PATENT LAW AND POLICY

SIXTH EDITION

2015 Supplement

Robert Patrick Merges
Wilson Sonsini Goodrich & Rosati Professor of Law and Technology
Director, Berkeley Center for Law & Technology
UC Berkeley School of Law

John Fitzgerald Duffy
Samuel H. McCoy II Professor of Law
University of Virginia School of Law

LexisNexis Law School Publishing Advisory Board

NOTE TO USERS

To ensure that you are using the latest materials available in this area, please be sure to periodically check the LexisNexis Law School web site for downloadable updates and supplements at www.lexisnexis.com/lawschool.

Editorial Offices
630 Central Ave., New Providence, NJ 07974 (908) 464-6800
201 Mission St., San Francisco, CA 94105-1831 (415) 908-3200
www.lexisnexis.com

(Pub. 3090)

Table of Contents

Chapter 2: Patentable Subject Matter

Chap. 2.B.1. Replace materials on Lab. Corp. of America v. Metabolite Labs., Inc. (pp. 120-122), with the following case:

Ariosa Diagnostics, Inc. v. Sequenom, Inc.
788 F.3d 1371 (Fed. Cir. 2015)

Reyna, Circuit Judge.

This appeal is from a grant of summary judgment of invalidity of the asserted claims of U.S. Patent No. 6,258,540 ("the '540 patent"). The United States District Court for the Northern District of California found that the asserted claims of the '540 patent are not directed to patent eligible subject matter and are therefore invalid under 35 U.S.C. § 101. For the reasons explained below, we affirm.

I

In 1996, Drs. Dennis Lo and James Wainscoat discovered cell-free fetal DNA ("cffDNA") in maternal plasma and serum, the portion of maternal blood samples that other researchers had previously discarded as medical waste. cffDNA is non-cellular fetal DNA that circulates freely in the blood stream of a pregnant woman. Applying a combination of known laboratory techniques to their discovery, Drs. Lo and Wainscoat implemented a method for detecting the small fraction of paternally inherited cffDNA in maternal plasma or serum to determine fetal characteristics, such as gender. The invention, commercialized by Sequenom as its MaterniT21 test, created an alternative for prenatal diagnosis of fetal DNA that avoids the risks of widely-used techniques that took samples from the fetus or placenta. In 2001, Drs. Lo and Wainscoat obtained the '540 patent, which relates to this discovery.

The parties agree that the patent does not claim cffDNA or paternally inherited cffDNA. Instead, the '540 patent claims certain methods of using cffDNA. The steps of the method of claim 1 of the '540 patent include amplifying the cffDNA contained in a sample of a plasma or serum from a pregnant female and detecting the paternally inherited cffDNA. Amplifying cffDNA results in a single copy, or a few copies, of a piece of cffDNA being multiplied across several orders of magnitude, generating thousands to millions of copies of that particular DNA sequence. In the amplification step, DNA is extracted from the serum or plasma samples and amplified by polymerase chain reaction ("PCR") or another method. PCR exponentially amplifies the cffDNA sample to detectable levels.

In the detecting step, the lab technician adds the amplified cffDNA to an agarose gel containing ethidium bromide to stain and visualize the paternally inherited cffDNA.

The '540 patent also provides for making a diagnosis of certain fetal characteristics based on the detection of paternally inherited cffDNA. The specification explains that analysis of cffDNA permits more efficient determination of genetic defects

and that a pregnant woman carrying a fetus with certain genetic defects will have more cffDNA in her blood than will a woman with a normal fetus. '540 patent col. 3 ll. 30-43.

Claims 1, 2, 4, 5, 8, 19-22, 24, and 25 of the '540 patent are at issue in this appeal. Independent claim 1 requires:

> 1. A method for detecting a paternally inherited nucleic acid of fetal origin performed on a maternal serum or plasma sample from a pregnant female, which method comprises
>
> > amplifying a paternally inherited nucleic acid from the serum or plasma sample and
> >
> > detecting the presence of a paternally inherited nucleic acid of fetal origin in the sample.

'540 patent col. 23 l. 61-67.

For comparison, independent claims 24 and 25 require:

> 24. A method for detecting a paternally inherited nucleic acid on a maternal blood sample, which method comprises:
>
> > removing all or substantially all nucleated and anucleated cell populations from the blood sample,
> >
> > amplifying a paternally inherited nucleic acid from the remaining fluid and subjecting the amplified nucleic acid to a test for the Paternally [sic] inherited fetal nucleic acid.
>
> 25. A method for performing a prenatal diagnosis on a maternal blood sample, which method comprises
>
> > obtaining a non-cellular fraction of the blood sample
> >
> > amplifying a paternally inherited nucleic acid from the non-cellular fraction
> >
> > and performing nucleic acid analysis on the amplified nucleic acid to detect paternally inherited fetal nucleic acid.

Id. at 26 ll. 20-36.

The remaining claims explain how the method of detection occurs or how it can be used. For example, claim 2 depends from claim 1 and claims amplification by polymerase chain reaction. Id. at col. 24 ll. 60-61. Claim 4 similarly depends from claim 1 and claims detection via a sequence specific probe. Id. col. 24 ll. 65-67. Claim 21 also depends from claim 1, but instead of focusing solely on a method for detecting, it focuses

on a method for performing a prenatal diagnosis, using claim 1's method for detecting. Id. col. 26 ll. 4-14.

II

Appellee Ariosa Diagnostics … makes and sells the Harmony Test, a non-invasive test used for prenatal diagnosis of certain fetal characteristics. [After receiving letters alleging infringement of the '540 patent, Ariosa filed a declaratory judgment action asserting, inter alia, that the '540 patent was directed to patentable subject matter and was thus invalid. The district court agreed with Ariosa. Sequenom appealed to the Federal Circuit.]

III

Section 101 of the Patent Act defines patent eligible subject matter:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

35 U.S.C. § 101. The Supreme Court has long held that there are certain exceptions to this provision: laws of nature, natural phenomena, and abstract ideas.

In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012), the Supreme Court set forth a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts. First, we determine whether the claims at issue are directed to a patent ineligible concept. Id. at 1297. If the answer is yes, then we next consider the elements of each claim both individually and "as an ordered combination" to determine whether additional elements "transform the nature of the claim" into a patent-eligible application. Id. at 1298. The Supreme Court has described the second step of this analysis as a search for an "inventive concept"—i.e., an element or combination of elements that is "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself." Id. at 1294; *see also Digitech Image Techs., LLC v. Elecs. For Imaging, Inc.*, 758 F.3d 1344, 1351 (Fed. Cir. 2014) ("Without additional limitations, a process that employs mathematical algorithms to manipulate existing information to generate additional information is not patent eligible.").

The claims of the '540 patent that are at issue in this appeal are method claims. Methods are generally eligible subject matter. In this case, the asserted claims of the '540 patent are directed to a multistep method that starts with cffDNA taken from a sample of maternal plasma or serum—a naturally occurring non-cellular fetal DNA that circulates freely in the blood stream of a pregnant woman. See, e.g., '540 patent claims 1, 24, 25. It is undisputed that the existence of cffDNA in maternal blood is a natural phenomenon. Sequenom does not contend that Drs. Lo and Wainscoat created or altered any of the genetic information encoded in the cffDNA, and it is undisputed that the location of the

nucleic acids existed in nature before Drs. Lo and Wainscoat found them. The method ends with paternally inherited cffDNA, which is also a natural phenomenon. The method therefore begins and ends with a natural phenomenon. Thus, the claims are directed to matter that is naturally occurring.

The written description supports the conclusion that the claims of the '540 patent are directed to a naturally occurring thing or natural phenomenon. In the Summary and Objects of the Invention section of the '540 patent, the patent states that "[i]t has now been discovered that foetal DNA is detectable in maternal serum or plasma samples."2Link to the text of the note '540 patent col. 1 ll. 50-51. The patent goes on to state that "[t]his is a surprising and unexpected finding; maternal plasma is the very material that is routinely discarded by investigators studying noninvasive prenatal diagnosis using foetal cells in maternal blood." Id. col. 1 ll. 51-55. In the discussion, the patent notes:

> In this study we have demonstrated the feasibility of performing non-invasive foetal RhD genotyping from maternal plasma. This represents the first description of single gene diagnosis from maternal plasma.

Id. col. 10 ll. 53-58. Further, the description of the invention notes: "[w]e have demonstrated that foetal DNA is present in maternal plasma and serum," id. col. 13 ll. 6-7, and "[t]hese observations indicate that maternal plasma/serum DNA may be a useful source of material for the non-invasive prenatal diagnosis of certain genetic disorders," id. col. 13 ll. 11-13. The patent also states: "[t]he most important observation in this study is the very high concentration of foetal DNA in maternal plasma and serum." Id. col. 16 ll. 12-14. Thus, the claims at issue, as informed by the specification, are generally directed to detecting the presence of a naturally occurring thing or a natural phenomenon, cffDNA in maternal plasma or serum. As we noted above, the claimed method begins and ends with a naturally occurring phenomenon.

Because the claims at issue are directed to naturally occurring phenomena, we turn to the second step of Mayo's framework. In the second step, we examine the elements of the claim to determine whether the claim contains an inventive concept sufficient to "transform" the claimed naturally occurring phenomenon into a patent-eligible application. 132 S. Ct. at 1294. We conclude that the practice of the method claims does not result in an inventive concept that transforms the natural phenomenon of cffDNA into a patentable invention.

Mayo made clear that transformation into a patent eligible application requires "more than simply stat[ing] the law of nature while adding the words 'apply it.'" Id. at 1294. A claim that recites an abstract idea, law of nature, or natural phenomenon must include "additional features" to ensure "that the [claim] is more than a drafting effort designed to monopolize the [abstract idea, law of nature, or natural phenomenon]." Id. at 1297. For process claims that encompass natural phenomenon, the process steps are the additional features that must be new and useful. See *Parker v. Flook*, 437 U.S. 584, 591

(1978) ("The process itself, not merely the mathematical algorithm, must be new and useful.").

In *Mayo*, the patents at issue claimed a method for measuring metabolites in the bloodstream in order to calibrate the appropriate dosage of thiopurine drugs in the treatment of autoimmune diseases. 132 S. Ct. at 1294. The respondent contended that the claimed method was a patent eligible application of a natural law that described the relationship between the concentration of certain metabolites and the likelihood that the drug dosage will be harmful or ineffective. Methods for determining metabolite levels, however, were already "well known in the art." Id. at 1298. Further, the process at issue amounted to "nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients." Id. In that case, "[s]imply appending conventional steps, specified at a high level of generality," was not enough to supply an inventive concept. Id. at 1300.

Like the patentee in *Mayo*, Sequenom contends that the claimed methods are patent eligible applications of a natural phenomenon, specifically a method for detecting paternally inherited cffDNA. Using methods like PCR to amplify and detect cffDNA was well-understood, routine, and conventional activity in 1997. The method at issue here amounts to a general instruction to doctors to apply routine, conventional techniques when seeking to detect cffDNA. Because the method steps were well-understood, conventional and routine, the method of detecting paternally inherited cffDNA is not new and useful. The only subject matter new and useful as of the date of the application was the discovery of the presence of cffDNA in maternal plasma or serum.

The specification of the '540 patent confirms that the preparation and amplification of DNA sequences in plasma or serum were well-understood, routine, conventional activities performed by doctors in 1997. The '540 patent provides that "[t]he preparation of serum or plasma from the maternal blood sample is carried out by standard techniques." '540 patent col. 2 ll. 27-28. It also provides that "[s]tandard nucleic acid amplification systems can be used, including PCR, the ligase chain reaction, nucleic acid sequence based amplification (NASBA), branched DNA methods, and so on." Id. col. 2 ll. 44-47.

Other evidence supports this conclusion. For example, Sequenom's expert, Dr. Evans, testified at deposition that PCR and other methodologies for amplifying DNA were "already well known in science [in 1997]." J.A. 1092-93, 1995-96. Similarly, in a declaration filed during prosecution of the '540 patent, Dr. Lo testified that "[s]uitable amplification techniques can be ordinary PCR or more sophisticated developments thereof, but these techniques were all known in the literature before the date of my invention."

The detecting step was similarly well-understood, routine, and conventional. During prosecution of the application that became the '540 patent, the applicant stated:

> [O]ne skilled in the art is aware of a variety of techniques which might be used to detect different nucleic acid species. For example, there are numerous techniques which might be used to detect repeat expansions, single gene mutations, deletions or translocations. These techniques are a matter of routine for one skilled in the art for the analysis of DNA.

J.A. 1052. The applicant went on to note:

> [O]ne skilled in the art is readily able to apply the teachings of the present application to any one of the well-known techniques for detection of DNA with a view to analysis of foetal DNA in paternal [sic] plasma or serum.

J.A. 1055. Similarly, the applicant later added that "[t]he person skilled in the art has a broad range of techniques available for the detection of DNA in a sample." J.A. 1057.

The dependent claims are broad examples of how to detect cffDNA in maternal plasma. The dependent claims are focused on the use of the natural phenomenon in combination with well-understood, routine, and conventional activity. For example, claim 2 identifies the polymerase chain reaction as the amplification technique to be used in the detection method of claim 1. As noted above, this technique was well-understood, routine, and conventional in 1997, as specified by the patent itself. Like claim 1, claims 5 and 8 focus on detecting a specific chromosome within the cffDNA—a natural phenomenon—again, adding no inventive concept to the limitations of claim 1. None of the remaining asserted dependent or independent claims differ substantially from these claims. Thus, in this case, appending routine, conventional steps to a natural phenomenon, specified at a high level of generality, is not enough to supply an inventive concept. Where claims of a method patent are directed to an application that starts and ends with a naturally occurring phenomenon, the patent fails to disclose patent eligible subject matter if the methods themselves are conventional, routine and well understood applications in the art. The claims of the '540 patent at issue in this appeal are not directed to patent eligible subject matter and are, therefore, invalid.

IV

In its opinion, the district court addressed the principle of preemption. The district court noted:

> It is important to note that the '540 patent does not merely claim uses or applications of cffDNA, it claims methods for detecting the natural phenomenon. Because generally one must be able to find a natural phenomenon to use it and apply it, claims covering the only commercially viable way of detecting that phenomenon do carry a substantial risk of preempting all practical uses of it.

J.A. 19.

Sequenom argues that there are numerous other uses of cffDNA aside from those claimed in the '540 patent, and thus, the '540 patent does not preempt all uses of cffDNA,

as shown by evidence in the record before the district court. Sequenom also argues that "a method applying or using a natural phenomenon in a manner that does not preclude alternative methods in the same field is non-preemptive, and, by definition, patent-eligible under Section 101." Appellants' Br. 30. Similarly, Sequenom and amici argue that because the particular application of the natural phenomena that the '540 patent claims embody are narrow and specific, the claims should be upheld. Ariosa argues that the principle of preemption does not alter the analysis. Ariosa argues that the claimed methods are not, as Sequenom asserts, limited and specific.

The Supreme Court has made clear that the principle of preemption is the basis for the judicial exceptions to patentability. *Alice*, 134 S. Ct at 2354 ("We have described the concern that drives this exclusionary principal as one of pre-emption"). For this reason, questions on preemption are inherent in and resolved by the § 101 analysis. The concern is that "patent law not inhibit further discovery by improperly tying up the future use of these building blocks of human ingenuity." Id. (internal quotations omitted). In other words, patent claims should not prevent the use of the basic building blocks of technology—abstract ideas, naturally occurring phenomena, and natural laws. While preemption may signal patent ineligible subject matter, the absence of complete preemption does not demonstrate patent eligibility. In this case, Sequenom's attempt to limit the breadth of the claims by showing alternative uses of cffDNA outside of the scope of the claims does not change the conclusion that the claims are directed to patent ineligible subject matter. Where a patent's claims are deemed only to disclose patent ineligible subject matter under the Mayo framework, as they are in this case, preemption concerns are fully addressed and made moot.

Sequenom and amici encourage us to draw distinctions among natural phenomena based on whether or not they will interfere significantly with innovation in other fields now or in the future. The Supreme Court cases, however, have not distinguished among different laws of nature or natural phenomenon according to whether or not the principles they embody are sufficiently narrow. See, e.g., *Parker v. Flook*, 437 U.S. 584 (1978) (holding narrow mathematical formula unpatentable). In *Parker v. Flook*, the Supreme Court stated the issue in the case as follows: "The question in this case is whether the identification of a limited category of useful, though conventional, post-solution applications of such a formula makes respondent's method eligible for patent protection." Id. at 585. The answer to that question was "no" because granting exclusive rights to the mathematical formula would be exempting it from any future use.

V

For completeness, we address Sequenom's remaining arguments. Sequenom argues that "before the '540 patent, no one was using the plasma or serum of pregnant mothers to amplify and detect paternally-inherited cffDNA." Appellants' Br. 49 (emphasis original). This argument implies that the inventive concept lies in the discovery of cffDNA in plasma or serum. Even if so, this is not the invention claimed by the '540 patent.

Sequenom further argues that "[o]ne simple measure of [Drs.] Lo and Wainscoat's contribution is that their 1997 Lancet publication has been cited over a thousand times." Appellants' Br. 25. Sequenom also notes that "the method reflects a significant human contribution in that [Drs.] Lo and Wainscoat combined and utilized man-made tools of biotechnology in a new way that revolutionized prenatal care." Id. We agree but note that the Supreme Court instructs that "[g]roundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry." Myriad Genetics, Inc., 133 S. Ct. at 2117. The discovery of the BRCA1 and BRCA2 genes was a significant contribution to the medical field, but it was not patentable. Id. at 2117. While Drs. Lo and Wainscoat's discovery regarding cffDNA may have been a significant contribution to the medical field, that alone does not make it patentable. We do not disagree that detecting cffDNA in maternal plasma or serum that before was discarded as waste material is a positive and valuable contribution to science. But even such valuable contributions can fall short of statutory patentable subject matter, as it does here.

VI

For each of the reasons stated above, we affirm the district court's summary judgment ruling.

AFFIRMED.

Linn, Circuit Judge, concurring.

I join the court's opinion invalidating the claims of the '540 patent only because I am bound by the sweeping language of the test set out in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.*, 132 S. Ct. 1289 (2012). In my view, the breadth of the second part of the test was unnecessary to the decision reached in *Mayo*. This case represents the consequence—perhaps unintended—of that broad language in excluding a meritorious invention from the patent protection it deserves and should have been entitled to retain.

It has long been established that "[l]aws of nature, natural phenomena, and abstract ideas are not patentable." *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2354 (2014) (citations omitted). In *Mayo*, the Supreme Court set forth a two-step framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts. The first step looks to determine whether claims are directed to a patent-ineligible concept. *Mayo*, 132 S. Ct. at 1297. If they are, the second step is to consider whether the additional elements recited in the claim "transform the nature of the claim" into a patent-eligible application by reciting an "inventive concept" that is "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself." Id. at 1294.

In applying the second part of the test, the Supreme Court in *Mayo* discounted, seemingly without qualification, any "[p]ost-solution activity that is purely conventional or obvious," id. at 1299 (original alterations omitted). This was unnecessary in *Mayo*, because doctors were already performing in combination all of the claimed steps of administering the drug at issue, measuring metabolite levels, and adjusting dosing based on the metabolite levels, id.

In *Diamond v. Diehr*, the Supreme Court held that "a new combination of steps in a process may be patentable even though all the constituents of the combination were well-known and in common use before the combination was made." 450 U.S. 175, 188 (1981). As *Mayo* explained: *Diehr* "pointed out that the basic mathematical equation, like a law of nature, was not patentable. But [*Diehr*] found the overall process patent eligible because of the way the additional steps of the process integrated the equation into the process as a whole." *Mayo* 132 S. Ct. at 1298. Despite that recognition, *Mayo* discounted entirely the "conventional activity" recited in the claims in that case because the steps "add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field." Id. at 1299. While that conclusion might have been warranted in that case, given the fact that the "conventional activities" in *Mayo* were the very steps that doctors were already doing—administering the drug at issue, measuring metabolite levels, and adjusting dosing based on the metabolite levels—the Supreme Court did not limit its ruling to those particular facts and circumstances.

The Supreme Court's blanket dismissal of conventional post-solution steps leaves no room to distinguish Mayo from this case, even though here no one was amplifying and detecting paternally-inherited cffDNA using the plasma or serum of pregnant mothers. Indeed, the maternal plasma used to be "routinely discarded," '540 patent col.1 ll.50-53, because, as Dr. Evans testified, "nobody thought that fetal cell-free DNA would be present."

It is hard to deny that Sequenom's invention is truly meritorious. Prior to the '540 patent, prenatal diagnoses required invasive methods, which "present[ed] a degree of risk to the mother and to the pregnancy." Id. at col.1 ll.16-17. The available "techniques [we]re time-consuming or require[d] expensive equipment." Id. at col.1 ll.17-37. Dr. Mark Evans testified that "despite years of trying by multiple methods, no one was ever able to achieve acceptable success and accuracy." In a ground-breaking invention, Drs. Lo and Wainscoat discovered that there was cell-free fetal DNA in the maternal plasma. The Royal Society lauded this discovery as "a paradigm shift in non-invasive prenatal diagnosis," and the inventors' article describing this invention has been cited well over a thousand times. The commercial embodiment of the invention, the MaterniT21 test, was the first marketed non-invasive prenatal diagnostic test for fetal aneuploidies, such as Down's syndrome, and presented fewer risks and a more dependable rate of abnormality detection than other tests. Unlike in *Mayo*, the '540 patent claims a new method that should be patent eligible. While the instructions in the claims at issue in Mayo had been

widely used by doctors—they had been measuring metabolites and recalculating dosages based on toxicity/ inefficacy limits for years—here, the amplification and detection of cffDNA had never before been done. The new use of the previously discarded maternal plasma to achieve such an advantageous result is deserving of patent protection. Cf. Rebecca S. Eisenberg, *Prometheus Rebound: Diagnostics, Nature, and Mathematical Algorithms*, 122 Yale L.J. Online 341, 343-44 (2013) (noting that despite *Mayo*'s declaration that a claim to "a new way of using an existing drug" is patentable, *Mayo*, 132 S. Ct. at 1302, it is unclear how a claim to new uses for existing drugs would survive *Mayo*'s sweeping test).

In short, Sequenom's invention is nothing like the invention at issue in Mayo. Sequenom "effectuate[d] a practical result and benefit not previously attained," so its patent would traditionally have been valid. *Le Roy v. Tatham*, 63 U.S. 132, 135-36 (1859) (quoting *Househill Coal & Iron Co. v. Neilson*, Webster's Patent Case 673, 683 (House of Lords 1843)); *Le Roy v. Tatham*, 55 U.S. 156, 175 (1852) (same); see generally Jeffrey A. Lefstin, Inventive Application: a History, 67 Fla. L. Rev. (forthcoming 2015), available at http://ssrn.com/abstract=2398696 (last visited June 10, 2015) (analyzing traditional notions of patent eligibility of newly discovered laws of nature). But for the sweeping language in the Supreme Court's *Mayo* opinion, I see no reason, in policy or statute, why this breakthrough invention should be deemed patent ineligible.

NOTES ON *MAYO*, *ARIOSA* AND TESTING PATENTS

1. The Fundamental Paradox of Patent Law's Exclusionary Principle. As the beginning portion of the *Ariosa* opinion recognizes, settled Supreme Court doctrine is that laws of nature, natural phenomena and abstract ideas are not patentable. The Supreme Court's opinion in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.,* 566 U.S. ––– (2012), dubbed this judge-made doctrine patent law's "exclusionary principle" and postulated that "monopolization" of such laws of nature, natural phenomena and abstract ideas "through the grant of a patent might tend to impede innovation more than it would tend to promote it."

The *Mayo* Court, however, also recognized an inherent danger of the exclusionary principle:

> [T]oo broad an interpretation of this exclusionary principle could eviscerate patent law. For all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas.

Of all that has been written about patentable subject matter in the past decade, that passage from *Mayo* explains best why patent lawyers and judges care so much about patentable subject matter: the judge-made doctrine has the ability to eviscerate the entire Patent Act. For judges who seek to restrict the domain of patent law, patentable subject matter is a tempting tool to accomplish a wholesale restriction on the number of patents without the bother of having to interpret the more specific textual requirements of the statute.

Judge Linn's concurrence tries to highlight the costs of a broad exclusionary principle—meritorious inventions based on real scientific research can receive no patent protections and, presumably, the absence of rights will greatly diminish the economic incentives to underwrite such research.

2. Testing Patents. Do decisions such as *Mayo* and *Ariosa* spell the end of any patent on a biological or nonbiological test, or at least the end of tests where the underlying components of the test were measureable with prior technology? Imagine that current technology can detect substances A, B, C, D and E in the human body and can measure the levels of those substances. No one, however, knows what those substances mean. Now a researcher discovers that people having elevated levels of A, B and E substances are in the early stages of Disease Z, which can be treated if detected in such early stages.

One way of looking that this discovery is that the researcher has found a highly useful method for detecting Disease Z in its early stages. (Such method comprises measuring substances A, B and E and diagnosing Disease Z where all three substances appear at elevated levels.) Under that view, the discovery should be patentable because it is a new and useful way to test for Disease Z.

Another way of looking at the discovery is that the researcher has found a new principle of nature, which is that when substances A, B and E are at elevated levels, then the person is in the early stages of Disease Z. That's an equally accurate way of describing the researcher's work, but that description means that the work is unpatentable because it is merely a new principle of nature.

Which perspective is correct? The only honest answer seems to be that both are correct, for any test relies rather directly on certain natural principles. That honest answer also shows why the judge-made "exclusionary principle" to § 101 does in fact have the ability to "eviscerate patent law" at least in some technological areas and perhaps more generally.

* * *

Chap. 2.B.2. After *Diamond v. Diehr* and the notes on that case (p. 147), insert the following new case:

Alice Corp. Pty. Ltd. v. CLS Bank International
134 S. Ct. 2347 (2014)

Justice THOMAS delivered the opinion of the Court.

The patents at issue in this case disclose a computer-implemented scheme for mitigating "settlement risk" (*i.e.,* the risk that only one party to a financial transaction will pay what it owes) by using a third-party intermediary. The question presented is whether these claims are patent eligible under 35 U.S.C. § 101, or are instead drawn to a patent-ineligible abstract idea. We hold that the claims at issue

are drawn to the abstract idea of intermediated settlement, and that merely requiring generic computer implementation fails to transform that abstract idea into a patent-eligible invention. We therefore affirm the judgment of the United States Court of Appeals for the Federal Circuit.

I

A

Petitioner Alice Corporation is the assignee of several patents that disclose schemes to manage certain forms of financial risk. [From fn: The patents at issue are United States Patent Nos. 5,970,479 (the '479 patent), 6,912,510, 7,149,720, and 7,725,375.] According to the specification largely shared by the patents, the invention "enabl[es] the management of risk relating to specified, yet unknown, future events." The specification further explains that the "invention relates to methods and apparatus, including electrical computers and data processing systems applied to financial matters and risk management." *Id.,* at 243.

The claims at issue relate to a computerized scheme for mitigating "settlement risk"—*i.e.,* the risk that only one party to an agreed-upon financial exchange will satisfy its obligation. In particular, the claims are designed to facilitate the exchange of financial obligations between two parties by using a computer system as a third-party intermediary. *Id.,* at 383–384.[1] The intermediary creates "shadow" credit and debit records (*i.e.,* account ledgers) that mirror the balances in the parties' real-world accounts at "exchange institutions" (*e.g.,* banks). The intermediary updates the shadow records in real time as transactions are entered, allowing "only those transactions for which the parties' updated shadow records indicate sufficient resources to satisfy their mutual obligations." 717 F.3d 1269, 1285 (C.A.Fed.2013) (Lourie, J., concurring). At the end of the day, the intermediary instructs the relevant

[1] The parties agree that claim 33 of the '479 patent is representative of the method claims. Claim 33 recites:

> A method of exchanging obligations as between parties, each party holding a credit record and a debit record with an exchange institution, the credit records and debit records for exchange of predetermined obligations, the method comprising the steps of:
>
> (a) creating a shadow credit record and a shadow debit record for each stakeholder party to be held independently by a supervisory institution from the exchange institutions;
>
> (b) obtaining from each exchange institution a start-of-day balance for each shadow credit record and shadow debit record;
>
> (c) for every transaction resulting in an exchange obligation, the supervisory institution adjusting each respective party's shadow credit record or shadow debit record, allowing only these transactions that do not result in the value of the shadow debit record being less than the value of the shadow credit record at any time, each said adjustment taking place in chronological order, and
>
> (d) at the end-of-day, the supervisory institution instructing on[e] of the exchange institutions to exchange credits or debits to the credit record and debit record of the respective parties in accordance with the adjustments of the said permitted transactions, the credits and debits being irrevocable, time invariant obligations placed on the exchange institutions."

financial institutions to carry out the "permitted" transactions in accordance with the updated shadow records, *ibid.,* thus mitigating the risk that only one party will perform the agreed-upon exchange.

In sum, the patents in suit claim (1) the foregoing method for exchanging obligations (the method claims), (2) a computer system configured to carry out the method for exchanging obligations (the system claims), and (3) a computer-readable medium containing program code for performing the method of exchanging obligations (the media claims). All of the claims are implemented using a computer; the system and media claims expressly recite a computer, and the parties have stipulated that the method claims require a computer as well.

B

Respondents CLS Bank International and CLS Services Ltd. (together, CLS Bank) operate a global network that facilitates currency transactions. In 2007, CLS Bank filed suit against petitioner, seeking a declaratory judgment that the claims at issue are invalid, unenforceable, or not infringed. Petitioner counterclaimed, alleging infringement. Following this Court's decision in *Bilski v. Kappos,* 561 U.S. 593 (2010), the parties filed cross-motions for summary judgment on whether the asserted claims are eligible for patent protection under 35 U.S.C. § 101. The District Court held that all of the claims are patent ineligible because they are directed to the abstract idea of "employing a neutral intermediary to facilitate simultaneous exchange of obligations in order to minimize risk." 768 F.Supp.2d 221, 252 (DC 2011).

A divided panel of the United States Court of Appeals for the Federal Circuit reversed, holding that it was not "manifestly evident" that petitioner's claims are directed to an abstract idea. 685 F.3d 1341, 1352, 1356 (2012). The Federal Circuit granted rehearing en banc, vacated the panel opinion, and affirmed the judgment of the District Court in a one-paragraph *per curiam* opinion. 717 F.3d, at 1273. Seven of the ten participating judges agreed that petitioner's method and media claims are patent ineligible. See *id.,* at 1274 (Lourie, J., concurring); *id.,* at 1312–1313 (Rader, C. J., concurring in part and dissenting in part). With respect to petitioner's system claims, the en banc Federal Circuit affirmed the District Court's judgment by an equally divided vote. *Id.,* at 1273.

Writing for a five-member plurality, Judge Lourie concluded that all of the claims at issue are patent ineligible. In the plurality's view, under this Court's decision in *Mayo Collaborative Services v. Prometheus Laboratories, Inc.,* 566 U.S. ––––– (2012), a court must first "identif[y] the abstract idea represented in the claim," and then determine "whether the balance of the claim adds 'significantly more.' " 717 F.3d, at 1286. The plurality concluded that petitioner's claims "draw on the abstract idea of reducing settlement risk by effecting trades through a third-party intermediary," and that the use of a computer to maintain, adjust, and reconcile shadow accounts added nothing of substance to that abstract idea. *Ibid.*

We granted certiorari and now affirm.

