between five and ten percent, and noted that "we should not be too concerned with settlement at this point and should push for very high rates." It is thus not clear error to conclude that Rambus reasonably foresaw that the manufacturers would reject its licensing offer. The same is true for the other listed contingencies. Thus, Rambus's preparations for litigation prior to the critical date, including choosing and prioritizing manufacturers to sue, selecting forums in which to bring suit within a planned time-frame, creating claim charts, and including litigation as an essential component of its business model, support the district court's decision that Rambus reasonably foresaw litigation before the second shredding party on August 26, 1999.

Fourth, when Rambus sued Hitachi on January 18, 2000, it was the plaintiff-patentee, and its decision whether to litigate or not was the determining factor in whether or not litigation would in fact ensue. In other words, whether litigation was reasonably foreseeable was largely dependent on whether Rambus chose to litigate. It is thus more reasonable for a party in Rambus's position as a patentee to foresee litigation that does in fact commence, than it is for a party in the manufacturers' position as the accused.[1]

Fifth, as discussed above, the relationship between Rambus and the manufacturers involving RDRAM did not make litigation significantly less likely, it only delayed the initiation of litigation until the manufacturers were either too invested in RDRAM for the SDRAM litigation to negatively impact Rambus's sales, or until Rambus had no choice but to sue because RDRAM was rejected. In general, when parties have a business relationship that is mutually beneficial and that ultimately turns sour, sparking litigation, the litigation will generally be less foreseeable than would litigation resulting from a relationship that is not mutually beneficial or is naturally adversarial. Thus, for example, document destruction occurring during the course of a long-standing and untroubled licensing relationship relating to the patents and the accused products that ultimately become the subject of litigation is relatively unlikely to constitute spoliation, while destruction of evidence following repeated failures of a licensee to properly mark products or remit royalties, is more likely to constitute spoliation. Because the relationship regarding RDRAM did nothing to make litigation significantly less likely, and because Rambus and the manufacturers did not have a longstanding and mutually beneficial relationship regarding SDRAM, Rambus cannot use its delay tactics regarding RDRAM to undermine the other considerations herein discussed.

Rambus argues that the district court clearly erred in setting December 1998 as the date at which litigation was reasonably foreseeable, because the only happening on that date was the issuance of the Nuclear Winter Memorandum, which addressed Rambus's potential response to the "very unlikely" scenario that Intel would drop its support for RDRAM. Rambus argues that a document addressing such a contingency cannot form the basis for reasonably foreseeable litigation. The district court found that litigation was reasonably foreseeable "no later than December 1998, when Karp had articulated a time frame and a motive for implementation of the Rambus litigation strategy." *Decision*, 255 F.R.D. at 150. The important inquiry is not whether a particular document made litigation reasonably foreseeable, but whether the totality of the circumstances as of the date of document destruction made litigation

reasonably foreseeable. As discussed above, there was no clear error in the district court's holding that they did.

This court thus affirms the district court's determination that Rambus destroyed documents during its second shred day in contravention of a duty to preserve them and, thus, engaged in spoliation.

B. The District Court's Choice of Sanction

District courts have the "inherent power to control litigation," *West,* 167 F.3d at 779, by imposing sanctions appropriate to rectify improper conduct by litigants. *Schmid,* 13 F.3d at 78. Such sanctions may include dismissal. *Leon v. IDX Sys. Corp.,* 464 F.3d 951, 958 (9th Cir.2006). The particular sanction imposed is within the sound discretion of the district court in exercising its inherent authority and in assuring the fairness of the proceedings before it. *See Silvestri,* 271 F.3d at 590 (quoting *Chambers v. NASCO, Inc.,* 501 U.S. 32, 45–46, 111 S.Ct. 2123, 115 L.Ed.2d 27 (1991)) ("The right to impose sanctions for spoliation arises from a court's inherent power to control the judicial process and litigation, but the power is limited to that necessary to redress conduct 'which abuses the judicial process.' "). As such, the district court's choice of sanction is reviewed for an abuse of discretion. *Mindek v. Rigatti,* 964 F.2d 1369, 1373–74 (3d Cir. 1992).

