2020 Summer/Fall Supplement

for

Merges & Duffy: Patent Law and Policy (7th ed. 2017)

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Chap. 1.A. Historical Overview of Patent Law

Update on Supreme Court Patent Cases

On pages 15-16, replace the charts set forth in the text with these new updated charts:

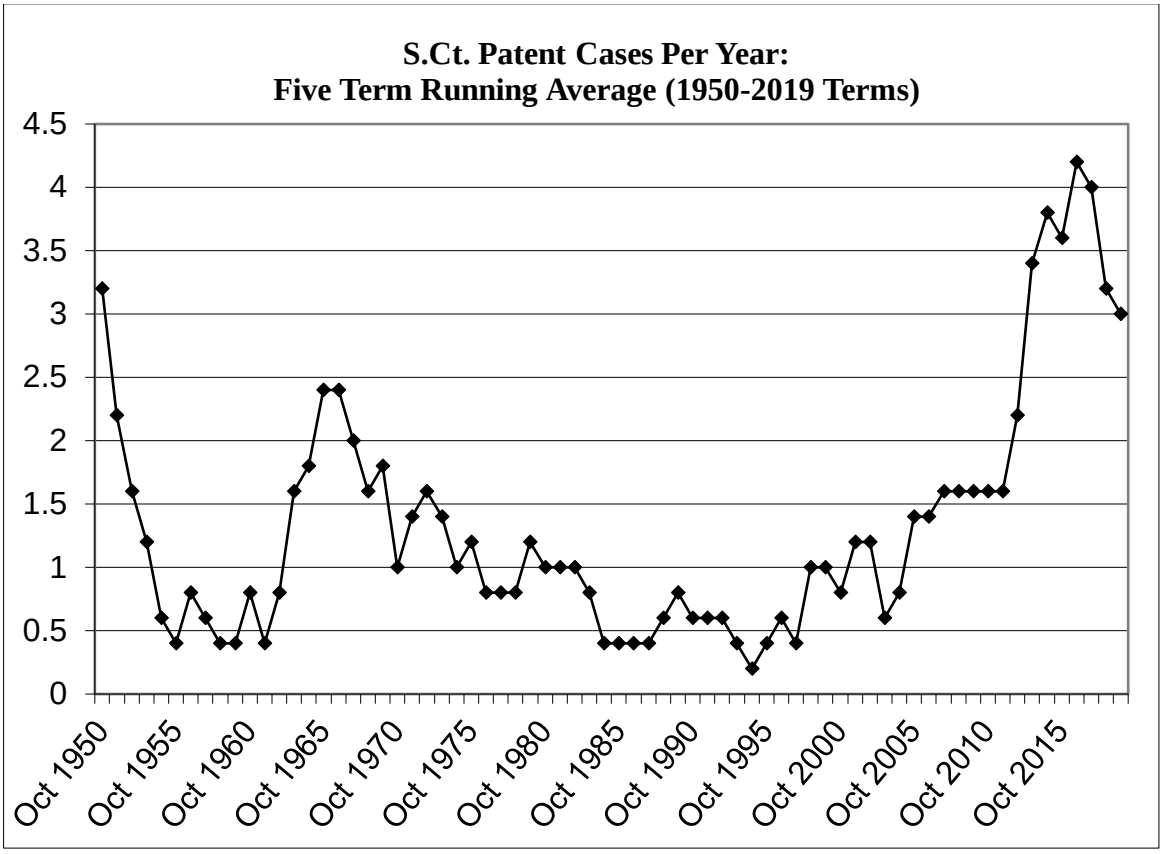


Figure 1-1. Average Number of Supreme Court Cases per Term, 1950 – 2019

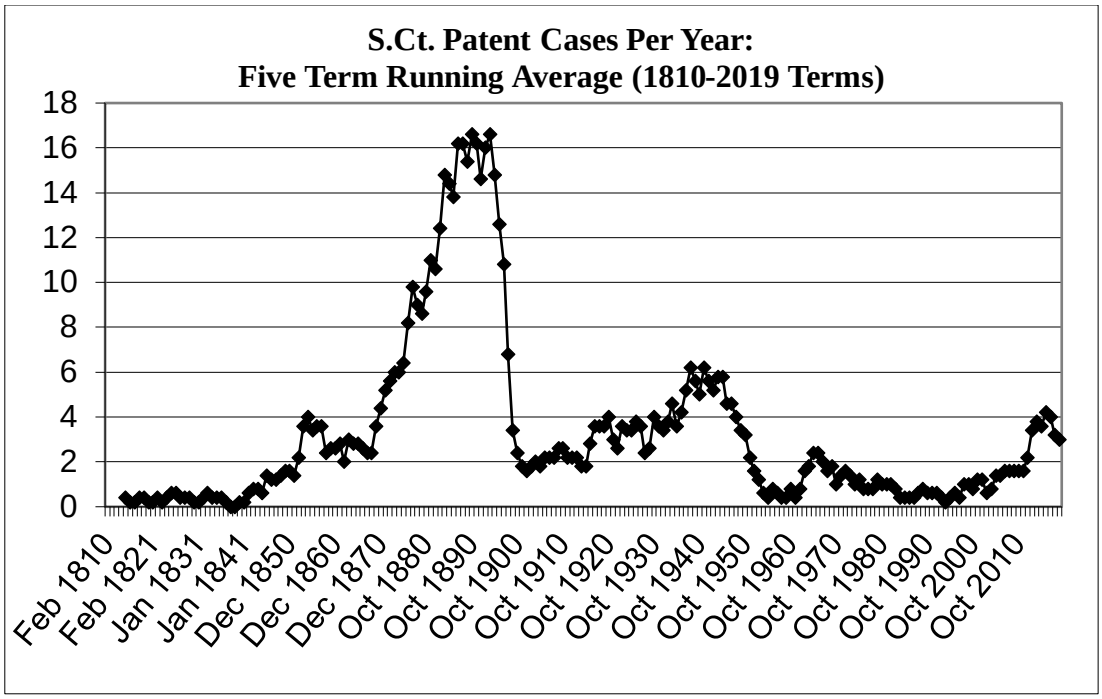


Figure 1-2. Average Number of Supreme Court Cases per Term, 1810 - 2019

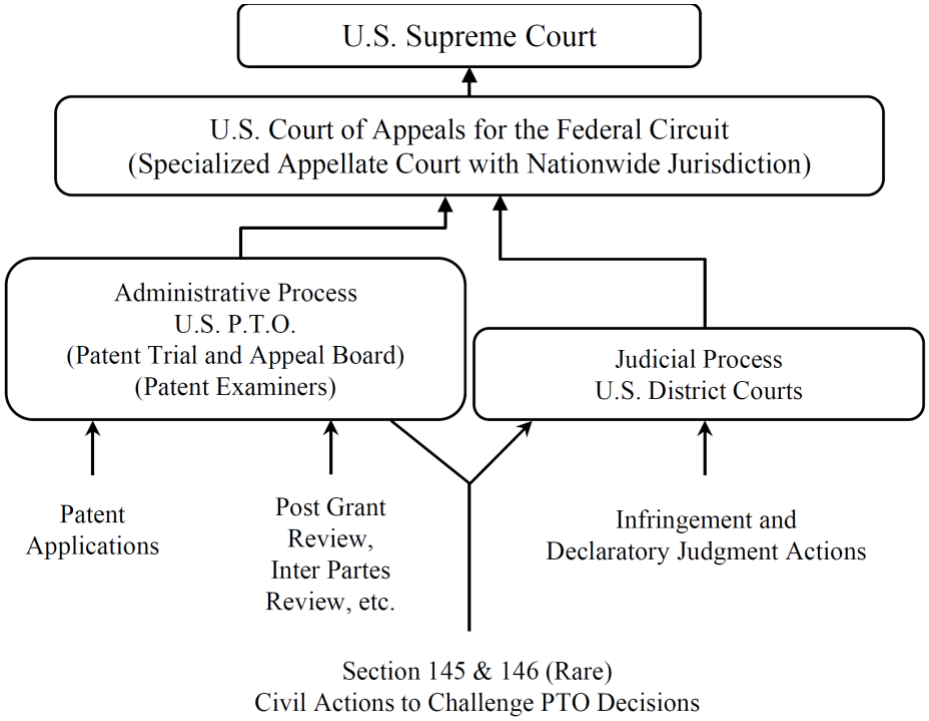
As the updated charts show, the Supreme Court's interest in patent law continues at near record levels for any time in the past half century. In its 2016 Term, the Supreme Court decided six cases on patent law, many of which are discussed in this casebook supplement. For the 2017 Term, the Court decided three cases, each of which has significant if not earth-shaking implications. Two of those cases—*Oil States Energy Servs., LLC v. Greene's Energy Grp.*, 138 S. Ct. 1365 (2018), and *SAS v. Iancu*, 138 S. Ct. 1348 (2018)—involve the propriety of the new *inter partes* review procedures that the PTO began to administer after the 2011 America Invents Act (AIA). Both of those cases are covered in Chapter 10 of this update. A third case— *WesternGeco LLC v. ION Geophysical Corp.*, 138 S. Ct. 2129 (2018)—represents an important development in the damages available for patent infringement. It is covered in Chapter 9 of this update. In its 2018 Term, the Court decided two patent cases. The case of *Helsinn v. Teva*, 139 S.Ct. 628 (2019), is the first case in which the Court has interpreted the new first-to-file system of priority in the AIA. It is covered in the update to Chapter 5. The other case—*Return Mail v. U.S. Postal Service*, 139 S.Ct. 1853 (2019)—held that the U.S. Government and its agencies cannot challenge patents under the AIA's *inter partes* review procedures. In its 2019 Term, the Court decided two more cases. The first, *Peter v. NantKwest, Inc.*, 140 S. Ct. 365 (2019), held that the PTO cannot collect the costs of paying its attorneys when parties challenge the denial of a patent through a district court trial under 35 U.S.C. § 145. The second, *Thryv, Inc. v. Click-To-Call Techs., LP*, 140 S. Ct. 1367 (2020), held that the PTO's decision to institute an *inter parties* review is not subject to judicial review even where the agency seemingly violates a statutory time limit on its ability to grant reviews. While some of these more recent cases will have only a limited impact (*e.g., Return Mail* and *NantKwest*), the cases collectively show that the Supreme Court remains intensely interested in patent law generally, and in the changes wrought by the AIA in particular.

Chap. 1.D Overview of Patent Rights and Patent Process

Revised Figure on the Legal Process of the U.S. Patent System

On page 57, replace Figure 1-7 with the following new Figure:

Figure 1-7. The Legal Process of the U.S. Patent System



Chap. 1.D.3 Post-Issuance Administrative Processes

On page 63, add the following note at the end of the section on post-issuance administrative processes:

NOTE ON THE CONSTITUTIONALITY OF ADMINISTRATIVE PROCESSES

In June of 2017, the Supreme Court granted certiorari in *Oil States Energy Servs., LLC v. Greene's Energy Grp., LLC*, 2017 U.S. LEXIS 3727 (June 12, 2017)—a case that could have upended the new post-issuance administrative processes authorized in the 2011 America Invents Act ("AIA"). The question presented in the case was:

> Whether inter partes review, an adversarial process used by the Patent and Trademark Office (PTO) to analyze the validity of existing patents, violates the Constitution by extinguishing private property rights through a non-Article III forum without a jury.

The basic theory of the petitioner in the case was that, once the U.S. PTO grants a patent, the validity of the issued patent cannot be challenged in an administrative forum, or at least it cannot be challenged administratively without the consent of the patentee.

By a 7-2 vote, the Court resoundingly rejected that argument. In an opinion by Justice Thomas, the Court reasoned that, because the decision to grant a patent is a matter involving so-called "public rights" (matters that are amenable to adjudication by the Executive Branch), subsequent administrative proceedings such as *inter partes* review are constitutionally permissible because those proceedings are simply a form of administrative "reconsideration" of the initial grant of public rights. The *Oil States* majority described the grant of a patent as equivalent to the grant of a "public franchise"—a phrase that clearly identifies patents as a species of "public rights" but also, some commentators fear, provides precedent for viewing patents as fundamentally not property. The Court, however, explicitly stated that the decision "should not be misconstrued as suggesting that patents are not property for purposes of the Due Process Clause or the Takings Clause." Slip op. at 17.

The *Oil States* case was enormously important. Over the first five years after the AIA's establishment of new post-issuance review procedures (2012-17), more than 7,000 petitions for some form of such review had been filed, and the agency instituted an administrative trial in more than half the cases. *See* https://www.uspto.gov/sites/default/files/documents/trial_statistics_june2017.pdf. Moreover, among the more than 1,600 cases that have reached a final decision by 2017, the agency had invalidated *all* of the reviewed claims in 65% of cases and at least one of the claims in more than 80% of the cases. Post-issuance administrative processes are thus a highly effective way either to weed out low quality patents (from the perspective of accused infringers) or to undermine the security of property rights (from the perspective of patentees). In sustaining the constitutionality of such post-issuance administrative proceedings, the *Oil States* case makes clear that such proceedings are here to stay.

Chapter 2: Patentable Subject Matter

Chap. 2.B. Natural Laws and Natural Principles

On page 118, add the new case below.

Athena Diagnostics, Inc. v. Mayo Collaborative Services, Inc.
915 F.3d 743 (Fed. Cir. 2019)

Before Newman, Lourie, and Stoll, JJ.

Dissenting opinion filed by *Circuit Judge* Newman.

Lourie, *Circuit Judge*.

Athena Diagnostics, Inc. [and other parties] (collectively, "Athena") appeal from the order of the United States District Court for the District of Massachusetts holding that claims 6-9 of U.S. Patent 7,267,820 (the "'820 patent") are invalid under 35 U.S.C. § 101. Because the district court correctly concluded that the claims at issue are directed to a natural law and lack an inventive concept, we affirm.

I. BACKGROUND

Athena Diagnostics is the exclusive licensee of the '820 patent, covering methods for diagnosing neurological disorders by detecting antibodies to a protein called muscle-specific tyrosine kinase ("MuSK"). Athena also markets a test called FMUSK that functions by evaluating those antibodies. After Mayo Collaborative Services, LLC ("Mayo") developed two competing tests that allegedly practice each step of one or more claims of the '820 patent, Athena accused Mayo of infringing its patent. Mayo moved to dismiss under Rule 12(b)(6), arguing that the asserted claims of the '820 patent were invalid under 35 U.S.C. § 101. The district court granted Mayo's motion, concluding that the claims were invalid under § 101 for claiming ineligible subject matter. This appeal solely concerns whether claims 6-9 are patent eligible under § 101.