II

Section 101 of the Patent Act defines the subject matter eligible for patent protection. It provides:

> "Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title." 35 U.S.C. § 101.

"We have long held that this provision contains an important implicit exception: Laws of nature, natural phenomena, and abstract ideas are not patentable." *Association for Molecular Pathology v. Myriad Genetics, Inc.,* 569 U.S. ––––, –––– (2013) (slip op., at 11) (internal quotation marks and brackets omitted). We have interpreted § 101 and its predecessors in light of this exception for more than 150 years. *Bilski, supra,* at 601–602; see also *O'Reilly v. Morse,* 15 How. 62 (1854); *Le Roy* v*. Tatham,* 14 How. 156 (1853).

We have described the concern that drives this exclusionary principle as one of pre-emption. See, *e.g., Bilski, supra,* at 611–612 (upholding the patent "would pre-empt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea"). Laws of nature, natural phenomena, and abstract ideas are " ' "the basic tools of scientific and technological work." ' " *Myriad, supra,* at –––– (slip op., at 11). "[M]onopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it," thereby thwarting the primary object of the patent laws. *Mayo, supra,* at –––– (slip op., at 2); see U.S. Const., Art. I, § 8, cl. 8 (Congress "shall have Power ... To promote the Progress of Science and useful Arts"). We have "repeatedly emphasized this ... concern that patent law not inhibit further discovery by improperly tying up the future use of" these building blocks of human ingenuity. *Mayo, supra,* at –––– (slip op., at 16) (citing *Morse, supra,* at 113).

At the same time, we tread carefully in construing this exclusionary principle lest it swallow all of patent law. *Mayo,* 566 U.S., at –––– (slip op., at 2). At some level, "all inventions ... embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Id.,* at –––– (slip op., at 2). Thus, an invention is not rendered ineligible for patent simply because it involves an abstract concept. See *Diamond v. Diehr,* 450 U.S. 175, 187 (1981). "[A]pplication[s]" of such concepts " 'to a new and useful end,' " we have said, remain eligible for patent protection. *Gottschalk v. Benson,* 409 U.S. 63, 67 (1972).

Accordingly, in applying the § 101 exception, we must distinguish between patents that claim the " 'buildin[g] block[s]' " of human ingenuity and those that

integrate the building blocks into something more, *Mayo,* 566 U.S., at –––– (slip op., at 20), thereby "transform[ing]" them into a patent-eligible invention, *id.,* at –––– (slip op., at 3). The former "would risk disproportionately tying up the use of the underlying" ideas, *id.,* at –––– (slip op., at 4), and are therefore ineligible for patent protection. The latter pose no comparable risk of pre-emption, and therefore remain eligible for the monopoly granted under our patent laws.

III

In *Mayo Collaborative Services v. Prometheus Laboratories, Inc.,* 566 U.S. –––– (2012), we set forth a framework for distinguishing patents that claim laws of nature, natural phenomena, and abstract ideas from those that claim patent-eligible applications of those concepts. First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts. *Id.,* at –––– (slip op., at 8). If so, we then ask, "[w]hat else is there in the claims before us?" *Id.,* at –––– (slip op., at 9). To answer that question, we consider the elements of each claim both individually and "as an ordered combination" to determine whether the additional elements "transform the nature of the claim" into a patent-eligible application. *Id.,* at –––– (slip op., at 10, 9). We have described step two of this analysis as a search for an " 'inventive concept' "—*i.e.,* an element or combination of elements that is "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself." *Id.,* at –––– (slip op., at 3).

A

We must first determine whether the claims at issue are directed to a patent-ineligible concept. We conclude that they are: These claims are drawn to the abstract idea of intermediated settlement.

The "abstract ideas" category embodies "the longstanding rule that '[a]n idea of itself is not patentable.' " *Benson, supra,* at 67 (quoting *Rubber–Tip Pencil Co. v. Howard,* 20 Wall. 498, 507 (1874)); see also *Le Roy, supra,* at 175 ("A principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right"). In *Benson,* for example, this Court rejected as ineligible patent claims involving an algorithm for converting binary-coded decimal numerals into pure binary form, holding that the claimed patent was "in practical effect ... a patent on the algorithm itself." 409 U.S., at 71–72. And in *Parker v. Flook,* 437 U.S. 584, 594–595 (1978), we held that a mathematical formula for computing "alarm limits" in a catalytic conversion process was also a patent-ineligible abstract idea.

We most recently addressed the category of abstract ideas in *Bilski v. Kappos,* 561 U.S. 593 (2010). The claims at issue in *Bilski* described a method for hedging against the financial risk of price fluctuations. Claim 1 recited a series of steps for hedging risk, including: (1) initiating a series of financial transactions between providers and consumers of a commodity; (2) identifying market participants that

have a counterrisk for the same commodity; and (3) initiating a series of transactions between those market participants and the commodity provider to balance the risk position of the first series of consumer transactions. *Id.,* at 599. Claim 4 "pu[t] the concept articulated in claim 1 into a simple mathematical formula." *Ibid.* The remaining claims were drawn to examples of hedging in commodities and energy markets.

"[A]ll members of the Court agree[d]" that the patent at issue in *Bilski* claimed an "abstract idea." *Id.,* at 609; see also *id.,* at 619 (Stevens, J., concurring in judgment). Specifically, the claims described "the basic concept of hedging, or protecting against risk." *Id.,* at 611. The Court explained that " '[h]edging is a fundamental economic practice long prevalent in our system of commerce and taught in any introductory finance class.' " *Ibid.* "The concept of hedging" as recited by the claims in suit was therefore a patent-ineligible "abstract idea, just like the algorithms at issue in *Benson* and *Flook." Ibid.*

It follows from our prior cases, and *Bilski* in particular, that the claims at issue here are directed to an abstract idea. Petitioner's claims involve a method of exchanging financial obligations between two parties using a third-party intermediary to mitigate settlement risk. The intermediary creates and updates "shadow" records to reflect the value of each party's actual accounts held at "exchange institutions," thereby permitting only those transactions for which the parties have sufficient resources. At the end of each day, the intermediary issues irrevocable instructions to the exchange institutions to carry out the permitted transactions.

On their face, the claims before us are drawn to the concept of intermediated settlement, *i.e.,* the use of a third party to mitigate settlement risk. Like the risk hedging in *Bilski,* the concept of intermediated settlement is " 'a fundamental economic practice long prevalent in our system of commerce.' " *Ibid.*; see, *e.g.,* Emery, Speculation on the Stock and Produce Exchanges of the United States, in 7 Studies in History, Economics and Public Law 283, 346–356 (1896) (discussing the use of a "clearing-house" as an intermediary to reduce settlement risk). The use of a third-party intermediary (or "clearing house") is also a building block of the modern economy. See, *e.g.,* Yadav, The Problematic Case of Clearinghouses in Complex Markets, 101 Geo. L.J. 387, 406–412 (2013); J. Hull, Risk Management and Financial Institutions 103–104 (3d ed.2012). Thus, intermediated settlement, like hedging, is an "abstract idea" beyond the scope of § 101.

Petitioner acknowledges that its claims describe intermediated settlement, see Brief for Petitioner 4, but rejects the conclusion that its claims recite an "abstract idea." Drawing on the presence of mathematical formulas in some of our abstract-ideas precedents, petitioner contends that the abstract-ideas category is confined to "preexisting, fundamental truth[s]" that " 'exis[t] in principle apart from any human action.' " *Id.,* at 23, 26 (quoting *Mayo,* 566 U.S., at –––– (slip op., at 8)).

Bilski belies petitioner's assertion. The concept of risk hedging we identified as an abstract idea in that case cannot be described as a "preexisting, fundamental truth." The patent in *Bilski* simply involved a "series of steps instructing how to hedge risk." 561 U.S., at 599. Although hedging is a longstanding commercial practice, *id.,* at 599, it is a method of organizing human activity, not a "truth" about the natural world " 'that has always existed,' " Brief for Petitioner 22 (quoting *Flook, supra,* at 593, n. 15). One of the claims in *Bilski* reduced hedging to a mathematical formula, but the Court did not assign any special significance to that fact, much less the sort of talismanic significance petitioner claims. Instead, the Court grounded its conclusion that all of the claims at issue were abstract ideas in the understanding that risk hedging was a " 'fundamental economic practice.' " 561 U.S., at 611.

In any event, we need not labor to delimit the precise contours of the "abstract ideas" category in this case. It is enough to recognize that there is no meaningful distinction between the concept of risk hedging in *Bilski* and the concept of intermediated settlement at issue here. Both are squarely within the realm of "abstract ideas" as we have used that term.

B

Because the claims at issue are directed to the abstract idea of intermediated settlement, we turn to the second step in *Mayo* 's framework. We conclude that the method claims, which merely require generic computer implementation, fail to transform that abstract idea into a patent-eligible invention.

1

At *Mayo* step two, we must examine the elements of the claim to determine whether it contains an " 'inventive concept' " sufficient to "transform" the claimed abstract idea into a patent-eligible application. 566 U.S., at ––––, –––– (slip op., at 3, 11). A claim that recites an abstract idea must include "additional features" to ensure "that the [claim] is more than a drafting effort designed to monopolize the [abstract idea]." *Id.,* at –––– (slip op., at 8–9). *Mayo* made clear that transformation into a patent-eligible application requires "more than simply stat[ing] the [abstract idea] while adding the words 'apply it.' " *Id.,* at –––– (slip op., at 3).

Mayo itself is instructive. The patents at issue in *Mayo* claimed a method for measuring metabolites in the bloodstream in order to calibrate the appropriate dosage of thiopurine drugs in the treatment of autoimmune diseases. *Id.,* at –––– (slip op., at 4–6). The respondent in that case contended that the claimed method was a patent-eligible application of natural laws that describe the relationship between the concentration of certain metabolites and the likelihood that the drug dosage will be harmful or ineffective. But methods for determining metabolite levels were already "well known in the art," and the process at issue amounted to "nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients." *Id.,* at –––– (slip op., at 10). "Simply appending conventional steps, specified at a high level of generality," was not "*enough* " to supply an "

'inventive concept.' " *Id.,* at ––––, ––––, –––– (slip op., at 14, 8, 3).

The introduction of a computer into the claims does not alter the analysis at *Mayo* step two. In *Benson,* for example, we considered a patent that claimed an algorithm implemented on "a general-purpose digital computer." 409 U.S., at 64. Because the algorithm was an abstract idea, see *supra,* at 8, the claim had to supply a " 'new and useful' " application of the idea in order to be patent eligible. 409 U.S., at 67. But the computer implementation did not supply the necessary inventive concept; the process could be "carried out in existing computers long in use." *Ibid.* We accordingly "held that simply implementing a mathematical principle on a physical machine, namely a computer, [i]s not a patentable application of that principle." *Mayo, supra,* at –––– (slip op., at 16) (citing *Benson, supra,* at 64).

Flook is to the same effect. There, we examined a computerized method for using a mathematical formula to adjust alarm limits for certain operating conditions (*e.g.,* temperature and pressure) that could signal inefficiency or danger in a catalytic conversion process. 437 U.S., at 585–586. Once again, the formula itself was an abstract idea, see *supra,* at 8, and the computer implementation was purely conventional. 437 U.S., at 594 (noting that the "use of computers for 'automatic monitoring-alarming' " was "well known"). In holding that the process was patent ineligible, we rejected the argument that "implement[ing] a principle in some specific fashion" will "automatically fal[l] within the patentable subject matter of § 101." *Id.,* at 593. Thus, "*Flook* stands for the proposition that the prohibition against patenting abstract ideas cannot be circumvented by attempting to limit the use of [the idea] to a particular technological environment." *Bilski,* 561 U.S., at 610–611 (internal quotation marks omitted).

In *Diehr,* 450 U.S. 175, by contrast, we held that a computer-implemented process for curing rubber was patent eligible, but not because it involved a computer. The claim employed a "well-known" mathematical equation, but it used that equation in a process designed to solve a technological problem in "conventional industry practice." *Id.,* at 177, 178. The invention in *Diehr* used a "thermocouple" to record constant temperature measurements inside the rubber mold—something "the industry ha[d] not been able to obtain." *Id.,* at 178, and n. 3. The temperature measurements were then fed into a computer, which repeatedly recalculated the remaining cure time by using the mathematical equation. *Id.,* at 178–179. These additional steps, we recently explained, "transformed the process into an inventive application of the formula." *Mayo, supra,* at –––– (slip op., at 12). In other words, the claims in *Diehr* were patent eligible because they improved an existing technological process, not because they were implemented on a computer.

These cases demonstrate that the mere recitation of a generic computer cannot transform a patent-ineligible abstract idea into a patent-eligible invention. Stating an abstract idea "while adding the words 'apply it' " is not enough for patent eligibility. *Mayo, supra,* at –––– (slip op., at 3). Nor is limiting the use of an abstract idea " 'to a particular technological environment.' " *Bilski, supra,* at 610–611. Stating

an abstract idea while adding the words "apply it with a computer" simply combines those two steps, with the same deficient result. Thus, if a patent's recitation of a computer amounts to a mere instruction to "implemen[t]" an abstract idea "on ... a computer," *Mayo, supra,* at ––– (slip op., at 16), that addition cannot impart patent eligibility. This conclusion accords with the pre-emption concern that undergirds our § 101 jurisprudence. Given the ubiquity of computers, see 717 F.3d, at 1286 (Lourie, J., concurring), wholly generic computer implementation is not generally the sort of "additional featur[e]" that provides any "practical assurance that the process is more than a drafting effort designed to monopolize the [abstract idea] itself." *Mayo,* 566 U.S., at ––– (slip op., at 8–9).

The fact that a computer "necessarily exist[s] in the physical, rather than purely conceptual, realm," Brief for Petitioner 39, is beside the point. There is no dispute that a computer is a tangible system (in § 101 terms, a "machine"), or that many computer-implemented claims are formally addressed to patent-eligible subject matter. But if that were the end of the § 101 inquiry, an applicant could claim any principle of the physical or social sciences by reciting a computer system configured to implement the relevant concept. Such a result would make the determination of patent eligibility "depend simply on the draftsman's art," *Flook, supra,* at 593, thereby eviscerating the rule that " '[l]aws of nature, natural phenomena, and abstract ideas are not patentable,' " *Myriad,* 569 U.S., at ––– (slip op., at 11).

2

The representative method claim in this case recites the following steps: (1) "creating" shadow records for each counterparty to a transaction; (2) "obtaining" start-of-day balances based on the parties' real-world accounts at exchange institutions; (3) "adjusting" the shadow records as transactions are entered, allowing only those transactions for which the parties have sufficient resources; and (4) issuing irrevocable end-of-day instructions to the exchange institutions to carry out the permitted transactions. See n. 2, *supra*. Petitioner principally contends that the claims are patent eligible because these steps "require a substantial and meaningful role for the computer." Brief for Petitioner 48. As stipulated, the claimed method requires the use of a computer to create electronic records, track multiple transactions, and issue simultaneous instructions; in other words, "[t]he computer is itself the intermediary." *Ibid.* (emphasis deleted).

In light of the foregoing, see *supra,* at 11–14, the relevant question is whether the claims here do more than simply instruct the practitioner to implement the abstract idea of intermediated settlement on a generic computer. They do not.

Taking the claim elements separately, the function performed by the computer at each step of the process is "[p]urely conventional." *Mayo, supra,* at ––– (slip op., at 10) (internal quotation marks omitted). Using a computer to create and maintain "shadow" accounts amounts to electronic recordkeeping—one of the most basic functions of a computer. See, *e.g., Benson,* 409 U.S., at 65 (noting that a computer

"operates ... upon both new and previously stored data"). The same is true with respect to the use of a computer to obtain data, adjust account balances, and issue automated instructions; all of these computer functions are "well-understood, routine, conventional activit[ies]" previously known to the industry. *Mayo,* 566 U.S., at –––– (slip op., at 4). In short, each step does no more than require a generic computer to perform generic computer functions.

Considered "as an ordered combination," the computer components of petitioner's method "ad[d] nothing ... that is not already present when the steps are considered separately." *Id.,* at –––– (slip op., at 10). Viewed as a whole, petitioner's method claims simply recite the concept of intermediated settlement as performed by a generic computer. See 717 F.3d, at 1286 (Lourie, J., concurring) (noting that the representative method claim "lacks *any* express language to define the computer's participation"). The method claims do not, for example, purport to improve the functioning of the computer itself. See *ibid.* ("There is no specific or limiting recitation of ... improved computer technology ..."); Brief for United States as *Amicus Curiae* 28–30. Nor do they effect an improvement in any other technology or technical field. See, *e.g., Diehr,* 450 U.S., at 177–178. Instead, the claims at issue amount to "nothing significantly more" than an instruction to apply the abstract idea of intermediated settlement using some unspecified, generic computer. *Mayo,* 566 U.S., at –––– (slip op., at 10). Under our precedents, that is not "*enough* " to transform an abstract idea into a patent-eligible invention. *Id.,* at –––– (slip op., at 8).

C

Petitioner's claims to a computer system and a computer-readable medium fail for substantially the same reasons. Petitioner conceded below that its media claims rise or fall with its method claims. En Banc Response Brief for Defendant–Appellant in No. 11–1301 (CA Fed.) p. 50, n. 3. As to its system claims, petitioner emphasizes that those claims recite "specific hardware" configured to perform "specific computerized functions." Brief for Petitioner 53. But what petitioner characterizes as specific hardware—a "data processing system" with a "communications controller" and "data storage unit," for example — is purely functional and generic. Nearly every computer will include a "communications controller" and "data storage unit" capable of performing the basic calculation, storage, and transmission functions required by the method claims. See 717 F.3d, at 1290 (Lourie, J., concurring). As a result, none of the hardware recited by the system claims "offers a meaningful limitation beyond generally linking 'the use of the [method] to a particular technological environment,' that is, implementation via computers." *Id.,* at 1291 (quoting *Bilski,* 561 U.S., at 610–611).

Put another way, the system claims are no different from the method claims in substance. The method claims recite the abstract idea implemented on a generic computer; the system claims recite a handful of generic computer components configured to implement the same idea. This Court has long "warn[ed] ... against" interpreting § 101 "in ways that make patent eligibility 'depend simply on the

draftsman's art.' " *Mayo, supra,* at ––––– (slip op., at 3) (quoting *Flook,* 437 U.S., at 593); see *id.,* at 590 *("*The concept of patentable subject matter under § 101 is not 'like a nose of wax which may be turned and twisted in any direction ...' *"*). Holding that the system claims are patent eligible would have exactly that result.

Because petitioner's system and media claims add nothing of substance to the underlying abstract idea, we hold that they too are patent ineligible under § 101.

* * *

For the foregoing reasons, the judgment of the Court of Appeals for the Federal Circuit is affirmed.

It is so ordered.

Justice SOTOMAYOR, with whom Justice GINSBURG and Justice BREYER join, concurring.

I adhere to the view that any "claim that merely describes a method of doing business does not qualify as a 'process' under § 101." *Bilski v. Kappos,* 561 U.S. 593, 614 (2010) (Stevens, J., concurring in judgment); see also *In re Bilski,* 545 F.3d 943, 972 (C.A.Fed.2008) (Dyk, J., concurring) ("There is no suggestion in any of th[e] early [English] consideration of process patents that processes for organizing human activity were or ever had been patentable"). As in *Bilski,* however, I further believe that the method claims at issue are drawn to an abstract idea. Cf. 561 U.S., at 619 (opinion of Stevens, J.). I therefore join the opinion of the Court.

NOTES AND COMMENTS ON *ALICE*

1. The Patentable Subject Matter Two-Step. The case applies the two-step "framework" first enunciated in *Mayo v. Prometheus* to patent claims involving "abstract ideas" (as opposed to natural phenomena and laws of nature, the other prohibited § 101 categories). First, the claimed invention is examined to see if it is an abstract idea. If so, then courts move on to the second step: an examination of whether the claim adds new, non-generic, unconventional material to the abstract idea in a way that transforms the claim into an application of an abstract idea rather than a pure idea. Do you think the framework works equally well for natural product cases and abstract idea cases?

2. The Scope of Preemption. The primary rationale for the decision, which harkens back to *Mayo* as well as *Bilski v. Kappos*, is stated in terms of "preemption":

> [I]n applying the § 101 exception, we must distinguish between patents that claim the " 'buildin[g] block[s]' " of human ingenuity and those that integrate the building blocks into something more, Mayo, 566 U.S., at —— (slip op., at 20),

> thereby "transform[ing]" them into a patent-eligible invention, id., at —— (slip op., at 3). The former "would risk disproportionately tying up the use of the underlying" ideas, id., at —— (slip op., at 4), and are therefore ineligible for patent protection. The latter pose no comparable risk of pre-emption, and therefore remain eligible for the monopoly granted under our patent laws.

The patent claims in *Bilski* and *Alice* might well cover concepts broad enough to be considered "building blocks." What about a narrow patent whose claims cover something simple like a pop-up calendar for picking dates, or a mobile phone display that allows users to easily rearrange applications by moving their icons with the touch of a finger? Are these broad building blocks? If not, does that mean they are not "abstract ideas"? Does the preemption rationale provide a way to differentiate unpatentable claims from those that are patentable? Or do toy interpret the "building blocks" statement to mean that abstract ideas are simply declared to be building blocks, and hence unpatentable? There is support for this reading in *Mayo v. Prometheus* where the Court says that even a narrow law of nature, one that not does not preempt a wide field, cannot be the sibject of a valid patent claim. Under this view, what is left of software patents unde the Patent Act?

3. Conventionality. The second step of the *Mayo-Bilski-Alice* framework asks whether an inventor has added anything unconventional and non-generic to an abstract idea. Some of the claims at issue in *Alice* – the "system" and computer media claims – did include what might be called nominal computer hardware limitations. But the Court found that these were not enough to transform the abstract concept of the claims into a patentable invention. Under this second step, what would be required to make the claim patentable? A new type of hardware, such as perhaps a new type of computer chip designed specifically to optimize financial transactions? How about a new way to make sure that bank account data was up to date – such as a program that monitored bank account overdraft indicators? If both a new chip and a new monitoring program were innovative (non-conventional and non-generic) is there any reason to permit a patent on the former (new chip) and not the latter (new monitoring program)?

Chap. 2.B.3.b:

On pp. 152-182 of the case book, replace the *Parke-Davis* and lower court version of the *Myriad* case with the Supreme Court decision in that case and the Federal Circuit case *In re Roslin Institute*, which holds artificial clones unpatentable:

Association for Molecular Pathology, Inc. v. Myriad Genetics, Inc.
133 S.Ct. 2107 (2013)

Justice THOMAS delivered the opinion of the Court

Respondent Myriad Genetics, Inc. (Myriad), discovered the precise location and sequence of two human genes, mutations of which can substantially increase the risks of breast and ovarian cancer. Myriad obtained a number of patents based upon its discovery. This case involves claims from three of them and requires us to resolve whether a naturally occurring segment of deoxyribonucleic acid (DNA) is patent eligible under 35 U.S.C. § 101 by virtue of its isolation from the rest of the human genome. We also address the patent eligibility of synthetically created DNA known as complementary DNA (cDNA), which contains the same protein-coding information found in a segment of natural DNA but omits portions within the DNA segment that do not code for proteins. For the reasons that follow, we hold that a naturally occurring DNA segment is a product of nature and not patent eligible merely because it has been isolated, but that cDNA is patent eligible because it is not naturally occurring. We, therefore, affirm in part and reverse in part the decision of the United States Court of Appeals for the Federal Circuit.

I
A

Genes form the basis for hereditary traits in living organisms. The human genome consists of approximately 22,000 genes packed into 23 pairs of chromosomes. Each gene is encoded as DNA, which takes the shape of the familiar "double helix" that Doctors James Watson and Francis Crick first described in 1953. Each "cross-bar" in the DNA helix consists of two chemically joined nucleotides. The possible nucleo-tides are adenine (A), thymine (T), cytosine (C), and guanine (G), each of which binds naturally with another nucleotide: A pairs with T; C pairs with G. The nucleotide cross-bars are chemically connected to a sugar-phosphate backbone that forms the outside framework of the DNA helix. Sequences of DNA nucleotides contain the information necessary to create strings of amino acids, which in turn are used in the body to build proteins. Only some DNA nucleotides, however, code for amino acids; these nucleotides are known as "exons." Nucleotides that do not code for amino acids, in contrast, are known as "introns."

Creation of proteins from DNA involves two principal steps, known as transcription and translation. In transcription, the bonds between DNA nucleotides separate, and the DNA helix unwinds into two single strands. A single strand is used

as a template to create a complementary ribonucleic acid (RNA) strand. The nucleotides on the DNA strand pair naturally with their counterparts, with the exception that RNA uses the nucleotide base uracil (U) instead of thymine (T). Transcription results in a single strand RNA molecule, known as pre-RNA, whose nucleo-tides form an inverse image of the DNA strand from which it was created. Pre–RNA still con-tains nucleotides corresponding to both the exons and introns in the DNA molecule. The pre-RNA is then naturally "spliced" by the physical removal of the introns. The resulting product is a strand of RNA that contains nucleotides corresponding only to the exons from the original DNA strand. The exons-only strand is known as messenger RNA (mRNA), which creates amino acids through translation. In translation, cellular structures known as ribosomes read each set of three nucleotides, known as codons, in the mRNA. Each codon either tells the ribosomes which of the 20 possible amino acids to synthesize or provides a stop signal that ends amino acid production.

DNA's informational sequences and the processes that create mRNA, amino acids, and proteins occur naturally within cells. Scientists can, however, extract DNA from cells using well known laboratory methods. These methods allow scientists to isolate specific segments of DNA—for instance, a particular gene or part of a gene—which can then be further studied, manipulated, or used. It is also possible to create DNA synthetically through processes similarly well known in the field of genetics. One such method begins with an mRNA molecule and uses the natural bonding properties of nucleotides to create a new, synthetic DNA molecule. The re-sult is the inverse of the mRNA's inverse image of the original DNA, with one important distinc-tion: Because the natural creation of mRNA involves splicing that removes introns, the synthetic DNA created from mRNA also contains only the exon sequences. This synthetic DNA created in the laboratory from mRNA is known as complementary DNA (cDNA).

Changes in the genetic sequence are called mutations. Mutations can be as small as the alteration of a single nucleotide—a change affecting only one letter in the genetic code. Such small-scale changes can produce an entirely different amino acid or can end protein production altogether. Large changes, involving the deletion, rearrangement, or duplication of hundreds or even millions of nucleotides, can result in the elimination, misplacement, or duplication of entire genes. Some mutations are harmless, but others can cause disease or increase the risk of disease. As a result, the study of genetics can lead to valuable medical breakthroughs.

B

This case involves patents filed by Myriad after it made one such medical breakthrough. Myriad discovered the precise location and sequence of what are now known as the BRCA1 and BRCA2 genes. Mutations in these genes can dramatically increase an individual's risk of developing breast and ovarian cancer. The average American woman has a 12– to 13–percent risk of developing breast cancer, but for women with certain genetic mutations, the risk can range between 50 and 80

percent for breast cancer and between 20 and 50 percent for ovarian cancer. Before Myriad's discovery of the BRCA1 and BRCA2 genes, scientists knew that heredity played a role in establishing a woman's risk of developing breast and ovarian cancer, but they did not know which genes were associated with those cancers.

Myriad identified the exact location of the BRCA1 and BRCA2 genes on chromosomes 17 and 13. Chromosome 17 has approximately 80 million nucleotides, and chromosome 13 has approximately 114 million. Association for Molecular Pathology v. United States Patent and Trademark Office, 689 F.3d 1303, 1328 (C.A. Fed. 2012). Within those chromosomes, the BRCA1 and BRCA2 genes are each about 80,000 nucleotides long. If just exons are counted, the BRCA1 gene is only about 5,500 nucleotides long; for the BRCA2 gene, that number is about 10,200. Ibid. Knowledge of the location of the BRCA1 and BRCA2 genes allowed Myriad to determine their typical nucleotide sequence. That information, in turn, enabled Myriad to develop medical tests that are useful for detecting mutations in a patient's BRCA1 and BRCA2 genes and thereby assessing whether the patient has an increased risk of cancer.

Once it found the location and sequence of the BRCA1 and BRCA2 genes, Myriad sought and obtained a number of patents. Nine composition claims from three of those patents are at is-sue in this case. [From Fn. 2: At issue are claims 1, 2, 5, 6, and 7 of U.S. Patent 5,747,282 (the '282 patent), claim 1 of U.S. Patent 5,693,473 (the '473 patent), and claims 1, 6, and 7 of U.S. Patent 5,837,492 (the '492 patent).] See id., at 1309, and n. 1 (noting composition claims). Claims 1, 2, 5, and 6 from the '282 patent are representative. The first claim asserts a patent on "[a]n isolated DNA coding for a BRCA1 polypeptide," which has "the amino acid sequence set forth in SEQ ID NO:2." App. 822. SEQ ID NO:2 sets forth a list of 1,863 amino acids that the typical BRCA1 gene encodes. See id., at 785–790. Put differently, claim 1 asserts a patent claim on the DNA code that tells a cell to produce the string of BRCA1 amino acids listed in SEQ ID NO:2.

Claim 2 of the '282 patent operates similarly. It claims "[t]he isolated DNA of claim 1, wherein said DNA has the nucleotide sequence set forth in SEQ ID NO:1." Id., at 822. Like SEQ ID NO:2, SEQ ID NO:1 sets forth a long list of data, in this instance the sequence of cDNA that codes for the BRCA1 amino acids listed in claim 1. Importantly, SEQ ID NO:1 lists only the cDNA exons in the BRCA1 gene, rather than a full DNA sequence containing both exons and introns. See id., at 779 (stating that SEQ ID NO:1's "MOLECULE TYPE:" is "cDNA"). As a result, the Federal Circuit recognized that claim 2 asserts a patent on the cDNA nucleotide sequence listed in SEQ ID NO:1, which codes for the typical BRCA1 gene.

Claim 5 of the '282 patent claims a subset of the data in claim 1. In particular, it claims "[a]n isolated DNA having at least 15 nucleotides of the DNA of claim 1." App. 822. The practical effect of claim 5 is to assert a patent on any series of 15 nucleotides that exist in the typical BRCA1 gene. Because the BRCA1 gene is

thousands of nucleotides long, even BRCA1 genes with substantial mutations are likely to contain at least one segment of 15 nucleotides that corre-spond to the typical BRCA1 gene. Similarly, claim 6 of the '282 patent claims "[a]n isolated DNA having at least 15 nucleotides of the DNA of claim 2." Ibid. This claim operates similarly to claim 5, except that it references the cDNA-based claim 2. The remaining claims at issue are similar, though several list common mutations rather than typical BRCA1 and BRCA2 se-quences. See ibid. (claim 7 of the '282 patent); id., at 930 (claim 1 of the '473 patent); id., at 1028 (claims 1, 6, and 7 of the '492 patent).

C

Myriad's patents would, if valid, give it the exclusive right to isolate an individual's BRCA1 and BRCA2 genes (or any strand of 15 or more nucleotides within the genes) by breaking the covalent bonds that connect the DNA to the rest of the individual's genome. The patents would also give Myriad the exclusive right to synthetically create BRCA cDNA.