Rambus challenges the district court's imposition of the dispositive sanction of dismissal, arguing that Micron failed to prove bad faith or prejudice, and that the district court was limited to applying some lesser sanction than dismissal. This court addresses Rambus's arguments in turn.

i. Bad Faith

To make a determination of bad faith, the district court must find that the spoliating party "intended to impair the ability of the potential defendant to defend itself." *Schmid,* 13 F.3d at 80. *See also Faas v. Sears, Roebuck & Co.,* 532 F.3d 633, 644 (7th Cir. 2008) ("A document is destroyed in bad faith if it is destroyed 'for the purpose of hiding adverse information.' ") (citation omitted); *In re Hechinger Inv. Co. of Del., Inc.,* 489 F.3d 568, 579 (3d Cir. 2007) (noting that bad faith requires a showing that the litigant "intentionally destroyed documents that it knew would be important or useful to [its opponent] in defending against [the] action"); *Anderson v. Cryovac, Inc.,* 862 F.2d 910, 925 (1st Cir. 1988) (finding bad faith "where concealment was knowing and purposeful," or where a party "intentionally shred[s] documents in order to stymie the opposition"); *Gumbs v. Int'l Harvester, Inc.,* 718 F.2d 88, 96 (3d Cir. 1983) (noting that an adverse inference from destruction of documents is permitted only when the destruction was "intentional, and indicates fraud and a desire to suppress the truth") (citation omitted). The fundamental element of bad faith spoliation is advantage-seeking behavior by the party with superior access to information necessary for the proper administration of justice.

Here, the district court's analysis of bad faith follows its conclusion on spoliation and does not fully explain the factual underpinnings of its bad faith determination:

> 55. The court concludes that litigation was reasonably foreseeable no later than December 1998, when Karp had articulated a time frame and a motive for implementation of the Rambus litigation strategy. Moreover, because the document retention policy was discussed and adopted within the context of Rambus' litigation strategy, the court finds that Rambus knew, or should have known, that a general implementation of the policy was inappropriate because the documents destroyed would become material at some point in the future. Therefore, a duty to preserve potentially relevant evidence arose in December 1998 and any documents purged from that time forward are deemed to have been intentionally destroyed, i.e. destroyed in bad faith.

Decision, 255 F.R.D. at 150. A determination of bad faith is normally a prerequisite to the imposition of dispositive sanctions for spoliation under the district court's inherent power, and must be made with caution. In determining that a spoliator acted in bad faith, a district court must do more than state the conclusion of spoliation and note that the document destruction was intentional. *See Mathis v. John Morden Buick, Inc.,* 136 F.3d 1153, 1155 (7th Cir. 1998) ("That the documents were destroyed *intentionally* no one can doubt, but 'bad faith' means destruction for the purpose of hiding adverse information.") (emphasis added). From the district court's sparse analysis, this court is unable to determine whether the district court applied the applicable exacting standard in making its factual determination that Rambus acted in bad faith.

The district court's opinion alludes to several key items, including: (1) facts tending to show that Rambus's document retention policy was adopted within the auspices of a firm litigation plan rather than merely carried out despite the reasonable foreseeability of such litigation, *e.g., Decision* ¶¶ 17, 53, 55 and n. 29; (2) facts tending to show the selective execution of the document retention policy, *e.g., Decision* ¶ 13 and n. 23, 27; (3) facts tending to show Rambus's acknowledgement of the impropriety of the document retention policy, *e.g., Decision* ¶¶ 6, 38 and n. 24, 47; and (4) Rambus's litigation misconduct, *Decision* ¶¶ 37–39. While these items may lead to a determination of bad faith, the district court did not make clear the basis on which it reached that conclusion.

"It is not our task to make factual findings," *Golden Hour Data Sys., Inc. v. emsCharts, Inc.,* 614 F.3d 1367, 1380 (Fed. Cir. 2010), and we will leave it to the district court's sound discretion on remand to analyze these, and any other, relevant facts as they apply to the determination of bad faith, *see Thomas v. Capital Sec. Servs., Inc.,* 836 F.2d 866, 873 (5th Cir. 1988) (en banc) ("[T]he district court will have a better grasp of what is acceptable trial-level practice among litigating members of the bar than will appellate judges.").