A.

Myasthenia gravis ("MG") is a neurological disorder where patients experience muscle weakness and symptoms including drooping eyelids, double vision, and slurred speech. It was previously discovered that MG is an autoimmune disease caused by a patient generating antibodies against her own acetylcholine receptors. Antibodies which recognize a person's own proteins as foreign antigens are known as autoantibodies.

About 80% of patients with MG produce acetylcholine receptor autoantibodies. The other 20% do not, but they do experience the same MG symptoms. The named inventors of the '820 patent discovered that many of the 20% of MG patients without acetylcholine receptor autoantibodies instead generate autoantibodies to a membrane protein called MuSK. Prior to their discovery, no disease had been associated with MuSK.

Having discovered the association between MuSK autoantibodies and MG, the inventors of the '820 patent disclosed and claimed methods of diagnosing neurological disorders such as MG by

detecting autoantibodies that bind to a MuSK epitope.[1] Claim 1, not at issue in this appeal, is the only independent claim and reads as follows:

> 1. A method for diagnosing neurotransmission or developmental disorders related to [MuSK] in a mammal comprising the step of detecting in a bodily fluid of said mammal autoantibodies to an epitope of [MuSK].

Claim 7 is at issue and depends from claim 1. It recites:

> 7. A method according to claim 1, comprising
>
> > contacting MuSK or an epitope or antigenic determinant thereof having a suitable label thereon, with said bodily fluid,
> >
> > immunoprecipitating any antibody/MuSK complex or antibody/MuSK epitope or antigenic determinant complex from said bodily fluid and
> >
> > monitoring for said label on any of said antibody/MuSK complex or antibody/MuSK epitope or antigen determinant complex,
> >
> > wherein the presence of said label is indicative of said mammal is suffering from said neurotransmission or developmental disorder related to [MuSK].

Claim 8 depends from claim 7 and recites that the label is a radioactive label. Claim 9 depends from claim 8 and further recites that the radioactive label is 125I, a radioactive isotope of iodine. We focus on claim 9, the most specific one at issue, which requires: (1) contacting MuSK or an epitope thereof having a 125I label, with bodily fluid; (2) immunoprecipitating any antibody/MuSK complex; and (3) monitoring for the label on the complex, wherein the presence of the label indicates the presence of a MuSK-related disorder.

The specification of the '820 patent further explains what the steps of iodination and immunoprecipitation entail. First, MuSK is iodinated using radioactive 125I. Then iodinated MuSK is separated from any free 125I by gel filtration. Next, the 125I-labeled MuSK is added to a small volume of the patient's bodily fluid and left overnight. If MuSK autoantibodies are present in the patient's bodily fluid, they will bind to the 125I-labeled MuSK. Any 125I-labeled MuSK in the sample is then immunoprecipitated by adding a secondary antibody that binds to any MuSK autoantibodies present. The resulting precipitate is finally centrifuged, washed, and counted for radioactivity, which may be indicative of MG.

It is undisputed that iodination and immunoprecipitation were known techniques at the time of the invention. The '820 patent specification states that "[t]he actual steps of detecting autoantibodies in a sample of bodily fluids may be performed in accordance with immunological assay techniques known per se in the art," such as radioimmunoassays. With respect to the relevant individual steps in the radioimmunoassay, the specification also discloses that "[i]odination and immunoprecipitation are standard techniques in the art."

[1] An epitope, also known as an antigenic determinant, is a segment of a protein recognized by an antibody. See Bruce Alberts, Molecular Biology of the Cell 449-50 (6th ed. 2015). The specification of the '820 patent disclosed that autoantibodies in MG patients recognize a MuSK epitope located on the protein's extracellular amino-terminal domain.

…

II. DISCUSSION

A.

Athena argues that claims 7-9 are not directed to a natural law at step one because they recite innovative, specific, and concrete steps that do not preempt a natural law. Rather, Athena contends that the claims are directed to a new laboratory technique that makes use of man-made molecules.

Mayo responds that the claims are directed to a natural law: the correlation between naturally-occurring MuSK autoantibodies and MuSK-related neurological diseases like MG. According to Mayo, the remaining steps apart from the natural law are concededly standard immunoassay techniques that still leave the claim directed to a natural law. Indeed, Mayo argues that the specificity and concreteness of the claimed steps are irrelevant to whether a claim is directed to a natural law. And, as in Mayo, Mayo contends that it makes no difference to eligibility that the claimed diagnostic method uses man-made materials.

We ultimately agree with Mayo that, under Mayo, the claims are directed to a natural law. As an initial matter, we must identify what the relevant natural law is. Here, it is the correlation between the presence of naturally-occurring MuSK autoantibodies in bodily fluid and MuSK-related neurological diseases like MG. This correlation exists in nature apart from any human action. There can thus be no dispute that it is an ineligible natural law.

However, as Athena correctly observes, not every claim that involves a natural law is directed to a natural law. "[A]ll inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Mayo*, 566 U.S. at 71. The Supreme Court's two-step test thus "plainly contemplates that the first step of the inquiry is a meaningful one, i.e., that a substantial class of claims are not directed to a patent-ineligible concept." *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1335 (Fed. Cir. 2016).

The step one "directed to" inquiry focuses on the claim as a whole. To determine whether a claim is directed to an ineligible concept, we have frequently considered whether the claimed advance improves upon a technological process or merely an ineligible concept, based on both the written description and the claims. See *Cleveland Clinic Found. v. True Health Diagnostics LLC*, 859 F.3d 1352, 1361 (Fed. Cir. 2017); *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, 827 F.3d 1042, 1047-49 (Fed. Cir. 2016); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1376 (Fed. Cir. 2015).

For example, in *CellzDirect* we considered claims that covered a method for producing a preparation of a type of liver cell (called hepatocytes) that involved multiple freeze-thaw cycles. 827 F.3d at 1046, 1048. Although the inventors discovered the cells' ability to survive multiple freezethaw cycles, a discovery that the district court understood to be a natural law, we concluded that the claims were not directed to that natural law. This was because the claims as a whole recited "a new and improved way of preserving hepatocyte cells for later use," "not simply an observation or detection of the ability of hepatocytes to survive multiple freeze-thaw cycles." *Id.* at 1048. The claimed advance harnessed a natural law to produce a technological improvement that was patent eligible. *See id.* at 1048-49; see also, e.g., *Enfish*, 822 F.3d at 1335-39 (holding improvement in computer-related technology not directed to abstract idea).

In contrast, in *Cleveland Clinic* we reiterated that claims that merely recite observing naturally occurring biological correlations "with no meaningful non-routine steps in between" are directed to a natural law. 859 F.3d at 1361; see *Ariosa*, 788 F.3d at 1376. There, the specification indicated that the claimed inventors discovered a natural correlation between a molecule called MPO and cardiovascular disease. *Cleveland Clinic*, 859 F.3d at 1360-61. The claims at issue recited detecting MPO or other MPO-related products in a patient sample and then predicting a patient's risk of having or developing cardiovascular disease. *Id.* at 1361. As the claims only covered the correlation between MPO and cardiovascular disease, an ineligible discovery, together with "well-known techniques to execute the claimed method," we held that the claims were directed to a natural law. *Id.*

The claims at issue here involve both the discovery of a natural law and certain concrete steps to observe its operation. Claim 9, the most specific claim at issue, recites the following method to detect MuSK autoantibodies: (1) mixing MuSK or an epitope thereof having a 125I label with bodily fluid; (2) immunoprecipitating any resulting antibody/MuSK complex; and (3) monitoring for the label on the complex.The claim then concludes in the wherein clause with a statement of the natural law, i.e., the discovery that MuSK autoantibodies naturally present in a patient sample, detected with the 125I label bound to the MuSK/antibody complex, indicate that the patient is suffering from a MuSK-related neurological disorder.

As in *Cleveland Clinic* and *Ariosa*, we conclude that claims 7-9 are directed to a natural law because the claimed advance was only in the discovery of a natural law, and that the additional recited steps only apply conventional techniques to detect that natural law. The specification of the '820 patent highlights the discovery of the natural law, explaining that "[t]he present inventors surprisingly found that many of the 20% of MG patients [who] do not exhibit any autoantibodies to [the acetylcholine receptor], instead have ... antibodies directed against the extracellular [amino]-terminal domains of MuSK." Further, the specification describes the claimed concrete steps for observing the natural law as conventional. It teaches that "[t]he actual steps of detecting autoantibodies in a sample of bodily fluids may be performed in accordance with immunological assay techniques known per se in the art," including radioimmunoassays and ELISA. Id. col. 3 ll. 33-37. Likewise, the specification identifies "[i]odination and immunoprecipitation" as "standard techniques in the art." The '820 patent thus describes the claimed invention principally as a discovery of a natural law, not as an improvement in the underlying immunoassay technology. Consistent with the specification, the claims are directed to that law.

Athena argues that the claims at issue, like the claims in *CellzDirect*, are directed to an innovative laboratory technique, not a law of nature. However, Athena does not point to any innovation other than its discovery of the natural law. *CellzDirect* did not suggest that appending standard techniques to detect a natural law rendered claims not directed to a natural law; rather, we expressly distinguished the eligible claims in that case from ineligible claims that "amounted to nothing more than observing or identifying the ineligible concept itself." 827 F.3d at 1048. In that case, we concluded that the "end result" of the claims at issue was "not simply an observation or detection" of a natural law. *Id.* We cannot so conclude here, since the claims before us only involve detecting a natural law "with no meaningful non-routine steps." *Cleveland Clinic*, 859 F.3d at 1361.

Athena also points to the specificity of the claimed concrete steps, contending that they preempt no natural law and therefore the claims cannot be directed to a natural law. Although we agree that claim 9 leaves open to the public other ways of interrogating the correlation between MuSK autoantibodies and MuSK-related disorders without practicing the claim's concrete steps, that does not disturb our conclusion at step one. Preemption is sufficient to render a claim ineligible

under § 101, but it is not necessary. Flook, 409 U.S. at 71-72 (holding claim involving mathematical formula invalid under § 101 that did not preempt a mathematical formula); *Ariosa*, 788 F.3d at 1379; *In re BRCA1- & BRCA2-Based Hereditary Cancer Test Patent Litig.*, 774 F.3d 755, 764 n.4 (Fed. Cir. 2014). The claims here are directed to a natural law because they recite only the natural law together with standard techniques for observing it. That the routine steps are set forth with some specificity is not enough to change that conclusion.

Finally, Athena argues that the claims at issue differ from prior diagnostic claims we have held ineligible under § 101 because they require labeling MuSK with a man-made substance. We disagree. As Mayo argues, the use of a man-made molecule is not decisive if it amounts to only a routine step in a conventional method for observing a natural law. For example, *Mayo* involved claims requiring administering a man-made molecule (a drug "providing" 6-thioguanine) to a patient. 566 U.S. at 74-75. Some of the claims in *Ariosa* likewise required amplification through the polymerase chain reaction, which makes use of man-made reagents, see U.S. Patent 6,258,540 col. 5 ll. 6-26, or using a specific probe that binds to DNA, 788 F.3d at 1374. And the claims in BRCA1 also involved hybridizing a synthetic DNA probe to a DNA strand. *BRCA1*, 774 F.3d at 763-64. Nonetheless, in each of these cases either the Supreme Court or this court held the claims directed to a natural law and invalid under § 101. *Mayo*, 566 U.S. at 92; *Ariosa*, 788 F.3d at 1380; *BRCA1*, 774 F.3d at 765. We thus reaffirm that use of a man-made molecule in a method claim employing standard techniques to detect or observe a natural law may still leave the claim directed to a natural law.

We consider it important at this point to note the difference between the claims before us here, which recite a natural law and conventional means for detecting it, and applications of natural laws, which are patent-eligible. See *Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1133-36 (Fed. Cir. 2018) (holding that method of treatment by administering drug at certain dosage ranges based on a patient's genotype was not directed to a natural law). Claiming a natural cause of an ailment and well-known means of observing it is not eligible for patent because such a claim in effect only encompasses the natural law itself. But claiming a new treatment for an ailment, albeit using a natural law, is not claiming the natural law.

As we conclude that claims 7-9 are directed to a natural law, we turn to the second step of the *Mayo/Alice* test.[4]

B.

[4] The dissent states much that one can agree with from the standpoint of policy, and history, including that "the public interest is poorly served by adding disincentive to the development of new diagnostic methods." Dissent at 762. We would add further that, in our view, providing patent protection to novel and non-obvious diagnostic methods would promote the progress of science and useful arts. But, whether or not we as individual judges might agree or not that these claims only recite a natural law, cf. *Berkheimer v. HP Inc.*, 890 F.3d 1369, 1374 (Fed. Cir. 2018) (Lourie, J., concurring in the denial of rehearing en banc) (discussing traditional laws of nature such as "Ohm's Law, Boyle's Law, [and] the equivalence of matter and energy"), the Supreme Court has effectively told us in *Mayo* that correlations between the presence of a biological material and a disease are laws of nature, see 566 U.S. at 77, and "[p]urely `conventional or obvious' `[pre]solution activity' is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law," *id.* at 79 (second alteration in original) (quoting *Flook*, 437 U.S. at 590). We have since confirmed that applying somewhat specific yet conventional techniques (such as the polymerase chain reaction) to detect a newly discovered natural law does not confer eligibility under § 101. *Ariosa*, 788 F.3d at 1377; see also *Cleveland Clinic*, 859 F.3d at 1356, 1362 (addressing other conventional techniques such as flow cytometry). Our precedent leaves no room for a different outcome here.

At step two, "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." *Alice*, 573 U.S. at 217 (quoting *Mayo*, 566 U.S. at 78, 79). "Purely `conventional or obvious' `[pre]-solution activity' is normally not sufficient to transform an unpatentable law of nature into a patent-eligible application of such a law." *Mayo*, 566 U.S. at 79 (alteration in original) (quoting *Flook*, 437 U.S. at 590). The transformative "inventive concept" supplied by the claim elements not drawn to ineligible subject matter must be "sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the [ineligible concept] itself." *Alice,* 573 U.S. at 217-18 (quoting *Mayo,* 566 U.S. at 73).