But isolation is necessary to conduct genetic testing, and Myriad was not the only entity to offer BRCA testing after it discovered the genes. The University of Pennsylvania's Genetic Diagnostic Laboratory (GDL) and others provided genetic testing services to women. Petitioner Dr. Harry Ostrer, then a researcher at New York University School of Medicine, routinely sent his patients' DNA samples to GDL for testing. After learning of GDL's testing and Ostrer's activities, Myriad sent letters to them asserting that the genetic testing infringed Myriad's patents. App. 94–95 (Ostrer letter). In response, GDL agreed to stop testing and informed Ostrer that it would no longer accept patient samples. Myriad also filed patent infringement suits against other entities that performed BRCA testing, resulting in settlements in which the defendants agreed to cease all allegedly infringing activity. 689 F.3d, at 1315. Myriad, thus, solidified its position as the only entity providing BRCA testing.

Some years later, petitioner Ostrer, along with medical patients, advocacy groups, and other doctors, filed this lawsuit seeking a declaration that Myriad's patents are invalid under 35 U.S.C. § 101. The District Court . . . granted summary judgment to petitioners on the composition claims at issue in this case based on its conclusion that Myriad's claims, including claims related to cDNA, were invalid be-cause they covered products of nature. The Federal Circuit reversed, and this Court granted the petition for certiorari, vacated the judgment, and remanded the case in light of Mayo Collaborative Services v. Prometheus Laboratories, Inc., 566 U.S. ––––– (2012).

On remand, the Federal Circuit affirmed the District Court in part and reversed in part, with each member of the panel writing separately.

[In three separate opinions,] the court held that both isolated DNA and cDNA were patent eligible under § 101. The central dispute among the panel members was whether the act of *isolating* DNA—separating a specific gene or sequence of

nucleotides from the rest of the chromo-some—is an inventive act that entitles the individual who first isolates it to a patent. Each of the judges on the panel had a different view on that question. Judges Lourie and Moore agreed that Myriad's claims were patent eligible under § 101 but disagreed on the rationale. Judge Lourie relied on the fact that the entire DNA molecule is held together by chemical bonds and that the covalent bonds at both ends of the segment must be severed in order to isolate segments of DNA. This process technically creates new molecules with unique chemical compositions. Judge Lourie found this chemical alteration to be dispositive, because isolating a particular strand of DNA creates a nonnaturally occurring molecule, even though the chemical alteration does not change the information-transmitting quality of the DNA.

Judge Moore concurred in part but did not rely exclusively on Judge Lourie's conclusion that chemically breaking covalent bonds was sufficient to render isolated DNA patent eligible. Instead, Judge Moore also relied on the United States Patent and Trademark Office's (PTO) practice of granting such patents and on the reliance interests of patent holders. Id., at 1343. However, she acknowledged that her vote might have come out differently if she "were deciding this case on a blank canvas." Ibid.

Finally, Judge Bryson concurred in part and dissented in part, concluding that isolated DNA is not patent eligible. As an initial matter, he emphasized that the breaking of chemical bonds was not dispositive: "[T]here is no magic to a chemical bond that requires us to recognize a new product when a chemical bond is created or broken." Id., at 1351. Instead, he relied on the fact that "[t]he nucleotide sequences of the claimed molecules are the same as the nucleotide sequences found in naturally occurring human genes." Id., at 1355. Judge Bryson then concluded that genetic "structural similarity dwarfs the significance of the structural differences between isolated DNA and naturally occurring DNA, especially where the structural differences are merely ancillary to the breaking of covalent bonds, a process that is itself not inventive." Ibid.

Although the judges expressed different views concerning the patentability of isolated DNA, all three agreed that patent claims relating to cDNA met the patent eligibility requirements of § 101.

II

A

Section 101 of the Patent Act provides:

> "Whoever invents or discovers any new and useful ... composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title."

35 U.S.C. § 101.

We have "long held that this provision contains an important implicit exception[:] Laws of nature, natural phenomena, and abstract ideas are not patentable." Mayo, 566 U.S., at ––– (slip op., at 1). Rather, " 'they are the basic tools of scientific and technological work' " that lie beyond the domain of patent protection. Id., at ––– (slip op., at 2). As the Court has explained, without this exception, there would be considerable danger that the grant of patents would "tie up" the use of such tools and thereby "inhibit future innovation premised upon them." Id., at ––– (slip op., at 17). This would be at odds with the very point of patents, which exist to promote creation.

The rule against patents on naturally occurring things is not without limits, however, for "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas," and "too broad an interpretation of this exclusionary principle could eviscerate patent law." 566 U.S., at ––– (slip op., at 2). As we have recognized before, patent protection strikes a delicate balance between creating "incentives that lead to creation, invention, and discovery" and "imped[ing] the flow of information that might permit, indeed spur, invention." Id., at ––– (slip op., at 23). We must apply this well-established standard to deter-mine whether Myriad's patents claim any "new and useful ... composition of matter," § 101, or instead claim naturally occurring phenomena.

B

It is undisputed that Myriad did not create or alter any of the genetic information encoded in the BRCA1 and BRCA2 genes. The location and order of the nucleotides existed in nature before Myriad found them. Nor did Myriad create or alter the genetic structure of DNA. Instead, Myriad's principal contribution was uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes within chromosomes 17 and 13. The question is whether this renders the genes patentable.

Myriad recognizes that our decision in [*Diamond v.*] *Chakrabarty*, 447 U.S. 303 (1980)] is central to this inquiry. In *Chakrabarty*, scientists added four plasmids to a bacterium, which enabled it to break down various components of crude oil. 447 U.S., at 305, and n. 1. The Court held that the modified bacterium was patentable. The Chakrabarty bacterium was new "with markedly different characteristics from any found in nature," 447 U.S., at 310, due to the additional plasmids and resultant "capacity for degrading oil." Id., at 305, n. 1. In this case, by contrast, Myriad did not create anything. To be sure, it found an important and useful gene, but separating that gene from its surrounding genetic material is not an act of invention.

Groundbreaking, innovative, or even brilliant discovery does not by itself satisfy the § 101 inquiry. In Funk Brothers Seed Co. v. Kalo Inoculant Co., 333 U.S. 127 (1948), this Court considered a composition patent that claimed a mixture of naturally occurring strains of bacteria that helped leguminous plants take nitrogen

from the air and fix it in the soil. Id., at 128–129. The Court held that the composition was not patent eligible because the patent holder did not alter the bacteria in any way. Id., at 132. His patent claim thus fell squarely within the law of nature exception. So do Myriad's. Myriad found the location of the BRCA1 and BRCA2 genes, but that discovery, by itself, does not render the BRCA genes "new ... composition[s] of matter," § 101, that are patent eligible.

Indeed, Myriad's patent descriptions highlight the problem with its claims. For example, a section of the '282 patent's Detailed Description of the Invention indicates that Myriad found the location of a gene associated with increased risk of breast cancer and identified mutations of that gene that increase the risk. In subsequent language Myriad explains that the location of the gene was unknown until Myriad found it among the approximately eight million nucleotide pairs contained in a subpart of chromosome 17. Many of Myriad's patent descriptions simply detail the "iterative process" of discovery by which Myriad narrowed the possible locations for the gene sequences that it sought. See, e.g., id., at 750. Myriad seeks to import these extensive research efforts into the § 101 patent-eligibility inquiry. But extensive effort alone is insufficient to satisfy the demands of § 101.

Nor are Myriad's claims saved by the fact that isolating DNA from the human genome severs chemical bonds and thereby creates a nonnaturally occurring molecule. Myriad's claims are simply not expressed in terms of chemical composition, nor do they rely in any way on the chemical changes that result from the isolation of a particular section of DNA. Instead, the claims understandably focus on the genetic information encoded in the BRCA1 and BRCA2 genes. If the patents depended upon the creation of a unique molecule, then a would-be infringer could arguably avoid at least Myriad's patent claims on entire genes (such as claims 1 and 2 of the '282 patent) by isolating a DNA sequence that included both the BRCA1 or BRCA2 gene and one additional nucleotide pair. Such a molecule would not be chemically identical to the molecule "invented" by Myriad. But Myriad obviously would resist that outcome because its claim is concerned primarily with the information contained in the genetic sequence, not with the specific chemical composition of a particular molecule.

Finally, Myriad argues that the PTO's past practice of awarding gene patents is entitled to deference, citing J.E.M. Ag Supply, Inc. v. Pioneer Hi–Bred Int'l, Inc., 534 U.S. 124 (2001). We disagree. Congress has not endorsed the views of the PTO in subsequent legislation.

Further undercutting the PTO's practice, the United States argued in the Federal Circuit and in this Court that isolated DNA was not patent eligible under § 101, Brief for United States as Amicus Curiae 20–33, and that the PTO's practice was not "a sufficient reason to hold that isolated DNA is patent-eligible." Id., at 26. See also id., at 28–29. These concessions weigh against deferring to the PTO's determination.

C

cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA segments. As already explained, creation of a cDNA sequence from mRNA results in an exons-only molecule that is not naturally occurring.FN8 Petitioners concede that cDNA differs from natural DNA in that "the non-coding regions have been removed." They nevertheless argue that cDNA is not patent eligible because "[t]he nucleotide sequence of cDNA is dictated by nature, not by the lab technician." That may be so, but the lab technician unquestionably creates something new when cDNA is made. cDNA retains the natu-rally occurring exons of DNA, but it is distinct from the DNA from which it was derived. As a result, cDNA is not a "product of nature" and is patent eligible under § 101, except insofar as very short series of DNA may have no intervening introns to remove when creating cDNA. In that situation, a short strand of cDNA may be indistinguishable from natural DNA.

III

It is important to note what is not implicated by this decision. First, there are no method claims before this Court. Had Myriad created an innovative method of manipulating genes while searching for the BRCA1 and BRCA2 genes, it could possibly have sought a method patent. But the processes used by Myriad to isolate DNA were well understood by geneticists at the time of Myriad's patents [and so method claims were not available].

Similarly, this case does not involve patents on new applications of knowledge about the BRCA1 and BRCA2 genes. Judge Bryson aptly noted that, "[a]s the first party with knowledge of the [BRCA1 and BRCA2] sequences, Myriad was in an excellent position to claim applications of that knowledge. Many of its unchallenged claims are limited to such applications." 689 F.3d, at 1349.

Nor do we consider the patentability of DNA in which the order of the naturally occurring nucleotides has been altered. Scientific alteration of the genetic code presents a different inquiry, and we express no opinion about the application of § 101 to such endeavors. We merely hold that genes and the information they encode are not patent eligible under § 101 simply because they have been isolated from the surrounding genetic material.

NOTES AND COMMENTS ON *MYRIAD*

1. Standing Issues. There were questions concerning standing in this case, but the Court resolved them under the 2007 *MedImmune* decision. From note 3:

> Myriad continues to challenge Dr. Ostrer's Declaratory Judgment Act standing in this Court. Brief for Respondents 17–22. But we find that, under the Court's decision in MedImmune, Inc. v. Genentech, Inc., Dr. Ostrer has alleged sufficient

> facts "under all the circumstances, [to] show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." 549 U.S. 118, 127 (2007) (internal quotation marks omitted).

2. The Limits of Judicial Scientific Knowledge. Justice Scalia concurred in part, and concurred in the judgment. Here is the entirety of his opinion:

> I join the judgment of the Court, and all of its opinion except Part I–A and some portions of the rest of the opinion going into fine details of molecular biology. I am unable to affirm those details on my own knowledge or even my own belief. It suffices for me to affirm, having studied the opinions below and the expert briefs presented here, that the portion of DNA isolated from its natural state sought to be patented is identical to that portion of the DNA in its natural state; and that complementary DNA (cDNA) is a synthetic creation not normally present in nature.

What do you make of this? Is Justice Scalia concerned that his colleagues on the Court have entwined patent law with technical details that he, and presumably other judges, may find difficult to understand? Is he expressing concern that the Supreme Court is verging on territory beyond its expertise in deciding this case?

3. Farewell to Reliance Interests? An omitted footnote in the case reads as follows:

> Myriad also argues that we should uphold its patents so as not to disturb the reliance interests of patent holders like itself. Brief for Respondents 38–39. Concerns about reliance interests arising from PTO determinations, insofar as they are relevant, are better directed to Congress.

Does this mean the Supreme Court should never take into account reliance interests of various parties? Note that the Court says the reliance interests here "aris[e] from PTO determinations" – and not, presumably, earlier opinions from the Supreme Court itself. Is it accurate to imply that the Supreme Court had never even indirectly condoned DNA patent claims? What about *Chakrabarty*? What about the many times the Court denied cert in earlier cases centering on § 101 challenges to gene patents?

4. Claiming Strategies? The Court makes much of the distinction between a claim to DNA as a chemical entity, a molecule, and a claim to the informational content of the DNA. The former, it implies, is patentable, partly because it is presumably a more limited claim. The latter, meanwhile, is not, because it is already present in nature and (the Court believes) it is also inherently broader. For example, the Court says "[Myriad's] claim is concerned primarily with the information contained in the genetic sequence, not with the specific chemical composition of a particular molecule." Can you come up with some drafting strategies that take advantage of this distinction? Is it always true that a "specific chemical composition"

claim is narrower than a claim that encompasses "information contained" in a genetic sequence? Does the Court imply that a very broad claim drafted in molecular terms – e.g., a "Markush group" for DNA molecules – would also be invalid under § 101? Is it the nature of the claim that is the problem from the Court's perspective – chemical versus informational – or instead the breadth of the claim? If breadth is the problem, what is the difference between the "meta-scope" focus of § 101 and the traditional scope-limiting doctrines of § 112?

* * *

In re Roslin Institute
750 F.3d 1333 (2014)

DYK, Circuit Judge.

The Roslin Institute of Edinburgh, Scotland (Roslin) is the assignee of U.S. Patent Application No. 09/225,233 (the '233 application) and appeals from a final decision of the Patent Trial and Appeal Board (Board). The Board held that all of Roslin's pending claims—claims 155–159 and 164—were unpatentable subject matter under 35 U.S.C. § 101. The Board also rejected Roslin's claims as anticipated and obvious under 35 U.S.C. §§ 102 and 103. We affirm the Board's rejection of the claims under § 101.

BACKGROUND

On July 5, 1996, Keith Henry Stockman Campbell and Ian Wilmut successfully produced the first mammal ever cloned from an adult somatic cell: Dolly the Sheep. A clone is an identical genetic copy of a cell, cell part, or organism.

The cloning method Campbell and Wilmut used to create Dolly constituted a breakthrough in scientific discovery. Known as somatic cell nuclear transfer, this process involves removing the nucleus of a somatic cell and implanting that nucleus into an enucleated (*i.e.,* without a nucleus) oocyte. A somatic cell is any body cell other than gametes (egg or sperm). An oocyte is a female gametocyte (an egg cell prior to maturation), and a nucleus is the organelle that holds a cell's genetic material (its DNA). Often referred to as "adult" cells, somatic cells are differentiated, *i.e.,* they are specialized to perform specific functions. For example, liver, heart, and muscle cells are all differentiated, somatic cells.

To create Dolly, Campbell and Wilmut fused the nucleus of an adult, somatic mammary cell with an enucleated oocyte. Specifically, Campbell and Wilmut found that if the donor, somatic cell is arrested in the stage of the cell cycle where it is dormant and non-replicating (the quiescent phase) prior to nuclear transfer, the resulting fused cell will develop into a reconstituted embryo. Once the nucleus of a somatic, donor cell is removed, that nucleus is fused with an oocyte, which develops into an embryo. The embryo can then be implanted into a surrogate mammal, where it develops into a baby animal. The resulting cloned animal is an exact genetic replica of the adult mammal from which the somatic cell nucleus was taken.

Campbell and Wilmut obtained a patent on the somatic method of cloning

mammals, which has been assigned to Roslin. *See* U.S. Patent No. 7,514,258 (the ′258 patent). The ′258 patent is not before us in this appeal. Instead, the dispute here concerns the Patent and Trademark Office's (PTO) rejection of Campbell's and Wilmut's claims to the clones themselves, set forth in the ′233 application, titled Quiescent Cell Populations for Nuclear Transfer.

The ′233 application claims the products of Campbell's and Wilmut's cloning method: cattle, sheep, pigs, and goats. Claims 155 and 164 are representative:

> 155. A live-born clone of a pre-existing, non-embryonic, donor mammal, wherein the mammal is selected from cattle, sheep, pigs, and goats.
>
> 164. The clone of any of claims 155–159, wherein the donor mammal is non-foetal.

As the Board described, "[c]laims 156–159 depend from claim 155 and further specify that the claimed clones are limited to clones of cattle, sheep, pigs, and goats, respectively."

[The PTO rejected the claims on several grounds, including that the claims were unpatentable subject matter under § 101. The Institute appealed.]

DISCUSSION

I

Even before the Supreme Court's recent decision in *Association for Molecular Pathology v. Myriad Genetics, Inc.,* 133 S.Ct. 2107 (2013), the Court's opinions in *Chakrabarty* and *Funk Bros. Seed Co. v. Kalo Inoculant Co.,* 333 U.S. 127 (1948), made clear that naturally occurring organisms are not patentable.

In *Funk Bros.,* the Supreme Court considered a patent that claimed a mixture of naturally occurring strains of bacteria that helped leguminous plants extract nitrogen from the air and fix it in soil. 333 U.S. at 128–29, 68 S.Ct. 440. The Court concluded that this mixture of bacteria strains was not patent eligible because the patentee did not alter the bacteria in any way. *Id.* at 132, 68 S.Ct. 440 ("[T]here is no invention here unless the discovery that certain strains of the several species of these bacteria are non-inhibitive and may thus be safely mixed is invention. But we cannot so hold without allowing a patent to issue on one of the ancient secrets of nature now disclosed."). Critically, in *Funk Bros.,* the Court explained:

> [w]e do not have presented the question whether the methods of selecting and testing the non-inhibitive strains are patentable. We have here only product claims. [The patentee] does not create a state of inhibition or of non-inhibition in the bacteria. Their qualities are the work of nature. Those qualities are of course not patentable. For patents cannot issue for the discovery of the phenomena of nature. The qualities of these bacteria, like the heat of the sun, electricity, or the qualities of metals, are part of the storehouse of knowledge of all men. They are manifestations of laws of nature, free to all men and reserved exclusively to none.

Id. at 130 (citation omitted). Thus, while the method of selecting the strains of bacteria might have been patent eligible, the natural organism itself—the mixture of bacteria—was unpatentable because its "qualities are the work of nature" unaltered by the hand of man. *Id.*

In *Chakrabarty,* the Court clarified the scope of *Funk.* The patent at issue in *Chakrabarty* claimed a genetically engineered bacterium that was capable of breaking down various components of crude oil. The patent applicant created this non-naturally occurring bacterium by adding four plasmids to a specific strain of bacteria. Overturning the Board's rejections, the Court held that the modified bacterium was patentable because it was "new" with "*markedly different characteristics from any found in nature* and one having the potential for significant utility." [447 U.S.] at 310 (emphasis added). As the Court explained, the patentee's "discovery is not nature's handiwork, but his own." *Id.*

Accordingly, discoveries that possess "markedly different characteristics from any found in nature," *id.,* are eligible for patent protection. In contrast, any existing organism or newly discovered plant found in the wild is not patentable. *Id.* at 309; *see also In re Beineke,* 690 F.3d 1344, 1352 (Fed.Cir.2012)(holding that a newly discovered type of plant is not eligible for plant patent protection, in part, because such a plant was not "in any way the result of [the patent applicant's] creative efforts or indeed anyone's creative efforts.").

More recently, in *Myriad,* the Court held that claims on two naturally occurring, isolated genes (BRCA1 and BRCA2), which can be examined to determine whether a person may develop breast cancer, were invalid under § 101. 133 S.Ct. at 2112–13, 2117–18. The Supreme Court concluded that the BRCA genes themselves were unpatentable products of nature.

While Roslin does not dispute that the donor sheep whose genetic material was used to create Dolly could not be patented, Roslin contends that copies (clones) are eligible for protection because they are "the product of human ingenuity" and "not nature's handiwork, but [their] own." Appellant's Br. 17, 18. Roslin argues that such copies are either compositions of matter or manufactures within the scope of § 101. However, Dolly herself is an exact genetic replica of another sheep and does not possess "markedly different characteristics from any [farm animals] found in nature." *Chakrabarty,* 447 U.S. at 310; *see* Reply Br. 13 (stating that "the clones are genetic copies"). Dolly's genetic identity to her donor parent renders her unpatentable.

In *Myriad,* the Court concluded that "isolated," naturally occurring DNA strands are not eligible for patent protection. 133 S.Ct. at 2111. Here, as in *Myriad,* Roslin "did not create or alter any of the genetic information" of its claimed clones, "[n]or did [Roslin] create or alter the genetic structure of [the] DNA" used to make its clones. *Myriad,* 133 S.Ct. at 2116. Instead, Roslin's chief innovation was the preservation of the donor DNA such that the clone is an exact copy of the mammal from which the somatic cell was taken. Such a copy is not eligible for patent protection.

II

However, Roslin argues that its claimed clones are patent eligible because they are distinguishable from the donor mammals used to create them. First, Roslin contends that "environmental factors" lead to phenotypic differences that distinguish its clones from their donor mammals. A phenotype refers to all the observable characteristics of an organism, such as shape, size, color, and behavior, that result from the interaction of the organism's genotype with its environment. A mammal's phenotype can change constantly throughout the life of that organism not only due to environmental changes, but also the physiological and morphological changes associated with aging.

Roslin argues that environmental factors lead to phenotypic differences between its clones and their donor mammals that render their claimed subject matter patentable. However, these differences are unclaimed. *See* J.A. 17. Indeed, the word "cloned" in the pending claims connotes genetic identity, and the claims say nothing about a phenotypic difference between the claimed subject matter and the donor mammals. Moreover, Roslin acknowledges that any phenotypic differences came about or were produced "quite independently of any effort of the patentee." *Funk Bros.,* 333 U.S. at 131, *see id.* at 130 ("Their qualities are the work of nature. Those qualities are of course not patentable. For patents cannot issue for the discovery of the phenomena of nature."); *Chakrabarty,* 447 U.S. at 310 ("Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101."). Contrary to Roslin's arguments, these phenotypic differences do not confer eligibility on their claimed subject matter. Any phenotypic differences between Roslin's donor mammals and its claimed clones are the result of "environmental factors," Appellant's Br. 21, uninfluenced by Roslin's efforts.

Second, Roslin urges that its clones are distinguishable from their original donor mammals because of differences in mitochondrial DNA, which originates from the donor oocyte rather than the donor nucleus. Mitochondria are the organelles (cellular bodies) that produce the energy eukaryotic cells need to function. Mitochondria possess their own DNA, which is distinct from the DNA housed in the cell's nucleus. In the cloning process, the clone inherits its mitochondrial DNA from its donor oocyte, instead of its donor somatic cell. Therefore, Dolly's mitochondrial DNA came from the oocyte used to create her, not her donor mammary cell. Roslin argues that this difference in mitochondrial DNA renders its product claims patent eligible.

But any difference in mitochondrial DNA between the donor and cloned mammals is, too, unclaimed. Furthermore, Roslin's patent application does not identify how differences in mitochondrial DNA influence or could influence the characteristics of cloned mammals. As the Board found below,

> [a]s for the influence of the oocyte into which the donor nucleus is transferred, the

> [']233 Specification teaches that "[a]nimals produced by transfer of nuclei from a source of genetically identical cells share the same nucleus, but are not strictly identical as they are derived from different oocytes. The significance of this different origin is not clear, but may affect commercial traits." The Specification cautions further that "[i]t remains ... to consider whether it is possible or necessary in specific situations to consider the selection of oocytes." Thus ... the Specification does not disclose any systematic differences in the clones that arise from the capture of the recipient oocyte.

J.A. 12 (third, fourth, and fifth alterations in original) (citations omitted). There is nothing in the claims, or even in the specification, that suggests that the clones are distinct in any relevant way from the donor animals of which they are copies. The clones are defined in terms of the identity of their nuclear DNA to that of the donor mammals. To be clear, having the same nuclear DNA as the donor mammal may not necessarily result in patent ineligibility in every case. Here, however, the claims do not describe clones that have markedly different characteristics from the donor animals of which they are copies.

Finally, Roslin argues that its clones are patent eligible because they are time-delayed versions of their donor mammals, and therefore different from their original mammals. But this distinction cannot confer patentability. As the Board noted, "[t]he difficulty with the time-delayed characteristic is that it is true of any copy of an original." J.A. 18. Thus, we affirm the Board's finding that Roslin's clones are unpatentable subject matter under § 101.

AFFIRMED.

NOTES ON PATENTING DOLLY THE SHEEP

1. Too Perfect a Copy. As the opinion here notes, the successful cloning of a sheep—the clone was named "Dolly the Sheep"—was considered a huge scientific breakthrough at the time. The development was widely covered in the press of the era, and Dolly rose to the true pinnacle of modern fame: her life is covered in its own Wikipedia page, see https://en.wikipedia.org/wiki/Dolly_(sheep).

Nevertheless, despite the magnitude of the breakthrough and the fame of the subject, the clone is held unpatentable. The reasoning in this case is straightforward even if the outcome seems counterintuitive: Dolly was an exact copy of a naturally occurring sheep. Indeed, the whole goal of the researchers was to imitate nature precisely, and the achievement of that goal was fatal to their patent claim to the resulting clones. *Roslin* is thus a good counterpoint to *Chakrabarty*. Where inventors artificially create an unnatural living thing (an oil-eating bacterium), they can obtain patents on their new organisms, but if they artificially duplicate nature, those artificial, yet natural, organisms will be unpatentable.

2. Processes May Be Patentable. If the result of this case seems a bit unfair, do not overlook first two sentences in fourth paragraph of the court's factual summary, which states that the inventors received a separate "patent on the somatic method of cloning mammals" and that patent is not being challenged. There is a

general point here: The prohibition on patenting products of nature operates against product claims, but not so much against process patents.

Of course, process claims can be attacked as unpatentable claims to abstract ideas or claims to natural laws. Here is claim 1 of the inventors' process patent (U.S. Patent No. 7,514,258):

> 1. A method for producing a mammalian cultured inner cell mass cell by nuclear transfer comprising:
>
> (i) inserting a nucleus of a quiescent mammalian differentiated cell into an enucleated mammalian oocyte of the same species to reconstruct an embryo;
>
> (ii) culturing the reconstructed embryo; and
>
> (iii) isolating and culturing inner cell mass cells obtained from said cultured, reconstructed embryo to obtain a cultured inner cell mass cell.

Should this claim be patent ineligible as a claim to an abstract idea or a principle of nature? Does it matter how close the claimed method is to naturally occurring processes?

Chapter 4: Disclosure and Enablement

Chap. 4.D: In place of the *Orthokinectics v. Safety Travel Chairs* case (p. 317), insert the new case:

Nautilus, Inc. v. Biosig Instruments, Inc.

134 S.Ct. 2120 (2014)

Justice GINSBURG delivered the opinion of the Court.

The Patent Act requires that a patent specification "conclude with one or more claims *particularly pointing out and distinctly claiming* the subject matter which the applicant regards as [the] invention." 35 U.S.C. § 112, ¶ 2 (2006 ed.) (emphasis added). This case, involving a heart-rate monitor used with exercise equipment, concerns the proper reading of the statute's clarity and precision demand. According to the Federal Circuit, a patent claim passes the § 112, ¶ 2 threshold so long as the claim is "amenable to construction," and the claim, as construed, is not "insolubly ambiguous." 715 F.3d 891, 898–899 (2013). We conclude that the Federal Circuit's formulation, which tolerates some ambiguous claims but not others, does not satisfy the statute's definiteness requirement. In place of the "insolubly ambiguous" standard, we hold that a patent is invalid for indefiniteness if its claims, read in light of the specification delineating the patent, and the prosecution history, fail to inform, with reasonable certainty, those skilled in the art about the scope of the invention. Expressing no opinion on the validity of the patent-in-suit, we remand, instructing the Federal Circuit to decide the case employing the standard we have prescribed.

I

Authorized by the Constitution "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to ... Inventors the exclusive Right to their ... Discoveries," Art. I, § 8, cl. 8, Congress has enacted patent laws rewarding inventors with a limited monopoly. "Th[at] monopoly is a property right," and "like any property right, its boundaries should be clear." Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 730 (2002). See also Markman v. Westview Instruments, Inc., 517 U.S. 370, 373 (1996) ("It has long been understood that a patent must describe the exact scope of an invention and its manufacture...."). Thus, when Congress enacted the first Patent Act in 1790, it directed that patent grantees file a written specification "containing a description ... of the thing or things ... invented or discovered," which "shall be so particular" as to "distinguish the invention or discovery from other things before known and used." Act of Apr. 10, 1790, § 2, 1 Stat. 110.

The patent laws have retained this requirement of definiteness even as the focus of patent construction has shifted. Under early patent practice in the United States, we have recounted, it was the written specification that "represented the key to the patent." Markman, 517 U.S., at 379. Eventually, however, patent applicants began to set out the invention's scope in a separate section known as the "claim." See generally 1 R. Moy, Walker on Patents § 4.2, pp. 4–17 to 4–20 (4th ed. 2012). The Patent Act of 1870 expressly conditioned the receipt of a patent on the inventor's inclusion of one or more such claims, described with particularity and distinct-ness. See Act of July 8, 1870, § 26, 16 Stat. 201 (to obtain a patent, the inventor must "particularly point out and distinctly claim the part, improvement, or combination which [the inventor] claims as his invention or discovery").

The 1870 Act's definiteness requirement survives today, largely unaltered. Section 112 of the Patent Act of 1952, applicable to this case, requires the patent applicant to conclude the specification with "one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." 35 U.S.C. § 112, ¶ 2 (2006 ed.). A lack of definiteness renders invalid "the patent or any claim in suit." § 282, ¶ 2(3).

II

A

The patent in dispute, U.S. Patent No. 5,337,753 ('753 patent), issued to Dr. Gregory Lekhtman in 1994 and assigned to respondent Biosig Instruments, Inc., concerns a heart-rate monitor for use during exercise. Previous heart-rate monitors, the patent asserts, were often inaccurate in measuring the electrical signals accompanying each heartbeat (electrocardiograph or ECG signals). The inaccuracy was caused by electrical signals of a different sort, known as electromyogram or EMG signals, generated by an exerciser's skeletal muscles when, for example, she moves her arm, or grips an exercise monitor with her hand. These EMG signals can "mask" ECG signals and thereby impede their detection

Dr. Lekhtman's invention claims to improve on prior art by eliminating that impediment. The invention focuses on a key difference between EMG and ECG waveforms: while ECG signals detected from a user's left hand have a polarity opposite to that of the signals detected from her right hand, EMG signals from each hand have the same polarity. [From footnote: This difference in polarity occurs because the heart is not aligned vertically in relation to the center of the body; the organ tilts leftward from apex to bottom.] The patented device works by measuring equalized EMG signals detected at each hand and then using circuitry to subtract the identical EMG signals from each other, thus filtering out the EMG interference.

As relevant here, the '753 patent describes a heart-rate monitor contained in a hollow cylindrical bar that a user grips with both hands, such that each hand comes into contact with two electrodes, one "live" and one "common." The device is illustrated in figure 1 of the patent, id., at 41, reproduced [at the end of] this opinion.