We note that the district court applied a "knew or should have known" standard in its bad faith determination. On remand, the district court should limit its bad faith

analysis to the proper inquiry: whether Rambus "intended to impair the ability of the potential defendant to defend itself," *Schmid*, 13 F.3d at 80, without regard to whether Rambus "should have known" of the propriety of its document destruction.

Litigations are fought and won with information. If the district court finds facts to conclude that Rambus's goal in implementing its document retention policy was to obtain an advantage in litigation through the control of information and evidence, it would be justified in making a finding of bad faith. If, on the other hand, the district court determines that Rambus implemented its document retention policy for legitimate business reasons such as general house-keeping, a finding of bad faith would be unwarranted. Without a finding either way, however, "the opinion explaining the decision lacks adequate fact findings, [and] meaningful review is not possible." *Dennison Mfg. Co. v. Panduit Corp.*, 475 U.S. 809, 811, 106 S.Ct. 1578, 89 L.Ed.2d 817 (1986). This court therefore remands for the district court to further assess the factual record in reaching a determination on bad faith.

ii. Prejudice

Prejudice to the opposing party requires a showing that the spoliation "materially affect[s] the substantial rights of the adverse party and is prejudicial to the presentation of his case." *Wilson v. Volkswagen of Am., Inc.,* 561 F.2d 494, 504 (4th Cir. 1977) (internal quotation marks omitted). In satisfying that burden, a party must only "come forward with plausible, concrete *suggestions* as to what [the destroyed] evidence *might have been*." *Schmid*, 13 F.3d at 80 (emphases added). *See also Leon*, 464 F.3d at 960 ("[B]ecause any number of the 2,200 files could have been relevant to IDX's claims or defenses, although it is impossible to identify which files and how they might have been used.... the district court did not clearly err in its finding of prejudice."). If it is shown that the spoliator acted in bad faith, the spoliator bears the "heavy burden" to show a lack of prejudice to the opposing party because "[a] party who is guilty of ... intentionally shredding documents ... should not easily be able to excuse the misconduct by claiming that the vanished documents were of minimal import." *Anderson v. Cryovac, Inc.*, 862 F.2d 910, 925 (1st Cir. 1988). *See also Coates v. Johnson & Johnson,* 756 F.2d 524, 551 (7th Cir. 1985) ("The prevailing rule is that bad faith destruction of a document relevant to proof of an issue at trial gives rise to a strong inference that production of the document would have been unfavorable to the party responsible for its destruction.").

It is undisputed that Rambus destroyed between 9,000 and 18,000 pounds of documents in 300 boxes. The district court concluded that the destroyed documents were relevant to at least the following defenses, which would have been "illuminated by evidence of a non-public nature, e.g. by internal Rambus documents": "unenforceability due to patent misuse and violation of the antitrust and unfair competition laws (based in part on Rambus's conduct at JEDEC), as well as inequitable conduct." *Decision*, 255 F.R.D. at 150–51. Documents relating to Rambus's conduct at JEDEC, together with documents reflecting Rambus's instructions to its patent prosecution counsel concerning its conduct at JEDEC, could have helped resolve Micron's claims relating to patent misuse, antitrust violations, and unfair

competition. Documents reflecting Rambus's knowledge of relevant prior art references could have helped resolve Micron's inequitable conduct claims. On the other hand, because it is not clear what documents were destroyed, it may be, as Rambus argues, that all the documents destroyed were either redundant or irrelevant to the trial.

The proper resolution of this issue turns largely on whether Rambus has the burden to show lack of prejudice or Micron has the burden to show prejudice. As discussed above, this turns on whether the district court, on remand, concludes that Rambus was a bad faith spoliator. The question of prejudice is therefore also remanded.

iii. Dispositive Sanction

In addition to reassessing on remand its determination of bad faith and prejudice, the district court should also explain the reasons for the propriety of the sanction chosen (if any) based on the degree of bad faith and prejudice and the efficacy of other lesser sanctions.