1.

Athena argues that the claims provide an inventive concept: an innovative sequence of steps involving man-made molecules. Prior to its discovery, Athena contends that there was no disclosed method to detect MuSK autoantibodies. … Mayo responds that the claims lack an inventive concept because the specification describes the steps for detecting MuSK autoantibodies as standard techniques in the art.

We agree with Mayo that the steps of the claims not drawn to ineligible subject matter, whether viewed individually or as an ordered combination, only require standard techniques to be applied in a standard way. As previously discussed, the specification of the '820 patent plainly states that "[t]he actual steps of detecting autoantibodies in a sample of bodily fluids may be performed in accordance with immunological assay techniques known per se in the art," such as radioimmunoassays. '820 patent col. 3 ll. 33-37. Iodination and immunoprecipitation are likewise described as standard techniques. Id. col. 4 ll. 9-12. Because the specification defines the individual immunoprecipitation and iodination steps and the overall radioimmunoassay as conventional techniques, the claims fail to provide an inventive concept. *Cleveland Clinic*, 859 F.3d at 1362; *Ariosa*, 788 F.3d at 1378.

Our decisions in *CellzDirect* and *BASCOM* are consistent with the principle that applying standard techniques in a standard way to observe a natural law does not provide an inventive concept. In *CellzDirect*, we considered a combination of claimed steps involving two freeze/thaw cycles. 827 F.3d at 1051. We held that this combination of steps was not conventional because the prior art methods only disclosed using one freeze/thaw cycle and, in fact, taught away from using multiple freeze/thaw cycles. Similarly, in *BASCOM* we held that the ordered combination of claim limitations was not routine and conventional because they placed a filtering tool at a specific location that improved on prior art technology. 827 F.3d at 1350. The inventive concept was "found in the non-conventional and non-generic arrangement of known, conventional pieces." Id. In contrast, claims 7-9 of the '820 patent employ a conventional technique for detecting autoantibodies, a radioimmunoassay, which the specification acknowledges was "known per se in the art."The individual constituent steps of that technique, iodination and immunoprecipitation, are similarly described as standard. Thus, unlike the claimed limitations at issue in *CellzDirect* and *BASCOM*, the recited steps here were conventional both as an ordered combination and individually.

Athena also argues that the claimed steps were unconventional because they had not been applied to detect MuSK autoantibodies prior to Athena's discovery of the correlation between MuSK autoantibodies and MG. Even accepting that fact, we cannot hold that performing standard techniques in a standard way to observe a newly discovered natural law provides an inventive concept. This is because "[t]he inventive concept necessary at step two... cannot be furnished by the

unpatentable law of nature ... itself." *Genetic Techs. Ltd. v. Merial L.L.C.*, 818 F.3d 1369, 1376 (Fed. Cir. 2016); *see Mayo*, 566 U.S. at 73, 132 S.Ct. 1289 (considering whether the "claimed processes (apart from the natural laws themselves)" were routine and conventional). Rather, to supply an inventive concept the sequence of claimed steps must do more than adapt a conventional assay to a newly discovered natural law; it must represent an inventive application beyond the discovery of the natural law itself. Because claims 7-9 fail to recite such an application, they do not provide an inventive concept.

Similar to its step one argument, Athena further argues that the claims recite an inventive concept because they use a man-made molecule, i.e., labeled MuSK. Athena analogizes its methods involving labeled MuSK to the composition claims involving cDNA held eligible in *Association for Molecular Pathology v. Myriad Genetics, Inc.*, 569 U.S. 576, 594-95 (2013). However, the method claims at issue here are unlike the claims held eligible in Myriad, which recited a new composition of matter that was not a natural product. Id. For the same reasons that we have concluded that attaching a label to MuSK did not make the claims directed to an eligible concept at step one, we conclude that appending labeling techniques to a natural law does not provide an inventive concept where, as here, the specification describes 125I labeling as a standard practice in a well-known assay. …

AFFIRMED

Newman, *Circuit Judge*, dissenting.

Until discovery of the diagnostic method described in U.S. Patent No. 7,267,820 ("the '820 patent"), some 20% of patients suffering from the neurological disorder Myasthenia Gravis were not capable of being diagnosed. My colleagues rule that this new diagnostic method is not patenteligible, although new and unobvious. However, "[t]his new and improved technique, for producing a tangible and useful result, falls squarely outside those categories of inventions that are `directed to' patent-ineligible concepts." *Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc*., 827 F.3d 1042, 1050 (Fed. Cir. 2016). The court again departs from the cautious restraints in the Supreme Court's *Mayo/Alice* application of laws of nature and abstract ideas.

This court's decisions on the patent-ineligibility of diagnostic methods are not consistent, and my colleagues today enlarge the inconsistencies and exacerbate the judge-made disincentives to development of new diagnostic methods, with no public benefit. I respectfully dissent.

The '820 inventors did not patent their scientific discovery of MuSK autoantibodies. Rather, they applied this discovery to create a new method of diagnosis, for a previously undiagnosable neurological condition. …

Claims 7-9 require specific steps by which the diagnostic method is performed. The panel majority ignores these steps, and instead holds that "claims 7-9 are directed to a natural law because the claimed advance was only in the discovery of a natural law, and that the additional recited steps only apply conventional techniques to detect that natural law." Maj. Op. at 751. This analysis of patent-eligibility is incorrect, for the claim is for a multi-step method of diagnosing neurotransmission disorders related to muscle specific tyrosine kinase, by detecting autoantibodies using a series of chemical and biological steps as set forth in the claims. Eligibility is determined for the claim considered as a whole, including all its elements and limitations. Claim limitations cannot be discarded when determining eligibility under Section 101, as explained in *Diamond v. Diehr*, 450 U.S. 175 (1981):

> In determining the eligibility of respondents' claimed process for patent protection under § 101, their claims must be considered as a whole. It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis.

Id. at 188; see Parker v. Flook, 437 U.S. 584, 594 (1978) ("[A] patent claim must be considered as a whole.").

The requirement that a claim is considered as a whole was not changed by the *Mayo/Alice* protocol of searching for an inventive concept within a claim that is directed to a law of nature or an abstract idea. … After eliminating the "conventional" procedures, my colleagues rule that this new method is a "law of nature." However, these inventors are not claiming the scientific fact of a newly described autoantibody; they are claiming a new multi-step diagnostic method. This is not a law of nature, but a man-made reaction sequence employing new components in a new combination to perform a new diagnostic procedure. …

In *Alice*, the Court summarized the procedural framework for eligibility for patenting:

> First, we determine whether the claims at issue are directed to one of those patent-ineligible concepts. If so, we then ask, "[w]hat else is there in the claims before us?" 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.

Alice, 573 U.S. at 217.

This analysis comports with precedent, and the Court reiterated its caution that "too 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." *Mayo*, 566 U.S. at 71; *see Alice*, 573 U.S. at 217 ("At the same time, we tread carefully in construing this exclusionary principle lest it swallow all of patent law."). We have echoed this concern, stating in *Rapid Litigation Management*, 827 F.3d at 1050, "[a]t step one, therefore, it is not enough to merely identify a patent-ineligible concept underlying the claim; we must determine whether that patent-ineligible concept is what the claim is `directed to,'" (quoting *Alice*, 573 U.S. at 217).

The panel majority departs from this guidance, for the claimed diagnostic method as a whole satisfies step one. The majority does not distinguish between the question of whether the claimed method as a whole is eligible, and the question of whether the separate steps use conventional procedures. Instead, my colleagues hold that since the separate procedures are conventional, it is irrelevant that the method as a whole is a new method. The majority misconstrues the claims, in holding that claims 7-9 are directed to the "concept" of "the correlation between the presence of naturally-occurring MuSK autoantibodies in bodily fluid and MuSK-related neurological diseases like MG." Maj. Op. at 750. The claimed method determines whether this correlation is present, for diagnostic purposes, but the concept itself is not claimed.

It is incorrect to separate the claim steps into whether a step is performed by conventional techniques, and then to remove those steps from the claims and their "conjunction with all of the other steps" for the purpose of Section 101 analysis. *Diehr*, 450 U.S. at 187. All of the claim steps must be considered in the claimed combination. "It is inappropriate to dissect the claims into old and new elements and then to ignore the presence of the old elements in the analysis." *Id*. at 188. …

The panel majority contravenes the requirements of precedent, now holding that all of the steps of claims 7-9—that is, radioactive labelling, complexing, precipitating, and monitoring—are removed from consideration in the Section 101 analysis because they use conventional procedures; the majority holds that "[t]he '820 patent thus describes the claimed invention principally as a discovery of a natural law, not as an improvement in the underlying immunoassay technology." Maj. Op. at 751. However, that is not the claimed invention. In *Mayo*, 566 U.S. at 71, the Court cautioned that "too 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."

Applying the *Mayo/Alice* protocol of two-step claim analysis, claims 7-9 of the '820 patent are patent-eligible under Step 1, for this method of diagnosing Myasthenia Gravis is not a law of nature, but a man-made chemical-biomedical procedure. Claims 7-9 recite a combination of technologic steps, all of which are limitations to the claims and cannot be disregarded whether for patentability or patent-eligibility or infringement. The court today violates this rule, in holding that because "the ... individual steps ... [of] `[i]odination and immunoprecipitation are standard techniques in the art,'" Maj. Op. at 748, these steps do not count under Section 101. Id. at 751-52.

Section 101 does not turn on whether any claim steps are "standard techniques." The appropriate analysis of the role of conventional process steps in claims to a new method is under Sections 102 and 103, not Section 101. …

Applying the statute correctly, diagnostic claims should be evaluated for novelty and unobviousness, specificity and enablement. A method that meets these statutory criteria is within the system of patents, whether the diagnosed event occurs in the human body or in an extraneous device. From my colleagues' contrary conclusion, I respectfully dissent.

NOTES ON *ATHENA* AND NATURAL LAWS IN § 101 DOCTRINE

1. Eight Opinions on the Denial of *En Banc* Review. Athena unsuccessfully petitioned the whole Federal Circuit for *en banc* review. The vote against the petition was 7-5, but eight judges wrote opinions on the matter, with four opinions in favor of granting *en banc* review and four against. *See Athena Diagnostics, Inc. v. Mayo Collaborative Servs., LLC,* 927 F.3d 1333 (Fed. Cir. 2019). No judge defended the result as (i) good policy; (ii) a justifiable interpretation of the text of the Patent Act; or (iii) a faithful adherence to congressional intent. Instead, the judges who voted in favor of denying *en banc* review placed responsibility for the result on the Supreme Court's judicially created exceptions to patentable subject matter. Thus, for example, Judge Lourie (the author of the panel decision) wrote:

> I concur in the court's decision not to rehear this case en banc. In my view, we can accomplish little in doing so, as we are bound by the Supreme Court's decision in *Mayo*. Some of us have already expressed our concerns over current precedent. E.g., *Athena Diagnostics, Inc. v. Mayo Collaborative Servs.*, LLC, 915 F.3d 743, 753 n.4 (Fed. Cir. 2019); *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 809 F.3d 1282, 1284 (Fed. Cir. 2015) (Lourie, J., concurring in the denial of rehearing en banc); id. at 1287 (Dyk, J., concurring in the denial of rehearing en banc).
>
> If I could write on a clean slate, I would write as an exception to patent eligibility, as respects natural laws, only claims directed to the natural law itself, e.g., E=mc2, F=ma, Boyle's Law, Maxwell's Equations, etc. I would not exclude uses or detection of natural

> laws. The laws of anticipation, obviousness, indefiniteness, and written description provide other filters to determine what is patentable.
>
> But we do not write here on a clean slate; we are bound by Supreme Court precedent. …

Athena, 927 F.3d at 1335 (Lourie, J., concurring in the denial of *en banc* review). That opinion was also joined by Judges Reyna and Chen.

An opinion by Judge Hughes, joined by Chief Judge Prost and Judge Taranto sounded a similar note, asserting that: (i) the result in the case was controlled by "the language in *Mayo*"; (ii) "the bottom line for diagnostics patents is problematic"; and (iii) "this is not a problem that we can solve" because the court is "bound by the Supreme Court." *Id.* at 1337 (Hughes, J., concurring).

In another concurring opinion, Judge Dyk offered some support for the Supreme Court's recent § 101 case law. He wrote that, "[i]n the realm of abstract ideas, the *Mayo/Alice* framework has successfully screened out claims that few would contend should be patent eligible," but that "[t]he problem with § 101 arises not in implementing the abstract idea approach of *Alice*, but rather in implementing the natural law approach of *Mayo*." *Id.* at 1337, 1339 (Dyk, J., concurring). He too, like the majority of Federal Circuit judges, thought that "it is the Supreme Court, not this court, that must reconsider the breadth of Mayo." *Id*. at 1339.

The judges dissenting from denial of *en banc* review thought that *Mayo* did not command such extreme results. Writing one of the dissents from the denial of *en banc* review, Judge Moore reasoned:

> This is not a case in which the judges of this court disagree over whether diagnostic claims, like those at issue in Athena, should be eligible for patent protection. They should. None of my colleagues defend the conclusion that claims to diagnostic kits and diagnostic techniques, like those at issue, should be ineligible. The only difference among us is whether the Supreme Court's Mayo decision requires this outcome. The majority of my colleagues believe that our hands are tied and that Mayo requires this outcome. I believe Mayo does not. The Patent Act renders eligible the invention or discovery of any new and useful process. 35 U.S.C. § 101. And the patent system exists to promote exactly this sort of specific, targeted application of a life-saving discovery, which is characterized by extraordinarily high initial market entry costs. The claims in this case should be held eligible, and they are distinguishable from Mayo.

Id. at 1352 (Moore, J., dissenting from the denial of *en banc* review). Judge Moore also noted that "[s]ince Mayo, we have held every single diagnostic claim in every case before us ineligible." *Id.* In effect, she argued, the Federal Circuit had "turned *Mayo* into a per se rule that diagnostic kits and techniques are ineligible." *Id.* at 1354. Such a per se rule cannot be the correct interpretation of *Mayo*, she argued, because the "Supreme Court has repeatedly cautioned against rigid or per se rules" in determining patentability. *Id.*

2. On Petition for Certiorari at the Supreme Court. Unsurprisingly, Athena Diagnostics sought review at the Supreme Court. At the Supreme Court, a very interesting and unusual thing happened: In a filing in *another* case, the United States Solicitor General went out of his way to refer to Athena's petition as a possible petition that the Court should grant.