Claim 1 of the '753 patent, which contains the limitations critical to this dispute, refers to a "heart rate monitor for use by a user in association with exercise apparatus and/or exercise procedures." Id., at 61. The claim "comprise[s]," among other elements, an "elongate member" (cylindrical bar) with a display device; "electronic circuitry including a difference amplifier"; and, on each half of the cylindrical bar, a live electrode and a common electrode "mounted ... in spaced relationship with each other." Ibid. [In Figure 1 from the patent, the live electrodes are identified by numbers 9 and 13, and the common electrodes, by 11 and 15.]

The claim sets forth additional elements, including that the cylindrical bar is to be held in such a way that each of the user's hands "contact[s]" both electrodes on each side of the bar. Id., at 62. Further, the EMG signals detected by the two electrode pairs are to be "of substantially equal magnitude and phase" so that the difference amplifier will "produce a substantially zero [EMG] signal" upon subtracting the [EMG from the ECG] signals.

B

The dispute between the parties arose in the 1990's, when Biosig allegedly disclosed the patented technology to StairMaster Sports Medical Products, Inc. According to Biosig, StairMaster, without ever obtaining a license, sold exercise machines that included Biosig's patented technology, and petitioner Nautilus, Inc., continued to do so after acquiring the StairMaster brand. In 2004, based on these allegations, Biosig brought a patent infringement suit against Nautilus in the U.S. District Court for the Southern District of New York.

With Biosig's lawsuit launched, Nautilus asked the U.S. Patent and Trademark Office (PTO) to reexamine the '753 patent. The reexamination proceedings centered on whether the patent was anticipated or rendered obvious by prior art—principally, a patent issued in 1984 to an inventor named Fujisaki, which similarly disclosed a heart-rate monitor using two pairs of electrodes and a difference amplifier. Endeavoring to distinguish the '753 patent from prior art, Biosig submitted a declaration from Dr. Lekhtman. The declaration attested, among other things, that the '753 patent sufficiently informed a person skilled in the art how to configure the detecting electrodes so as "to produce equal EMG [signals] from the left and right hands." Id., at 160. Although the electrodes' design variables—including spacing, shape, size, and material—cannot be standardized across all exercise machines, Dr. Lekhtman explained, a skilled artisan could undertake a "trial and error" process of equalization. This would entail experimentation with different electrode configurations in order to optimize EMG signal cancellation. [Dr. Lekhtman's declaration also referred to an expert report prepared by Dr. Henrietta Galiana, Chair of the Department of Biomedical Engineering at McGill University, for use in the infringement litigation. That report described how Dr. Galiana's laboratory technician, equipped with a wooden dowel, wire, metal foil, glue, electrical tape, and the drawings from the '753 patent, was able in two hours to build a monitor that "worked just as described in the ... patent."

Id., at 226.] In 2010, the PTO issued a determination confirming the patentability of the '753 patent's claims.

Biosig thereafter reinstituted its infringement suit, which the parties had voluntarily dismissed without prejudice while PTO reexamination was underway. In 2011, the District Court conducted a hearing to determine the proper construction of the patent's claims, see Markman v. Westview Instruments, Inc., 517 U.S. 370 (1996) (claim construction is a matter of law reserved for court decision), including the claim term "in spaced relationship with each other." According to Biosig, that "spaced relationship" referred to the distance between the live electrode and the common electrode in each electrode pair. Nautilus, seizing on Biosig's submissions to the PTO during the reexamination, maintained that the "spaced relationship" must be a distance "greater than the width of each electrode." The District Court ultimately construed the term to mean "there is a defined relationship between the live electrode and the common electrode on one side of the cylindrical bar and the same or a different defined relationship between the live electrode and the common electrode on the other side of the cylindrical bar," without any reference to the electrodes' width.

Nautilus moved for summary judgment, arguing that the term "spaced relationship," as construed, was indefinite under § 112, ¶ 2. The District Court granted the motion. Those words, the District Court concluded, "did not tell [the court] or anyone what precisely the space should be," or even supply "any parameters" for determining the appropriate spacing.

The Federal Circuit reversed and remanded. A claim is indefinite, the majority opinion stated, "only when it is 'not amenable to construction' or 'insolubly ambiguous.' " 715 F.3d 891, 898 (2013) (quoting Datamize, LLC v. Plumtree Software, Inc., 417 F.3d 1342, 1347 (C.A.Fed.2005)). Under that standard, the majority determined, the '753 patent survived indefiniteness review. Considering first the "intrinsic evidence"—i.e., the claim language, the specification, and the prosecution history—the majority discerned "certain inherent parameters of the claimed apparatus, which to a skilled artisan may be sufficient to understand the metes and bounds of 'spaced relationship.' " 715 F.3d, at 899. These sources of meaning, the majority explained, make plain that the distance separating the live and common electrodes on each half of the bar "cannot be greater than the width of a user's hands"; that is so "because claim 1 requires the live and common electrodes to independently detect electrical signals at two distinct points of a hand." Ibid. Furthermore, the majority noted, the intrinsic evidence teaches that this distance cannot be "infinitesimally small, effectively merging the live and common electrodes into a single electrode with one detection point." Ibid. The claim's functional provisions, the majority went on to observe, shed additional light on the meaning of "spaced relationship." Surveying the record before the PTO on reexamination, the majority concluded that a skilled artisan would know that she could attain the indicated functions of equalizing and removing EMG signals by adjusting design variables, including spacing.

In a concurring opinion, Judge Schall reached the majority's result employing "a more limited analysis." Id., at 905. Judge Schall accepted the majority's recitation of the definiteness standard, under which claims amenable to construction are nonetheless indefinite when "the construction remains insolubly ambiguous." Ibid. (internal quotation marks omitted). The District Court's construction of "spaced relationship," Judge Schall maintained, was sufficiently clear: the term means "there is a fixed spatial relationship between the live electrode and the common electrode" on each side of the cylindrical bar. Ibid. Judge Schall agreed with the majority that the intrinsic evidence discloses inherent limits of that spacing. But, unlike the majority, Judge Schall did not "presum[e] a functional linkage between the 'spaced relationship' limitation and the removal of EMG signals." Id., at 906. Other limitations of the claim, in his view, and not the " 'spaced relationship' limitation itself," "included a functional requirement to remove EMG signals." Ibid.

We granted certiorari, and now vacate and remand.

III

A

Although the parties here disagree on the dispositive question—does the '753 patent withstand definiteness scrutiny—they are in accord on several aspects of the § 112, ¶ 2 inquiry. First, definiteness is to be evaluated from the perspective of someone skilled in the relevant art. See, e.g., General Elec. Co. v. Wabash Appliance Corp., 304 U.S. 364, 371 (1938). See also § 112, ¶ 1 (patent's specification "shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable *any person skilled in the art* to which it pertains, or with which it is most nearly connected, to make and use the same" (emphasis added)). Second, in assessing definiteness, claims are to be read in light of the patent's specification and prosecution history. See, e.g., United States v. Adams, 383 U.S. 39, 48–49 (1966) (specification); Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co., 535 U.S. 722, 741 (2002) (prosecution history). Third, "[d]efiniteness is measured from the viewpoint of a person skilled in [the] art *at the time the patent was filed*." Brief for Respondent 55 (emphasis added).

The parties differ, however, in their articulations of just how much imprecision § 112, ¶ 2 tolerates. In Nautilus' view, a patent is invalid when a claim is "ambiguous, such that readers could reasonably interpret the claim's scope differently." Brief for Petitioner 37. Biosig and the Solicitor General would require only that the patent provide reasonable notice of the scope of the claimed invention. See Brief for Respondent 18; Brief for United States as Amicus Curiae 9–10.

Section 112, we have said, entails a "delicate balance." Festo, 535 U.S., at 731. On the one hand, the definiteness requirement must take into account the inherent limitations of language. See ibid. Some modicum of uncertainty, the Court has

recognized, is the "price of ensuring the appropriate incentives for innovation." Id., at 732. One must bear in mind, moreover, that patents are "not addressed to lawyers, or even to the public generally," but rather to those skilled in the relevant art. Carnegie Steel Co. v. Cambria Iron Co., 185 U.S. 403, 437 (1902) (also stating that "any description which is sufficient to apprise [steel manufacturers] in the language of the art of the definite feature of the invention, and to serve as a warning to others of what the patent claims as a monopoly, is sufficiently definite to sustain the patent").

At the same time, a patent must be precise enough to afford clear notice of what is claimed, thereby " 'appris[ing] the public of what is still open to them.' " Markman, 517 U.S., at 373 (quoting McClain v. Ortmayer, 141 U.S. 419, 424 (1891)). Otherwise there would be "[a] zone of uncertainty which enterprise and experimentation may enter only at the risk of infringement claims." United Carbon Co. v. Binney & Smith Co., 317 U.S. 228, 236 (1942). And absent a meaningful definiteness check, we are told, patent applicants face powerful incentives to inject ambiguity into their claims. See Brief for Petitioner 30–32 (citing patent treatises and drafting guides). See also Federal Trade Commission, The Evolving IP Marketplace: Aligning Patent Notice and Remedies With Competition 85 (2011) (quoting testimony that patent system fosters "an incentive to be as vague and ambiguous as you can with your claims" and "defer clarity at all costs"). [Online at http:// www.ftc.gov/sites/default/files/documents/reports/evolving-ip-marketplace-aligning-patent-notice-and-remedies-competition-report-federal-trade/110307patentreport.pdf .] Eliminating that temptation is in order, and "the patent drafter is in the best position to resolve the ambiguity in ... patent claims." Halliburton Energy Servs., Inc. v. M–I LLC, 514 F.3d 1244, 1255 (C.A.Fed.2008). See also Hormone Research Foundation, Inc. v. Genentech, Inc., 904 F.2d 1558, 1563 (C.A.Fed.1990) ("It is a well-established axiom in patent law that a patentee is free to be his or her own lexicographer....").

To determine the proper office of the definiteness command, therefore, we must reconcile concerns that tug in opposite directions. Cognizant of the competing concerns, we read § 112, ¶ 2 to require that a patent's claims, viewed in light of the specification and prosecution history, inform those skilled in the art about the scope of the invention with reasonable certainty. The definiteness requirement, so understood, mandates clarity, while recognizing that absolute precision is unattainable. The standard we adopt accords with opinions of this Court stating that "the certainty which the law requires in patents is not greater than is reasonable, having regard to their subject-matter." Minerals Separation, Ltd. v. Hyde, 242 U.S. 261, 270 (1916). See also United Carbon, 317 U.S., at 236 ("claims must be reasonably clear-cut"); Markman, 517 U.S., at 389 (claim construction calls for "the necessarily sophisticated analysis of the whole document," and may turn on evaluations of expert testimony).

B

In resolving Nautilus' definiteness challenge, the Federal Circuit asked whether the '753 patent's claims were "amenable to construction" or "insolubly ambiguous." Those formulations can breed lower court confusion, for they lack the precision § 112, ¶ 2 demands. [From footnote: See, e.g., Every Penny Counts, Inc. v. Wells Fargo Bank, N. A., ––– F.Supp.2d ––––, ––––, 2014 WL 869092, *4 (M.D.Fla., Mar. 5, 2014) (finding that "the account," as used in claim, "lacks definiteness," because it might mean several different things and "no informed and confident choice is available among the contending definitions," but that "the extent of the indefiniteness ... falls far short of the 'insoluble ambiguity' required to invalidate the claim").] It cannot be sufficient that a court can ascribe some meaning to a patent's claims; the definiteness inquiry trains on the understanding of a skilled artisan at the time of the patent application, not that of a court viewing matters post hoc. To tolerate imprecision just short of that rendering a claim "insolubly ambiguous" would diminish the definiteness requirement's public-notice function and foster the innovation-discouraging "zone of uncertainty," United Carbon, 317 U.S., at 236, against which this Court has warned.

Appreciating that "terms like 'insolubly ambiguous' may not be felicitous," Brief for Respondent 34, Biosig argues the phrase is a shorthand label for a more probing inquiry that the Federal Circuit applies in practice. The Federal Circuit's fuller explications of the term "insolubly ambiguous," we recognize, may come closer to tracking the statutory prescription. See, e.g., 715 F.3d, at 898 (case below) ("[I]f reasonable efforts at claim construction result in a definition that does not provide sufficient particularity and clarity to inform skilled artisans of the bounds of the claim, the claim is insolubly ambiguous and invalid for indefiniteness." (internal quotation marks omitted)). But although this Court does not "micromanag[e] the Federal Circuit's particular word choice" in applying patent-law doctrines, we must ensure that the Federal Circuit's test is at least "probative of the essential inquiry." Warner–Jenkinson Co. v. Hilton Davis Chemical Co., 520 U.S. 17, 40 (1997). Falling short in that regard, the expressions "insolubly ambiguous" and "amenable to construction" permeate the Federal Circuit's recent decisions concerning § 112, ¶ 2's requirement. We agree with Nautilus and its amici that such terminology can leave courts and the patent bar at sea without a reliable compass.

The parties nonetheless dispute whether factual findings subsidiary to the ultimate issue of definiteness trigger the clear-and-convincing-evidence standard and, relatedly, whether deference is due to the PTO's resolution of disputed issues of fact. We leave these questions for another day. The court below treated definiteness as "a legal issue [the] court reviews without deference," 715 F.3d, at 897, and Biosig has not called our attention to any contested factual matter—or PTO determination thereof—pertinent to its infringement claims.

IV

Both here and in the courts below, the parties have advanced conflicting arguments as to the definiteness of the claims in the '753 patent. Nautilus maintains that the claim term "spaced relationship" is open to multiple interpretations reflecting markedly different understandings of the patent's scope, as exemplified by the disagreement among the members of the Federal Circuit panel. [From footnote: Notably, however, all three panel members found Nautilus' arguments unavailing.] Biosig responds that "spaced relationship," read in light of the specification and as illustrated in the accompanying drawings, delineates the permissible spacing with sufficient precision.

"[M]indful that we are a court of review, not of first view," Cutter v. Wilkinson, 544 U.S. 709, 718, n. 7 (2005), we decline to apply the standard we have announced to the controversy between Nautilus and Biosig. As we have explained, the Federal Circuit invoked a standard more amorphous than the statutory definiteness requirement allows. We therefore follow our ordinary practice of remanding so that the Court of Appeals can reconsider, under the proper standard, whether the relevant claims in the '753 patent are sufficiently definite.

* * *

For the reasons stated, we vacate the judgment of the United States Court of Appeals for the Federal Circuit and remand the case for further proceedings consistent with this opinion.

It is so ordered.

APPENDIX

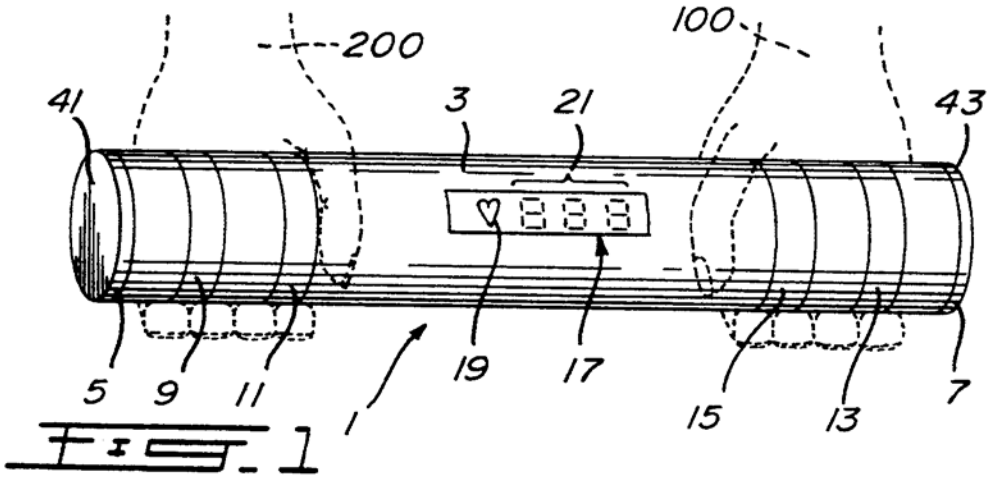

FIG. 1

NOTES AND COMMENTS ON *NAUTILUS*

1. Questions Left for Later. The Court states the new test for indefiniteness: a claim is indefinite if it "fail[s] to inform, with reasonable certainty, those skilled in the art about the scope of the invention." It is left to the Federal Circuit to apply the new test to the patent at issue in this case. Does the claim term "spaced relationship" fail to inform about the scope of the invention? What about the evidence regarding what this term would mean to one skilled in the art, discussed especially by the Federal Circuit judges in their opinions below? How much should the stated purpose of the invention bear on the question of reasonable certainty regarding claim scope?

2. Same Result on Remand. Nautilus won at the Supreme Court, but it lost once again on remand at the Federal Circuit. *See Biosig Instruments, Inc. v. Nautilus*, Inc., 783 F.3d 1374 (Fed. Cir. 2015). With perhaps more than a touch of sarcasm, the Federal Circuit stated that, after the Supreme Court's teaching *Nautilus*, the court "may now steer by the bright star of 'reasonable certainty,' rather than the unreliable compass of 'insoluble ambiguity.'" *Id.* at 1379. Applying reasoning very similar to its prior opinion, the court concluded that "term 'spaced relationship' does not run afoul of 'the innovation-discouraging 'zone of uncertainty' against which [the Supreme Court] has warned,' and to the contrary, informs a skilled artisan with reasonable certainty of the scope of the claim." *Id.* at 1384 (quoting *Interval Licensing LLC v. AOL, Inc.*, 766 F.3d 1364, 1374 (Fed. Cir. 2014)). Does the result on remand suggest that *Nautilus*'s "reasonable certainty" standard will not make a big difference?

3. Failing the New Standard. A contrast to the result on remand in *Nautilus* is provided by In Ex Parte Breed, 2014 WL 2536964 (PTAB June 04, 2014), which held claims indefinite under the Supreme Court's new "reasonable certainty" standard even though the claims might have been valid under the Federal Circuit's now-discredited "insolubly ambiguous" standard. The claimed system included a series of roadside sensors that collect data about traffic and other conditions from at least one vehicle travelling on the roadway and send the resultant data to a remote facility for processing; the claims state that information so gathered "can be directed from the remote facility to other vehicles on the roadway or roadways from which the information is obtained." The examiner said that the phrase "can be" in this claim is ambiguous. It might mean that the information is in fact directed to other vehicles, because the system has this capability. Or it may mean that the information might *optionally* be so directed, but that this was not a necessary feature of the claimed invention. Under the "insolubly ambiguous" standard the examiner might have been required to choose one of the two meanings, thus resolving the ambiguity and rendering the claim definite. But under the *Nautilus* standard, the PTAB agreed with the examiner that the claim was invalid due to indefiniteness.

4. Approximations and the Person of Skill in the Art. In footnote 5 of the opinion (omitted in the excerpt above), the Court mentions some cases involving the common issue of claims that include terms of approximation:

> See also Eibel Process Co. v. Minnesota & Ontario Paper Co., 261 U.S. 45, 58, 65–66 (1923) (upholding as definite a patent for an improvement to a paper-making machine, which provided that a wire be placed at a "high" or "substantial elevation," where "readers ... skilled in the art of paper making and versed in the use of the ... machine" would have "no difficulty ... in determining ... the substantial [elevation] needed" for the machine to operate as specified).

134 S.Ct. 2120, at 2129 n. 5. It is important to remember, as the Court emphasizes in *Nautilus*, that definiteness is to be viewed from the perspective of someone skilled in the art. Hence the "reasonable certainty" required by the opinion is the reasonable certainty of an expert in the field. This may render many terms of approximation quite definite, because knowledge of the field may often supply implicit parameters in areas where the layperson would be quite uncertain about claim scope.

5. Relationship to the Statutory Presumption of Validity. In footnote 10 (omitted), the Court says:

> The Federal Circuit suggests that a permissive definiteness standard "'accord[s] respect to the statutory presumption of patent validity.' " 715 F.3d 891, 902 (2013) (quoting Exxon Research, 265 F.3d, at 1375). See also § 282, ¶ 1 ("[a] patent shall be presumed valid," and "[t]he burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity"); Microsoft Corp. v. i4i Ltd. Partnership, 564 U.S. ––––, ––––, 131 S.Ct. 2238, 2242 (2011) (invalidity defenses must be proved by "clear and convincing evidence"). As the parties appear to agree, however, this presumption of validity does not alter the degree of clarity that § 112, ¶ 2 demands from patent applicants; to the contrary, it incorporates that definiteness requirement by reference. See § 282, ¶ 2(3) (defenses to infringement actions include "[i]nvalidity of the patent or any claim in suit for failure to comply with ... any requirement of [§ 112]").

134 S.Ct. 2120, at 2130 n. 10. It is worth pondering how one attacking a patent for indefiniteness can go about establishing the invalidity case. How does one establish a lack of reasonable certainty regarding claim scope, in clear and convincing terms, so as to overcome the statutory presumption of validity?

Chapter 8: Infringement

Chap. 8.B.4: On page 789, replace the Federal Circuit's *Akamai v. Limelight* decision with the Supreme Court's decision reversing the Federal Circuit:

Limelight Networks, Inc. v. Akamai Technologies, Inc.

134 S.Ct. 2111 (2014)

Justice ALITO delivered the opinion of the Court.

This case presents the question whether a defendant may be liable for inducing infringement of a patent under 35 U.S.C. § 271(b) when no one has directly infringed the patent under § 271(a) or any other statutory provision. The statutory text and structure and our prior case law require that we answer this question in the negative. We accordingly reverse the Federal Circuit, which reached the opposite conclusion.

I

A

Respondent the Massachusetts Institute of Technology is the assignee of U.S. Patent No. 6,108,703 ('703 patent), which claims a method of delivering electronic data using a "content delivery network," or "CDN." Respondent Akamai Technologies, Inc., is the exclusive licensee. Akamai maintains many servers distributed in various locations. Proprietors of Web sites, known as "content providers," contract with Akamai to deliver their Web sites' content to individual Internet users. The '703 patent provides for the designation of certain components of a content provider's Web site (often large files, such as video or music files) to be stored on Akamai's servers and accessed from those servers by Internet users. The process of designating components to be stored on Akamai's servers is known as "tagging." By "aggregat[ing] the data demands of multiple content providers with differing peak usage patterns and serv[ing] that content from multiple servers in multiple locations," 614 F.Supp.2d 90, 96 (D.Mass.2009), as well as by delivering content from servers located in the same geographic area as the users who are attempting to access it, Akamai is able to increase the speed with which Internet users access the content of its customers' Web sites.

Petitioner Limelight Networks, Inc., also operates a CDN and carries out several of the steps claimed in the '703 patent. But instead of tagging those components of its customers' Web sites that it intends to store on its servers (a step included in the '703 patent), Limelight requires its customers to do their own tagging. Respondents claim that Limelight "provides instructions and offers technical assistance" to its customers regarding how to tag, 629 F.3d 1311, 1321

(C.A.Fed.2010), but the record is undisputed that Limelight does not tag the components to be stored on its servers.

B

In 2006, respondents sued Limelight in the United States District Court for the District of Massachusetts, claiming patent infringement. The case was tried to a jury, which found that Limelight had committed infringement and awarded more than $40 million in damages. [The district court then granted reconsideration and vacated the judgment in light of a recently-decided Federal Circuit case, Muniauction, Inc. v. Thomson Corp., 532 F.3d 1318 (2008), which held that there can be no direct infringement when no single entity performs all the steps of a claimed process. A three-judge panel of the Federal Circuit affirmed.]

The Federal Circuit [then] granted en banc review and reversed. The en banc court found it unnecessary to revisit its § 271(a) direct infringement case law. Instead, it concluded that the "evidence could support a judgment in [respondents'] favor on a theory of induced infringement" under § 271(b). 692 F.3d 1301, 1319 (2012) (per curiam). This was true, the court explained, because § 271(b) liability arises when a defendant carries out some steps constituting a method patent and encourages others to carry out the remaining steps—even if no one would be liable as a direct infringer in such circumstances, because those who performed the remaining steps did not act as agents of, or under the direction or control of, the defendant. The Court of Appeals did not dis-pute that "there can be no indirect infringement without direct infringement," id., at 1308, but it explained that "[r]equiring proof that there has been direct infringement ... is not the same as re-quiring proof that a single party would be liable as a direct *2117 infringer," id., at 1308–1309 (emphasis deleted). Judge Newman and Judge Linn both dissented (with the latter joined by Judges Dyk, Prost, and O'Malley).

Limelight sought certiorari, which we granted.

II

A

Neither the Federal Circuit, see 692 F.3d, at 1308, nor respondents, dispute the proposition that liability for inducement must be predicated on direct infringement. This is for good reason, as our case law leaves no doubt that inducement liability may arise "if, but only if, [there is] ... direct infringement." Aro Mfg. Co. v. Convertible Top Replacement Co., 365 U.S. 336, 341, 81 S.Ct. 599, 5 L.Ed.2d 592 (1961) (emphasis deleted). [From footnote: Aro addressed contributory infringement under § 271(c), rather than inducement of infringement under § 271(b), but we see no basis to distinguish for these purposes between the two, which after all spring from common stock. See Global–Tech Appliances, Inc. v. SEB S.A., 131 S.Ct. 2060, 2067–2068 (2011).]

One might think that this simple truth is enough to dispose of this appeal. But the Federal Circuit reasoned that a defendant can be liable for inducing infringement under § 271(b) even if no one has committed direct infringement within the terms of § 271(a) (or any other provision of the patent laws), because direct infringement can exist independently of a violation of these statutory provisions. See 692 F.3d, at 1314.

The Federal Circuit's analysis fundamentally misunderstands what it means to infringe a method patent. A method patent claims a number of steps; under this Court's case law, the patent is not infringed unless all the steps are carried out. This principle follows ineluctably from what a patent is: the conferral of rights in a particular claimed set of elements. "Each element contained in a patent claim is deemed material to defining the scope of the patented invention," Warner–Jenkinson Co. v. Hilton Davis Chemical Co., 520 U.S. 17, 29 (1997), and a patentee's rights extend only to the claimed combination of elements, and no further.

The Federal Circuit held in Muniauction that a method's steps have not all been per-formed as claimed by the patent unless they are all attributable to the same defendant, either because the defendant actually performed those steps or because he directed or controlled others who performed them. See 532 F.3d, at 1329–1330. Assuming without deciding that the Federal Circuit's holding in Muniauction is correct, there has simply been no infringement of the method in which respondents have staked out an interest, because the performance of all the patent's steps is not attributable to any one person. And, as both the Federal Circuit and respondents admit, where there has been no direct infringement, there can be no inducement of infringement under § 271(b).

The Federal Circuit's contrary view would deprive § 271(b) of ascertainable standards. If a defendant can be held liable under § 271(b) for inducing conduct that does not constitute infringement, then how can a court assess when a patent holder's rights have been invaded? What if a defendant pays another to perform just one step of a 12–step process, and no one performs the other steps, but that one step can be viewed as the most important step in the process? In that case the defendant has not encouraged infringement, but no principled reason prevents him from being held liable for inducement under the Federal Circuit's reasoning, which permits inducement liability when fewer than all of a method's steps have been performed within the meaning of the patent. The decision below would require the courts to develop two parallel bodies of infringement law: one for liability for direct infringement, and one for liability for inducement.

Section 271(f)(1) reinforces our reading of § 271(b). That subsection imposes liability on a party who "supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention ... in such manner as to actively induce the combination of such components outside of the United States in a manner that would infringe the patent *if such combination occurred within the United States*" (emphasis added). As this provision illustrates,

when Congress wishes to impose liability for inducing activity that does not itself constitute direct infringement, it knows precisely how to do so. The courts should not create liability for inducement of non-infringing conduct where Congress has elected not to extend that concept.

The Federal Circuit seems to have adopted the view that Limelight induced infringement on the theory that the steps that Limelight and its customers perform would infringe the '703 patent if all the steps were performed by the same person. But we have already rejected the notion that conduct which would be infringing in altered circumstances can form the basis for contributory infringement, and we see no reason to apply a different rule for inducement. In Deepsouth Packing Co. v. Laitram Corp., 406 U.S. 518 (1972), a manufacturer produced components of a patented machine and then exported those components overseas to be assembled by its foreign customers. [From footnote: Section 271(f) now prohibits the exporter's conduct at issue in Deepsouth.] (The assembly by the foreign customers did not violate U.S. patent laws.) In both Deepsouth and this case, the conduct that the defendant induced or contributed to would have been infringing if committed in altered circumstances: in Deepsouth if the machines had been assembled in the United States, see id., at 526, and in this case if performance of all of the claimed steps had been attributable to the same person. In Deepsouth, we rejected the possibility of contributory infringement because the machines had not been assembled in the United States, and direct infringement had consequently never occurred. See id., at 526–527. Similarly, in this case, performance of all the claimed steps cannot be attributed to a single person, so direct infringement never occurred. Limelight cannot be liable for inducing infringement that never came to pass.

B

Respondents' arguments in support of the Federal Circuit's reading of the statute are unpersuasive. First, respondents note that tort law imposes liability on a defendant who harms another through a third party, even if that third party would not himself be liable, and respondents contend that, given the background tort principles against which the Patent Act of 1952 was en-acted, it should not matter that no one is liable for direct infringement in this case. But the reason Limelight could not have induced infringement under § 271(b) is not that no third party is liable for direct infringement; the problem, instead, is that no direct infringement was committed. Muniauction (which, again, we assume to be correct) instructs that a method patent is not directly infringed—and the patentee's interest is thus not violated—unless a single actor can be held responsible for the performance of all steps of the patent. Because Limelight did not undertake all steps of the '703 patent and cannot otherwise be held responsible for all those steps, respondents' rights have not been violated. Unsurprisingly, respondents point us to no tort case in which liability was imposed because a defendant caused an innocent third party to undertake action that did not violate the plaintiff's legal rights.

In a related argument, respondents contend that, at tort, liability sometimes attaches where two or more defendants inflict injury, even if each defendant's conduct, standing alone, would not be actionable. See W. Keeton, D. Dobbs, R. Keeton, & D. Owen, Prosser and Keeton on Torts § 52, p. 354 (5th ed. 1984) (multiple defendants who each add negligible impurities to stream liable if aggregate impurities cause harm). But the rationale for imposing liability in these circumstances is that the defendants collectively invaded the plaintiff's protected interests. See ibid. By contrast, under the Muniauction rule, respondents' interests in the '713 patent have not been invaded.

Second, respondents seek to analogize § 271(b) to the federal aiding and abetting statute, 18 U.S.C. § 2, and they argue that two parties who divide all the necessary elements of a crime between them are both guilty under § 2. The analogy does not hold up. The aiding and abetting statute must be read "against its common-law background," Standefer v. United States, 447 U.S. 10, 19 (1980), and at common law two or more defendants, each of whom committed an element of a crime, were liable as principals. See, e.g., 1 J. Bishop, Commentaries on the Criminal Law § 649, p. 392 (7th ed. 1882). While we have drawn on criminal law concepts in the past in interpreting § 271(b), see Global–Tech Appliances, Inc. v. SEB S. A., 563 U.S. ––––, ––––, 131 S.Ct. 2060, 2068–2070 (2011), we think it unlikely that Congress had this particular doctrine in mind when it enacted the Patent Act of 1952, given the doctrine's inconsistency with the Act's cornerstone principle that patentees have a right only to the set of elements claimed in their patents and nothing further.