Dismissal is a "harsh sanction," to be imposed only in particularly egregious situations where "a party has engaged deliberately in deceptive practices that undermine the integrity of judicial proceedings." *Leon,* 464 F.3d at 958 (internal citations omitted). This court agrees that such sanctions should not be imposed unless there is clear and convincing evidence of both bad-faith spoliation and prejudice to the opposing party. *Shepherd v. ABC*, 62 F.3d 1469, 1472, 1477 (D.C. Cir. 1995) (noting that dismissal requires proof by clear and convincing evidence); *Gates Rubber Co. v. Bando Chem. Indus., Ltd.,* 167 F.R.D. 90, 108 (D. Colo. 1996) (requiring clear and convincing evidence because "[t]o do otherwise would be to contravene the strong public policy which favors adjudication of cases on their merits"). Moreover, the presence of bad faith and prejudice, without more, do not justify the imposition of dispositive sanctions. In gauging the propriety of the sanction, the district court must take into account "(1) the *degree* of fault of the party who altered or destroyed the evidence; (2) the *degree* of prejudice suffered by the opposing party; and (3) *whether there is a lesser sanction* that will avoid substantial unfairness to the opposing party and, where the offending party is seriously at fault, will serve to deter such conduct by others in the future." *Schmid*, 13 F.3d at 79 (emphases added). *See also Leon*, 464 F.3d at 958 (noting that the district court must consider "(1) the public's interest in expeditious resolution of litigation; (2) the court's need to manage its dockets; (3) the risk of prejudice to the party seeking sanctions; (4) the public policy favoring disposition of cases on their merits; and (5) the availability of less drastic sanction"). The sanction ultimately imposed must be commensurate with the analysis of these factors.

The district court must "select the least onerous sanction corresponding to the willfulness of the destructive act and the prejudice suffered by the victim." *Schmid*, 13 F.3d at 79 (citing Jamie S. Gorelick, Steven Marzen and Lawrence Solum, *Destruction of Evidence,* § 3.16, p. 117 (1989)). While the district court noted that "[s]anctions such as adverse jury instructions and preclusion of evidence are impractical, bordering on meaningless, under these circumstances and in the context

of a typical jury trial," and that "the simple imposition of fees and costs is wholly inadequate under the facts of this case," *Decision*, 255 F.R.D. at 151, it did not explain why only dismissal would "vindicate the trifold aims of: (1) deterring future spoliation of evidence; (2) protecting the defendants' interests; and (3) remedying the prejudice defendants suffered as a result of [Rambus's] actions." *See West*, 167 F.3d at 780.

If the district court again concludes on remand that there was bad faith and prejudice, the record evidence may indeed justify a dispositive sanction, but the seriousness of such a sanction warrants an analysis of all of the factors discussed above. *Cf. Roadway Express v. Piper*, 447 U.S. 752, 764 (1980) (noting that because "inherent powers are shielded from direct democratic controls," they "must be exercised with restraint and discretion").

. . .

[*Affirmed-in-part, vacated-in-part, and remanded.*]

GAJARSA, Circuit Judge, concurring-in-part and dissenting-in-part.

While I agree with the majority that there was spoliation of evidence by Rambus, I dissent from that part of the majority's opinion that remands for a reexamination of the evidence for bad faith and vacates the district court's sanction award. Even though the majority applauds with one hand the district court's "inherent power to control litigation," *West v. Goodyear Tire & Rubber Co.*, 167 F.3d 776, 779 (2d Cir. 1999), with the other hand it strangles this power by vacating the district court's sanction award. Indeed, the majority does not review the district court's sanction award for an abuse of discretion, instead it reviews the facts and weighs the evidence before it substitutes its judgment for that of the district court, deciding that based on the district court's thorough factual analysis, it would not have granted the dispositive sanctions. Because we should not "disarm the [district] court of its important power to police its proceedings to ensure transparency and predictability and to discourage mischievous conduct by litigants," I dissent. *Transclean Corp. v. Bridgewood Servs., Inc.*, 290 F.3d 1364, 1374 (Fed. Cir. 2002).