The other case was *Hikma Pharmaceuticals USA Inc. v. Vanda Pharmaceuticals Inc.*, No. 18-817, pet. for cert. filed Oct. 28, 2018. In that case, a divided Federal Circuit upheld the patentability of a claim drawn to a method for treating a disease with a drug, where the claimed invention varied the dosage of the drug based on measurements of the patient's genotype. The claim in that case reads:

> A method for treating a patient with iloperidone, wherein the patient is suffering from schizophrenia, the method comprising the steps of:
>
> > determining whether the patient is a CYP2D6 poor metabolizer by:
> >
> > > obtaining or having obtained a biological sample from the patient;
> > >
> > > and
> > >
> > > performing or having performed a genotyping assay on the biological sample to determine if the patient has a CYP2D6 poor metabolizer genotype;
> >
> > *and if the patient has a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient in an amount of 12 mg/day or less,*
> >
> > *and if the patient does not have a CYP2D6 poor metabolizer genotype, then internally administering iloperidone to the patient in an amount that is greater than 12 mg/day, up to 24 mg/day,*
> >
> > wherein a risk of QTc prolongation [an undesirable side effect concerning heart rhythms] for a patient having a CYP2D6 poor metabolizer genotype is lower following the internal administration of 12 mg/day or less than it would be if the iloperidone were administered in an amount of greater than 12 mg/day, up to 24 mg/day.

Vanda Pharmaceuticals v. West Ward Pharmaceuticals, 887 F.3d 1117, 1121 (Fed. Cir. 2018) (emphasis added). Note that the claim is quite similar to the claim in *Mayo* except that this claim includes *treatment* steps: the italicized steps require certain levels of a drug to be administered based on the detected genotype. The wherein clause of the claim tells *why* the dosage level is different for different genotype (it's to avoid the undesirable side effect of "QTc prolongation"). In sustaining the claim as eligible subject matter, the Federal Circuit emphasized that, while the inventors recognized the natural relationship among the drug iloperidone, a particular genotype, and the undesirable side effect, "that is not what they claimed." *Id.* at 1135. They instead "claimed an application of that relationship." *Id.*

The petition for certiorari in that case presented the question:

> [W]hether patents that claim a method of medically treating a patient automatically satisfy Section 101 of the Patent Act, even if they apply a natural law using only routine and conventional steps.

That question was potentially misleading because the Federal Circuit did not hold that any particular class of patent claims "automatically" satisfies patentable subject matter doctrine—indeed, the word "automatically" never appears in the Federal Circuit's opinion. Rather, the lower court held that the

challenged patent claims were "directed to a specific method of treatment" for a disease, not "directed to" a natural law or principle. *Id.* at 1136. Accordingly, the court held that the claims were not patent ineligible under step 1 of the two-step test articulated in *Mayo* and *Alice*.

In response to the certiorari petition, the Supreme Court called for the views of the Solicitor General. *See Hikma Pharmaceuticals USA Inc. v. Vanda Pharmaceuticals Inc.*, 139 S.Ct. 1368 (2019). The resulting brief by the Solicitor General agreed with the Federal Circuit that: "A method of treating a medical condition with an existing drug—such as Vanda's claimed method of using iloperidone to treat schizophrenia—is a patent eligible process." Brief for the United States at 9, in *Hikma Pharmaceuticals USA Inc. v. Vanda Pharmaceuticals Inc.*, No. 18-817 (S.Ct. filed Dec. 6, 2019). The brief recommended denying certiorari in *Hikma* (thus preserving Vanda's victory below), but the brief also told the Court that "further guidance from this Court [on patentable subject matter doctrine] is amply warranted." Brief for the United States at 23, in *Hikma Pharmaceuticals*. The Solicitor General also took the unusual step of pointing to the then-pending petition for certiorari in *Athena* as a good case for review, even though the Supreme Court had not asked the Solicitor General to opine on that case:

> The Court instead should provide additional guidance in a case where the current confusion has a material effect on the outcome of the Section 101 analysis. For example, *Mayo* has had particularly significant practical effects with respect to medical-diagnostic methods. See *Athena Diagnostics, Inc. v. Mayo Collaborative Servs.*, LLC, 927 F.3d 1333, 1352-1353 (Fed. Cir. 2019) (Moore, J., dissenting from the denial of rehearing en banc) ("Since Mayo, we have held every single diagnostic claim in every case before us ineligible."), petition for cert. pending, No. 19-430 (filed Oct. 1, 2019). In contrast to this case [*Hikma*], where rehearing was denied without recorded dissent, the Federal Circuit's recent order denying rehearing en banc in *Athena* was accompanied by multiple separate opinions articulating different understandings of Mayo and seeking clarification from this Court.

Brief for the United States at 22, in *Hikma Pharmaceuticals*.

Despite the Solicitor General's recommendation, the Court denied certiorari in both *Hikma* and *Athena* on January 13, 2020. The end result is that the Court has now rejected all petitions for certiorari in patentable subject matter cases filed since its 2014 decision in *Alice*.

NOTE ON *AMERICAN AXLE* AND NEW PATENTABLE SUBJECT MATTER ISSUES

While the many judicial opinions accompanying the denial of *en banc* review in *Athena* emphasized the difficulties that diagnostic patents have in avoiding the "natural law" exclusion from patentable subject matter, recent litigation demonstrates that the problems are much more general. The patent at issue in *American Axle & Manufacturing v. Neapco Holdings*, 939 F. 3d 1355 (Fed. Cir. 2019), was U.S. Patent No. 7,774,911, which claims processes for making "a shaft assembly of a driveline system" for cars and trucks. Figures 1 & 2 from the patent show generally what such a "shaft assembly" looks like:

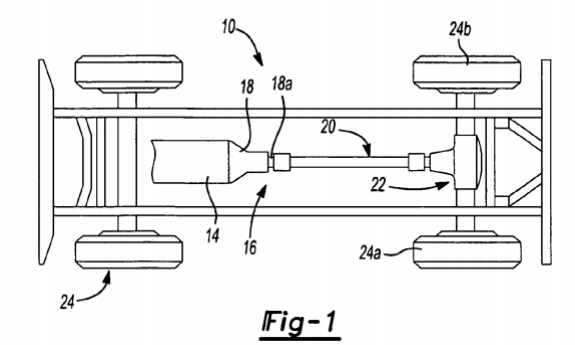


Figure 1 from the patent: The vehicle's engine (14) transmits power through the driveline assembly (16) to the rear axle (22). Vibrations in the propshaft assembly (20) must be damped for the system to work well.

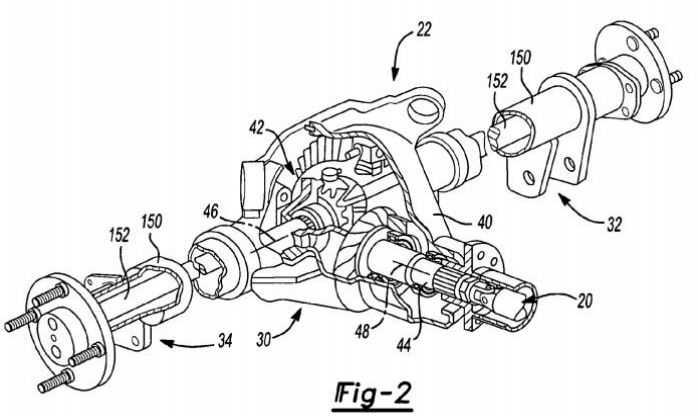


Figure 2 from the patent shows some details of the interface between the propshaft (20) and the rear axle (22).

The basic technological problem with such driveline assemblies is that the propshaft is made of relatively thin-walled metal tubing that can vibrate as it rotates under power. The vibrations can occur in three modes: bending mode, torsion mode, and shell mode. Such vibrations are undesirable for various reasons, including that they generate noise. To dampen the vibrations, engineers had previously employed various techniques including the use of "liners" inserted into the shaft to dampen the vibrations.

The patentee's asserted advance in the art was described by the court:

> AAM [American Axle & Manufacturing] urges both that it "conceiv[ed] of the novel and unconventional concept of 'tuning' a liner," and that it conceived of a tuned liner that "unlike previous dampers and absorbers ... [can] dampen multiple types of vibration" simultaneously. AAM explains that "particular liners that are specifically tuned to match and damp multiple vibration modes and are utilized to manufacture improved propshafts... w[ere] entirely new and far from well-understood" at the time of the '911 patent. Neither the claims nor the specification describes how to achieve such tuning. The specification also discloses a solitary example describing the structure of a tuned liner, but does not discuss the process by which that liner was tuned.

Id. at 1360.

Claim 22 of the patent reads:

> 22. A method for manufacturing a shaft assembly of a driveline system, the driveline system further including a first driveline component and a second driveline component, the shaft assembly being adapted to transmit torque between the first driveline component and the second driveline component, the method comprising:
>
> providing a hollow shaft member;
>
> tuning a mass and a stiffness of at least one liner, and
>
> inserting the at least one liner into the shaft member;
>
> wherein the at least one liner is a tuned resistive absorber for attenuating shell mode vibrations and wherein the at least one liner is a tuned reactive absorber for attenuating bending mode vibrations.

The district court held Claim 22 unpatentable on the ground that it was directed to a law of nature, specifically "Hooke's Law," which calculates the frequency at which an object naturally vibrates. The Federal Circuit affirmed, reasoning:

> The claims are directed to tuning liners —i.e., "controlling a mass and stiffness of at least one liner to configure the liner to match the relevant frequency or frequencies." As is clear from the specification itself, most aspects of the '911 patent were well known in the art. It was known that driveline propshafts were prone to bending, shell, and torsion mode vibrations. It was known that shell mode vibrations could be damped by resistive attenuation and that bending mode vibrations could be damped by reactive attenuation. It was also known that a liner or weight could be designed specifically to have a frequency that would allow it to function as either a resistive attenuation means or as a reactive attenuation means. Id. AAM does not dispute that these features were known in the art. AAM agrees that the selection of frequencies for the liners to damp the vibrations of the propshaft at least in part involves an application of Hooke's law.
>
> Hooke's law is a natural law that mathematically relates the mass and/or stiffness of an object to the frequency with which that object oscillates (vibrates). Here, both parties' witnesses agree that Hooke's law undergirds the design of a liner so that it exhibits a desired damping frequency pursuant to the claimed invention. …
>
> But AAM argues that the claims are not merely directed to Hooke's law. AAM points to testimony suggesting that tuning a liner such that it attenuates two different vibration modes is a process that involves more than simple application of Hooke's law. For example, AAM's expert, Dr. Rahn, testified that a "liner is not a spring with a single stiffness, it is a complex, distributed object with different stiffnesses in different directions (e.g., shell and bending) that depend on the location of the applied force and the measured displacement." … In essence, AAM's argument is that the system of the invention (a driveline propshaft and its liner) is too complex to be described by mere application of Hooke's law, which itself is a simple approximation of a single-degree-of-freedom spring-mass system. AAM also appears to argue that liners had not previously been used to dampen bending mode—as opposed to shell mode—vibrations.

> The problem with AAM's argument is that the solution to these desired results is not claimed in the patent. We have repeatedly held that features that are not claimed are irrelevant as to step 1 or step 2 of the *Mayo/Alice* analysis. …
>
> The elements of the method here that AAM argues take the patent outside the realm of ineligible subject matter—i.e., the mechanisms for achieving the desired result —are not actually claimed in … claim 22 of the patent. To be sure, as AAM indicates in its brief, the process of tuning a liner may involve extensive computer modelling and experimental modal analysis, a process utilized in the prior art. But even the patent specification recites only a nonexclusive list of variables that can be altered to change the frequencies exhibited by a liner and a solitary example of a tuned liner (though not the process by which that liner was tuned). Most significantly, the claims do not instruct how the variables would need to be changed to produce the multiple frequencies required to achieve a dual-damping result, or to tune a liner to dampen bending mode vibrations.

American Axel, 939 F.3d at 1362-1364.

Judge Moore dissented from the panel decision. She argued:

> The majority's decision expands § 101 well beyond its statutory gate-keeping function and the role of this appellate court well beyond its authority. …
>
> The majority's concern with the claims at issue has nothing to do with a natural law and its preemption and everything to do with concern that the claims are not enabled. Respectfully, there is a clear and explicit statutory section for enablement, § 112. We cannot convert § 101 into a panacea for every concern we have over an invention's patentability, especially where the patent statute expressly addresses the other conditions of patentability and where the defendant has not challenged them.
>
> The district court held that the claims at issue are ineligible under § 101 because they are directed to a natural law, specifically, "applications of Hooke's law with the result of friction damping." J.A. 11. Even the majority does not agree with the district court that the claims are directed to Hooke's Law. Instead the majority concludes that the claims are ineligible because they are "directed to the utilization of a natural law (here, Hooke's law *and possibly other natural laws*) in a particular context." Maj. at 1366 [emphasis added by the dissenting opinion]…. Section 101 is monstrous enough, it cannot be that now you need not even identify the precise natural law which the claims are purportedly directed to.

939 F.3d at 1368-69 (Moore, J., dissenting) (emphasis in original).

En banc review was denied, just as in *Athena*, with the same five dissenting judges as in *Athena* (Newman, O'Malley, Reyna, and Stoll, JJ.). The losing patentee will almost surely file a petition for certiorari at the Supreme Court. In the meanwhile, the judge-made exceptions to patentable subject matter will likely continue generating a great deal of litigation.

Chap. 2.D. Abstract Ideas

On page 165, add the three new cases below. Note that the first case addresses the substance of the abstract idea exclusion from patentable subject matter, while the last two cases address the procedure to be followed in applying that exclusion.

McRO, Inc. v. Bandai Namco Games Am. Inc.
837 F.3d 1299 (Fed. Cir. 2016)

REYNA, *Circuit Judge*.