Third, respondents contend that patent law principles established before the enactment of the Patent Act demonstrate that a defendant that performs some steps of a patent with the purpose of having its customers perform the remaining steps is liable for inducing infringement. But here, too, the nature of the rights created by the Patent Act defeats the notion that Congress could have intended to permit inducement liability where there is no underlying direct infringement. According to respondents, their understanding of the pre–1952 doctrine casts doubt on the Muniauction rule for direct infringement under § 271(a), on the ground that that rule has the indirect effect of preventing inducement liability where Congress would have wanted it. But the possibility that the Federal Circuit erred by too narrowly circumscribing the scope of § 271(a) is no reason for this Court to err a second time by misconstruing § 271(b) to impose liability for inducing infringement where no infringement has occurred.

Finally, respondents, like the Federal Circuit, criticize our interpretation of § 271(b) as permitting a would-be infringer to evade liability by dividing performance of a method patent's steps with another whom the defendant neither directs nor controls. We acknowledge this concern. Any such anomaly, however, would result from the Federal Circuit's interpretation of § 271(a) in Muniauction. A desire to avoid Muniauction 's natural consequences does not justify fundamentally altering the rules of inducement liability that the text and structure of the Pat-ent Act clearly require—an alteration that would result in its own serious and problematic conse-

quences, namely, creating for § 271(b) purposes some free-floating concept of "infringement" both untethered to the statutory text and difficult for the lower courts to apply consistently.

III

Respondents ask us to review the merits of the Federal Circuit's Muniauction rule for direct infringement under § 271(a). We decline to do so today.

In the first place, the question presented is clearly focused on § 271(b), not § 271(a). The question presupposes that Limelight has not committed direct infringement under § 271(a). And since the question on which we granted certiorari did not involve § 271(a), petitioner did not address that important issue in its opening brief. Our decision on the § 271(b) question necessitates a remand to the Federal Circuit, and on remand, the Federal Circuit will have the opportunity to revisit the § 271(a) question if it so chooses.

IV

The judgment below is reversed, and the case is remanded for further proceedings consistent with this opinion.

It is so ordered.

NOTES AND COMMENTS ON *LIMELIGHT*

1. Closing Loopholes. As the Court noted, Congress has often responded when it perceives that court rulings create an unfair "loophole" in the law of patent infringement. Thus, § 271 was amended in the wake of the *Deepsouth* opinion, which had permitted competitors to ship overseas all the components of a patented invention and simply complete the final assembly outside the jurisdiction of US patent law. Do you sense the same degree of unfairness in the result in this case? Is it a mere "technicality" that the accused infringer requires the content owner – rather than the accused service provider – to "tag" the content for distribution? Do you believe the statutory fix is in order? Would you be in favor of such a change to § 271?

2. The Muniauction Problem. The Court noted at several points that the "problem" sought to be resolved by the Federal Circuit's en banc opinion in *Akamai* was created by the Federal Circuit itself in its decision in *Muniauction.* The Supreme Court was referring here to *Muniauction*'s restrictive rule concerning direct infringement. The holding in *Muniauction* established that when multiple people, belonging to multiple distinct organizations, participate in collectively practicing the steps of a process patent, there is no infringement liability unless one organization exercises direct supervisory or contractual control over the actions of the other organization. That rule is arguably an overly restrictive interpretation of the text of § 271(a). It is quite plausible under general common law principles to more broadly attribute the actions of one organization to the other.

The restrictive rule of *Muniauction* is, the Supreme Court stated, an "[a]nomaly."

The Court, through references like this, seemed to be inviting the Federal Circuit to revisit *Muniauction*. If the Federal Circuit had taken the hint, the result in cases like *Akamai* would have been liability for the accused infringer but not because the accused infringer has induced infringement under § 271(b). Liability would instead be based on direct infringement under § 271(a), once the actions of the related party (here the content owner) are taken into account and attributed to the accused infringer.

4. Federal Circuit Does Take the Hint. On remand, the Federal Circuit adhered to its *Muniauction* rule for direct infringement under § 271(a) and thus held that Akamai could not prevail against Limelight because Akamai could not prove "that Limelight's customers were acting as agents of or otherwise contractually obligated to Limelight or that they were acting in a joint enterprise when performing [certain steps in the patented method]." Akamai v. Limelight, 786 F.3d 899 (Fed. Cir. 2015). Judge Moore wrote a strongly-worded dissent. Do not be surprised if this case takes another trip to the Supreme Court.

Chap. 8.B.5. Procedural Aspects of Claim Interpretation

Teva Pharmaceuticals USA, Inc. v. Sandoz, Inc.,
135 S. Ct. 831 (January 20, 2015)

Justice Breyer delivered the opinion of the Court.

In *Markman v. Westview Instruments, Inc.*, 517 U.S. 370 (1996), we explained that a patent claim is that "portion of the patent document that defines the scope of the patentee's rights." Id., at 372. We held that "the construction of a patent, including terms of art within its claim," is not for a jury but "exclusively" for "the court" to determine. Ibid. That is so even where the construction of a term of art has "evidentiary underpinnings." Id., at 390.

Today's case involves claim construction with "evidentiary underpinnings." See Part III, infra. And, it requires us to determine what standard the Court of Appeals should use when it reviews a trial judge's resolution of an underlying factual dispute. Should the Court of Appeals review the district court's factfinding de novo as it would review a question of law? Or, should it review that factfinding as it would review a trial judge's factfinding in other cases, namely by taking them as correct "unless clearly erroneous?" See Fed. Rule Civ. Proc. 52(a)(6). We hold that the appellate court must apply a "clear error," not a de novo, standard of review.

I

The basic dispute in this case concerns the meaning of the words "molecular weight" as those words appear in a patent claim. The petitioners, Teva Pharmaceuticals (along with related firms), own the relevant patent. The patent covers a manufacturing method for Copaxone, a drug used to treat multiple sclerosis. The drug's active ingredient, called "copolymer-1," is made up of

molecules of varying sizes. And the relevant claim describes that ingredient as having "a molecular weight of 5 to 9 kilodaltons."

[Sandoz, the accused infringer, argued that the patent claim was invalid because the "a molecular weight of 5 to 9 kilodaltons" failed the definiteness requirement of 35 U.S.C. § 112. Sandoz argued that] the term "molecular weight" might mean any one of three different things. The phrase might refer (1) to molecular weight as calculated by the weight of the molecule that is most prevalent in the mix that makes up copolymer-1. (The scientific term for molecular weight so calculated is, we are told, "peak average molecular weight.") The phrase might refer (2) to molecular weight as calculated by taking all the different-sized molecules in the mix that makes up copolymer-1 and calculating the average weight, i.e., adding up the weight of each molecule and dividing by the number of molecules. (The scientific term for molecular weight so calculated is, we are told, "number average molecular weight.") Or, the phrase might refer (3) to molecular weight as calculated by taking all the different-sized molecules in the mix that makes up copolymer-1 and calculating their average weight while giving heavier molecules a weight-related bonus when doing so. (The scientific term for molecular weight so calculated, we are told, is "weight average molecular weight.") In Sandoz's view, since Teva's patent claim does not say which method of calculation should be used, the claim's phrase "molecular weight" is indefinite [and thus the patent claim is invalid.]

The District Court, after taking evidence from experts, concluded that the patent claim was sufficiently definite. Among other things, it found that in context a skilled artisan would understand that the term "molecular weight" referred to molecular weight as calculated by the first method, i.e., "peak average molecular weight." … On appeal, the Federal Circuit held to the contrary. It found that the term "molecular weight" was indefinite. And it consequently held the patent invalid. 723 F. 3d, at 1369. In reaching this conclusion, the Federal Circuit reviewed de novo all aspects of the District Court's claim construction, including the District Court's determination of subsidiary facts. [Teva sought and obtained certiorari to review the Federal Circuit's de novo standard of review.]

II

A

Federal Rule of Civil Procedure 52(a)(6) states that a court of appeals "must not . . . set aside" a district court's "[f]indings of fact" unless they are "clearly erroneous." In our view, this rule and the standard it sets forth must apply when a court of appeals reviews a district court's resolution of subsidiary factual matters made in the course of its construction of a patent claim. We have made clear that the Rule sets forth a "clear command." *Anderson v. Bessemer City*, 470 U.S. 564, 574 (1985). "It does not make exceptions or purport to exclude certain categories of factual findings from the obligation of a court of appeals to accept a district court's findings unless clearly erroneous." *Pullman-Standard v. Swint*, 456 U.S. 273, 287 (1982). Accordingly, the Rule applies to both subsidiary and ultimate facts. Ibid. And

we have said that, when reviewing the findings of a "'district court sitting without a jury, appellate courts must constantly have in mind that their function is not to decide factual issues de novo.'" *Anderson*, supra, at 57 (quoting *Zenith Radio Corp. v. Hazeltine Research, Inc.*, 395 U.S. 100, 123 (1969)).

Even if exceptions to the Rule were permissible, we cannot find any convincing ground for creating an exception to that Rule here. The Rules Advisory Committee pointed out that, in general, exceptions "would tend to undermine the legitimacy of the district courts . . ., multiply appeals . . ., and needlessly reallocate judicial authority." Advisory Committee's 1985 Note on subd. (a) of Fed. Rule Civ. Proc. 52, 28 U.S.C. App., pp. 908-909 see also *Anderson*, supra, at 574-575 (de novo review of factual findings "would very likely contribute only negligibly" to accuracy "at a huge cost in diversion of judicial resources").

Our opinion in *Markman* neither created, nor argued for, an exception to Rule 52(a). The question presented in that case was a Seventh Amendment question: Should a jury or a judge construe patent claims? 517 U.S., at 372. We pointed out that history provides no clear answer. Id., at 388.The task primarily involves the construction of written instruments. Id., at 386, 388, 389. And that task is better matched to a judge's skills. Id., at 388 ("The construction of written instruments is one of those things that judges often do and are likely to do better than jurors unburdened by training in exegesis"). We consequently held that claim construction falls "exclusively within the province of the court," not that of the jury. Id., at 372.

When describing claim construction we concluded that it was proper to treat the ultimate question of the proper construction of the patent as a question of law in the way that we treat document construction as a question of law. Id., at 388-391. But this does not imply an exception to Rule 52(a) for underlying factual disputes. We used the term "question of law" while pointing out that a judge, in construing a patent claim, is engaged in much the same task as the judge would be in construing other written instruments, such as deeds, contracts, or tariffs. Id., at 384, 386, 388, 389; see also *Motion Picture Patents Co. v. Universal Film Mfg. Co.*, 243 U.S. 502, 510 (1917) (patent claims are "aptly likened to the description in a deed, which sets the bounds to the grant which it contains"); *Goodyear Dental Vulcanite Co. v. Davis*, 102 U.S. 222, 227 (1880) (analogizing patent construction to the construction of other written instruments like contracts). Construction of written instruments often presents a "question solely of law," at least when the words in those instruments are "used in their ordinary meaning." *Great Northern R. Co. v. Merchants Elevator Co.*, 259 U.S. 285, 291. But sometimes, say when a written instrument uses "technical words or phrases not commonly understood," id., at 292, those words may give rise to a factual dispute. If so, extrinsic evidence may help to "establish a usage of trade or locality." Ibid. And in that circumstance, the "determination of the matter of fact" will "preced[e]" the "function of construction." Ibid.; see also 12 R. Lord, Williston on Contracts §§34:1, p. 2, 34:19, p. 174 (4th ed. 2012) (In contract interpretation, the existence of a "usage"—a "practice or method" in the relevant industry—"is a question of fact" (internal quotation marks omitted)). This factual determination, like all other factual determinations, must be reviewed for clear error. See *Pullman-*

Standard, supra at 287 (The Rule does not "exclude certain categories of factual findings" and applies to both "subsidiary" and "ultimate" facts (internal quotation marks omitted)).

Accordingly, when we held in *Markman* that the ultimate question of claim construction is for the judge and not the jury, we did not create an exception from the ordinary rule governing appellate review of factual matters. *Markman* no more creates an exception to Rule 52(a) than would a holding that judges, not juries, determine equitable claims, such as requests for injunctions. A conclusion that an issue is for the judge does not indicate that Rule 52(a) is inapplicable. See Fed. Rule Civ. Proc. 52 (setting the standard of review for "[Factual] Findings and Conclusions by the Court" (emphasis added)).

While we held in that the ultimate issue of the proper construction of a claim should be treated as a question of law, we also recognized that in patent construction, subsidiary factfinding is sometimes necessary. Indeed, we referred to claim construction as a practice with "evidentiary underpinnings," a practice that "falls somewhere between a pristine legal standard and a simple historical fact." 517 U.S., at 378, 388. We added that sometimes courts may have to make "credibility judgments" about witnesses. Id., at 389. In other words, we recognized that courts may have to resolve subsidiary factual disputes. And, as explained above, the Rule requires appellate courts to review all such subsidiary factual findings under the "clearly erroneous" standard.

Precedent further supports application of the "clearly erroneous" standard. Before the creation of the Federal Circuit, the Second Circuit explained that in claim construction, the subsidiary "question . . . of how the art understood the term . . . was plainly a question of fact; and unless the [district court's] finding was 'clearly erroneous,' we are to take" it "as controlling." *Harries v. Air King Products, Co.*, 183 F. 2d 158, 164 (CA2 1950) (L. Hand, C. J.). We have said the same as to subsidiary factual findings concerning other patent law inquiries, including "obviousness." *Dennison Mfg. Co. v. Panduit Corp*., 475 U.S. 809, 811, 106 S. Ct. 1578, 89 L. Ed. 2d 817 (1986) (per curiam) ("subsidiary determinations of the District Court" subject to Rule 52(a)'s clear error standard).

Finally, practical considerations favor clear error review. We have previously pointed out that clear error review is "particularly" important where patent law is at issue because patent law is "a field where so much depends upon familiarity with specific scientific problems and principles not usually contained in the general storehouse of knowledge and experience." *Graver Tank & Mfg. Co. v. Linde Air Products Co.*, 339 U.S. 605, 610 (1950). A district court judge who has presided over, and listened to, the entirety of a proceeding has a comparatively greater opportunity to gain that familiarity than an appeals court judge who must read a written transcript or perhaps just those portions to which the parties have referred.

B

The Federal] Circuit feared that "clear error" review would bring about less uniformity. Neither the Circuit nor Sandoz, however, has shown that (or explained

why) divergent claim construction stemming from divergent findings of fact (on subsidiary matters) should occur more than occasionally. After all, the Federal Circuit will continue to review de novo the district court's ultimate interpretation of the patent claims. And the attorneys will no doubt bring cases construing the same claim to the attention of the trial judge; those prior cases will sometimes be binding because of issue preclusion, see *Markman*, 517 U.S., at 391, and sometimes will serve as persuasive authority. Moreover, it is always possible to consolidate for discovery different cases that involve construction of the same claims. And, as we said in *Markman*, subsidiary factfinding is unlikely to loom large in the universe of litigated claim construction. Id., at 389-390.

…

D

Now that we have set forth why the Federal Circuit must apply clear error review when reviewing subsidiary factfinding in patent claim construction, it is necessary to explain how the rule must be applied in that context. We recognize that a district court's construction of a patent claim, like a district court's interpretation of a written instrument, often requires the judge only to examine and to construe the document's words without requiring the judge to resolve any underlying factual disputes. As all parties agree, when the district court reviews only evidence intrinsic to the patent (the patent claims and specifications, along with the patent's prosecution history), the judge's determination will amount solely to a determination of law, and the Court of Appeals will review that construction de novo. See Brief for Petitioners 27, Reply Brief 16; Brief for Respondents 43; see also Brief for United States as Amicus Curiae 12-13.

In some cases, however, the district court will need to look beyond the patent's intrinsic evidence and to consult extrinsic evidence in order to understand, for example, the background science or the meaning of a term in the relevant art during the relevant time period. See, e.g., *Seymour v. Osborne*, 78 U.S. 516 (1871) (a patent may be "so interspersed with technical terms and terms of art that the testimony of scientific witnesses is indispensable to a correct understanding of its meaning"). In cases where those subsidiary facts are in dispute, courts will need to make subsidiary factual findings about that extrinsic evidence. These are the "evidentiary underpinnings" of claim construction that we discussed in *Markman*, and this subsidiary factfinding must be reviewed for clear error on appeal.

For example, if a district court resolves a dispute between experts and makes a factual finding that, in general, a certain term of art had a particular meaning to a person of ordinary skill in the art at the time of the invention, the district court must then conduct a legal analysis: whether a skilled artisan would ascribe that same meaning to that term in the context of the specific patent claim under review. That is because "[e]xperts may be examined to explain terms of art, and the state of the art, at any given time," but they cannot be used to prove "the proper or legal construction of any instrument of writing." *Winans v. New York & Erie R. Co.*, 62 U.S. 88 (1859); see also *Markman*, supra, at 388 ("'Where technical terms are used, or

where the qualities of substances . . . or any similar data necessary to the comprehension of the language of the patent are unknown to the judge, the testimony of witnesses may be received upon these subjects, and any other means of information be employed. But in the actual interpretation of the patent the court proceeds upon its own responsibility, as an arbiter of the law, giving to the patent its true and final character and force'" (quoting 2 W. Robinson, Law of Patents §732, pp. 482-483 (1890); emphasis in original)).

Accordingly, the question we have answered here concerns review of the district court's resolution of a subsidiary factual dispute that helps that court determine the proper interpretation of the written patent claim. The district judge, after deciding the factual dispute, will then interpret the patent claim in light of the facts as he has found them. This ultimate interpretation is a legal conclusion. The appellate court can still review the district court's ultimate construction of the claim de novo. But, to overturn the judge's resolution of an underlying factual dispute, the Court of Appeals must find that the judge, in respect to those factual findings, has made a clear error. Fed. Rule Civ. Proc. 52(a)(6).

In some instances, a factual finding will play only a small role in a judge's ultimate legal conclusion about the meaning of the patent term. But in some instances, a factual finding may be close to dispositive of the ultimate legal question of the proper meaning of the term in the context of the patent. Nonetheless, the ultimate question of construction will remain a legal question. Simply because a factual finding may be nearly dispositive does not render the subsidiary question a legal one. "[A]n issue does not lose its factual character merely because its resolution is dispositive of the ultimate" legal question. *Miller v. Fenton*, 474 U.S. 104, 113 (1985). It is analogous to a judge (sitting without a jury) deciding whether a defendant gave a confession voluntarily. The answer to the legal question about the voluntariness of the confession may turn upon the answer to a subsidiary factual question, say "whether in fact the police engaged in the intimidation tactics alleged by the defendant." Id., at 112. An appellate court will review the trial judge's factual determination about the alleged intimidation deferentially (though, after reviewing the factual findings, it will review a judge's ultimate determination of voluntariness de novo). See id., at 112-118. An appellate court similarly should review for clear error those factual findings that underlie a district court's claim construction.

III

We can illustrate our holding by considering an instance in which Teva, with the support of the Solicitor General, argues that the Federal Circuit wrongly reviewed the District Court's factual finding de novo. Recall that Teva's patent claim specifies an active ingredient with a "molecular weight of about 5 to 9 kilodaltons." Recall Sandoz's basic argument, namely that the term "molecular weight" is indefinite or ambiguous. The term might refer to [i] the weight of the most numerous molecule, it might refer to [ii] weight as calculated by the average weight of all molecules, or it might refer to [iii] weight as calculated by an average in which heavier molecules count for more. The claim, Sandoz argues, does not tell us which way we should calculate weight. See Part I, supra.

Teva argued in the District Court that the term "molecular weight" in the patent meant molecular weight calculated in the first way (the weight of the most prevalent molecule, or peak average molecular weight). Sandoz, however, argued that figure 1 of the patent showed that Teva could not be right. [Figure 1 is set forth below.] That figure, said Sandoz, helped to show that the patent term did not refer to the first method of calculation. Figure 1 shows how the weights of a sample's molecules were distributed in three different samples. The curves indicate the number of molecules of each weight that were present in each of the three. For example, the figure's legend says that the first sample's "molecular weight" is 7.7. According to Teva, that should mean that molecules weighing 7.7 kilodaltons were the most prevalent molecules in the sample. But, look at the curve, said Sandoz. It shows that the most prevalent molecule weighed, not 7.7 kilodaltons, but slightly less than 7.7 (about 6.8) kilodaltons. After all, the peak of the first molecular weight distribution curve (the solid curve in the figure) is not at precisely 7.7 kilodaltons, but at a point just before 7.7. Thus, argued Sandoz, the figure shows that the patent claim term "molecular weight" did not mean molecular weight calculated by the first method. It must mean something else. It is indefinite.

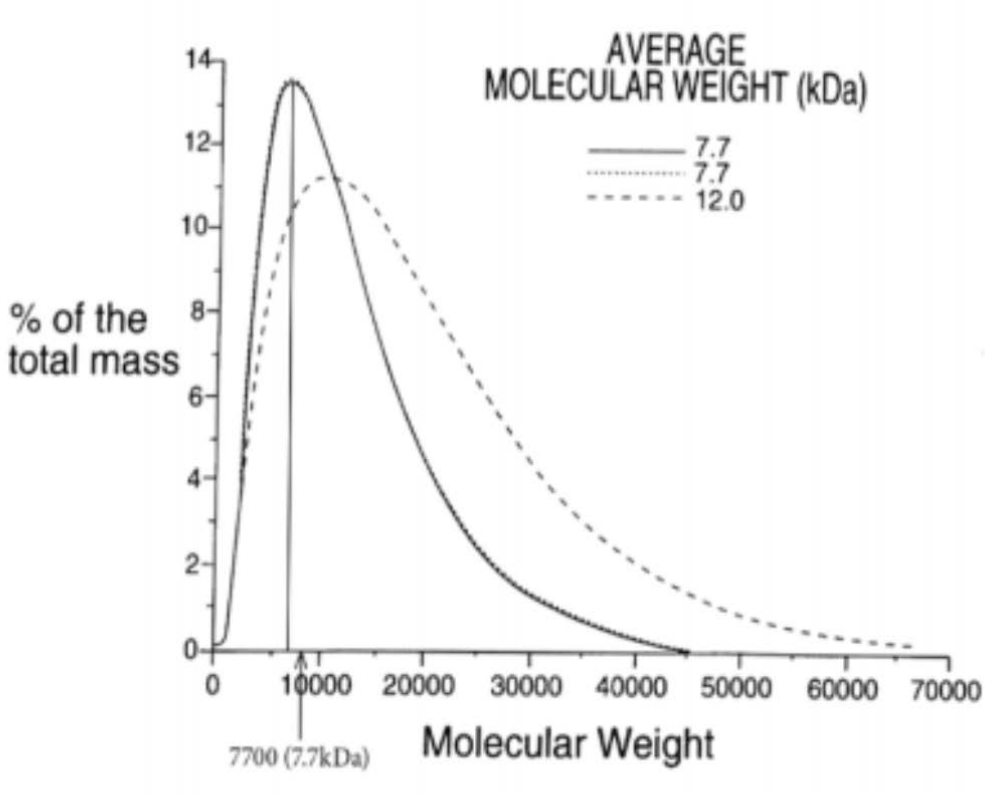

FIG. 1 (with minor additions to emphasize that the peak of the solid curve does not correspond precisely to 7.7kDa)

The District Court did not accept Sandoz's argument. Teva's expert testified that a skilled artisan would understand that converting data from a chromatogram to molecular weight distribution curves like those in figure 1 would cause the peak on each curve to shift slightly; this could explain the difference between the value

indicated by the peak of the curve (about 6.8) and the value in the figure's legend (7.7). Sandoz's expert testified that no such shift would occur. The District Court credited Teva's expert's account, thereby rejecting Sandoz's expert's explanation. The District Court's finding about this matter was a factual finding—about how a skilled artisan would understand the way in which a curve created from chromatogram data reflects molecular weights. Based on that factual finding, the District Court reached the legal conclusion that figure 1 did not undermine Teva's argument that molecular weight referred to the first method of calculation (peak average molecular weight).

When the Federal Circuit reviewed the District Court's decision, it recognized that the peak of the curve did not match the 7.7 kilodaltons listed in the legend of figure 1. But the Federal Circuit did not accept Teva's expert's explanation as to how a skilled artisan would expect the peaks of the curves to shift. And it failed to accept that explanation without finding that the District Court's contrary determination was "clearly erroneous." The Federal Circuit should have accepted the District Court's finding unless it was "clearly erroneous." Our holding today makes clear that, in failing to do so, the Federal Circuit was wrong.

Teva claims that there are two additional instances in which the Federal Circuit rejected the District Court's factual findings without concluding that they were clearly erroneous. We leave these matters for the Federal Circuit to consider on remand in light of today's opinion.

We vacate the Federal Circuit's judgment, and we remand the case for further proceedings consistent with this opinion.

It is so ordered.

[A dissent by Justice Thomas, joined by Justice Alito, is omitted.]

NOTES AND QUESTIONS ON *TEVA*

1. Seemingly Small But Important Issue. *Teva* resolves a seemingly small but actually quite important procedural issue that Federal Circuit judges had debated in various opinions for more than a decade. The resolution of the issue is somewhat of a split decision. Trial court decisions on claim construction will be entitled to deference to the extent that the trial judge (i) relied on "extrinsic evidence" and (ii) made explicit findings of fact based on that extrinsic evidence. In other circumstances, trial courts will still have their claim constructions review *de novo* even if, as is often the case, the trial judge bases a claim construction on a careful reading of the specification, the prosecution file history and lengthy briefs containing much argumentation.

Does this split in the standard of review create incentives for parties to introduce extrinsic evidence and for judges to rely on such evidence in interpreting the claims?

2. Deference to PTO Interpretations. Though this case involved the standard by which the Federal Circuit reviews district court claim interpretations, it has implications for how the appellate court will review PTO claim interpretations.

Certainly, the Federal Circuit's prior rule—under which all administrative claim interpretations were reviewed *de novo*—must be wrong at least in those circumstances where a party before the agency introduces extrinsic evidence and the agency relies on that evidence. In other words, *SDRAM Corp. v. AD-II Eng'g, Inc.,* 465 F.3d 1351 (Fed. Cir. 2006) (discussed in the casebook in note 5 on pp. 863-64) must now be viewed as bad law. The interesting question is whether the agency should get deference in other circumstances too. For example, if the agency merely asserts, based on its expertise but without record evidence, that a particular term would have a certain meaning to a person of ordinary skill in the art, would the Federal Circuit be required to afford some deference to that interpretation. *See* casebook note 5, p. 864, for cases suggesting that deference would be due.

3. Hinting at a New Procedure for Determining Claim Validity? Prior to *Teva*, the Federal Circuit's case law seemed to require a quite different procedure for determining the meaning, versus the validity, of patent claims. Claim meaning could be determined by a district judge in a pre-trial hearing. Claim validity had to await trial because the underlying facts associated with validity were supposed to be decided by a jury. That difference could be justified, prior to *Teva*, by the view that claim interpretation was almost exclusive legal whereas claim validity, while ultimately an issue of law, depended much more heavily on fact finding. After *Teva*, however, that distinction no longer holds water. Indeed, the *Teva* Court explicitly drew an analogy between (i) review of the factual issues underlying claim construction and (ii) review of the factual issues underlying obviousness.

The apparent question now is whether the same process for claim interpretation—a pretrial hearing with district judges ruling on the ultimate legal issue based on their own subsidiary fact findings—can now be used for patent validity issues. The procedural posture of *Teva* strongly suggests an affirmative answer to that question, and in fact, the ultimate legal issue being decided in *Teva* itself was a patent validity issue—claim definiteness.

Chap. 8.G. Indirect Infringement.

Commil USA, LLC v. Cisco Systems

135 S. Ct. 1920 (May 26, 2015)

JUSTICE KENNEDY delivered the opinion of the Court.*

A patent holder, and the holder's lawful licensees, can recover for monetary injury when their exclusive rights are violated by others' wrongful conduct. One form of patent injury occurs if unauthorized persons or entities copy, use, or otherwise infringe upon the patented invention. Another form of injury to the patent holder or his licensees can occur when the actor induces others to infringe the patent. In the instant case, both forms of in-jury—direct infringement and wrongful inducement of others to commit infringement—were alleged. After two trials, the

* JUSTICE THOMAS joins Parts II-B and III of this opinion.

defendant was found liable for both types of injury. The dispute now before the Court concerns the inducement aspect of the case.

I

The patent holder who commenced this action is the petitioner here, Commil USA, LLC. The technical details of Commil's patent are not at issue. So it suffices to say, with much oversimplification, that the patent is for a method of implementing short-range wireless networks. Suppose an extensive business headquarters or a resort or a college campus wants a single, central wireless system (sometimes called a Wi-Fi network). In order to cover the large space, the system needs multiple base stations so a user can move around the area and still stay connected. Commil's patent relates to a method of providing faster and more reliable communications between devices and base stations. The particular claims of Commil's patent are discussed in the opinion of the United States Court of Appeals for the Federal Circuit. 720 F. 3d 1361, 1364-1365, 1372 (2013).

Commil brought this action against Cisco Systems, Inc., which makes and sells wireless networking equipment. In 2007, Commil sued Cisco in the United States District Court for the Eastern District of Texas. Cisco is the respondent here. Commil alleged that Cisco had infringed Commil's patent by making and using networking equipment. In addition Commil alleged that Cisco had induced others to infringe the patent by selling the infringing equipment for them to use, in contravention of Commil's exclusive patent rights.

At the first trial, the jury concluded that Commil's patent was valid and that Cisco had directly infringed. The jury awarded Commil $3.7 million in damages. As to induced infringement, the jury found Cisco not liable. Commil filed a motion for a new trial on induced infringement and damages, which the District Court granted because of certain inappropriate comments Cisco's counsel had made during the first trial. [*]

A month before the second trial Cisco went to the United States Patent and Trademark Office and asked it to reexamine the validity of Commil's patent. The Office granted the request; but, undoubtedly to Cisco's disappointment, it confirmed the validity of Commil's patent.

Back in the District Court, the second trial proceeded, limited to the issues of inducement and damages on that issue and direct infringement. As a defense to the claim of inducement, Cisco argued it had a good-faith belief that Commil's patent was invalid. It sought to introduce evidence to support that assertion. The District Court, however, ruled that Cisco's proffered evidence of its good-faith belief in the patent's invalidity was inadmissible. While the District Court's order does not

[*] [Eds. note: Commil is an Israeli company and the inventors in the case were Jewish. In affirming the district court's new trial order, the Federal Circuit found that Cisco's lawyers had "attempted to instill in the jury, through irrelevant references to ethnicity and religion, an 'us versus them' mentality," and that Cisco's lawyers "persisted in its course of conduct even after the court warned counsel" to avoid religious references. 720 F.3d at 1369-70. The Federal Circuit's account of the prejudicial comments by Cisco's lawyers provides a cautionary lesson about inappropriate behavior during trial.]

provide the reason for the ruling, it seems the court excluded this evidence on the assumption that belief in invalidity is not a defense to a plaintiff's claim that the defendant induced others to infringe.