The district court found that Rambus' conduct "impugned" the very integrity of the judicial system. *Micron Tech., Inc. v. Rambus Inc.*, 255 F.R.D. 135, 151 (D. Del. 2009) ("*District Court Op.*"). In so doing, Rambus also abused the privilege of owning a patent monopoly. "As recognized by the Constitution, [a patent] is a special privilege designed to serve the public purpose of promoting the 'Progress of Science and useful Arts' " and "is an exception to the general rule against monopolies and to the right to access to a free and open market." *Precision Instrument Mfg. Co. v. Automotive Maint. Mach. Co.*, 324 U.S. 806, 816 (1945). Thus, the public has a "paramount interest in seeing that patent monopolies spring from backgrounds free from fraud or other types of inequitable conduct...." *Id.* Here, Rambus abused its privilege by intentionally—as found by the district court—destroying evidence in bad faith to protect its exclusive monopoly.

Instead of recognizing this abuse by Rambus, the majority searches to find a needle in the haystack because, in its collective superior judgment, Rambus' conduct does not require taking away that privilege. In fact, the majority fails to consider the "high hurdle" that Rambus must overcome in showing that the district court abused its discretion. *Tex. Digital Sys., Inc. v. Telegenix, Inc.*, 308 F.3d 1193, 1218 (Fed. Cir. 2002). In so doing, the majority reweighs the evidence and decides that "several key items" on which the district court relied "may lead to a determination of bad faith," but the basis on which the district court "reached that conclusion" was not "clear." Majority Op. at 1327.

As an appellate court, we should not decide whether the facts before us "may" lead to a conclusion that we agree with, but whether by so concluding the district court abused its discretion. Indeed, "[t]he question, of course, is not whether ... the Court of Appeals, would as an original matter have [resolved the case in the same way as the District Court]; it is whether the District Court abused its discretion in so doing." *Nat'l Hockey League v. Metro. Hockey Club, Inc.*, 427 U.S. 639, 642 (1976) (citations omitted) (rejecting appellate court's reweighing of evidence and upholding district court's imposition of terminating sanctions for discovery violations as this did not amount to an abuse of discretion).

Here, the district court followed the appropriate Third Circuit standard and provided ample basis in fact for its decision to award dispositive sanctions. *District Court Op.* at 148–51. In the Third Circuit, a spoliating party acts in bad faith when it "intended to impair the ability of the potential defendant to defend itself." *Schmid v. Milwaukee Elec. Tool Corp.*, 13 F.3d 76, 80 (3d Cir. 1994). Under this standard, the district court did not abuse its discretion in finding that Rambus did, in fact, act in bad faith.

First, Rambus used its document retention plan to disguise and hide its destruction of relevant documents. Rambus "instructed patent counsel to purge [its] patent files," which would have at least been relevant to inequitable conduct. *District Court Op.* at 150. Further, Micron's defenses of patent misuse and violations of unfair trade and antitrust laws could all be "illuminated by evidence of a non-public nature, e.g., by internal Rambus documents," *id.* at 151, which almost certainly could have been included in the 300 boxes of documents destroyed in the second shred day in August 1999, *id.* at 145, or the 480 boxes destroyed on December 28, 2000, *id.* at 147. The district court, however, did not make a blanket determination that Rambus' document destruction impeded all of Micron's defenses. In fact, the district court found Micron's ability to assert anticipation and obviousness would not have been impaired by Rambus' spoliation, as the prior art used to assert such defenses is publicly available. *Id.*

Second, Rambus' document retention policy informed employees they should "LOOK FOR THINGS TO KEEP," including documents that would help establish conception but "expunge" "documents questioning the patentability of Rambus inventions." *Id.* at 142 n. 26. This policy remained in effect even after December 1998, the date after which destruction of documents was deemed to be spoliation. *Id.* at 150.

Third, Rambus' own documents (or, more accurately, those that did not make it to the

shredding bin) demonstrate that it was aware that its document retention policy resulted in destruction of documents relevant to litigation. Outside counsel Neil Steinberg e-mailed Rambus executives on July 12, 2000 explaining his desire for a new document retention policy that "is similar to the previous policy—however, this time the IP group will attempt to execute the policy more effectively." *Id.* at 147 n. 57. In addition, Rambus' numerous misrepresentations about its document retention policy during the litigation are evidence, as found by the district court, of a guilty conscience. *Id.* at 147–48, 151.