This appeal is from a grant of judgment on the pleadings under Fed. R. Civ. P. 12(c) that the asserted claims of U.S. Patent Nos. 6,307,576 ("the '576 patent") and 6,611,278 ("the '278 patent") are invalid. The United States District Court for the Central District of California found that the asserted claims are directed to patent-ineligible subject matter and are therefore invalid under 35 U.S.C. § 101 ("§ 101"). *McRO, Inc. v. Sony Computer Entm't Am., LLC*, 55 F. Supp. 3d 1214 (C.D. Cal. 2014) ("*Patentability Op.*"). We hold that the ordered combination of claimed steps, using unconventional rules that relate sub-sequences of phonemes, timings, and morph weight sets, is not directed to an abstract idea and is therefore patent-eligible subject matter under § 101. Accordingly, we *reverse*.

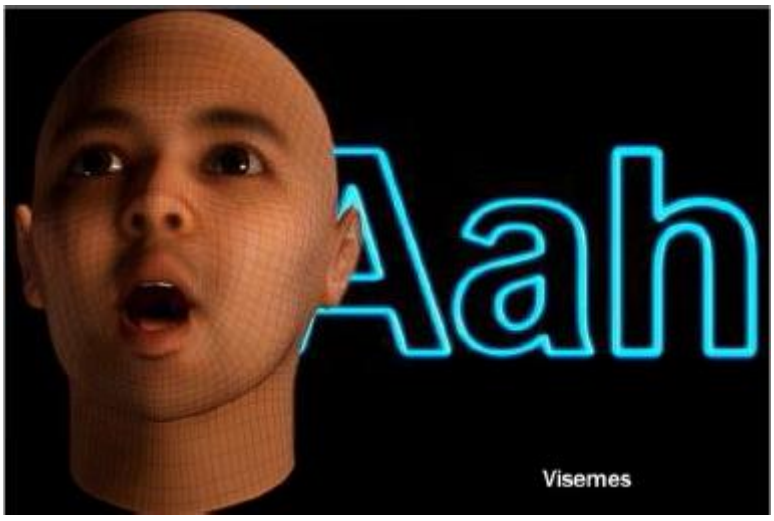
I. Background

A. Factual Background

The '576 patent and the '278 patent were both issued to Maury Rosenfeld and are both titled "Method for Automatically Animating Lip Synchronization and Facial Expression of Animated Characters." The '278 patent is a continuation of the '576 patent and shares the same written description.

1. Admitted Prior Art

The patents relate to automating part of a preexisting 3-D animation method. As explained in the background of the patents, the admitted prior art method uses multiple 3-D models of a character's face to depict various facial expressions made during speech. *See generally* '576 patent col. 1 l. 14 to col. 2 l. 37. To animate the character as it speaks, the method morphs the character's expression between the models. The "neutral model" is the 3-D representation of the resting, neutral facial expression of an animated character. The other models of the character's face are known as "morph targets," and each one represents that face as it pronounces a phoneme, i.e., makes a certain sound. This visual representation of the character's face making a sound is also called a "viseme." An example morph target for the "ahh" phoneme is shown below. Each of these morph targets and the neutral model has identified points, called "vertices," in certain places on the face. The set of differences in the location of these vertices (and the corresponding point on the face) between the neutral model and the morph target form a "delta set" of vectors representing the change in location of the vertices between the two models. For each morph target, there is a corresponding delta set consisting of the vectors by which the vertices on that morph target differ from the neutral model.



Facial expressions are described as a function of the amount each morph target, and its corresponding delta set, is applied to modify the character model. "In producing animation products, a value usually from 0 to 1 is assigned to each delta set by the animator and the value is called the 'morph weight.'" '576 patent col. 1 ll. 63-65. The set of morph weights for all the delta sets is called a "morph weight set." The neutral model is represented by a morph weight set with all morph weights of 0. A desired morph target is represented by the morph weight of 1 for that morph target's delta set and a morph weight of 0 for all other delta sets.

The power of this prior art animation method is in generating intermediate faces by using morph weights between 0 and 1 to blend together multiple morph targets. For example, the face halfway between the neutral model and the "oh" face can be expressed simply by setting the "oh" morph weight to 0.5, i.e., 50%, as shown below at the left. The model halfway to the next syllable, in turn, could be expressed by setting both the "oh" morph weight and that for the next syllable each to 0.5, creating a blend of those two delta sets. For each morph weight set, the resulting facial expression is calculated by determining the displacement of each vertex from the neutral model as the product of the morph weights in the morph weight set and the corresponding delta sets for the morph targets. '576 patent col. 2 ll. 2-15.

Animation of the character and lip synchronization preexisting the invention was generally accomplished by an animator with the assistance of a computer. Animators used "a 'keyframe' approach, where the artist set[] the appropriate [morph] weights at certain important times ('keyframes')" instead of at every frame. '576 patent col. 2 ll. 31-33. Animators knew what

phoneme a character pronounced at a given time from a "time aligned phonetic transcription" ("timed transcript"). This listed the "occurrence in time" of each phoneme the character pronounced, as shown in the example below. *Id.* at col. 1 ll. 32-34.

time (sec)	phoneme	word
0		Sil
1.895	h	hello
1.965	eh	
1.995	l	
2.105	o	
2.137	w	
2.165	dh	there
2.235	eh	
2.335	r	
2.435	sil	
2.475	h	how
2.545	a	
2.601	w	
2.635	AA	are
2.66	r	
2.695	y	you
2.835	uw	
2.885	t	today
2.945	ah	
2.985	d	
3.045	e	
3.16	y	
3.225	sil	

Animators, using a computer, manually determined the appropriate morph weight sets for each keyframe based on the phoneme timings in the timed transcript. "For each keyframe, the artist would look at the screen and, relying on her judgment, manipulate the character model until it looked right—a visual and subjective process." McRO Reply Br. 4 (emphasis removed); Defs.' Br. 10 ("Using the [timed transcript], the animator would decide what the animated face should look like at key points in time between the start and end times, and then 'draw' the face at those times."). Because the pronounced phoneme and drawn keyframe corresponded in time, this prior art process synchronized the lips and facial expression of the 3-D character. A computer program would then interpolate between the keyframes set by the animator, creating the intermediate frames by determining the appropriate morph weight sets at intermediate points in time simply based on continuously transitioning between the keyframes. '576 patent col. 2 ll. 32-36.

2. Claimed Invention

The patents criticize the preexisting keyframe approach as "very tedious and time consuming, as well as inaccurate due to the large number of keyframes necessary to depict speech." '576 patent col. 2 ll. 35-37. They suggest the present invention overcomes many of the deficiencies of the prior art and obtains its objectives by providing an integrated method embodied in computer software for use with a computer for the rapid, efficient lip synchronization and manipulation of character facial expressions, thereby allowing for rapid, creative, and expressive animation products to be produced in a very cost effective manner.
Id. at col. 2 ll. 38-44. "Accordingly, it is the primary object of this invention to provide a method for automatically . . . producing accurate and realistic lip synchronization and facial expressions in animated characters." *Id.* at col. 2 ll. 45-50.

Essentially, the patents aim to automate a 3-D animator's tasks, specifically, determining when to set keyframes and setting those keyframes. This automation is accomplished through rules that are applied to the timed transcript to determine the morph weight outputs. The patents describe many exemplary rule sets that go beyond simply matching single phonemes from the timed transcript with the appropriate morph target. Instead, these rule sets aim to produce more realistic speech by "tak[ing] into consideration the differences in mouth positions for similar phonemes based on context." *Id.* at col. 10 ll. 6-7.

One exemplary set of rules provided and applied in the specification of the '576 patent is for a character transitioning from silence through saying "hello." *See* '576 patent col. 7 l. 36 to col. 9 l. 22. This exemplary set of rules provides for inserting a transition starting shortly before the first syllable after a silence. *Id.* at col. 8 ll. 24-28. The transition marks when the character begins to transition from silence, shown by the closed-mouthed neutral model, to the morph target for the first syllable, with its open-mouthed shape. *Id.* at col. 8 ll. 61-63. That is, the rule automates a character's facial expressions so the character will wait until shortly before it starts speaking to begin opening its mouth. In terms of the prior art method, the effect of this rule is to automatically create a keyframe at a point that no phoneme is being pronounced. *Id.* at col. 9 ll. 10-11. If instead no transition were placed at that position, the resulting animation would have an unrealistic quality. The character would open its mouth gradually from the beginning of the sequence through its first utterance as a result of the computer interpolating a continuous transition between those two points. In the prior art system, an animator would have to subjectively identify the problematic sequence and manually fix it by adding an appropriate keyframe. The invention, however, uses rules to automatically set a keyframe at the correct point to depict more realistic speech, achieving results similar to those previously achieved manually by animators.

Claim 1 of the '576 patent is representative and dispositive of the asserted claims for the purposes of appeal:

> A method for automatically animating lip synchronization and facial expression of three-dimensional characters comprising:
>
> > obtaining a first set of rules that define output morph weight set stream as a function of phoneme sequence and time of said phoneme sequence;
> >
> > obtaining a timed data file of phonemes having a plurality of sub-sequences;
> >
> > generating an intermediate stream of output morph weight sets and a plurality of transition parameters between two adjacent morph weight sets by evaluating said plurality of sub-sequences against said first set of rules;
> >
> > generating a final stream of output morph weight sets at a desired frame rate from said intermediate stream of output morph weight sets and said plurality of transition parameters; and
> >
> > applying said final stream of output morph weight sets to a sequence of animated characters to produce lip synchronization and facial expression control of said animated characters.

'576 patent, cl. 1, col. 11 ll. 27-47.

B. Procedural History

[The district court for the Central District of California held all asserted claims ineligible for patent protection under 35 U.S.C. § 101. McRO appealed.]

II. Parties' Arguments

The parties' principal dispute is over the meaning and application of two Supreme Court cases in light of *Alice* [*Corp. v. CLS Bank*, 134 S. Ct. 2347 (2014)]: *Parker v. Flook*, 437 U.S. 584 (1978) ("*Flook*") and *Diamond v. Diehr*, 450 U.S. 175 (1981) ("*Diehr*"). Both cases addressed the patentability of process claims that include steps requiring calculation.

[After summarizing the parties' positions and holding that a *de novo* standard applies to review of patent ineligibility issues under § 101, the court turned to its analysis.]

IV. Discussion

A. Claim Interpretation

As an initial matter, we note that, in this case, claim construction is helpful to resolve the question of patentability under § 101. Specifically, the parties' dispute about whether the "first set of rules" must evaluate sequential phonemes or can evaluate individual phonemes is resolved by the claim language. We agree with McRO that the claims are limited to rules that evaluate sub-sequences consisting of multiple sequential phonemes. This limitation is apparent on the face of the claims. *See Phillips v. AWH Corp.*, 415 F.3d 1303, 1314 (Fed. Cir. 2005) (en banc). In particular, the intermediate morph weight sets and transition parameters are generated "by evaluating said plurality of sub-sequences against said first set of rules." '576 patent, cl. 1, col. 11 ll. 36-39. This limitation could not be satisfied by rules that only evaluate individual phonemes. Instead, the claimed "first set of rules" must be formulated to evaluate sub-sequences of phonemes.

B. Patentability Under § 101

Section 101 defines patent eligible subject matter as "any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof," subject to the other limitations of the Patent Act. Apart from the Patent Act, the courts have created exceptions to the literal scope of § 101. "Laws of nature, natural phenomena, and abstract ideas are not patentable." *Alice*, 134 S. Ct. at 2354 (quoting *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107 (2013) ("*Myriad*")). This appeal involves the abstract idea exception.

In *Alice*, the Court applied a two-step framework for analyzing whether claims are patent eligible. First, we determine whether the claim at issue is "directed to" a judicial exception, such as an abstract idea. *Alice*, 134 S. Ct. at 2355. Mathematical formulas are a type of abstract idea. *Gottschalk v. Benson*, 409 U.S. 63, 64 (1972) ("*Benson*"). The abstract idea exception prevents patenting a result where "it matters not by what process or machinery the result is accomplished." *O'Reilly v. Morse*, 56 U.S. 62, 113 (1854). We do not assume that such claims are directed to patent ineligible subject matter because "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 132 S. Ct. 1289, 1293 (2012) ("*Mayo*"); *see also In re TLI Commc'ns LLC Patent Litig.*, 823 F.3d 607, 611 (Fed. Cir. 2016) ("*TLI Commc'ns*"). Instead, "the claims are considered in their entirety to ascertain whether their character as a whole is directed to excluded subject matter." *Internet Patents Corp. v. Active Network, Inc.*, 790 F.3d 1343, 1346 (Fed.

Cir. 2015). If the claims are not directed to an abstract idea, the inquiry ends. If the claims are "directed to" an abstract idea, then the inquiry proceeds to the second step of the *Alice* framework.

In step two we consider whether the claims contain an "inventive concept" sufficient to "transform the nature of the claim into a patent-eligible application." *Alice*, 134 S. Ct. at 2355 (quotation omitted). To do so we look to both the claim as a whole and the individual claim elements to determine whether the claims contain "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.* (quoting *Mayo*, 132 S. Ct. at 1294) (alteration in original).

In *Alice*, the Court applied some of its § 101 jurisprudence that preceded the two-step framework, including *Flook* and *Diehr*. In *Flook*, claims requiring the use of a specific equation were unpatentable because they "simply provide[d] a new and presumably better method of calculating alarm limit values." *Flook*, 437 U.S. at 594-95. The mathematical "formula itself was an abstract idea" and "the computer implementation was purely conventional" because "the 'use of computers for "automatic monitoring-alarming"' was 'well known'." *Alice*, 134 S. Ct. at 2358 (quoting *Flook*, 437 U.S. at 594). "*Flook* stands for the propositionthat the prohibition against patenting abstract ideas cannot be circumvented by attempting to limit the use of [the idea] to a particular technological environment." *Alice*, 134 S. Ct. at 2358 (quoting *Bilski v. Kappos*, 561 U.S. 593, 610-611 (2010) ("*Bilski*")) (internal quotation marks omitted).

The claims in *Diehr*, in contrast, were patentable. The claims likewise "employed a 'well-known' mathematical equation." *Alice*, 134 S. Ct. at 2358 (quoting *Diehr*, 450 U.S. at 177). A computer performed the calculations as part of a broader process for curing rubber, but "the process as a whole [did] not thereby become unpatentable subject matter." *Diehr*, 450 U.S. at 187. Instead, the Court looked to how the claims "used that equation in a process designed to solve a technological problem in 'conventional industry practice.'" *Alice*, 134 S. Ct. at 2358 (quoting *Diehr*, 450 U.S. at 178). When looked at as a whole, "the claims in *Diehr* were patent eligible because they improved an existing technological process, not because they were implemented on a computer." *Alice*, 134 S. Ct. at 2358.