At the close of trial, and over Cisco's objection, the District Court instructed the jury that it could find inducement if "Cisco actually intended to cause the acts that constitute . . . direct infringement and that Cisco knew or should have known that its actions would induce actual infringement." The jury returned a verdict for Commil on induced infringement and awarded $63.7 million in damages.

After the verdict, but before judgment, this Court issued its decision in *Global-Tech Appliances, Inc. v. SEB S. A*., 563 U.S. ___, 131 S. Ct. 2060 (2011). That case, as will be discussed in more detail, held that, in an action for induced infringement, it is necessary for the plaintiff to show that the alleged inducer knew of the patent in question and knew the induced acts were infringing. Relying on that case, Cisco again urged that the jury instruction was incorrect because it did not state knowledge as the governing standard for inducement liability. The District Court denied Cisco's motion and entered judgment in Commil's favor.

Cisco appealed to the United States Court of Appeals for the Federal Circuit. The Court of Appeals affirmed in part, vacated in part, and remanded for further proceedings. The court concluded it was error for the District Court to have instructed the jury that Cisco could be liable for induced infringement if it "'knew or should have known'" that its customers infringed. 720 F. 3d, at 1366. The panel held that "induced infringement 'requires knowledge that the induced acts constitute patent infringement.'" Ibid. (quoting Global-Tech, supra, at ___, 131 S. Ct. 2060, 2068). By stating that Cisco could be found liable if it "'knew or should have known that its actions would induce actual infringement,'" the Court of Appeals explained, the District Court had allowed "the jury to find [Cisco] liable based on mere negligence where knowledge is required." 720 F. 3d, at 1366. That ruling, which requires a new trial on the inducement claim with a corrected instruction on knowledge, is not in question here.

What is at issue is the second holding of the Court of Appeals, addressing Cisco's contention that the trial court committed further error in excluding Cisco's evidence that it had a good-faith belief that Commil's patent was invalid. Beginning with the observation that it is "axiomatic that one cannot infringe an invalid patent," the Court of Appeals reasoned that "evidence of an accused inducer's good-faith belief of invalidity may negate the requisite intent for induced infringement." The court saw "no principled distinction between a good-faith belief of invalidity and a good-faith belief of non-infringement for the purpose of whether a defendant possessed the specific intent to induce infringement of a patent."

Judge Newman dissented on that point. In Judge Newman's view a defendant's good-faith belief in a patent's invalidity is not a defense to induced infringement. She reasoned that "whether there is infringement in fact does not depend on the belief of the accused infringer that it might succeed in invalidating the patent." Both parties filed petitions for rehearing en banc, which were denied.

737 F. 3d 699, 700 (2013). Five judges, however, would have granted rehearing en banc to consider the question whether a good-faith belief in invalidity is a defense to induced infringement. Id., at 700 (Reyna, J., dissenting from denial of rehearing en banc).

This Court granted certiorari to decide that question.

II

Although the precise issue to be addressed concerns a claim of improper inducement to infringe, the discussion to follow refers as well to direct infringement and contributory infringement, so it is instructive at the outset to set forth the statutory provisions pertaining to these three forms of liability. These three relevant provisions are found in §271 of the Patent Act. 35 U.S.C. §271.

Subsection (a) governs direct infringement and provides:

> "Except as otherwise provided in this title, whoever without authority makes, uses, offers to sell, or sells any patented invention, within the United States or imports into the United States any patented invention during the term of the patent therefor, infringes the patent."

Under this form of liability, a defendant's mental state is irrelevant. Direct infringement is a strict-liability offense. *Global-Tech*, 563 U.S., at ___.

Subsection (b) governs induced infringement:

> "Whoever actively induces infringement of a patent shall be liable as an infringer."

In contrast to direct infringement, liability for inducing infringement attaches only if the defendant knew of the patent and that "the induced acts constitute patent infringement." Id., at ___. In Commil and the Government's view, not only is knowledge or belief in the patent's validity irrelevant, they further argue the party charged with inducing infringement need not know that the acts it induced would infringe. On this latter point, they are incorrect, as will be explained below.

Subsection (c) deals with contributory infringement:

> "Whoever offers to sell or sells within the United States or imports into the United States a component of a patented machine, manufacture, combination or composition, or a material or apparatus for use in practicing a patented process, constituting a material part of the invention, knowing the same to be especially made or especially adapted for use in an infringement of such patent, and not a staple article or commodity of commerce suitable for substantial noninfringing use, shall be liable as a contributory infringer."

Like induced infringement, contributory infringement requires knowledge of the patent in suit and knowledge of patent infringement. *Aro Mfg. Co. v. Convertible Top Replacement Co*., 377 U.S. 476, 488 (1964) (*Aro II*).

This case asks a question of first impression: whether knowledge of, or belief in, a patent's validity is required for induced infringement under §271(b).

A

Before turning to the question presented, it is necessary to reaffirm what the Court held in *Global-Tech*. Commil and the Government (which supports Commil in this case) argue that *Global-Tech* should be read as holding that only knowledge of the patent is required for induced infringement. That, as will be explained, would contravene *Global-Tech*'s explicit holding that liability for induced infringement can only attach if the defendant knew of the patent and knew as well that "the induced acts constitute patent infringement." 563 U.S., at ___.

In *Global-Tech*, the plaintiff, SEB, had invented and patented a deep fryer. A few years later, Sunbeam asked Pentalpha to supply deep fryers for Sunbeam to sell. To make the deep fryer, Pentalpha bought an SEB fryer and copied all but the cosmetic features. Pentalpha then sold the fryers to Sunbeam, which in turn sold them to customers. SEB sued Pentalpha for induced infringement, arguing Pentalpha had induced Sunbeam and others to sell the infringing fryers in violation of SEB's patent rights. In defense, Pentalpha argued it did not know the deep fryer it copied was patented and therefore could not be liable for inducing anyone to infringe SEB's patent. The question presented to this Court was "whether a party who 'actively induces infringement of a patent' under 35 U.S.C. §271(b) must know that the induced acts constitute patent infringement." Id., at ___.

After noting the language of §271(b) and the case law prior to passage of the Patent Act did not resolve the question, the *Global-Tech* Court turned to Aro II, a case about contributory infringement. The *Global-Tech* Court deemed that rules concerning contributory infringement were relevant to induced infringement, because the mental state imposed in each instance is similar. Before the Patent Act, inducing infringement was not a separate theory of indirect liability but was evidence of contributory infringement. 563 U.S., at ___. Thus, in many respects, it is proper to find common ground in the two theories of liability.

Aro II concluded that to be liable for contributory infringement, a defendant must know the acts were infringing. 377 U.S., at 488. In *Global-Tech*, the Court said this reasoning was applicable, explaining as follows:

> "Based on this premise, it follows that the same knowledge is needed for induced infringement under §271(b). As noted, the two provisions have a common origin in the pre-1952 understanding of contributory infringement, and the language of the two provisions creates the same difficult interpretive choice. It would thus be strange to hold that knowledge of the relevant patent is needed under §271(c) but not under §271(b).
>
> "Accordingly, we now hold that induced infringement under §271(b) requires knowledge that the induced acts constitute patent infringement." 563 U.S., at ___.

In support of Commil, the Government argues against the clear language of *Global-Tech*. According to the Government, all *Global-Tech* requires is knowledge of the patent: "The Court did not definitively resolve whether Section 271(b) additionally requires knowledge of the infringing nature of the induced acts." Brief

for United States as Amicus Curiae 9. Together, Commil and the Government claim the "factual circumstances" of *Global-Tech* "did not require" the Court to decide whether knowledge of infringement is required for inducement liability. Brief for United States as Amicus Curiae 12. See also Brief for Petitioner 23-24. But in the Court's *Global-Tech* decision, its description of the factual circumstances suggests otherwise. The Court concluded there was enough evidence to support a finding that Pentalpha knew "the infringing nature of the sales it encouraged Sunbeam to make." 563 U.S., at ___, 131 S. Ct. 2060, 2071. It was not only knowledge of the existence of SEB's patent that led the Court to affirm the liability finding but also it was the fact that Pentalpha copied "all but the cosmetic features of SEB's fryer," demonstrating Pentalpha knew it would be causing customers to infringe SEB's patent. Id., at ___, 131 S. Ct. 2060.

Accepting the Government and Commil's argument would require this Court to depart from its prior holding. See id., at ___ . See also id., at ___ (KENNEDY, J., dissenting) ("The Court is correct, in my view, to conclude that . . . to induce infringement a defendant must know the acts constitute patent infringement" (internal quotation marks omitted)). And the *Global-Tech* rationale is sound. Qualifying or limiting its holding, as the Government and Commil seek to do, would lead to the conclusion, both in inducement and contributory infringement cases, that a person, or entity, could be liable even though he did not know the acts were infringing. In other words, even if the defendant reads the patent's claims differently from the plaintiff, and that reading is reasonable, he would still be liable because he knew the acts might infringe. *Global-Tech* requires more. It requires proof the defendant knew the acts were infringing. And the Court's opinion was clear in rejecting any lesser mental state as the standard. Id., at ___.

B

The question the Court confronts today concerns whether a defendant's belief regarding patent validity is a defense to a claim of induced infringement. It is not. The scienter element for induced infringement concerns infringement; that is a different issue than validity. Section 271(b) requires that the defendant "actively induce[d] infringement." That language requires intent to "bring about the desired result," which is infringement. Id., at ___. And because infringement and validity are separate issues under the Act, belief regarding validity cannot negate the scienter required under §271(b).

When infringement is the issue, the validity of the patent is not the question to be confronted. In *Cardinal Chemical Co. v. Morton Int'l, Inc.*, 508 U.S. 83 (1993), the Court explained, "A party seeking a declaratory judgment of invalidity presents a claim independent of the patentee's charge of infringement." Id., at 96. It further held noninfringement and invalidity were "alternative grounds" for dismissing the suit. Id., at 98. … These explanations are in accord with the long-accepted truth—perhaps the axiom—that infringement and invalidity are separate matters under patent law. See *Pandrol USA, LP v. Airboss R. Prods., Inc.*, 320 F. 3d 1354, 1365 (CA Fed. 2003).

Indeed, the issues of infringement and validity appear in separate parts of the Patent Act. Part III of the Act deals with "Patents and Protection of Patent Rights," including the right to be free from infringement. §§251-329. Part II, entitled "Patentability of Inventions and Grants of Patents," defines what constitutes a valid patent. §§100-212. Further, noninfringement and invalidity are listed as two separate defenses, see §§282(b)(1), (2), and defendants are free to raise either or both of them. See Cardinal, supra, at 98. Were this Court to interpret §271(b) as permitting a defense of belief in invalidity, it would conflate the issues of infringement and validity.

Allowing this new defense would also undermine a presumption that is a "common core of thought and truth" reflected in this Court's precedents for a century. *Radio Corp. of America v. Radio Engineering Laboratories, Inc.*, 293 U.S. 1, 8 (1934). Under the Patent Act, and the case law before its passage, a patent is "presumed valid." §282(a); id., at 8. That presumption takes away any need for a plaintiff to prove his patent is valid to bring a claim. But if belief in invalidity were a defense to induced infringement, the force of that presumption would be lessened to a drastic degree, for a defendant could prevail if he proved he reasonably believed the patent was invalid. That would circumvent the high bar Congress is presumed to have chosen: the clear and convincing standard. See *Microsoft Corp. v. i4i Ltd. Partnership*, 564 U.S. ___, ___-___ (2011). Defendants must meet that standard to rebut the presumption of validity. Ibid.

To say that an invalid patent cannot be infringed, or that someone cannot be induced to infringe an invalid patent, is in one sense a simple truth, both as a matter of logic and semantics. See *M. Swift & Sons, Inc. v. W. H. Coe Mfg. Co.*, 102 F. 2d 391, 396 (CA1 1939). But the questions courts must address when interpreting and implementing the statutory framework require a determination of the procedures and sequences that the parties must follow to prove the act of wrongful inducement and any related issues of patent validity. "Validity and infringement are distinct issues, bearing different burdens, different presumptions, and different evidence." 720 F. 3d, at 1374 (opinion of Newman, J.). To be sure, if at the end of the day, an act that would have been an infringement or an inducement to infringe pertains to a patent that is shown to be invalid, there is no patent to be infringed. But the allocation of the burden to persuade on these questions, and the timing for the presentations of the relevant arguments, are concerns of central relevance to the orderly administration of the patent system.

Invalidity is an affirmative defense that "can preclude enforcement of a patent against otherwise infringing conduct." 6A Chisum on Patents §19.01, p. 19-5 (2015). An accused infringer can, of course, attempt to prove that the patent in suit is invalid; if the patent is indeed invalid, and shown to be so under proper procedures, there is no liability. See *i4i*, supra, at ___-___, 131 S. Ct. 2238. That is because invalidity is not a defense to infringement, it is a defense to liability. And because of that fact, a belief as to invalidity cannot negate the scienter required for induced infringement.

There are also practical reasons not to create a defense based on a good-faith belief in invalidity. First and foremost, accused inducers who believe a patent is invalid have various proper ways to obtain a ruling to that effect. They can file a declaratory judgment action asking a federal court to declare the patent invalid. See *MedImmune, Inc. v. Genentech, Inc.*, 549 U.S. 118, 137 (2007). They can seek inter partes review at the Patent Trial and Appeal Board and receive a decision as to validity within 12 to 18 months. See §316. Or they can, as Cisco did here, seek ex parte reexamination of the patent by the Patent and Trademark Office. §302. And, of course, any accused infringer who believes the patent in suit is invalid may raise the affirmative defense of invalidity. §282(b)(2). If the defendant is successful, he will be immune from liability.

Creating a defense of belief in invalidity, furthermore, would have negative consequences. It can render litigation more burdensome for everyone involved. Every accused inducer would have an incentive to put forth a theory of invalidity and could likely come up with myriad arguments. See Sloan, Think it is Invalid? A New Defense to Negate Intent for Induced Infringement, 23 Fed. Cir. B. J. 613, 618 (2013). And since "it is often more difficult to determine whether a patent is valid than whether it has been infringed," *Cardinal*, 508 U.S., at 99, accused inducers would likely find it easier to prevail on a defense regarding the belief of invalidity than noninfringement. In addition the need to respond to the defense will increase discovery costs and multiply the issues the jury must resolve. Indeed, the jury would be put to the difficult task of separating the defendant's belief regarding validity from the actual issue of validity.

As a final note, "[o]ur law is . . . no stranger to the possibility that an act may be 'intentional' for purposes of civil liability, even if the actor lacked actual knowledge that her conduct violated the law." *Jerman v. Carlisle, McNellie, Rini, Kramer & Ulrich, L. P. A.*, 559 U.S. 573, 582-583 (2010). Tortious interference with a contract provides an apt example. While the invalidity of a contract is a defense to tortious interference, belief in validity is irrelevant. Restatement (Second) of Torts §766, Comment i (1979). See also W. Keeton, D. Dobbs, R. Keeton, & D. Owen, Prosser and Keeton on Law of Torts 110 (5th ed. 1984). In a similar way, a trespass "can be committed despite the actor's mistaken belief that she has a legal right to enter the property." Jerman, supra, at 583 (citing Restatement (Second) of Torts §164, and Comment e (1963-1964)). And of course, "[t]he general rule that ignorance of the law or a mistake of law is no defense to criminal prosecution is deeply rooted in the American legal system." *Cheek v. United States*, 498 U.S. 192, 199 (1991). In the usual case, "I thought it was legal" is no defense. That concept mirrors this Court's holding that belief in invalidity will not negate the scienter required under §271(b).

III

The Court is well aware that an "industry has developed in which firms use patents not as a basis for producing and selling goods but, instead, primarily for obtaining licensing fees." *eBay Inc. v. MercExchange, L.L.C.*, 547 U.S. 388, 396 (2006) (KENNEDY, J., concurring). Some companies may use patents as a sword to go after

defendants for money, even when their claims are frivolous. This tactic is often pursued through demand letters, which "may be sent very broadly and without prior investigation, may assert vague claims of infringement, and may be designed to obtain payments that are based more on the costs of defending litigation than on the merit of the patent claims." L. Greisman, Prepared Statement of the Federal Trade Commission on Discussion Draft of Patent Demand Letter Legislation before the Subcommittee on Commerce, Manufacturing, and Trade of the House Committee on Energy and Commerce 2 (2014). This behavior can impose a "harmful tax on innovation." Ibid.

No issue of frivolity has been raised by the parties in this case, nor does it arise on the facts presented to this Court. Nonetheless, it is still necessary and proper to stress that district courts have the authority and responsibility to ensure frivolous cases are dissuaded. If frivolous cases are filed in federal court, it is within the power of the court to sanction attorneys for bringing such suits. Fed. Rule Civ. Proc. 11. It is also within the district court's discretion to award attorney's fees to prevailing parties in "exceptional cases." 35 U.S.C. §285; see also *Octane Fitness, LLC v. ICON Health & Fitness, Inc.*, 572 U.S. ___, ___-___ (2014). These safeguards, combined with the avenues that accused inducers have to obtain rulings on the validity of patents, militate in favor of maintaining the separation expressed throughout the Patent Act between infringement and validity. This dichotomy means that belief in invalidity is no defense to a claim of induced infringement.

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

It is so ordered.

JUSTICE BREYER took no part in the consideration or decision of this case.

JUSTICE SCALIA, with whom THE CHIEF JUSTICE joins, dissenting.

I agree with the Court's rejection of the main argument advanced by Commil and the United States, that induced infringement under 35 U.S.C. §271(b) does not "requir[e] knowledge of the infringing nature of the induced acts." Brief for United States as Amicus Curiae 9; see also Brief for Petitioner 15-44. I disagree, however, with the Court's holding that good-faith belief in a patent's invalidity is not a defense to induced infringement.

Infringing a patent means invading a patentee's exclusive right to practice his claimed invention. *Crown Die & Tool Co. v. Nye Tool & Machine Works*, 261 U.S. 24, 40 (1923) (quoting 3 W. Robinson, Law of Patents §937, pp. 122-123 (1890)). Only valid patents confer this right to exclusivity—invalid patents do not. FTC v. Actavis, Inc., 570 U.S. ___, ___ (2013). It follows, as night the day, that only valid patents can be infringed. To talk of infringing an invalid patent is to talk nonsense.

Induced infringement, we have said, "requires knowledge that the induced acts constitute patent infringement." Global-Tech Appliances, Inc. v. SEB S. A., 563 U.S. ___, ___, 131 S. Ct. 2060, 2068 (2011) . Because only valid patents can be

infringed, anyone with a good-faith belief in a patent's invalidity necessarily believes the patent cannot be infringed. And it is impossible for anyone who believes that a patent cannot be infringed to induce actions that he knows will infringe it. A good-faith belief that a patent is invalid is therefore a defense to induced infringement of that patent. …

NOTES AND QUESTIONS ON *COMMIL*

1. The Infringement-Validity Split. Together *Commil* and the prior *Global-Tech* decision define a split: Induced infringement requires proof that the defendant the induced acts constituted infringement (or was willfully blind to that possibility), but it requires no proof concerning the defendant's awareness of patent validity. Thus, a good faith belief in non-infringement will protect a defendant from liability, but a good faith belief in a patent's invalidity will not. Does this split make sense? Is it true, as the Court asserts, that "it is often more difficult to determine whether a patent is valid than whether it has been infringed"? Is the statutory presumption of patent validity the key to the Court's holding in *Commil*?

2. Claim-by-Claim or Patent-by-Patent. Consider this hypothetical: A patent issues with a broader claim 1 and a narrower claim 2. Company A is inducing its customers to take steps that it knows infringe claim 1, but Company A does not believe that the induced steps infringe claim 2 (and the company is not being willfully blind to the possibility of infringement of claim 2). The patentee sues Company A for infringement of claims 1 & 2. Claim 1 is held invalid; claim 2 valid. Should Company A be liable for inducing infringement of the patent? Or equivalently, which of the following two jury instructions is valid:

> a. "To find that the defendant induced infringement, you the members of the jury must find that the defendant knew that the actions induced by it constituted infringement of *the plaintiff's patent*."
>
> b. "To find that the defendant induced infringement, you the members of the jury must find that the defendant knew that the actions induced by it constituted infringement of *at least one claim in the plaintiff's patent that has been determined in this litigation to be not invalid*."

3. The Market for Beliefs. Imagine you are the general counsel of a large company and you are hiring a new outside patent counsel for your firm. Two candidates X and Y from different law firms are being interviewed. You give each of the candidates a test about how they would interpret patent claims. Candidate X tends to interpret claims broadly; Candidate Y tends to interpret them narrowly. If your firm is frequently charged with inducing infringement, do the results of the test give you a reason to prefer one candidate over another?

Chapter 9: Remedies

Chap. 9.A. Insert after *eBay*, p. 902, the following new note:

11. **Injunction Statistics After *eBay.*** The very useful "Patstats" website from the University of Houston Law School provides some useful information. See http://www.patstats.org/Patstats2.html, at tab "Post-eBay Permanent Injunction Rulings in Patent Cases to 12/31/13". The spreadsheet available at this site shows 234 cases since *eBay* in 2006 where permanent injunctions were considered; the courts granted injunctions in 76% of the cases (178 out of 234 cases).

Chap. 9.F. In place of the short note on page 984, add the following Supreme Court cases:

Octane Fitness, LLC.
v.
Icon Health & Fitness, Inc.

134 S.Ct. 1749 (2014)

Justice SOTOMAYOR delivered the opinion of the Court.

Section 285 of the Patent Act authorizes a district court to award attorney's fees in patent litigation. It provides, in its entirety, that "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285. In Brooks Furniture Mfg., Inc. v. Dutailier Int'l, Inc., 393 F.3d 1378 (2005), the United States Court of Appeals for the Federal Circuit held that "[a] case may be deemed exceptional" under § 285 only in two limited circumstances: "when there has been some material inappropriate conduct," or when the litigation is both "brought in subjective bad faith" and "objectively baseless." Id., at 1381. The question before us is whether the Brooks Furniture framework is consistent with the statutory text. We hold that it is not.

I
A

Prior to 1946, the Patent Act did not authorize the awarding of attorney's fees to the prevailing party in patent litigation. Rather, the "American Rule" governed: " '[E]ach litigant pa[id] his own attorney's fees, win or lose....' " Marx v. General Revenue Corp., 568 U.S. ––––, ––––, 133 S.Ct. 1166, 1175, 185 L.Ed.2d 242 (2013). In 1946, Congress amended the Patent Act to add a discretionary fee-shifting provision, then codified in § 70, which stated that a court "may in its

discretion award reasonable attorney's fees to the prevailing party upon the entry of judgment in any patent case." 35 U.S.C. § 70 (1946 ed.).1

Courts did not award fees under § 70 as a matter of course. They viewed the award of fees not "as a penalty for failure to win a patent infringement suit," but as appropriate "only in extraordinary circumstances." Park–In–Theatres, Inc. v. Perkins, 190 F.2d 137, 142 (C.A.9 1951). The provision enabled them to address "unfairness or bad faith in the conduct of the losing party, or some other equitable consideration of similar force," which made a case so unusual as to warrant fee-shifting. Ibid.; see also Pennsylvania Crusher Co. v. Bethlehem Steel Co., 193 F.2d 445, 451 (C.A.3 1951) (listing as "adequate justification[s]" for fee awards "fraud practiced on the Patent Office or vexatious or unjustified litigation").

Six years later, Congress amended the fee-shifting provision and recodified it as § 285. Whereas § 70 had specified that a district court could "in its discretion award reasonable attorney's fees to the prevailing party," the revised language of § 285 (which remains in force today) provides that "[t]he court in exceptional cases may award reasonable attorney fees to the prevailing party." We have observed, in interpreting the damages provision of the Patent Act, that the addition of the phrase "exceptional cases" to § 285 was "for purposes of clarification only."2 General Motors Corp. v. Devex Corp., 461 U.S. 648, 653, n. 8, 103 S.Ct. 2058, 76 L.Ed.2d 211 (1983); see also id., at 652, n. 6, 103 S.Ct. 2058. And the parties agree that the recodification did not substantively alter the meaning of the statute.3

For three decades after the enactment of § 285, courts applied it—as they had applied § 70—in a discretionary manner, assessing various factors to determine whether a given case was sufficiently "exceptional" to warrant a fee award. See, e.g., True Temper Corp. v. CF & I Steel Corp., 601 F.2d 495, 508–509 (C.A.10 1979); Kearney & Trecker Corp. v. Giddings & Lewis, Inc., 452 F.2d 579, 597 (C.A.7 1971); Siebring v. Hansen, 346 F.2d 474, 480–481 (C.A.8 1965).

In 1982, Congress created the Federal Circuit and vested it with exclusive appellate jurisdiction in patent cases. 28 U.S.C. § 1295. In the two decades that followed, the Federal Circuit, like the regional circuits before it, instructed district courts to consider the totality of the circumstances when making fee determinations under § 285. See, e.g., Rohm & Haas Co. v. Crystal Chemical Co., 736 F.2d 688, 691 (C.A.Fed.1984) ("Cases decided under § 285 have noted that 'the substitution of the phrase "in exceptional cases" has not done away with the discretionary feature' "); Yamanouchi Pharmaceutical Co., Ltd. v. Danbury Pharmacal, Inc., 231 F.3d 1339, 1347 (C.A.Fed.2000) ("In assessing whether a case qualifies as exceptional, the district court must look at the totality of the circumstances").

In 2005, however, the Federal Circuit abandoned that holistic, equitable approach in favor of a more rigid and mechanical formulation. In Brooks Furniture Mfg., Inc. v. Dutailier Int'l, Inc., 393 F.3d 1378 (2005), the court held that a case is "exceptional" under § 285 only "when there has been some material inappropriate

conduct related to the matter in litigation, such as willful infringement, fraud or inequitable conduct in procuring the patent, misconduct during litigation, vexatious or unjustified litigation, conduct that violates Fed.R.Civ.P. 11, or like infractions." Id., at 1381. "Absent misconduct in conduct of the litigation or in securing the patent," the Federal Circuit continued, fees "may be imposed against the patentee only if both (1) the litigation is brought in subjective bad faith, and (2) the litigation is objectively baseless." Ibid. The Federal Circuit subsequently clarified that litigation is objectively baseless only if it is "so unreasonable that no reasonable litigant could believe it would succeed," iLOR, LLC v. Google, Inc., 631 F.3d 1372, 1378 (2011), and that litigation is brought in subjective bad faith only if the plaintiff "actually know[s]" that it is objectively baseless, id., at 1377.4

Finally, Brooks Furniture held that because "[t]here is a presumption that the assertion of infringement of a duly granted patent is made in good faith[,] ... the underlying improper conduct and the characterization of the case as exceptional must be established by clear and convincing evidence." 393 F.3d, at 1382.

B

The parties to this litigation are manufacturers of exercise equipment. The respondent, ICON Health & Fitness, Inc., owns U.S. Patent No. 6,019,710 ('710 patent), which discloses an elliptical exercise machine that allows for adjustments to fit the individual stride paths of users. ICON is a major manufacturer of exercise equipment, but it has never commercially sold the machine disclosed in the ′710 patent. The petitioner, Octane Fitness, LLC, also manufactures exercise equipment, including elliptical machines known as the Q45 and Q47.

ICON sued Octane, alleging that the Q45 and Q47 infringed several claims of the '710 patent. The District Court granted Octane's motion for summary judgment, concluding that Octane's machines did not infringe ICON's patent. 2011 WL 2457914 (D.Minn., June 17, 2011). Octane then moved for attorney's fees under § 285. Applying the Brooks Furniture standard, the District Court denied Octane's motion. 2011 WL 3900975 (D.Minn., Sept. 6, 2011). It determined that Octane could show neither that ICON's claim was objectively baseless nor that ICON had brought it in subjective bad faith. As to objective baselessness, the District Court rejected Octane's argument that the judgment of noninfringement "should have been a foregone conclusion to anyone who visually inspected" Octane's machines. Id., *2. The court explained that although it had rejected ICON's infringement arguments, they were neither "frivolous" nor "objectively baseless." Id., *2–*3. The court also found no subjective bad faith on ICON's part, dismissing as insufficient both "the fact that [ICON] is a bigger company which never commercialized the ′710 patent" and an e-mail exchange between two ICON sales executives, which Octane had offered as evidence that ICON had brought the infringement action "as a matter of commercial strategy."5 Id., *4.

ICON appealed the judgment of noninfringement, and Octane cross-appealed the denial of attorney's fees. The Federal Circuit affirmed both orders. 496 Fed.Appx. 57 (2012). In upholding the denial of attorney's fees, it rejected Octane's argument that the District Court had "applied an overly restrictive standard in refusing to find the case exceptional under § 285." Id., at 65. The Federal Circuit declined to "revisit the settled standard for exceptionality." Ibid.

We granted certiorari, 570 U.S. ––––, 134 S.Ct. 49, 186 L.Ed.2d 962 (2013), and now reverse.

II

The framework established by the Federal Circuit in Brooks Furniture is unduly rigid, and it impermissibly encumbers the statutory grant of discretion to district courts.

A

Our analysis begins and ends with the text of § 285: "The court in exceptional cases may award reasonable attorney fees to the prevailing party." This text is patently clear. It imposes one and only one constraint on district courts' discretion to award attorney's fees in patent litigation: The power is reserved for "exceptional" cases.

The Patent Act does not define "exceptional," so we construe it " 'in accordance with [its] ordinary meaning.' " Sebelius v. Cloer, 569 U.S. ––––, ––––, 133 S.Ct. 1886, 1893, 185 L.Ed.2d 1003 (2013); see also Bilski v. Kappos, 561 U.S. 593, ––––, 130 S.Ct. 3218, 3226, 177 L.Ed.2d 792 (2010) ("In patent law, as in all statutory construction, '[u]nless otherwise defined, "words will be interpreted as taking their ordinary, contemporary, common meaning" ' "). In 1952, when Congress used the word in § 285 (and today, for that matter), "[e]xceptional" meant "uncommon," "rare," or "not ordinary." Webster's New International Dictionary 889 (2d ed. 1934); see also 3 Oxford English Dictionary 374 (1933) (defining "exceptional" as "out of the ordinary course," "unusual," or "special"); Merriam–Webster's Collegiate Dictionary 435 (11th ed. 2008) (defining "exceptional" as "rare"); Noxell Corp. v. Firehouse No. 1 Bar–B–Que Restaurant, 771 F.2d 521, 526 (C.A.D.C.1985) (R.B. Ginsburg, J., joined by Scalia, J.) (interpreting the term "exceptional" in the Lanham Act's identical fee-shifting provision, 15 U.S.C. § 1117(a), to mean "uncommon" or "not run-of-the-mill").

We hold, then, that an "exceptional" case is simply one that stands out from others with respect to the substantive strength of a party's litigating position (considering both the governing law and the facts of the case) or the unreasonable

manner in which the case was litigated. District courts may determine whether a case is "exceptional" in the case-by-case exercise of their discretion, considering the totality of the circumstances.6 As in the comparable context of the Copyright Act, " '[t]here is no precise rule or formula for making these determinations,' but instead equitable discretion should be exercised 'in light of the considerations we have identified.' " Fogerty v. Fantasy, Inc., 510 U.S. 517, 534, 114 S.Ct. 1023, 127 L.Ed.2d 455 (1994).