In criticizing the district court's sanctions award, the majority claims that the district court must explain the propriety of the sanction "based on the degree of bad faith and prejudice and the efficacy of other sanctions." Majority Op. at 1328. This misstates the analysis a district court must undertake to award sanctions for spoliation in the Third Circuit. *Schmid* requires that a district court determine:

> (1) the degree of fault of the party who altered or destroyed the evidence; (2) the degree of prejudice suffered by the opposing party; and (3) whether there is a lesser sanction that will avoid substantial unfairness to the opposing party and, where the offending party is seriously at fault, will serve to deter such conduct by others in the future.

13 F.3d at 79 (citations omitted). With regard to the first factor, the district court must determine the "degree of fault" of the spoliating party, not the degree of bad faith. It is incongruous to establish a "degree" of bad faith—a party either did or did not act in bad faith. Indeed, *Schmid* recognized this by defining bad faith as whether the spoliator "*intended* to impair the ability of the potential defendant to defend itself...." *Id.* at 80 (emphasis added). Requiring degrees of bad faith is the equivalent of finding whether or not a party is "just a little bit pregnant." The majority's desire for the district court to define how "bad is bad" is contrary to Third Circuit law, which this court must apply.

The majority further states that the district court failed to satisfy the third *Schmid* factor by not explaining how holding Rambus' patents unenforceable would deter future spoliation of evidence, protect Micron's interests, and remedy the prejudice to Micron. Majority Op. at 1329–30. Not only is this contrary to the record, but the majority is now creating requirements for the imposition of dispositive sanctions that do not exist in the controlling regional circuit law. As explained above, the district court did not abuse its discretion in finding that Rambus acted in bad faith or that the destruction of these documents prevented Micron from mounting an appropriate defense. Further, the district court specifically found that any sanction other than a dispositive one would be "impractical [and] border[ ] on meaningless" due to the egregiousness of Rambus' conduct. *District Court Op.* at 151. Indeed, Rambus' conduct "impugned" "the very integrity of the litigation process." *Id.* Obviously, a dispositive sanction will serve to deter others from the egregious conduct seen here. There is no better way for the district court to have complied with the third *Schmid* factor.

In vacating the sanctions award, the majority has called the firing squad to the ready, the squad cocking their guns and taking aim, but instead of shooting the appropriate

and culpable party, the squad aimed at the district court's proper determinations of fact. The majority selectively chooses those facts that support its desired outcome, while ignoring those that do not. Weighing evidence as a fact finder is not our function as an appellate court. If the evidence that was considered and weighed by the district court is objectively analyzed by this court under the abuse of discretion standard, it would lead all reasonable people to affirm. *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 143 (1997) (holding that the appellate court erred in excluding expert testimony by "applying an overly 'stringent' review to that ruling [and thereby] fail[ing] to give the trial court the deference that is the hallmark of abuse-of-discretion review"). On remand, the district court would not, in my judgment, need to review any additional evidence; it may only be required to parse the facts more specifically and again determine that the only appropriate sanction for Rambus' egregious conduct is dismissal of this suit. Moreover, I agree with the district court that under these facts, such a sanction would be appropriate.

In substituting its own views for those of the district court, the majority directly interferes with the sound discretion of the trial courts in managing their cases and prevents them from protecting the litigation process, which they are inherently bound to do. *Cooter & Gell v. Hartmarx Corp.*, 496 U.S. 384, 404 (1990) ("Deference to the determination of courts on the front lines of litigation will enhance these court's ability to control litigants before them."). Because the majority ignores this essential and inherent power of the district court, I dissent from its vacatur of the sanction imposed by the district court.

NOTES AND QUESTIONS

1. *Companion case.* In the companion case of *Hynix Semiconductor Inc. v. Rambus Inc.*, 645 F.3d 1336 (Fed. Cir. 2011), which like *Micron* was a declaratory judgment action filed by an accused infringer, the Federal Circuit vacated a judgment of the Northern District of California *rejecting* the plaintiff's argument that Rambus's patents were unenforceable due to spoliation of evidence, and remanded for further consideration. In his opinions concurring in part and dissenting in part in these two cases, Judge Gajarsa argued that in both instances the majority should have deferred to the trial court (i.e., in favor of Rambus in *Hynix*, and against it in *Micron*). Would such a resolution be desirable? Why or why not?