1. Specific Limitations

The district court determined that claim 1 of the '576 patent is "drawn to the [abstract] idea of automated rules-based use of morph targets and delta sets for lip-synchronized three-dimensional animation." *Patentability Op.*, 55 F. Supp. 3d at 1226. We disagree. We have previously cautioned that courts "must be careful to avoid oversimplifying the claims" by looking at them generally and failing to account for the specific requirements of the claims. *TLI Commc'ns*, 823 F.3d at 611; *see also Diehr*, 450 U.S. at 189 n.12. Here, the claims are limited to rules with specific characteristics. As the district court recognized during claim construction, "the claims themselves set out meaningful requirements for the first set of rules: they 'define[] a morph weight set stream as a function of phoneme sequence and times associated with said phoneme sequence.'" J.A. 4171 (Dist. Ct. Claim Construction Op. 16) (quoting '576 patent, cl. 1). They further require "applying said first set of rules to each sub-sequence . . . of timed phonemes." *Id.* Whether at step one or step two of the *Alice* test, in determining the patentability of a method, a court must look to the claims as an ordered combination, without ignoring the requirements of the individual steps. The specific, claimed features of these rules allow for the improvement realized by the invention.

As the specification confirms, the claimed improvement here is allowing computers to produce "accurate and realistic lip synchronization and facial expressions in animated characters" that previously could only be produced by human animators. '576 patent col. 2 ll. 49-50. As the

district court correctly recognized, this computer automation is realized by improving the prior art through "the use of rules, rather than artists, to set the morph weights and transitions between phonemes." *Patentability Op.*, 55 F. Supp. 3d at 1227. The rules are limiting in that they define morph weight sets as a function of the timing of phoneme sub-sequences. *See, e.g.*, '576 patent col. 3 ll. 19-33. Defendants do not dispute that processes that automate tasks that humans are capable of performing are patent eligible if properly claimed; instead, they argue that the claims here are abstract because they do not claim specific rules.[12] This argument echoes the district court's finding that the claims improperly purport to cover all rules. *Patentability Op.*, at 1227. The claimed rules here, however, are limited to rules with certain common characteristics, i.e., a genus.

Claims to the genus of an invention, rather than a particular species, have long been acknowledged as patentable. *E.g., Diamond v. Chakrabarty*, 447 U.S. 303, 305 (1980) (patentable claim to "a bacterium from the genus *Pseudomonas* containing therein at least two stable energy-generating plasmids, each of said plasmids providing a separate hydrocarbon degradative pathway."). Patent law has evolved to place additional requirements on patentees seeking to claim a genus; however, these limits have not been in relation to the abstract idea exception to § 101. Rather they have principally been in terms of whether the patentee has satisfied the tradeoff of broad disclosure for broad claim scope implicit in 35 U.S.C. § 112. *E.g., Carnegie Mellon Univ. v. Hoffmann-La Roche Inc.*, 541 F.3d 1115, 1122 (Fed. Cir. 2008). It is self-evident that genus claims create a greater risk of preemption, thus implicating the primary concern driving § 101 jurisprudence, but this does not mean they are unpatentable.

The preemption concern arises when the claims are not directed to a specific invention and instead improperly monopolize "the basic tools of scientific and technological work." *Alice*, 134 S. Ct. at 2354 (quoting *Myriad*, 133 S. Ct. at 2116). The abstract idea exception has been applied to prevent patenting of claims that abstractly cover results where "it matters not by what process or machinery the result is accomplished." *Morse*, 56 U.S. at 113; *see also Mayo*, 132 S. Ct. at 1301. "A patent is not good for an effect, or the result of a certain process" because such patents "would prohibit all other persons from making the same thing by any means whatsoever." *Le Roy v. Tatham*, 55 U.S. 156, 175 (1853). A patent may issue "for the means or method of producing a certain result, or effect, and not for the result or effect produced." *Diehr*, 450 U.S. 175, 182 n.7. We therefore look to whether the claims in these patents focus on a specific means or method that improves the relevant technology or are instead directed to a result or effect that itself is the abstract idea and merely invoke generic processes and machinery. *Enfish, LLC v. Microsoft Corp.*, 822 F.3d 1327, 1336 (Fed. Cir. 2016) ("*Enfish*"); *see also Rapid Litig. Mgmt. Ltd. v. CellzDirect, Inc.*, No. 2015-1570, 827 F.3d 1042 (Fed. Cir. July 5, 2016).

2. Claims Directed To

Claim 1 of the '576 patent is focused on a specific asserted improvement in computer animation, i.e., the automatic use of rules of a particular type. We disagree with Defendants' arguments that the claims simply use a computer as a tool to automate conventional activity. While the rules are embodied in computer software that is processed by general-purpose computers, Defendants provided no evidence that the process previously used by animators is the same as the process required by the claims. *See* Defs.' Br. 10-15, 39-40. In support, Defendants point to the

[12] *See, e.g.*, Hearing Tr. at 14:00-15:09 (Defendants' counsel acknowledging that a process for autopilot or facial recognition using rules could be patented, but arguing the claims here are unpatentable because they do not claim specific rules), *available at* http://oralarguments.cafc.uscourts.gov/default.aspx?fl=2015-1080.mp3.

background section of the patents, but that information makes no suggestion that animators were previously employing the type of rules required by claim 1. Defendants concede an animator's process was driven by subjective determinations rather than specific, limited mathematical rules. The prior art "animator would decide what the animated face should look like at key points in time between the start and end times, and then 'draw' the face at those times." Defs.' Br. 10. The computer here is employed to perform a distinct process to automate a task previously performed by humans. McRO states that animators would initially set keyframes at the point a phoneme was pronounced to represent the corresponding morph target as a starting point for further fine tuning. J.A. 3573 at 8:53 (McRO's Claim Construction Presentation). This activity, even if automated by rules, would not be within the scope of the claims because it does not evaluate sub-sequences, generate transition parameters or apply transition parameters to create a final morph weight set. It is the incorporation of the claimed rules, not the use of the computer, that "improved [the] existing technological process" by allowing the automation of further tasks. *Alice*, 134 S. Ct. at 2358. This is unlike *Flook*, *Bilski*, and *Alice*, where the claimed computer-automated process and the prior method were carried out in the same way. *Flook*, 437 U.S. at 585-86; *Bilski*, 561 U.S. at 611; *Alice*, 134 S. Ct. at 2356.

Further, the automation goes beyond merely "organizing [existing] information into a new form" or carrying out a fundamental economic practice. *Digitech*, 758 F.3d at 1351; *see also Alice*, 134 S. Ct. at 2356. The claimed process uses a combined order of specific rules that renders information into a specific format that is then used and applied to create desired results: a sequence of synchronized, animated characters. While the result may not be tangible, there is nothing that requires a method "be tied to a machine or transform an article" to be patentable. *Bilski*, 561 U.S. at 603 (discussing 35 U.S.C. § 100(b)). The concern underlying the exceptions to § 101 is not tangibility, but preemption. *Mayo*, 132 S. Ct. at 1301.

The limitations in claim 1 prevent preemption of all processes for achieving automated lip-synchronization of 3-D characters. McRO has demonstrated that motion capture animation provides an alternative process for automatically animating lip synchronization and facial expressions. Even so, we have recognized that "the absence of complete preemption does not demonstrate patent eligibility." *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371, 1379 (Fed. Cir. 2015). The narrower concern here is whether the claimed genus of rules preempts all techniques for automating 3-D animation that rely on rules. Claim 1 requires that the rules be rendered in a specific way: as a relationship between sub-sequences of phonemes, timing, and the weight to which each phoneme is expressed visually at a particular timing (as represented by the morph weight set). The specific structure of the claimed rules would prevent broad preemption of all rules-based means of automating lip synchronization, unless the limits of the rules themselves are broad enough to cover all possible approaches.[13] There has been no showing that any rules-based lip-synchronization process must use rules with the specifically claimed characteristics.

Defendants' attorney's argument that any rules-based lip-synchronization process must use the claimed type of rules has appeal, but no record evidence supports this conclusion. Defendants again rely only on the patents' description of one type of rules, but the description of one set of rules does not mean that there exists only one set of rules, and does not support the view that other possible types of rules with different characteristics do not exist. The only information cited to this court about the relationship between speech and face shape points to the conclusion that there are

[13] This is not a case where the patentee's principal contribution was in discovering relationships that existed in nature, *e.g.*, *Myriad*, 133 S. Ct. at 2112; animators were previously able to naturally depict the relationship between speech, timing, and facial expression.

many other possible approaches to automating lip synchronization using rules. For example, Amicus cites Kiyoshi Honda, *Physiological Processes of Speech Processing, in Springer Handbook of Speech Production* 7 (Jacob Benesty et al. eds., 2008) ("Honda"), as support for the proposition that the claimed rules reflect natural laws. Amicus Public Knowledge Br. 12. Honda shows, however, that the interaction between vocalization and facial expression is very complex, and there are relationships present other than those required by the claimed rules. Honda at 24 ("Physiological processes during speech are multidimensional in nature as described in this chapter."). This complex interaction permits development of alternative rules-based methods of animating lip synchronization and facial expressions of three-dimensional characters, such as simulating the muscle action underlying characters' facial expressions. Under these circumstances, therefore, we need not assume that future alternative discoveries are foreclosed.

Here, the structure of the limited rules reflects a specific implementation not demonstrated as that which "any [animator] engaged in the search for [an automation process] would likely have utilized." *Myriad*, 133 S. Ct. at 2119-20 (quotation marks omitted). By incorporating the specific features of the rules as claim limitations, claim 1 is limited to a specific process for automatically animating characters using particular information and techniques and does not preempt approaches that use rules of a different structure or different techniques. *See Morse*, 56 U.S. at 113. When looked at as a whole, claim 1 is directed to a patentable, technological improvement over the existing, manual 3-D animation techniques. The claim uses the limited rules in a process specifically designed to achieve an improved technological result in conventional industry practice. *Alice*, 134 S. Ct. at 2358 (citing *Diehr*, 450 U.S. at 177). Claim 1 of the '576 patent, therefore, is not directed to an abstract idea.

Because we find that claim 1 is not directed to ineligible subject matter, we do not reach *Alice* step two. *Enfish*, 822 F.3d at 1339.

V. Conclusion

Claim 1 is not directed to an abstract idea and recites subject matter as a patentable process under § 101. Accordingly, we *reverse* and hold that claims 1, 7-9, and 13 of the '576 patent and claims 1-4, 6, 9, 13, and 15-17 of the '278 patent are patentable under 35 U.S.C. § 101.

REVERSED AND REMANDED

* * *

Berkheimer v. HP Inc.

881 F.3d 1360 (Fed. Cir. 2018)

MOORE, *Circuit Judge*.

Steven E. Berkheimer appeals the United States District Court for the Northern District of Illinois' summary judgment holding claims 1–7 and 9 of U.S. Patent No. 7,447,713 ('713 patent) invalid as ineligible under 35 U.S.C. § 101. …

BACKGROUND

The '713 patent relates to digitally processing and archiving files in a digital asset management system. The system parses files into multiple objects and tags the objects to create relationships between them. These objects are analyzed and compared, either manually or automatically, to archived objects to determine whether variations exist based on predetermined

standards and rules. This system eliminates redundant storage of common text and graphical elements, which improves system operating efficiency and reduces storage costs. The relationships between the objects within the archive allow a user to "carry out a one-to-many editing process of object-oriented data," in which a change to one object carries over to all archived documents containing the same object.

Mr. Berkheimer sued HP Inc. in the Northern District of Illinois …. HP moved for summary judgment that claims 1–7 and 9 are patent ineligible under 35 U.S.C. § 101, and the district court granted the motion. Mr. Berkheimer appeals. …

DISCUSSION

[After reciting the two-step test of patent eligibility articulated by the Supreme Court in *Alice*, the court discussed the appropriate procedure for determining relevant factual issues such as whether a claim element is routine and conventional.] The question of whether a claim element or combination of elements is well-understood, routine and conventional to a skilled artisan in the relevant field is a question of fact. Any fact, such as this one, that is pertinent to the invalidity conclusion must be proven by clear and convincing evidence. See *Microsoft Corp. v. i4i Ltd. P'ship*, 564 U.S. 91, 95 (2011). Like indefiniteness, enablement, or obviousness, whether a claim recites patent eligible subject matter is a question of law which may contain underlying facts. . . . And the Supreme Court recognized that in making the § 101 determination, the inquiry "might sometimes overlap" with other fact-intensive inquiries like novelty under § 102. *Mayo*, 566 U.S. at 90.

.

As our cases demonstrate, not every § 101 determination contains genuine disputes over the underlying facts material to the § 101 inquiry. See, e.g., *Content Extraction [& Transmission LLC v. Wells Fargo Bank, Nat'l Ass'n*, 776 F.3d 1343, 1347 (Fed. Cir. 2014)], at 1349 (patent owner conceded the argued inventive concept "was a routine function of scanning technology at the time the claims were filed"); *Intellectual Ventures I LLC v. Capital One Bank (USA)*, 792 F.3d 1363, 1370 (Fed. Cir. 2015) (patent owner argued an "interactive interface" is "a specific application of the abstract idea that provides an inventive concept" and did not dispute that the computer interface was generic). Whether a claim recites patent eligible subject matter is a question of law which may contain disputes over underlying facts. Patent eligibility has in many cases been resolved on motions to dismiss or summary judgment. Nothing in this decision should be viewed as casting doubt on the propriety of those cases. When there is no genuine issue of material fact regarding whether the claim element or claimed combination is well-understood, routine, conventional to a skilled artisan in the relevant field, this issue can be decided on summary judgment as a matter of law.