B

1

The Federal Circuit's formulation is overly rigid. Under the standard crafted in Brooks Furniture, a case is "exceptional" only if a district court either finds litigation-related misconduct of an independently sanctionable magnitude or determines that the litigation was both "brought in subjective bad faith" and "objectively baseless." 393 F.3d, at 1381. This formulation superimposes an inflexible framework onto statutory text that is inherently flexible.

For one thing, the first category of cases in which the Federal Circuit allows fee awards—those involving litigation misconduct or certain other misconduct—appears to extend largely to independently sanctionable conduct. See ibid. (defining litigation-related misconduct to include "willful infringement, fraud or inequitable conduct in procuring the patent, misconduct during litigation, vexatious or unjustified litigation, conduct that violates Fed.R.Civ.P. 11, or like infractions"). But sanctionable conduct is not the appropriate benchmark. Under the standard announced today, a district court may award fees in the rare case in which a party's unreasonable conduct—while not necessarily independently sanctionable—is nonetheless so "exceptional" as to justify an award of fees.

The second category of cases in which the Federal Circuit allows fee awards is also too restrictive. In order for a case to fall within this second category, a district court must determine both that the litigation is objectively baseless and that the plaintiff brought it in subjective bad faith. But a case presenting either subjective bad faith or exceptionally meritless claims may sufficiently set itself apart from mine-run cases to warrant a fee award. Cf. Noxell, 771 F.2d, at 526 ("[W]e think it fair to assume that Congress did not intend rigidly to limit recovery of fees by a [Lanham Act] defendant to the rare case in which a court finds that the plaintiff 'acted in bad faith, vexatiously, wantonly, or for oppressive reasons'.... Something less than 'bad faith,' we believe, suffices to mark a case as 'exceptional' ").

ICON argues that the dual requirement of "subjective bad faith" and "objective baselessness" follows from this Court's decision in Professional Real Estate Investors, Inc. v. Columbia Pictures Industries, Inc., 508 U.S. 49, 113 S.Ct. 1920, 123 L.Ed.2d 611 (1993) (PRE), which involved an exception to the Noerr–Pennington doctrine of antitrust law. It does not. Under the Noerr–Pennington doctrine—established by Eastern Railroad Presidents Conference v. Noerr Motor Freight, Inc., 365 U.S. 127, 81 S.Ct. 523, 5 L.Ed.2d 464 (1961), and United Mine

Workers v. Pennington, 381 U.S. 657, 85 S.Ct. 1585, 14 L.Ed.2d 626 (1965)—defendants are immune from antitrust liability for engaging in conduct (including litigation) aimed at influencing decisionmaking by the government. PRE, 508 U.S., at 56, 113 S.Ct. 1920. But under a "sham exception" to this doctrine, "activity 'ostensibly directed toward influencing governmental action' does not qualify for Noerr immunity if it 'is a mere sham to cover ... an attempt to interfere directly with the business relationships of a competitor.' " Id., at 51, 113 S.Ct. 1920. In PRE, we held that to qualify as a "sham," a "lawsuit must be objectively baseless" and must "concea[l] 'an attempt to interfere directly with the business relationships of a competitor....' " Id., at 60–61, 113 S.Ct. 1920 (emphasis deleted). In other words, the plaintiff must have brought baseless claims in an attempt to thwart competition (i.e., in bad faith).

In Brooks Furniture, the Federal Circuit imported the PRE standard into § 285. See 393 F.3d, at 1381. But the PRE standard finds no roots in the text of § 285, and it makes little sense in the context of determining whether a case is so "exceptional" as to justify an award of attorney's fees in patent litigation. We crafted the Noerr–Pennington doctrine—and carved out only a narrow exception for "sham" litigation—to avoid chilling the exercise of the First Amendment right to petition the government for the redress of grievances. See PRE, 508 U.S., at 56, 113 S.Ct. 1920 ("Those who petition government for redress are generally immune from antitrust liability"). But to the extent that patent suits are similarly protected as acts of petitioning, it is not clear why the shifting of fees in an "exceptional" case would diminish that right. The threat of antitrust liability (and the attendant treble damages, 15 U.S.C. § 15) far more significantly chills the exercise of the right to petition than does the mere shifting of attorney's fees. In the Noerr–Pennington context, defendants seek immunity from a judicial declaration that their filing of a * lawsuit was actually unlawful; here, they seek immunity from a far less onerous declaration that they should bear the costs of that lawsuit in exceptional cases.

2

We reject Brooks Furniture for another reason: It is so demanding that it would appear to render § 285 largely superfluous. We have long recognized a common-law exception to the general "American rule" against fee-shifting—an exception, "inherent" in the "power [of] the courts" that applies for " 'willful disobedience of a court order' " or "when the losing party has 'acted in bad faith, vexatiously, wantonly, or for oppressive reasons....' " Alyeska Pipeline Service Co. v. Wilderness Society, 421 U.S. 240, 258–259, 95 S.Ct. 1612, 44 L.Ed.2d 141 (1975). We have twice declined to construe fee-shifting provisions narrowly on the basis that doing so would render them superfluous, given the background exception to the American rule, see Christiansburg Garment Co. v. EEOC, 434 U.S. 412, 419, 98 S.Ct. 694, 54 L.Ed.2d 648 (1978); Newman v. Piggie Park Enterprises, Inc., 390 U.S. 400, 402, n. 4, 88 S.Ct. 964, 19 L.Ed.2d 1263 (1968) (per curiam), and we again decline to do so here.

3

Finally, we reject the Federal Circuit's requirement that patent litigants establish their entitlement to fees under § 285 by "clear and convincing evidence," Brooks Furniture, 393 F.3d, at 1382. We have not interpreted comparable fee-shifting statutes to require proof of entitlement to fees by clear and convincing evidence. See, e.g., Fogerty, 510 U.S., at 519, 114 S.Ct. 1023; Cooter & Gell v. Hartmarx Corp., 496 U.S. 384, 110 S.Ct. 2447, 110 L.Ed.2d 359 (1990); Pierce v. Underwood, 487 U.S. 552, 558, 108 S.Ct. 2541, 101 L.Ed.2d 490 (1988). And nothing in § 285 justifies such a high standard of proof. Section 285 demands a simple discretionary inquiry; it imposes no specific evidentiary burden, much less such a high one. Indeed, patent-infringement litigation has always been governed by a preponderance of the evidence standard, see, e.g., Bene v. Jeantet, 129 U.S. 683, 688, 9 S.Ct. 428, 32 L.Ed. 803 (1889), and that is the "standard generally applicable in civil actions," because it "allows both parties to 'share the risk of error in roughly equal fashion,' " Herman & MacLean v. Huddleston, 459 U.S. 375, 390, 103 S.Ct. 683, 74 L.Ed.2d 548 (1983).

* * *

For the foregoing reasons, 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

Highmark Inc.
v.
Allcare Health Management System

134 S.Ct. 1744 (2014)

Justice SOTOMAYOR delivered the opinion of the Court.

Section 285 of the Patent Act provides: "The court in exceptional cases may award reasonable attorney fees to the prevailing party." 35 U.S.C. § 285. In Brooks Furniture Mfg., Inc. v. Dutailier Int'l, Inc., 393 F.3d 1378 (2005), the United States Court of Appeals for the Federal Circuit interpreted § 285 as authorizing fee awards only in two circumstances. It held that "[a] case may be deemed exceptional" under § 285 "when there has been some material inappropriate conduct," or when it is both "brought in subjective bad faith" and "objectively baseless." Id., at 1381. We granted certiorari to determine whether an appellate court should accord deference to a district court's determination that litigation is "objectively baseless." *1747 On the basis of our opinion in Octane Fitness, LLC v. Icon Health & Fitness, Inc., ––– U.S. ––––, 134 S.Ct. 1749, ––– L.Ed.2d ––––, 2014 WL 1672251 (2014) argued

together with this case and also issued today, we hold that an appellate court should review all aspects of a district court's § 285 determination for abuse of discretion.

I

Allcare Health Management System, Inc., owns U.S. Patent No. 5,301,105 (105 patent), which covers "utilization review" in " 'managed health care systems.' " 1 687 F.3d 1300, 1306 (C.A.Fed.2012). Highmark Inc., a health insurance company, sued Allcare seeking a declaratory judgment that the '105 patent was invalid and unenforceable and that, to the extent it was valid, Highmark's actions were not infringing it. Allcare counterclaimed for patent infringement. Both parties filed motions for summary judgment, and the District Court entered a final judgment of noninfringement in favor of Highmark. The Federal Circuit affirmed. 329 Fed.Appx. 280 (2009) (per curiam).

Highmark then moved for fees under § 285. The District Court granted Highmark's motion. 706 F.Supp.2d 713 (N.D.Tex.2010). The court reasoned that Allcare had engaged in a pattern of "vexatious" and "deceitful" conduct throughout the litigation. Id., at 737. Specifically, it found that Allcare had "pursued this suit as part of a bigger plan to identify companies potentially infringing the '105 patent under the guise of an informational survey, and then to force those companies to purchase a license of the '105 patent under threat of litigation." Id., at 736–737. And it found that Allcare had "maintained infringement claims [against Highmark] well after such claims had been shown by its own experts to be without merit" and had "asserted defenses it and its attorneys knew to be frivolous." Id., at 737. In a subsequent opinion, the District Court fixed the amount of the award at $4,694,727.40 in attorney's fees and $209,626.56 in expenses, in addition to $375,400.05 in expert fees. 2010 WL 6432945, *7 (N.D.Tex., Nov. 5, 2010).

The Federal Circuit affirmed in part and reversed in part. 687 F.3d 1300. It affirmed the District Court's exceptional-case determination with respect to the allegations that Highmark's system infringed one claim of the '105 patent, id., at 1311–1313, but reversed the determination with respect to another claim of the patent, id., at 1313–1315. In reversing the exceptional-case determination as to one claim, the court reviewed it de novo. The court held that because the question whether litigation is "objectively baseless" under Brooks Furniture " 'is a question of law based on underlying mixed questions of law and fact,' " an objective-baselessness determination is reviewed on appeal " 'de novo ' " and "without deference." 687 F.3d, at 1309; see also ibid., n. 1. It then determined, contrary to the judgment of the District Court, that "Allcare's argument" as to claim construction "was not 'so unreasonable that no reasonable litigant could believe it would succeed.' " Id., at 1315. The court further found that none of Allcare's conduct

warranted an award of fees under the litigation-misconduct prong of Brooks Furniture. 687 F.3d, at 1315–1319.

Judge Mayer dissented in part, disagreeing with the view "that no deference is owed to a district court's finding that the infringement claims asserted by a litigant *1748 at trial were objectively unreasonable." Id., at 1319. He would have held that "reasonableness is a finding of fact which may be set aside only for clear error." Ibid. The Federal Circuit denied rehearing en banc, over the dissent of five judges. 701 F.3d 1351 (2012). The dissenting judges criticized the court's decision to adopt a de novo standard of review for the "objectively baseless" determination as an impermissible invasion of the province of the district court. Id., at 1357.

We granted certiorari, 570 U.S. ––––, 134 S.Ct. 48, 186 L.Ed.2d 962 (2013), and now vacate and remand.

II

Our opinion in Octane Fitness, LLC v. Icon Health & Fitness, Inc., rejects the Brooks Furniture framework as unduly rigid and inconsistent with the text of § 285. It holds, instead, that the word "exceptional" in § 285 should be interpreted in accordance with its ordinary meaning. ––– U.S., at ––––, 134 S.Ct., at 1755 – 1756, 2014 WL 1672251 *5. An "exceptional" case, it explains, "is simply one that stands out from others with respect to the substantive strength of a party's litigating position (considering both the governing law and the facts of the case) or the unreasonable manner in which the case was litigated." ––– U.S., at ––––, 134 S.Ct., at 1756, 2014 WL 1672251, *5. And it instructs that "[d]istrict courts may determine whether a case is 'exceptional' in the case-by-case exercise of their discretion, considering the totality of the circumstances." ––– U.S., at ––––, 134 S.Ct., at 1748, 2014 WL 1672251, *5. Our holding in Octane settles this case: Because § 285 commits the determination whether a case is "exceptional" to the discretion of the district court, that decision is to be reviewed on appeal for abuse of discretion.

Traditionally, decisions on "questions of law" are "reviewable de novo," decisions on "questions of fact" are "reviewable for clear error," and decisions on "matters of discretion" are "reviewable for 'abuse of discretion.' " Pierce v. Underwood, 487 U.S. 552, 558, 108 S.Ct. 2541, 101 L.Ed.2d 490 (1988). For reasons we explain in Octane, the determination whether a case is "exceptional" under § 285 is a matter of discretion. And as in our prior cases involving similar determinations, the exceptional-case determination is to be reviewed only for abuse of discretion.2 See Pierce, 487 U.S., at 559, 108 S.Ct. 2541 (determinations whether a litigating position is "substantially justified" for purposes of fee-shifting under the Equal Access to Justice Act are to be reviewed for abuse of discretion); Cooter & Gell v. Hartmarx Corp., 496 U.S. 384, 405, 110 S.Ct. 2447, 110 L.Ed.2d 359 (1990) (sanctions under Federal Rule of Civil Procedure 11 are to be reviewed for abuse of discretion).

As in Pierce, the text of the statute "emphasizes the fact that the determination is for the district court," which "suggests some deference to the district court upon appeal," 487 U.S., at 559, 108 S.Ct. 2541. As in Pierce, "as a matter of the sound administration of justice," the district court "is better positioned" to decide whether a case is exceptional, id., at 559–560, 108 S.Ct. 2541, because it lives with the case over a prolonged period of time. And as in Pierce, the question is "multifarious *1749 and novel," not susceptible to "useful generalization" of the sort that de novo review provides, and "likely to profit from the experience that an abuse-of-discretion rule will permit to develop," id., at 562, 108 S.Ct. 2541.

We therefore hold that an appellate court should apply an abuse-of-discretion standard in reviewing all aspects of a district court's § 285 determination. Although questions of law may in some cases be relevant to the § 285 inquiry, that inquiry generally is, at heart, "rooted in factual determinations," Cooter, 496 U.S., at 401, 110 S.Ct. 2447.

* * *

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

It is so ordered.

Chapter 10: The Legal Process of the Patent System

Chap. 10.A.4. On pages, 1005-1012, omit the *Holmes Group v. Vornado* case and notes 1-3 after the case. In place of note 4, include the following:

***Holmes Group* Overruled.** In *Holmes Group v. Vornado,* 535 U.S. 826 (2002), the Supreme Court held that the Federal Circuit's patent appellate jurisdiction was limited to those cases "arising under" the patent statutes—meaning the appellate jurisdiction extended only to those cases in which patent issues were raised by the plaintiff's properly pleaded complaint and not to cases in which patent issues were raised by way of counterclaim. In § 19 of the America Invents Act, Congress changed the law on that point and gave the Federal Circuit a more complete appellate jurisdiction over cases raising patent issues. The new statute provides that the Federal Circuit has exclusive appellate jurisdiction over any "any civil action arising under, *or in any civil action in which a party has asserted a compulsory counterclaim arising under*, any Act of Congress relating to patents or plant variety protection." § 19(b), 125 Stat. at 332.

On page 1013, add the following paragraph to the end of note 6 on "Splitting the Federal Circuit's Jurisdiction":

Despite the AIA's extension of the Federal Circuit's exclusive jurisdiction, the move to split that court's appellate jurisdiction over patent case received a big boost in 2013 when Diane Wood, Chief Judge of the Seventh Circuit (and a former law professor) delivered a speech entitled "Is It Time to Abolish the Federal Circuit's Exclusive Jurisdiction in Patent Cases?" For links to a video of the speech and a draft of the published version, see http://studentorgs.kentlaw.iit.edu/ckjip/chief-judge-diane-woods-keynote-address-at-scipr-2013-is-it-time-to-abolish-the-federal-circuits-exclusive-jurisdiction-in-patent-cases/. Chief Judge Wood cited the 2007 article by Nard and Duffy, which also proposed abolishing the Federal Circuit's exclusive jurisdiction, but Chief Judge Wood appeared to propose even further decentralization of appeals. While the 2007 article by Nard and Duffy argued for authorizing a small number of other appellate courts with patent jurisdiction, Chief Judge Wood believe all circuits should have patent jurisdiction, with the Federal Circuit taking jurisdiction over cases only if the appellant chose that circuit as an alternative over the regional circuit. Note that under Chief Judge Wood's proposal, the existence of the Federal Circuit would not centralize appeals at all; it would provide merely a 13th appellate court in which patent appeals could be heard.

The debate over the Federal Circuit's jurisdiction has even received press coverage. See "Critics Fault Court's Grip on Appeals for Patents: Calls to Loosen Federal Circuit's Hold Grows Amid Complaints Over Rulings," Wall Street Journal (July 6, 2014) (available at http://online.wsj.com/articles/critics-fault-courts-grip-on-appeals-for-patents-1404688219). It remains unclear whether Congress has any interest in changing the court's jurisdiction.

Chap. 10.C: At the end of the discussion of administrative proceedings on page 1056, add the following new note and exercise:

Note on Patent Office Proceedings

Evidence is that the first administrative procedure created by the America Invents Act to become widely available is quickly gaining in popularity. Reliable statistics showed over 500 inter partes reviews (IPRs) were instituted in the first year and a half after they became available in September, 2012. As of the summer of 2014, almost 1500 IPRs had been requested. Among all the administrative trial procedures created by the AIA, over 70% have involved electrical/computer technology patents. See http://www.uspto.gov/ip/boards/bpai/stats/aia_statistics_07_02_2014.pdf. Also of note is that the an IPR is initiated in over 80% of the cases when one is requested, and that the majority of IPR proceedings result in the cancellation or narrowing of at least one claim in the contested patent. See http://www.ipwatchdog.com/2014/02/09/inter-partes-review-overview-and-statistics/id=47894/. If the trend continues it will mark a significant change in the conduct of patent litigation – particularly if district courts come to regularly grant litigation stays during the pendency of an IPR proceeding. Some at least believe this is likely. See Christopher E. Loh and Christopher P. Hill, How to Stay Patent Troll Litigation in Favor of IPR and CBM Proceedings at the Patent and Trademark Office, 87 Pat. Trademark & Copyrt. J. (BNA) 1567, April 25, 2014. If this occurs, it will go a long way toward becoming a preferred, low-cost alternative over expensive district court litigation. For a useful early resource on this topic, see Erika Harmon Arner and Joseph E. Palys, eds., Trials Before the Patent Trial and Appeal Board (Am. Bar Ass'n 2014).

The following optional exercise is designed to help improve knowledge of the changes made by the AIA to the PTO's Administrative Procedures:

Exercise: Administrative Processes After the AIA

After the enactment of the AIA, the PTO has at least 13 possible administrative processes relevant to the practice of patent law (those in bold are new or substantially revised by the AIA):

1. Initial examination - §§ 131-34
2. Pre-issuance submissions by third parties - § 122(e)
3. Interference - old § 135
4. Derivation - new § 135
5. Reissue – § 251-52
6. Disclaimer - § 253
7. Correction - §§ 254-56
8. Supplemental examination - § 257
9. Ex parte reexamination (revised by AIA) - §§ 301-07
10. Inter partes reexamination (revised by AIA) - old §§ 311-18
11. Inter partes review - new §§ 311-19
12. Post-grant review - §§ 321-29
13. Transitional post-grant review for covered business methods ("CBM") proceedings - §§ 321-29 + AIA § 18

The following exercise is designed to provide questions that will require some attention to the statute. The best way to answer these questions is to work through them with the Patent Act at your side. While it is possible simply to skip ahead to the answers, such an approach will result in little or no learning. We therefore suggest that you try to find the answer in the statute—for hunting through the statutory provisions is a good way for you to become familiar with the new law.

For all thirteen proceedings, please try to answer the following question:

1. Is the proceeding after the enactment of the AIA being: (i) phased in, phased out, continued with changes, or continue unchanged and, (ii) if the proceeding is being phased in, phased out or changed, what is the precise transition rule?

For proceedings 9, 11, 12 and 13 (which are the four main ways to challenge the validity of a patent after the AIA), please try to answer the following questions:

2. Who can initiate the proceeding? Please provide the citation for the statutory section that gives an answer.

(a) An inventor
(b) The patent owner
(c) Competitors of a patent holder
(d) Consumers of the patented product
(e) Anyone harmed by the patent
(f) Any member of the public
(g) Other _____.

3. When can the process be initiated? Please provide the citation for the statutory section that gives an answer.

(a) Anytime
(b) While a patent application is pending
(c) Any time after patent issuance
(d) During a certain window beginning _____ and ending _____.

4. What patent validity issues can be raised in the proceeding? Please provide the citation for the statutory section that gives an answer.

5. What showing, if any, does the party have to make in order to invoke the process? Please provide the citation for the statutory section that gives an answer.

6. Does the PTO have discretion to decline to initiate the process or is the agency legally obligated to initiate the process if the party invoking the process makes any relevant threshold showing? Please provide the citation for the statutory section that gives an answer.

7. What administrative hearing rights and administrative appeal rights do the parties have? Please provide the citation for the statutory section that gives an answer.

8. What are the possible outcomes of the process? Please provide the citation for the statutory section that gives an answer.

(a) Issuance of a patent.
(b) Revocation of a patent.
(c) Issuance of a new patent with (i) broader claims and/or (ii) narrower claims.
(d) Other: _____

9. What is the process for judicial review after the completion of the process? Please provide the citation for the statutory section that gives an answer.

(a) Judicial review in a district court under the Administrative Procedure Act? (This is the default rule unless the statute says otherwise.)
(b) Other type of review specified by statute: _____
(c) Both.
(d) Neither.

10. What are the possible negative consequences for the party that initiated the process?
(a) Discipline or disbarment of the attorneys who participated in the process.
(b) Criminal sanctions.
(c) Estoppel in the following future circumstances _____.
(d) All of the above.

(Answers begin on next page.)

Answers:

1. Is the proceeding after the enactment of the AIA being: (i) phased in, phased out, continued with changes, or continue unchanged and, (ii) if the proceeding is being phased in, phased out or changed, what is the precise transition rule?

Proceeding Type	**Answer:**
1. Initial examination - §§ 131-34	Continued with substantial changes (the first-to-file priority system). Transition Rule: **18 months after AIA** (changes apply to all applications filed **on or after March 16, 2013** or applications filed before that date but that were later amended to contain claims with priority dates on or after March 16, 2013). Because several parts of the AIA have the same transition rules we will refer to this category of patent applications as **AIA first-to-file applications**.
2. Pre-issuance submissions by third parties - § 122(e)	Phased in: The AIA enacted an entirely new statutory process for third party submissions, though the PTO had previously allowed some third party submissions under its administrative rules. Transition Rule: **One year after AIA** (the new process began on September 16, 2012 and applied to all pending and future patent applications).
3. Interference - old § 135	Phased Out (interferences decide which patent applicant invented first, and that issue is irrelevant under the AIA first-to-file system). Transition Rule: **Ends 18 months after AIA** (continues to apply to applications filed before March 16, 2013, and to patents issued on such applications)
4. Derivation - new § 135	New with AIA (tries to determine whether one party derived an invention from another). Transition Rule: Applies to **AIA first-to-file applications**.
5. Reissue (minor revisions by AIA) – § 251-52	Continued with small changes (reissue applicant no longer has to prove that the error to be changed with reissue occurred without "deceptive intent"). Transition Rule: **One year after AIA** (applies to all reissue proceedings

	commenced on or after September 16, 2012).
6. Disclaimer - § 253	Continued with small changes (applicant no longer has to prove that the error in claiming occurred without "deceptive intent"). Transition Rule: **One year after AIA** (applies to all proceedings commenced on or after September 16, 2012).
7. Correction - §§ 254-56	Continued with small changes (where proceeding is being used to correct error with the named inventor, the applicant no longer has to prove that the error occurred without "deceptive intent"). Transition Rule: **One year after AIA** (applies to all proceedings commenced on or after September 16, 2012).
8. Supplemental examination - § 257	Entirely new with AIA. Transition Rule: **One year after AIA** (began on September 16, 2012 and can be applied to any existing or subsequently issued patent).
9. Ex parte reexamination (revised by AIA) - §§ 301-07	Modified by the AIA. Transition Rule: **One year after AIA** (applies to all proceedings commenced on or after September 16, 2012).
10. Inter partes reexamination (revised by AIA) - old §§ 311-18	Both revised by AIA and repealed. Transitions Rules: Revisions were effective **immediately** (on Sept. 16, 2011). Repeal of the inter partes reexam occurred **one year after** enactment of AIA (applicable to filings on or after Sept. 16, 2011).
11. Inter partes review - new §§ 311-19	New but similar to old inter partes reexaminations. Transition Rule: **One year after AIA** (filings for inter partes review could begin on Sept. 16, 2012 and could challenge any issued patent).
12. Post-grant review - §§ 321-29	Entirely new. Transition Rule: Applies to **AIA first-to-file applications**.
13. Covered Business Method ("CBM") Proceedings - §§ 321-29 + AIA § 18	Entirely new. Transition Rule: **One year after AIA** (filings for could begin on Sept. 16, 2012 and could challenge any issued patent).

2. Who can initiate the proceeding? Please provide the citation for the statutory section that gives an answer.

(a) An inventor
(b) The patent owner
(c) Competitors of a patent holder
(d) Consumers of the patented product
(e) Anyone harmed by the patent
(f) Any member of the public
(g) Other _____.

Proceeding Type	**Answer:**
9. Ex parte reexam – §§ 301-07	(f), 35 U.S.C. § 301(a).
11. Inter partes review (IPR) – new §§ 311-19	(g) – anyone **except** the patent owner (see 35 U.S.C. § 311(a)).
12. Post-grant review (PGR) – §§ 321-29	(g) – anyone **except** the patent owner (see 35 U.S.C. § 321(a)).
13. Covered Business Method ("CBM") Proceedings – §§ 321-29 + AIA § 18	(g) – anyone **except** the patent owner (see 35 U.S.C. § 311(a) as made applicable by AIA § 18).

3. When can the process be initiated? Please provide the citation for the statutory section that gives an answer.

(a) Anytime
(b) While a patent application is pending
(c) Any time after patent issuance
(d) Any time after _____
(e) During a certain window beginning _____ and ending _____.

Proceeding Type	**Answer:**
9. Ex parte reexam – §§ 301-07	(c), 35 U.S.C. § 302(a). (Although the statute says that the request for reexam can be filed *anytime*, the request has to be made with respect to an issued patent.)
11. Inter partes review (IPR) – new §§ 311-19	There are two answers here. For patents that issue from **non-AIA first-to-file applications** (i.e., that were filed before March 16, 2013), the answer is (c). (This rule was made by § 1(d)(1) of the AIA Technical Correction Act, 126 Stat. 2456, 2456 (2013).) For patents that issue from **AIA first-to-file applications** (i.e., those filed on or after March 16, 2013), the answer is (d), any time after the later of 9 months after patent issuance or after the end of any post-grant review proceeding. See 35 U.S.C. § 311(c).
12. Post-grant review (PGR) – §§ 321-29	(e), a window beginning with patent issuance and ending 9 months thereafter. See 35 U.S.C. § 321(c).
13. Covered Business Method ("CBM") Proceedings – §§ 321-29 + AIA § 18	(c), § 18(a)(1)(A) of the AIA allows the PGR process to be used to review covered business method patents without regard to filing time.

4. What patent validity issues can be raised in the proceeding? Please provide the citation for the statutory section that gives an answer.

Proceeding Type	**Answer:**
9. Ex parte reexam – §§ 301-07	For certain, §§ 102 and 103 issues can be raised where patents and printed publications constitute the basis for invalidity. See 35 U.S.C. § 301(a)(1). It is possible that some other invalidity grounds can be raised too. 35 U.S.C. § 301(a)(2) allows a requester to obtain reexam because the patent owner has taken certain positions in litigation. Presumably, a broad construction of a patent claim by the owner could make the claim vulnerable not only under §§ 102 and 103 but also under § 101 or § 112.
11. Inter partes review (IPR) – new §§ 311-19	Only §§ 102 and 103 issues and only on the basis of prior art consisting of patents and printed publications. 35 U.S.C. § 311(b).
12. Post-grant review (PGR) – §§ 321-29	Any ground that could be raised as an invalidity defense in patent litigation. See 35 U.S.C. § 321(b).
13. Covered Business Method ("CBM") Proceedings – §§ 321-29 + AIA § 18	Same as PGR, except that §18 of the AIA imposes some limits on the prior art that can be used in making 102 and 103 arguments.

5. What showing, if any, does the party have to make in order to invoke the process? Please provide the citation for the statutory section that gives an answer.

Proceeding Type	**Answer:**
9. Ex parte reexam – §§ 301-07	Reexamination requires the Director to determine that there is a "substantial new question of patentability." See 35 U.S.C. § 303(a). Technically, the requesting party does not have to have proof to meet that standard because the Director is allowed to make his own inquiry into the matter.
11. Inter partes review (IPR) – new §§ 311-19	35 U.S.C. § 314(a) – the Director cannot institute inter partes review unless he finds that there is a "reasonable likelihood" that the petitioner would prevail in invalidating at least 1 claim.
12. Post-grant review (PGR) – §§ 321-29	35 U.S.C. § 324(a) & (b) – the Director cannot institute PGR unless he finds that "it is more likely than not" that the proceeding will result in at least 1 claim being held unpatentable or the petition raises a novel or unsettled legal issue.
13. Covered Business Method ("CBM") Proceedings – §§ 321-29 + AIA § 18	Same as PGR.

6. Does the PTO have discretion to decline to initiate the process or is the agency legally obligated to initiate the process if the party invoking the process makes any relevant threshold showing? Please provide the citation for the statutory section that gives an answer.

Proceeding Type	**Answer:**
9. Ex parte reexam – §§ 301-07	Technically, the PTO is legally obligated. The Director is required under 35 U.S.C. § 303 to make a determination and required under § 304 to initiate reexamination if the determination comes out in a particular way.
11. Inter partes review (IPR) – new §§ 311-19	The Director has discretion; the statute 35 U.S.C. § 314(a) limits the Director's ability to grant review but not to deny it.
12. Post-grant review (PGR) – §§ 321-29	The Director has discretion; the statute 35 U.S.C. § 324 limits the Director's ability to grant review but not to deny it.
13. Covered Business Method ("CBM") Proceedings – §§ 321-29 + AIA § 18	Same as PGR.

7. What administrative hearing rights and administrative appeal rights do the parties have? Please provide the citation for the statutory section that gives an answer.

Proceeding Type	**Answer:**
9. Ex parte reexam – §§ 301-07	The patent owner has rights similar to initial examination, including the right to appeal to the PTO Board. See 35 U.S.C. § 305. The party requesting reexamination has no rights (hence it's called "ex parte").
11. Inter partes review (IPR) – new §§ 311-19	Each side has significant procedural rights as noted in 35 U.S.C. § 316 and rights to appeal under 35 U.S.C. § 319.
12. Post-grant review (PGR) – §§ 321-29	Each side has significant procedural rights as noted in 35 U.S.C. § 326 and rights to appeal under 35 U.S.C. § 329.
13. Covered Business Method ("CBM") Proceedings – §§ 321-29 + AIA § 18	Same as PGR.

8. What are the possible outcomes of the process? Please provide the citation for the statutory section that gives an answer.