2. *Reasonable foreseeability.* Presumably, the point at which litigation becomes "reasonably foreseeable" for purposes of triggering a duty to retain documents will vary from case to case. Nevertheless, are there any precautions you would advise a client to take before shredding documents? What factors might be relevant in determining which documents to preserve?

3. *Bad faith, prejudice, and sanctions.* The *Micron* court states that "[i]n determining that a spoliator acted in bad faith, a district court must do more than state the conclusion of spoliation and note that the document destruction was intentional." 645 F.3d at 1327. What factors, if present, would support an inference of bad faith? Are there any that would refute it? Where does prejudice fit into all of

this? May a court enter a lesser sanction—or should it enter no sanction at all—absent a showing of *some* degree of bad faith and prejudice? What other sanctions might be available, and what factors might be relevant in determining an appropriate sanction?

4. *Unclean hands and terminating sanctions.* We end this Chapter with where we began—with unclean hands (not literally, to be sure). As noted in earlier this Chapter, inequitable conduct and patent misuse are derived from the equitable defense of unclean hands. But what about "general" unclean hands? In *Gilead Sciences, Inc. v. Merck & Co., Inc.*, the Federal Circuit upheld the application of this defense in a patent case. 888 F.3d 1231, 1240 (Fed. Cir. 2018). "A determination of unclean hands," the court explained, "may be reached when 'misconduct' of a party seeking relief 'has immediate and necessary relation to the equity that he seems in respect of the matter in litigation," *i.e.*, "for such violations of conscience as in some measure affect the equitable relations between the parties in respect of something brought before the court." *Id.* at 1239 (quoting *Keystone Driller Co. v. General Excavator Co.*, 290 U.S. 240, 245 (1933)). The Federal Circuit found that Merck committed "pre-litigation business misconduct . . . [that] was immediately and necessarily related to the equity of Merck's obtaining enforcement of its patent" against Gilead, as well as "litigation misconduct." *Id.* at 1244. To summarize, a Merck patent attorney improperly learned of the structure of a molecule that ultimately became a target of Merck's infringement lawsuit against Gilead, used that knowledge to tailor the claims of the asserted patent accordingly, and lied about those things both in his deposition and in his trial testimony. With respect to the litigation misconduct, the Federal Circuit approvingly cited the district court's conclusion that "the untruthful testimony offered by [the patent attorney] in his deposition and at trial was not incidental, but rather was directed at and supported Merck's validity arguments, and went to the heart of significant issues in this case." *Id.* at 1247 (citation omitted).

In addition, a district court in a patent case, as in any other, can enter a so-called terminating sanction, *e.g.*, a judgment against a party based on particularly egregious forms of litigation misconduct. This power derives from the courts' inherent authority or, in cases in which a party fails to obey the court's discovery orders, from Rule 37 of the *Federal Rules of Civil Procedure*. *See* Fed. R. Civ. P. 37(b)(2)(A)(iii) and (v). Consistent with its choice-of-law approach to issues that are not patent-specific (unclean hands, discussed in the previous paragraph, is another example), the Federal Circuit applies the law of the regional circuit from which the case has originated in reviewing dismissals based on terminating sanctions. *See, e.g.*, *ClearValue, Inc. v. Pearl River Polymers, Inc.*, 560 F.3d 1291, 1306 (Fed. Cir. 2009) ("[T]he Fifth Circuit considers four factors in determining whether a dismissal is appropriate. Dismissal is only appropriate in cases of willfulness and bad faith. Further, the court must find that the deterrent value of Rule 37 could not be achieved through the imposition of lesser sanctions. In addition, the non-sanctioned party's trial preparation must also be substantially prejudiced by the violation. Finally, dismissal may be inappropriate when neglect is attributable to the attorney rather than the client, or when a party honestly misunderstood the court's instructions.") (citations omitted). District courts, of course, also have authority to impose narrower sanctions. *Monsanto Co. v. E.I. Du*

Pont de Nemours & Co., 748 F.3d 1189 (Fed. Cir. 2014) (affirming, under Eighth Circuit law, sanctions that included striking of certain defenses and counterclaims).