Here, the district court concluded that the claims do not contain an inventive concept under Alice step two because they describe "steps that employ only 'well-understood, routine, and conventional' computer functions" and are claimed "at a relatively high level of generality." [*Berkheimer v. Hewlett-Packard Co.*, 224 F. Supp. 3d 635, 647-48 (N.D. Ill. 2016)] (quoting *Content Extraction*, 776 F.3d at 1348). Mr. Berkheimer argues portions of the specification referring to reducing redundancy and enabling one-to-many editing contradict the district court's finding that the claims describe well-understood, routine, and conventional activities. He argues, both below and on appeal, that summary judgment is improper because whether the claimed invention is well-understood, routine, and conventional is an underlying fact question for which HP offered no evidence.

While patent eligibility is ultimately a question of law, the district court erred in concluding there are no underlying factual questions to the § 101 inquiry. *Id*. at 642. Whether something is well-understood, routine, and conventional to a skilled artisan at the time of the patent is a factual

determination. Whether a particular technology is well-understood, routine, and conventional goes beyond what was simply known in the prior art. The mere fact that something is disclosed in a piece of prior art, for example, does not mean it was well-understood, routine, and conventional.

Mr. Berkheimer argues that the claimed combination improves computer functionality through the elimination of redundancy and the one-to-many editing feature, which provides inventive concepts. The specification of the '713 patent discusses the state of the art at the time the patent was filed and the purported improvements of the invention. Conventional digital asset management systems at the time included "numerous documents containing multiple instances of redundant document elements." '713 patent at 1:24–27. This redundancy in conventional systems led to "inefficiencies and increased costs." Id. at 2:22–26. The specification explains that the claimed improvement increases efficiency and computer functionality over the prior art systems:

> By eliminating redundancy in the archive 14, system operating efficiency will be improved, storage costs will be reduced and a one-to-many editing process can be implemented wherein a singular linked object, common to many documents or files, can be edited once and have the consequence of the editing process propagate through all of the linked documents and files. The one-to-many editing capability substantially reduces effort needed to up-date files which represent packages or packaging manuals or the like as would be understood by those of skill in the art.

Id. at 16:52–60.

The specification describes an inventive feature that stores parsed data in a purportedly unconventional manner. This eliminates redundancies, improves system efficiency, reduces storage requirements, and enables a single edit to a stored object to propagate throughout all documents linked to that object. Id. The improvements in the specification, to the extent they are captured in the claims, create a factual dispute regarding whether the invention describes well-understood, routine, and conventional activities, see *Content Extraction*, 776 F.3d at 1347–48, so we must analyze the asserted claims and determine whether they capture these improvements, *Alice*, 134 S.Ct. at 2357.

The parties dispute whether these improvements to computer functionality are captured in the claims. We conclude that claim 1 does not recite an inventive concept sufficient to transform the abstract idea into a patent eligible application. Claim 1 recites a method of archiving including parsing data, analyzing and comparing the data to previously stored data, and presenting the data for reconciliation when there is a variance. It does not include limitations which incorporate eliminating redundancy of stored object structures or effecting a one-to-many change of linked documents within an archive. It does not even require the storage of data after it is presented for manual reconciliation. Thus, it does not recite any of the purportedly unconventional activities disclosed in the specification. Mr. Berkheimer does not advance any separate arguments regarding claims 2–3 and 9. Even considering these claims separately, they recite patent ineligible subject matter for the same reason. …

Claims 4–7, in contrast, contain limitations directed to the arguably unconventional inventive concept described in the specification. Claim 4 recites "storing a reconciled object structure in the archive without substantial redundancy." The specification states that storing object structures in the archive without substantial redundancy improves system operating efficiency and reduces storage costs. '713 patent at 16:52–58. It also states that known asset management systems did not archive documents in this manner. Id. at 2:22–26. Claim 5 depends on claim 4 and further recites "selectively editing an object structure, linked to other structures to thereby effect a one-to-many change in a plurality of archived items." The specification states one-to-many editing

substantially reduces effort needed to update files because a single edit can update every document in the archive linked to that object structure. Id. at 16:58–60. This one-to-many functionality is more than "editing data in a straightforward copy-and-paste fashion," as characterized by the district court. Berkheimer, 224 F.Supp.3d at 645. According to the specification, conventional digital asset management systems cannot perform one-to-many editing because they store documents with numerous instances of redundant elements, rather than eliminate redundancies through the storage of linked object structures. '713 patent at 1:22–55, 4:4–9, 16:52–60. Claims 6–7 depend from claim 5 and accordingly contain the same limitations. These claims recite a specific method of archiving that, according to the specification, provides benefits that improve computer functionality.

HP argues that redundancy and efficiency are considerations in any archival system, including paper-based systems. The district court agreed. Berkheimer, 224 F.Supp.3d at 647. At this stage of the case, however, there is at least a genuine issue of material fact in light of the specification regarding whether claims 4–7 archive documents in an inventive manner that improves these aspects of the disclosed archival system. Whether claims 4–7 perform well-understood, routine, and conventional activities to a skilled artisan is a genuine issue of material fact making summary judgment inappropriate with respect to these claims.

We do not decide today that claims 4–7 are patent eligible under § 101. We only decide that on this record summary judgment was improper, given the fact questions created by the specification's disclosure.

[Vacated in relevant part and remanded.]

* * *

After the *Berkheimer* decision, the Federal Circuit decided *Aatrix Software, Inc. v. Green Shades Software, Inc.*, 882 F.3d 1121, 1123 (Fed. Cir. 2018) (Moore, J.), which reversed a district court grant of 12(b)(6) motion to dismiss. Consistent with *Berkheimer*, the court ruled that courts could not decide patent eligibility disputes summarily where the patentee disputed crucial issues of fact. Both *Berkheimer* and *Aatrix* were thereafter discussed in an opinion concurring in the court's decision not to reconsider *Aatrix* en banc:

Aatrix Software, Inc. v. Green Shades Software, Inc.
890 F.3d 1354 (Fed. Cir. 2018) (denial of rehearing en banc)

MOORE, *Circuit Judge*, with whom DYK, O'MALLEY, TARANTO, and STOLL, *Circuit Judges*, join, concurring in the denial of the petition for rehearing en banc:

Berkheimer and *Aatrix* stand for the unremarkable proposition that whether a claim element or combination of elements would have been well-understood, routine, and conventional to a skilled artisan in the relevant field at a particular point in time is a question of fact. The Supreme Court has described historical facts as "a recital of external events." *Thompson v. Keohane*, 516 U.S. 99, 110 (1995). In other words, facts relating to "who did what, when or where, how or why." *U.S. Bank Nat'l Ass'n ex rel. CWCapital Asset Mgmt. LLC v. The Village at Lakeridge, LLC*, —— U.S. ——, 138 S.Ct. 960, 966 (2018).

Whether a claim element or combination of elements would have been well-understood, routine, and conventional to a skilled artisan in the relevant field at a particular point in time may require "weigh[ing] evidence," "mak[ing] credibility judgments," and addressing "narrow facts that utterly resist generalization." Id. at 967 (quoting *Pierce v. Underwood*, 487 U.S. 552, 561–62

(1988)). The Supreme Court in *Alice* asked whether the claimed activities were "previously known to the industry," and in Mayo asked whether they were "previously engaged in by researchers in the field." *Alice Corp. Pty. v. CLS Bank Int'l*, 134 S.Ct. 2347, 2359 (2014); *Mayo Collaborative Servs. v. Prometheus Labs., Inc.*, 566 U.S. 66, 73 (2012). Indeed, the Court recognized that "in evaluating the significance of additional steps, the § 101 patent-eligibility inquiry and, say, the § 102 novelty inquiry might sometimes overlap." *Mayo*, 566 U.S. at 90. "[C]ase law from the Supreme Court and this court has stated for decades that anticipation is a factual question." *Microsoft Corp. v. Biscotti, Inc.*, 878 F.3d 1052, 1068 (Fed. Cir. 2017). While the ultimate question of patent eligibility is one of law, it is not surprising that it may contain underlying issues of fact. Every other type of validity challenge is either entirely factual (e.g., anticipation, written description, utility), a question of law with underlying facts (e.g., obviousness, enablement), or a question of law that may contain underlying facts (e.g., indefiniteness). . . .

If patent eligibility is challenged in a motion to dismiss for failure to state a claim pursuant to Rule 12(b)(6), we must apply the well-settled Rule 12(b)(6) standard which is consistently applied in every area of law. A motion to dismiss for failure to state a claim must be denied if "in the light most favorable to the plaintiff and with every doubt resolved in the pleader's favor—but disregarding mere conclusory statements—the complaint states any legally cognizable claim for relief." 5B Charles Alan Wright & Arthur R. Miller, Federal Practice and Procedure § 1357 (3d ed. 2018). In the Eleventh Circuit, the Rule 12(b)(6) standard requires accepting as true the complaint's factual allegations and construing them in the light most favorable to the plaintiff. *Aatrix Software, Inc. v. Green Shades Software, Inc*., 882 F.3d 1121, 1124 (Fed. Cir. 2018) (citing *Speaker v. U.S. Dep't of Health & Human Servs. Ctrs. for Disease Control & Prevention*, 623 F.3d 1371, 1379 (11th Cir. 2010)). The second amended complaint in Aatrix included "concrete allegations ... that individual elements and the claimed combination are not well-understood, routine, or conventional activity." Id. at 1128. For example, it alleged that the patents "improve the functioning of the data processing systems, computers, and other hardware" and explained in detail how the invention achieves these improvements. J.A. at 454 ¶ 107, *Aatrix*, 882 F.3d 1121; id. at 429 ¶¶38–39. "These allegations suggest[ed] that the claimed invention is directed to an improvement in the computer technology itself and not directed to generic components performing conventional activities." *Aatrix*, 882 F.3d at 1127. As we have previously held, "[i]n ruling on a 12(b)(6) motion, a court need not 'accept as true allegations that contradict matters properly subject to judicial notice or by exhibit,' such as the claims and the patent specification." *Secured Mail Sols. LLC v. Universal Wilde, Inc.*, 873 F.3d 905, 913 (Fed. Cir. 2017). But nothing in the limited record we could consider at the Rule 12(b)(6) stage refuted these allegations, so there was no legal basis to affirm the dismissal of the complaint. …

NOTES ON RECENT DEVELOPMENTS IN § 101 DOCTRINE

1. *Berkheimer* at the Supreme Court. On September 28, 2018, HP (which lost at the Federal Circuit) filed a petition for certiorari presenting a single question:

> [W]hether patent eligibility is a question of law for the court based on the scope of the claims or a question of fact for the jury based on the state of the art at the time of the patent.

Note that this question is somewhat misleading because the Federal Circuit held only that summary judgment was inappropriate due to the existence of disputed facts. Such a holding does not necessarily mean that the issue of patent eligibility must be decided by a jury. For the analogous issue of determining the scope of claims (see Chapter 8, *infra*), the Supreme Court has held that the issue is ultimately a question of law for the judge but that the issue could involve subsidiary fact matters, which are to be resolved by a judge (not a jury). *See Teva Pharms. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831 (2015).

Thus, three possibilities exist: (i) the issue could be wholly a question of law that should always be decided on summary judgment (HP's position); (ii) the issue could be a question of law with underlying facts to be resolved by the judge (similar to the process used in claim construction); or (iii) the issue could be a question of law with underlying facts to be resolved by the jury. A fourth possibility—that patent eligibility is wholly a question of fact—does not appear to be presented by the case because the *Berkheimer* court expressly analogized patent eligibility to other patent validity issues such as "indefiniteness, enablement, or obviousness," which have been held to be "question[s] of law which may contain underlying facts." *Berkheimer*, 881 F.3d at 1368.

On January 7, 2019, the Supreme Court called for the views of the Solicitor General (CVSG) on the case. *HP Inc. v. Berkheimer*, 139 S.Ct. 860 (2019). In response to that invitation, the Solicitor General filed a brief urging the Court to deny certiorari, which the Court subsequent did. The Solicitor General's brief did not, however, endorse the Federal Circuit's reasoning. Rather, the Solicitor General argued that the procedural question posed by HP's petition could not logically be answered without the Court first clarifying its own precedent on patentable subject matter:

> Resolution of the question presented in the petition logically depends on the substantive standard for assessing patent-eligibility under Section 101. [T]his Court's recent decisions have fostered uncertainty concerning those substantive Section 101 standards. In light of that uncertainty, review to address the logically subsequent, procedural question presented in the petition here is premature. The Court should grant review in an appropriate case to clarify the substantive Section 101 standards and then address any ancillary issues that remain.

Brief for the United States at 10 in *HP Inc. v. Berkheimer* (S.Ct. filed Dec. 6, 2019). The brief referred to the government's separate brief filed in response to the Court's CVSG in *Hikma Pharmaceuticals USA Inc. v. Vanda Pharmaceuticals Inc.*, 139 S.Ct. 1368 (2019), which presented a substantive question concerning the scope of patentable subject matter. As noted above, the government's brief in that case expressly took the position that "further guidance" from the Court on the scope of patentable subject matter "is amply warranted" and also hinted that *Athena Diagnostics, Inc. v. Mayo Collaborative Servs.* would be an appropriate case for the Court to give such guidance. During its 2019 Term, however, the Supreme Court denied certiorari in all the cases presenting patentable subject matter issues. Thus, guidance on both the substance standards and procedural rules governing patentable subject matter remain uncertain.

2. The Frequency of § 101 Invalidations. The importance of patentable subject matter doctrine is underscored by just how frequently the doctrine has been successfully used to invalidate patents in recent years. According to a running tally of all post-Alice § 101 litigation (at the PTAB in Covered Business Method proceedings, and in district courts and at Federal Circuit), only in about 21% (117/total of 548) of cases did the patents challenged under § 101 survive invalidation. *See* Fenwick & West, "Decoding Patent Eligibility Post-Alice," avail. at https://www.fenwick.com/pages/post-alice.aspx (showing, as of Aug. 23, 2020, 548 total § 101 decisions since July, 2014).

The Fenwick and West data cover administrative and judicial cases decided on the validity of *issued* patents. Data on PTO rejections of patent *applications*, gathered a few years after Alice, showed an even higher invalidity rate: depending on the particular field, between 70 and 94% of patent applications were being rejected under § 101 (and often other sections also). See Robert R. Sachs, *Alicestorm Update for Fall 2016*, Bilski Blog, Oct. 19, 2016, avail. at http://www.bilskiblog.com/blog/2016/10/alicestorm-update-turbulence-and-troubles-.html.)