(a) Issuance of a patent.
(b) Revocation of a patent.
(c) Issuance of a new patent with (i) broader claims and/or (ii) narrower claims.
(d) Other: _____

Proceeding Type	**Answer:**
9. Ex parte reexam – §§ 301-07	Answer is either (b) + (c)(ii), or (d). The process can result in issuance of certificate holding all claims unpatentable, which is equivalent to answer (b). See 35 U.S.C. § 307. In addition, the process can hold unpatentable only some of the claims in the patent, and the patentee can also add new claims provided that they do not "enlarge[] the scope of a claim." 35 U.S.C. § 305.
11. Inter partes review (IPR) – new §§ 311-19	Similar to ex parte reexam. Patent claims can be confirmed, invalidated or narrowed by amendment (see 35 U.S.C. § 316(d)).
12. Post-grant review (PGR) – §§ 321-29	Similar to ex parte reexam. Patent claims can be confirmed, invalidated or narrowed by amendment (see 35 U.S.C. § 326(d)).
13. Covered Business Method ("CBM") Proceedings – §§ 321-29 + AIA § 18	Same as PGR.

9. What is the process for judicial review after the completion of the process? Please provide the citation for the statutory section that gives an answer.

(a) Judicial review in a district court under the Administrative Procedure Act? (This is the default rule unless the statute says otherwise.)
(b) Other type of review specified by statute: _____
(c) Both.
(d) Neither.

Proceeding Type	**Answer:**
9. Ex parte reexam – §§ 301-07	(b), review is by direct appeal from the PTO to the Federal Circuit. See 35 U.S.C. § 306.
11. Inter partes review (IPR) – new §§ 311-19	(b), review is by direct appeal from the PTO to the Federal Circuit. See 35 U.S.C. § 319.
12. Post-grant review (PGR) – §§ 321-29	(b), review is by direct appeal from the PTO to the Federal Circuit. See 35 U.S.C. § 329.
13. Covered Business Method ("CBM") Proceedings – §§ 321-29 + AIA § 18	(b), review is by direct appeal from the PTO to the Federal Circuit. See 35 U.S.C. § 329.

10. What are the possible negative consequences for the party that initiated the process?

(a) Discipline or disbarment of the attorneys who participated in the process.
(b) Criminal sanctions.
(c) Estoppel in the following future circumstances _____.
(d) All of the above.

(d). All of the above. Parties who file any documents at the PTO are always subject to a duty of honesty and can be administratively sanctioned for improper behavior. Administrative sanctions can include even the severe sanction of disbarment from the patent bar. Also, the criminal statute 18 U.S.C. § 1001 offers sanctions for any person who makes false statements to government agencies, including the PTO.

In addition to a duty of honesty, parties to PTO proceedings sometimes have a duty of candor, which can include a duty to disclose some adverse material information. Patent applicants and patents owners generally have that duty of candor in all PTO proceedings. The requesters in inter partes review, post-grant review and CBM proceedings also have a duty of candor. It appears to be true that the PTO imposes no duty of candor on requesters for ex parte reexam (possibly the absence of any such duty is due to the requester's limited participation in the process).

The estoppel effects are summarized here:

Proceeding Type	**Answer:**
9. Ex parte reexam – §§ 301-07	No estoppel.
11. Inter partes review (IPR) – new §§ 311-19	The estoppel provision is set forth in 35 U.S.C. § 315(e). Note that it imposes an estoppel on any ground that the petitioner raised or *reasonably could have raised* during the inter partes review. It is not entirely clear whether the estoppel operates if the petitioner raises the issue in the petition seeking review and the Director denies review.
12. Post-grant review (PGR) – §§ 321-29	The estoppel provision is set forth in 35 U.S.C. § 325(e). Note that it imposes an estoppel on any ground that the petitioner raised or *reasonably could have raised* during PGR. It is not entirely clear whether the estoppel operates if the petitioner raises the issue in the petition seeking review and the Director denies review.
13. Covered Business Method ("CBM") Proceedings – §§ 321-29 + AIA § 18	Estoppel effect of CBM proceeding is more limited; petitioner in the CBM proceeding is estopped only on grounds actually raised in the proceeding (not on grounds that could have been raised). See AIA § 18.

Chapter 12: Antitrust and Patent Misuse

Chap. 12.A.2: After note 4 on p. 1197, add the following note on *Kimble v. Marvel Entertainment*, 135 S. Ct. 2401 (2015):

5. *Kimble v. Marvel Entertainment*: *Brulotte* Sustained. As noted in the casebook, the *Brulotte* rule was repeatedly criticized by judges and commentators. In 2014, the Supreme Court finally granted certiorari on question whether *Brulotte* should be overruled. On June 22, 2015, the Court issued an anticlimactic decision that relied on the doctrine of *stare decisis* and refused to overturn *Brulotte*. Though the *Kimble* decision could be viewed as a non-event—the whole point of the ruling was that the law should stay the same—there are nonetheless four aspects of the decision worth noting.

First, the facts of the case provide a cautionary tale: attorneys writing patent licenses need to be aware of *Brulotte* and other highly specific rules about patent licensing.

The facts of the case are both simple and fun. The invention in the case was a "toy that allows children (and young-at-heart adults) to role-play as 'a spider person' by shooting webs—really, pressurized foam string—'from the palm of [the] hand.'" 135 S.Ct. at 2405. The inventor, Stephen Kimble, obtained patent rights on the device, and sometime later, Marvel Entertainment (the originator of the Spider-Man comic series) began producing an arguably infringing product. Kimble sued Marvel, and the parties were ultimately able to reach a settlement. In the following passage, the Supreme Court describes that settlement and what happened next:

> Their [settlement] agreement provided that Marvel would purchase Kimble's patent in exchange for a lump sum (of about a half-million dollars) and a 3% royalty on Marvel's future sales of the Web Blaster and similar products. The parties set no end date for royalties, apparently contemplating that they would continue for as long as kids want to imitate Spider-Man (by doing whatever a spider can).
>
> And then Marvel stumbled across *Brulotte*, the case at the heart of this dispute. *In negotiating the settlement, neither side was aware of Brulotte*. But Marvel must have been pleased to learn of it. *Brulotte* had read the patent laws to prevent a patentee from receiving royalties for sales made after his patent's expiration. See 379 U.S., at 32. So the decision's effect was to sunset the settlement's royalty clause. On making that discovery, Marvel sought a declaratory judgment in federal district court confirming that the company could cease paying royalties come 2010—the end of Kimble's patent term. The court approved that relief, holding that *Brulotte* made "the royalty provision . . . unenforceable after the expiration of the Kimble patent." 692 F. Supp. 2d 1156, 1161 (Ariz. 2010). The Court of Appeals for the Ninth Circuit affirmed, though making clear that it was none too happy about doing so. "[T]he *Brulotte* rule," the court complained, "is counterintuitive and its rationale is arguably unconvincing." 727 F. 3d 856, 857 (2013).

135 S.Ct. at 2406 (emphasis added). Note the italicized sentence: the lawyers negotiating the Kimble-Marvel settlement *did not know about the Brulotte rule*! That's just terrible lawyering for Kimble—don't let the same thing happen to you!!!

Second, the *Kimble* Court did a fairly good job—better than the *Brulotte* opinion itself—of trying to explain the basis for the rule:

> Patents endow their holders with certain superpowers, but only for a limited time. In crafting the patent laws, Congress struck a balance between fostering innovation and ensuring public access to discoveries. While a patent lasts, the patentee possesses exclusive rights to the patented article—rights he may sell or license for royalty payments if he so chooses. See 35 U.S.C. § 154(a)(1). But a patent typically expires 20 years from the day the application for it was filed. See § 154(a)(2). And when the patent expires, the patentee's prerogatives expire too, and the right to make or use the article, free from all restriction, passes to the public. *See Sears, Roebuck & Co. v. Stiffel Co.*, 376 U.S. 225, 230 (1964).
>
> This Court has carefully guarded that cut-off date, just as it has the patent laws' subject-matter limits: In case after case, the Court has construed those laws to preclude measures that restrict free access to formerly patented, as well as unpatentable, inventions. In one line of cases, we have struck down state statutes with that consequence. *See, e.g., id*., at 230–233; *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 152, 167–168 (1989); *Compco Corp. v. Day–Brite Lighting, Inc.*, 376 U.S. 234, 237–238 (1964). By virtue of federal law, we reasoned, "an article on which the patent has expired," like an unpatentable article, "is in the public domain and may be made and sold by whoever chooses to do so." *Sears*, 376 U.S., at 231. In a related line of decisions, we have deemed unenforceable private contract provisions limiting free use of such inventions. In S*cott Paper Co. v. Marcalus Mfg. Co.*, 326 U.S. 249 (1945), for example, we determined that a manufacturer could not agree to refrain from challenging a patent's validity. Allowing even a single company to restrict its use of an expired or invalid patent, we explained, "would deprive ... the consuming public of the advantage to be derived" from free exploitation of the discovery. Id., at 256. And to permit such a result, whether or not authorized "by express contract," would impermissibly undermine the patent laws. Id., at 255–256; see also, e.g., *Edward Katzinger Co. v. Chicago Metallic Mfg. Co*., 329 U.S. 394, 400–401 (1947) (ruling that *Scott Paper* applies to licensees); *Lear, Inc. v. Adkins*, 395 U.S. 653, 668–675 (1969) (refusing to enforce a contract requiring a licensee to pay royalties while contesting a patent's validity).
>
> *Brulotte* was brewed in the same barrel. …

135 S.Ct. at 2406-07. This passage is one good way of viewing cases like *Brulotte*—that the federal Patent Act protects not only patentee's rights in patents, but also the public's right to practice unpatented technologies freely. That's a controversial view, however, because while the Patent Act quite plainly provides patentees exclusive

rights to their inventions (e.g., in 35 U.S.C. §§ 154 & 271), it does not explicitly provide any rights to members of the public concerning unpatented or previously patented technologies.

Third, the *Kimble* Court noted—and seemingly accepted—that the *Brulotte* rule could be avoided through several contractual structures:

> [P]arties can often find ways around *Brulotte*, enabling them to achieve those same ends. To start, *Brulotte* allows a licensee to defer payments for pre-expiration use of a patent into the post-expiration period; all the decision bars are royalties for using an invention after it has moved into the public domain. See 379 U.S., at 31. A licensee could agree, for example, to pay the licensor a sum equal to 10% of sales during the 20–year patent term, but to amortize that amount over 40 years. That arrangement would at least bring down early outlays, even if it would not do everything the parties might want to allocate risk over a long timeframe. And parties have still more options when a licensing agreement covers either multiple patents or additional non-patent rights. Under *Brulotte*, royalties may run until the latest-running patent covered in the parties' agreement expires. See 379 U.S., at 30. Too, post-expiration royalties are allowable so long as tied to a non-patent right—even when closely related to a patent. See, e.g., 3 Milgrim on Licensing § 18.07, at 18–16 to 18–17. That means, for example, that a license involving both a patent and a trade secret can set a 5% royalty during the patent period (as compensation for the two combined) and a 4% royalty afterward (as payment for the trade secret alone). Finally and most broadly, *Brulotte* poses no bar to business arrangements other than royalties—all kinds of joint ventures, for example—that enable parties to share the risks and rewards of commercializing an invention.

135 S.Ct. at 2408. That passage provides a nice template of ways for complying with *Brulotte* but still achieving the legitimate business goals of parties. How could the Kimble-Marvel deal have been originally structured so that Kimble could continue to get a share in the profits of the product after his patent has expired?

In thinking about that prior question, remember one thing that makes the Kimble-Marvel product different from many other products. Theoretically, when a patent expires, the price of the product previously covered by the patent will fall down to a competitive price. That's not likely to happen for the product made possible under the Kimble-Marvel agreement because Marvel has Spider-Man trademarks and copyrights that are going to remain in force and remain very valuable in connection with a toy web-string-shooter. (Many little Johnny and Janes are going to want the Spider-Man® web-shooter, not some generic web-string-shooter.) Imagine that Kimble and Marvel each licensed all of the necessary IP (all of the trademark, copyright and patent rights) to a separate company (or joint venture) that produced the product. If Kimble received 50% of the stock of that separate company, he would continue reap rewards from sales of the toys long after the expiration of his patent. Would that arrangement violate *Brulotte*?

Fourth, *Kimble* articulates a fairly strong version of stare decisis in statutory cases *even where the earlier decision is not grounded in any specific statutory text*:

> [*S*]*tare decisis* carries enhanced force when a decision, like *Brulotte*, interprets a statute. Then, unlike in a constitutional case, critics of our ruling can take their objections across the street, and Congress can correct any mistake it sees. See, e.g., *Patterson v. McLean Credit Union*, 491 U.S. 164, 172–173 (1989). That is true, contrary to the dissent's view, see post, at 2417 – 2418 (opinion of ALito, J.), regardless whether our decision focused only on statutory text or also relied, as Brulotte did, on the policies and purposes animating the law. See, e.g., *Bilski v. Kappos*, 561 U.S. 593, 601–602 (2010). Indeed, we apply statutory stare decisis even when a decision has announced a "judicially created doctrine" designed to implement a federal statute. *Halliburton*, 573 U.S., at ––––, 134 S.Ct., at 2411. All our interpretive decisions, in whatever way reasoned, effectively become part of the statutory scheme, subject (just like the rest) to congressional change. Absent special justification, they are balls tossed into Congress's court, for acceptance or not as that branch elects.

135 S.Ct. at 2409. That view of *stare decisis* has general applicability to many areas of law, but it is also especially important in patent law, where at least some significant Supreme Court decisions do not seem especially well-grounded in the text of the Patent Act. *Kimble* means that such policy-infused decisions are likely to remain good law until Congress can be persuaded to change them.

Chap. 12.B: In place of note 6 on pp. 1210-11, add the following case:

Bowman v. Monsanto Co.
133 S.Ct. 1761 (2013)

Justice KAGAN delivered the opinion of the Court.

Under the doctrine of patent exhaustion, the authorized sale of a patented article gives the purchaser, or any subsequent owner, a right to use or resell that article. Such a sale, however, does not allow the purchaser to make new copies of the patented invention. The question in this case is whether a farmer who buys patented seeds may reproduce them through planting and harvesting without the patent holder's permission. We hold that he may not.

I

Respondent Monsanto invented a genetic modification that enables soybean plants to survive exposure to glyphosate, the active ingredient in many herbicides (including Monsanto's own Roundup). Monsanto markets soybean seed containing this altered genetic material as Roundup Ready seed. Farmers planting that seed can

use a glyphosate-based herbicide to kill weeds without damaging their crops. Two patents issued to Monsanto cover various aspects of its Roundup Ready technology, including a seed incorporating the genetic alteration.

Monsanto sells, and allows other companies to sell, Roundup Ready soybean seeds to growers who assent to a special licensing agreement. See App. 27a. That agreement permits a grower to plant the purchased seeds in one (and only one) season. He can then consume the resulting crop or sell it as a commodity, usually to a grain elevator or agricultural processor. See 657 F.3d, at 1344–1345. But under the agreement, the farmer may not save any of the harvested soybeans for replanting, nor may he supply them to anyone else for that purpose. These restrictions reflect the ease of producing new generations of Roundup Ready seed. Because glyphosate resistance comes from the seed's genetic material, that trait is passed on from the planted seed to the *1765 harvested soybeans: Indeed, a single Roundup Ready seed can grow a plant containing dozens of genetically identical beans, each of which, if replanted, can grow another such plant—and so on and so on. See App. 100a. The agreement's terms prevent the farmer from co-opting that process to produce his own Roundup Ready seeds, forcing him instead to buy from Monsanto each sea-son.

Petitioner Vernon Bowman is a farmer in Indiana who, it is fair to say, appreciates Roundup Ready soybean seed. He purchased Roundup Ready each year, from a company affiliated with Monsanto, for his first crop of the season. In accord with the agreement just described, he used all of that seed for planting, and sold his entire crop to a grain elevator (which typically would resell it to an agricultural processor for human or animal consumption).

Bowman, however, devised a less orthodox approach for his second crop of each season. Because he thought such late-season planting “risky,” he did not want to pay the premium price that Monsanto charges for Roundup Ready seed. He therefore went to a grain elevator; purchased “commodity soybeans” intended for human or animal consumption; and planted them in his fields. Those soybeans came from prior harvests of other local farmers. And because most of those farmers also used Roundup Ready seed, Bowman could anticipate that many of the purchased soybeans would contain Monsanto's patented technology. When he applied a glyphosate-based herbicide to his fields, he confirmed that this was so; a significant proportion of the new plants survived the treatment, and produced in their turn a new crop of soybeans with the Roundup Ready trait. Bowman saved seed from that crop to use in his late-season planting the next year—and then the next, and the next, until he had harvested eight crops in that way. Each year, that is, he planted saved seed from the year before (sometimes adding more soybeans bought from the grain elevator), sprayed his fields with glyphosate to kill weeds (and any non-resistant plants), and produced a new crop of glyphosate-resistant—i.e., Roundup Ready—soybeans.

After discovering this practice, Monsanto sued Bowman for infringing its patents on Roundup Ready seed. Bowman raised patent exhaustion as a defense, 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). The District Court rejected that argument, and awarded damages to Monsanto of $84,456. The Federal Circuit affirmed. It reasoned that patent exhaus-tion did not protect Bowman because he had "created a newly infringing article." 657 F.3d, at 1348. The "right to use" a patented article following an authorized sale, the court explained, "does not include the right to construct an essentially new article on the template of the original, for the right to make the article remains with the patentee." Ibid. (brackets and internal quotation marks omitted). Accordingly, Bowman could not " 'replicate' Monsanto's patented technology by planting it in the ground to create newly infringing genetic material, seeds, and plants." Ibid.

The doctrine of patent exhaustion limits a patentee's right to control what others can do with an article embodying or containing an invention. Under the doctrine, "the initial authorized sale of a patented item terminates all patent rights to that item." Quanta Computer, Inc. v. LG Electronics, Inc., 553 U.S. 617, 625 (2008). And by "exhaust[ing] the [patentee's] monopoly" in that item, the sale confers on the purchaser, or any subsequent owner, "the right to use [or] sell" the thing as he sees fit. United States v. Univis Lens Co., 316 U.S. 241, 249–250 (1942). We have explained the basis for the doctrine as follows: "[T]he purpose of the patent law is fulfilled with respect to any particular article when the patentee has received his reward . . . by the sale of the article"; once that "purpose is realized the patent law affords no basis for restraining the use and enjoyment of the thing sold." Id., at 251.

Consistent with that rationale, the doctrine restricts a patentee's rights only as to the "particular article" sold, ibid.; it leaves untouched the patentee's ability to prevent a buyer from making new copies of the patented item. "[T]he purchaser of the [patented] machine ... does not acquire any right to construct another machine either for his own use or to be vended to another." Mitchell v. Hawley, 16 Wall. 544, 548, 21 L.Ed. 322 (1873). Rather, "a second creation" of the patented item "call[s] the monopoly, conferred by the patent grant, into play for a second time." Aro Mfg. Co. v. Convertible Top Replacement Co., 365 U.S. 336, 346 (1961). That is because the patent holder has "received his reward" only for the actual article sold, and not for subsequent recreations of it. Univis, 316 U.S., at 251. If the purchaser of that article could make and sell endless copies, the patent would effectively protect the invention for just a single sale. Bowman himself disputes none of this analysis as a general matter: He forthrightly acknowledges the "well settled" principle "that the exhaustion doctrine does not extend to the right to 'make' a new product." Brief for Petitioner 37.

Unfortunately for Bowman, that principle decides this case against him. 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. Monsanto, although the patent holder, would have no

business interfering in those uses of Roundup Ready beans. But the exhaustion doctrine does not enable Bowman to make *additional* patented soybeans without Monsanto's permission (either express or implied). And that is precisely what Bowman did. He took the soybeans he purchased home; planted them in his fields at the time he thought best; applied glyphosate to kill weeds (as well as any soy plants lacking the Roundup Ready trait); and finally harvested more (many more) beans than he started with. That is how "to 'make' a new product," to use Bowman's words, when the original product is a seed. Brief for Petitioner 37; see Webster's Third New International Dictionary 1363 (1961) ("make" means "cause to exist, occur, or appear," or more specifically, "plant and raise (a crop)"). Because Bowman thus reproduced Monsanto's patented invention, the exhaustion doctrine does not protect him.

Were the matter otherwise, Monsanto's patent would provide scant benefit. After inventing the Roundup Ready trait, Monsanto would, to be sure, "receiv[e] [its] reward" for the first seeds it sells. Univis, 316 U.S., at 251. But in short order, other seed companies could reproduce the product and market it to growers, thus depriving Monsanto of its monopoly. And farmers themselves need only buy the seed once, whether from Monsanto, a competitor, or (as here) a grain elevator. The grower could multiply his initial purchase, and then multiply that new creation, *ad infinitum*—each time profiting from the patented seed without compensating its inventor. Bowman's late-season plantings offer a prime illustration. After buying beans for a single harvest, Bowman saved enough seed each year to reduce or eliminate the need for additional purchases. Monsanto still held its patent, but received no gain from Bowman's annual production and sale of Roundup Ready soybeans. The exhaustion doctrine is limited to the "particular item" sold to avoid just such a mismatch between invention and reward.

Bowman principally argues that exhaustion should apply here because seeds are meant to be planted. The exhaustion doctrine, he reminds us, typically prevents a patentee from controlling the use of a patented product following an authorized sale. And in planting Roundup Ready seeds, Bowman continues, he is merely using them in the normal way farmers do. Bowman thus concludes that allowing Monsanto to interfere with that use would "creat[e] an impermissible exception to the exhaustion doctrine" for patented seeds and other "self-replicating technologies." Brief for Petitioner 16.

But it is really Bowman who is asking for an unprecedented exception. Reproducing a patented article no doubt "uses" it after a fashion. But as already explained, we have always drawn the boundaries of the exhaustion doctrine to exclude that activity, so that the patentee retains an undiminished right to prohibit others from making the thing his patent protects. See, e.g., Cotton–Tie Co. v. Simmons, 106 U.S. 89, 93–94 (1882) (holding that a purchaser could not "use" the buckle from a patented cotton-bale tie to "make" a new tie). That is because, once again, if simple copying were a protected use, a patent would plummet in value after the first sale of the first item containing the invention. The undiluted patent

monopoly, it might be said, would extend not for 20 years (as the Patent Act promises), but for only one transaction. And that would result in less incentive for innovation than Congress wanted. Hence our repeated insistence that exhaustion applies only to the particular item sold, and not to reproductions.

Nor do we think that rule will prevent farmers from making appropriate use of the Roundup Ready seed they buy. Bowman himself stands in a peculiarly poor position to assert such a claim. As noted earlier, the commodity soybeans he purchased were intended not for planting, but for consumption. [I]n the more ordinary case, when a farmer purchases Roundup Ready seed qua seed—that is, seed intended to grow a crop—he will be able to plant it. Monsanto, to be sure, conditions the farmer's ability to reproduce Roundup Ready; but it does not—could not realistically—preclude all planting. No sane farmer, after all, would buy the product without some ability to grow soybeans from it. And so Monsanto, predictably enough, sells Roundup Ready seed to farmers with a license to use it to make a crop. Applying our usual rule in this context therefore will allow farmers to benefit from Roundup Ready, even as it rewards Monsanto for its innovation.

Still, Bowman has another seeds-are-special argument: that soybeans naturally "self-replicate or 'sprout' unless stored in a controlled manner," and thus "it was the planted soybean, not Bowman" himself. Brief for Petitioner 42. But we think that blame-the-bean defense tough to credit. Bowman was not a passive observer of his soybeans' multiplication; or put another way, the seeds he purchased (miraculous though they might be in other respects) did not spontaneously create eight successive soybean crops. As we have explained, Bowman devised and executed a novel way to harvest crops from Roundup Ready seeds without paying the usual premium. In all this, the bean surely figured. But it was Bowman, and not the bean, who controlled the reproduction (unto the eighth generation) of Monsanto's patented invention.

Our holding today is limited—addressing the situation before us, rather than every one involving a self-replicating product. We recognize that such inventions are becoming ever more prevalent, complex, and diverse. In another case, the article's self-replication might occur outside the purchaser's control. Or it might be a necessary but incidental step in using the item for another purpose. We need not address here whether or how the doctrine of patent exhaustion would apply in such circumstances. In the case at hand, Bowman planted Monsanto's patented soybeans solely to make and market replicas of them. Patent exhaustion provides no haven for that conduct. We accordingly affirm the judgment of the Court of Appeals for the Federal Circuit.

NOTES AND QUESTIONS ON *BOWMAN*

1. Necessity for a License to Make. Footnote 3 from the Court's opinion, excluded from the excerpt above, reads as follows:

> This conclusion applies however Bowman acquired Roundup Ready seed: The doctrine of patent exhaustion no more protected Bowman's reproduction of the seed he purchased for his first crop (from a Monsanto-affiliated seed company) than the beans he bought for his second (from a grain elevator). The difference between the two purchases was that the first—but not the second—came with a license from Monsanto to plant the seed and then harvest and market one crop of beans. We do not here confront a case in which Monsanto (or an affiliated seed company) sold Roundup Ready to a farmer without an express license agreement. For reasons we explain below, we think that case unlikely to arise. And in the event it did, the farmer might reasonably claim that the sale came with an implied license to plant and harvest one soybean crop.

The Court later explains that a farmer is unlikely to purchase patented seeds from Monsanto without an express license to plant them and grow a crop. It also states that the doctrine of implied license would probably protect the farmer in this situation anyway. The point is important, because it touches on the difference between behavior that is explicitly licensed by a patent owner and acts that are permissible even in the absence of a license. It is interesting that the Court does not say that an express contract may undercut rights otherwise protected under patent exhaustion – a theory that some cases, and more than a few business models, have relied on in recent years.

2. The Absence of a Saved Seed Exemption in the Patent Act. Another omitted part of the opinion emphasizes the differences between a patent and protection of plant varieties under the Plant Variety Protection Act (PVPA). The latter statute includes an explicit "saved seed exemption" from infringement liability, and the Court points out that a ruling in favor of Bowman in this case would effectively undermine the different regimes for plant variety protection and patents. The idea is that, compared to plant variety protection, patent law applies higher standards to an invention seeking protection, but, once a patent issues, confers broader rights.

NOTE ON LEXMARK v. IMPRESSION PRODUCTS

1. En Banc Questions. On April 14, 2015, the Federal Circuit ordered an *en banc* proceeding to decide two questions:

> (a) In light of *Kirtsaeng v. John Wiley & Sons, Inc.*, 133 S. Ct. 1351 (2012), should this court overrule *Jazz Photo Corp. v. International Trade Commission*, 264 F.3d 1094 (Fed. Cir. 2001), to the extent it ruled that a sale of a patented item outside the United States never gives rise to United States patent exhaustion?
>
> (b) In light of *Quanta Computer, Inc. v. LG Electronics, Inc.*, 553 U.S. 617 (2008), should this court overrule *Mallinckrodt, Inc. v. Medipart, Inc.*, 976

F.2d 700 (Fed. Cir. 1992), to the extent it ruled that a sale of a patented article, when the sale is made under a restriction that is otherwise lawful and within the scope of the patent grant, does not give rise to patent exhaustion?

2. The Government's Position. As this supplement was being completed, the en banc case was in the middle of its briefing cycle, but the United States had already its amicus brief, which suggested a negative answer to the first question (i.e., that the Federal Circuit's rule against international exhaustion should be retained in large measure) and a positive answer to the second question (i.e., that the Federal Circuit should overrule the "conditional sale" doctrine announced in *Mallinckrodt v. Medipart*).

On the first issue, the government relies heavily on the "territorial" nature of patent law, arguing that "J*azz Photo Corp. v. International Trade Commission*, 264 F.3d 1094 (Fed. Cir. 2001), correctly recognized that patent law is territorial and that sales consummated under foreign law do not necessarily convey rights under United States patent laws." Brief of the United States as Amicus Curiae at 14. Thus, the government supports a rule under which the patentee is free to grant or to withhold U.S. patent rights when it makes a foreign sale: "When a U.S. patentee makes or authorizes such a foreign sale, the patentee may convey its authority to import the article into the United States, but it may withhold that authority if it wishes." Id.

On the second issue, however, the government argues that the Federal Circuit's *Mallinckrodt* decision must be overruled because the "the Supreme Court has held for over 150 years that the patent exhaustion doctrine bars a patentee from invoking the patent laws to enforce restrictions on the use or resale of a patented article after the first authorized sale of the article in the United States." Id. at 4. Note that this rule cuts off only the possibility of relief under *patent law*. As the government's brief explicitly notes elsewhere, the patent exhaustion doctrine says nothing about using other areas of law—e.g., contract law—to enforce conditions placed upon the sale of goods.

3. Exhaustion as a Limit on Statutory Domain. One way to understand exhaustion is that the doctrine polices the outer limits or "domain" of the Patent Act so as to prevent patent law from interfering with other areas of commercial law, including not merely contract law, but also the law governing tortious interference with contract, security interests, personal property servitudes, etc. Under this view, the exhaustion doctrine rests not on a policy forbidding contractual conditions or property-based encumbrances on patented goods, but on a policy of making sure that any such conditions are enforced through those other areas of law.

Consider, for example, a patentee who wants to sell patented lasers both for (i) educational and research purposes and (ii) for other commercial purposes. The patentee wants to give a steep discount to those purchasing the lasers for educational and research purposes. (Such discounts are common in goods embodying intellectual property, and universities and their students are frequently the beneficiaries.) If the patentee sells a laser at $100 for research and educational

purposes but is also selling the same laser at $1000 for commercial purposes, the patentee might worry that some educational purchasers could resell their lasers to commercial users and thereby undermine the higher price for commercial purposes. That worry is legitimate because the exhaustion doctrine holds that, once the laser is sold, the patentee cannot rely on patent infringement actions to control the downstream uses of the laser.

What can the patentee do to enforce the limitation-on-use condition in such circumstances? Quite a lot, it turns out. First, the patentee can impose a contractual condition on the purchaser that it use the laser only for research and educational purposes *and* that it not sell the laser to anyone else except those who would also be using the laser for research and educational purposes. If the purchaser resells to a commercial entity, the patentee will have a contract remedy against the first purchaser (i.e., against the entity that purchased from the patentee, not against the commercial entity).

That's one remedy, but suppose that the patentee really wants to sue the downstream commercial entity that bought from the first purchaser? Commercial law provides several ways to do that too. For example, the patentee may be able to sue the downstream commercial purchaser for tortious interference with contract. Alternatively, the patentee could impose a security interest on the laser, and the security interest would allow suit against the downstream purchaser.

Each of those causes of action are subject to caveats and conditions—most importantly, the patentee is almost certainly going to have to prove that the downstream commercial entity had actual or constructive notice of the limitation on the laser's use. Such caveats and conditions are what's really at stake with the exhaustion doctrine because patent infringement actions are generally not subject to those limitations. But once those stakes are appreciated, the exhaustion doctrine begins to make a lot more sense, for the doctrine merely forces patentees, when they seek impose binding conditions on property that is being sold into commerce, to enforce those conditions using the same generally commercial law rules that governs all other sales of goods. This view is explained more fully in John F. Duffy and Richard M. Hynes, *Statutory Domain and the Commercial Law of Intellectual Property*, 102 Va. L. Rev. ___ (forthcoming 2016) (http://ssrn.com/abstract=2599074).