3. Legislative Proposals to Amend § 101. The dramatic increase of patents being invalidated under § 101 has led to proposals to revise the statute through legislation, in an effort to restore something akin to the pre-*Alice* standard. See, e.g., Dennis Crouch, *Eligibility: Explaining the IPO Legislative Proposa*l, Feb. 9, 2017, avail. at https://patentlyo.com/patent/2017/02/eligibility-explaining-legislative.html. For an excellent overview of the issues and a clear-sighted discussion of legislative solutions, see Jeffrey A. Lefstin, Peter Menell and David O. Taylor, *Final Report of the Berkeley Center for Law & Technology Section 101 Workshop: Addressing Patent Eligibility Challenges*, 33 Berkeley Tech. L.J. 551 (2018) (summarizing framework for possible legislative solutions to the § 101 problem).

The most recent proposal being discussed in Congress is a draft bill co-sponsored by Senators Thom Tillis (R-NC) and Chris Coons (D-DE). The proposal would make the following amendments to the Patent Act:

Section 100:

(k) The term "useful" means any invention or discovery that provides specific and practical utility in any field of technology through human intervention.

Section 101:

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

(b) Eligibility under this section shall be determined only while considering the claimed invention as a whole, without discounting or disregarding any claim limitation.

Section 112:

(f) Functional Claim Elements— An element in a claim expressed as a specified function without the recital of structure, material, or acts in support thereof shall be construed to cover the corresponding structure, material, or acts described in the specification and equivalents thereof.

Additional Legislative Provisions:

The provisions of section 101 shall be construed in favor of eligibility.

No implicit or other judicially created exceptions to subject matter eligibility, including "abstract ideas," "laws of nature," or "natural phenomena," shall be used to determine patent eligibility under section 101, and all cases establishing or interpreting those exceptions to eligibility are hereby abrogated.

The eligibility of a claimed invention under section 101 shall be determined without regard to: the manner in which the claimed invention was made; whether individual limitations of a claim are well known, conventional or routine; the state of the art at the time of the invention; or any other considerations relating to sections 102, 103, or 112 of this title.

Would this legislative language eliminate the doctrinal complexities of the modern patent subject matter case law? Or would the addition of the phrase "field of technology" in the proposed new

definition of "useful" in proposed § 100(k) merely shift the doctrinal uncertainties to new ground as courts try to decide what counts as a "field of technology" and what does not? Is the language disavowing the "judicial created exceptions to subject matter eligibility" helpful?

Chapter 3: Utility

Chap. 3.C. Substantial, Practical, and Specific Utility

On page 241 after note 6, insert the following note:

NOTE ON THE DEMISE OF CANADA'S "PROMISE" DOCTRINE IN UTILITY LAW

As discussed in note 6 in the casebook, the lower courts in Canada had developed a stringent variant of the utility doctrine—dubbed the "Promise Doctrine"—under which courts invalidated the patents that failed to live up to all the predicted qualities or features disclosed in the patent specification, even if the invention had utility in the conventional sense that it was still good for something (just not as good as promised in the specification). That heightened utility standard was highly controversial and was used in invalidating a number of valuable pharmaceutical patents. Eventually, one pharmaceutical company (Eli Lilly) challenged the Promise Doctrine as being inconsistent with the terms of NAFTA. (As mentioned in the casebook, one of the coauthors of this casebook—Professor Merges—was an expert witness for Eli Lilly in the NAFTA proceeding.)

Two developments in this controversy occurred in the first half of 2017. First, Eli Lilly lost its NAFTA suit against the Government of Canada. In its final opinion, the NAFTA arbitration tribunal ruled that, even if NAFTA would be violated by an "arbitrary" legal doctrine that (i) is "unpredictable and incoherent" (even if not motivated by bad faith); and (ii) has "no legitimate purpose," Eli Lilly failed to demonstrate that Canada's Promise Doctrine met that standard of arbitrariness. *See Eli Lilly and Company v. The Government of Canada*, Final Award (March 16, 2017), at 133 (available at http://icsidfiles.worldbank.org/icsid/ICSIDBLOBS/OnlineAwards/C3544/DC10133_En.pdf. The tribunal found the Promise Doctrine to be "coherent and consistent with the policy justifications stated by [the Canadian Government]" and emphasized that the tribunal's role was not to "question the correctness of the policies or the courts' decisions." *Id.* at 134.

Yet, while Eli Lilly lost the NAFTA battle, it and other pharmaceutical companies won the war. On June 30, the Canadian Supreme Court issued an opinion rejecting the Promise Doctrine. The Court ruled:

> [The Promise Doctrine] is unsound. It is an interpretation of the utility requirement that is incongruent with both the words and the scheme of the Patent Act.
>
> The Promise Doctrine is excessively onerous in two ways: (1) it determines the standard of utility that is required of a patent by reference to the promises expressed in the patent; and (2) where there are multiple expressed promises of utility, it requires that all be fulfilled for a patent to be valid.

AstraZeneca Canada Inc. v. Apotex Inc., 2017 S.C.C. 36 (June 30, 2017) (available at https://scc-csc.lexum.com/scc-csc/scc-csc/en/16713/1/document.do), at 22 ¶¶ 36-37. The Court also articulated the "correct approach" to utility, instructing that the Canadian patent statute "does not prescribe the degree or quantum of usefulness required, or that every potential use be realized — a scintilla of utility will do. A single use related to the nature of the subject-matter is sufficient, and the utility must be established by either demonstration or sound prediction as of the filing date." Id. at 28, ¶ 55.

Chapter 5: Novelty Under the AIA.

Chap. 5.A. Prior Art under AIA § 102(a)

1. One-Time-Period Prior Art in § 102(a)(1).

a. "Described in a Printed Publication"

On page 338, add the following to the end of note 4:

A recent example of *Jockmus*-type prior art appears in *GoPro, Inc. v. Contour IP Holding, LLC*, 908 F.3d 690 (Fed. Cir. 2018), which held that a catalog of GoPro's video cameras did constitute prior art as of the time when hundreds of copies of it were distributed at a trade show with over 1,000 attendees. The PTO had held that the distribution at the trade show was not prior art because the show was limited to dealers and not "advertised or announced to the public" in a way that would allow a "person interested and ordinarily skilled in the art" to know about it. *Id*. at 694. The agency also found that a person of skill in the relevant art (cameras) "would not be interested in the dealer show because it was not an academic conference or camera industry conference, but rather a dealer show for action sports vehicles like motorcycles, motorbikes, ATVs, snowmobiles, and watercraft." *Id.*

In reversing the PTO's decision, the Federal Circuit noted that "[i]f one desires to examine certain new products on the market, attending a trade show involving identical or similar products is a good option." *Id.* The patents at issue claimed technology designed for sports cameras for use on vehicles in extreme action environments, and the trade show was directed not only to sport vehicles but also to accessories (such as cameras) for such vehicles. Because the "show was attended by actual and potential dealers, retailers, and customers of [sports] cameras and the catalog "was disseminated with no restrictions and was intended to reach the general public," *id.* at 695, the catalog could be considered a printed publication under decisions such as *Klopfenstein*.

c. "In Public Use"

On pages 360-61, skip all of the material following the citation accompanying the block quote from the PTO "Examination Guidelines for Implementing the First Inventor to File Provisions" (which appears about 10 lines from the top of page 360) through to the section heading "d. 'On Sale'" (which appears on the bottom of page 361). Replace that material with the following paragraph:

> The PTO's views on the significance of the AIA's addition of the phrase "otherwise available to the public" were, however, rejected by the Supreme Court in *Helsinn Heathcare v. Teva Pharmaceuticals*, 139 S. Ct. 628 (2019). The Court's *Helsinn* opinion is set forth in the supplement to the next section; it should be read only after reading the Supreme Court's earlier opinion in *Pfaff v. Wells*, which is a principal opinion in the casebook.

d. "On Sale"

On page 377, omit note 10.

Also on page 377, add the following case after note 11:

Helsinn Healthcare S.A. v. Teva Pharms. USA, Inc.
139 S.Ct. 628 (Jan. 22, 2019)

Justice Thomas delivered the opinion of the Court.

The Leahy-Smith America Invents Act (AIA) bars a person from receiving a patent on an invention that was "in public use, on sale, or otherwise available to the public before the effective filing date of the claimed invention." 35 U. S. C. §102(a)(1). This case requires us to decide whether the sale of an invention to a third party who is contractually obligated to keep the invention confidential places the invention "on sale" within the meaning of §102(a).

More than 20 years ago, this Court determined that an invention was "on sale" within the meaning of an earlier version of §102(a) when it was "the subject of a commercial offer for sale" and "ready for patenting." *Pfaff v. Wells Electronics, Inc*., 525 U. S. 55, 67 (1998). We did not further require that the sale make the details of the invention available to the public. In light of this earlier construction, we determine that the reenactment of the phrase "on sale" in the AIA did not alter this meaning. Accordingly, a commercial sale to a third party who is required to keep the invention confidential may place the invention "on sale" under the AIA.

I

Petitioner Helsinn Healthcare S. A. (Helsinn) is a Swiss pharmaceutical company that [owns U. S. Patent No. 8,598,219 ('219 patent), which issued in December of 2013 and covers pharmaceutical product containing a fixed dose of 0.25 mg of "palonosetron," a previously known anti-nausea drug often prescribed to combat the effects of chemotherapy. Helsinn originally acquired the right to develop palonosetron] in 1998. In early 2000, it submitted protocols for Phase III clinical trials to the Food and Drug Administration (FDA), proposing to study a 0.25 mg and a 0.75mg dose of palonosetron. …

[In April of 2001, Helsinn entered into a license agreement and a supply and purchase agreement with] MGI Pharma, Inc. (MGI), a Minnesota pharmaceutical company that markets and distributes drugs in the United States. … The license agreement granted MGI the right to distribute, promote, market, and sell [Helsinn's] 0.25mg and 0.75mg doses of palonosetron [products] in the United States. … Under the supply and purchase agreement, MGI agreed to purchase exclusively from Helsinn any palonosetron product approved by the FDA. Helsinn in turn agreed to supply MGI however much of the approved doses it required. Both agreements included dosage information and required MGI to keep confidential any proprietary information received under the agreements.

Helsinn and MGI announced the agreements in a joint press release, and MGI also reported the agreements in its Form 8-K filing with the Securities and Exchange Commission. Although the 8-K filing included redacted copies of the agreements, neither the 8-K filing nor the press releases disclosed the specific dosage formulations covered by the agreements.

On January 30, 2003, nearly two years after Helsinn and MGI entered into the agreements, Helsinn filed a provisional patent application covering the 0.25 mg and 0.75 mg doses of palonosetron. Over the next 10 years, Helsinn filed four patent applications that claimed priority to the January 30, 2003, date of the provisional application. Helsinn filed its fourth patent application—the one relevant here—in May 2013, and it issued as [the '219 patent.] By virtue of its effective date, the '219 patent is governed by the AIA. See §100(i).[1]

[1] [Eds. note: For the complicated reasons why Helsinn's patent application, although filed in 2003, was ultimately governed by the AIA, see note 1 in the notes after the case.]

Respondents Teva Pharmaceutical Industries, Ltd., and Teva Pharmaceuticals USA, Inc. (Teva), are, respectively, an Israeli company that manufactures generic drugs and its American affiliate. In 2011, Teva sought approval from the FDA to market a generic 0.25 mg palonosetron product. Helsinn then sued Teva for infringing its patents, including the '219 patent. In defense, Teva asserted that the '219 patent was invalid because the 0.25 mg dose was "on sale" more than one year before Helsinn filed the provisional patent application covering that dose in January 2003. …

The District Court determined that the "on sale" provision did not apply. It concluded that, under the AIA, an invention is not "on sale" unless the sale or offer in question made the claimed invention available to the public. … The Federal Circuit reversed. It concluded that "if the existence of the sale is public, the details of the invention need not be publicly disclosed in the terms of sale" to fall within the AIA's on-sale bar. Because the sale between Helsinn and MGI was publicly disclosed, it held that the on-sale bar applied.

We granted certiorari to determine whether, under the AIA, an inventor's sale of an invention to a third party who is obligated to keep the invention confidential qualifies as prior art for purposes of determining the patentability of the invention. We conclude that such a sale can qualify as prior art.

II

A

The United States Constitution authorizes Congress "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." Art. 1, §8, cl. 8. Under this grant of authority, Congress has crafted a federal patent system that encourages "the creation and disclosure of new, useful, and nonobvious advances in technology and design" by granting inventors "the exclusive right to practice the invention for a period of years." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U. S. 141, 151 (1989).

To further the goal of "motivating innovation and enlightenment" while also "avoiding monopolies that unnecessarily stifle competition," *Pfaff*, 525 U. S., at 63, Congress has imposed several conditions on the "limited opportunity to obtain a property right in an idea," Bonito Boats, *supra*, at 149. One such condition is the on-sale bar, which reflects Congress' "reluctance to allow an inventor to remove existing knowledge from public use" by obtaining a patent covering that knowledge. *Pfaff*, supra, at 64; see also *Pennock v. Dialogue*, 27 U.S. 1 (1829) (explaining that "it would materially retard the progress of science and the useful arts" to allow an inventor to "sell his invention publicly" and later "take out a patent" and "exclude the public from any farther use than what should be derived under it").

Every patent statute since 1836 has included an on-sale bar. *Pfaff, supra*, at 65. The patent statute in force immediately before the AIA prevented a person from receiving a patent if, "more than one year prior to the date of the application for patent in the United States," "the invention was . . . on sale" in the United States. 35 U. S. C. §102(b). The AIA, as relevant here, retained the on-sale bar and added the catchall phrase "or otherwise available to the public." §102(a)(1) (2012 ed.) ("A person shall be entitled to a patent unless" the "claimed invention was . . . in public use, on sale, or otherwise available to the public . . . "). We must decide whether these changes altered the meaning of the "on sale" bar. We hold that they did not.

B

Congress enacted the AIA in 2011 against the backdrop of a substantial body of law interpreting §102's on-sale bar. In 1998, we determined that the pre-AIA on-sale bar applies "when

two conditions are satisfied" more than a year before an inventor files a patent application. *Pfaff*, 525 U. S., at 67. "First, the product must be the subject of a commercial offer for sale." *Ibid.* "Second, the invention must be ready for patenting," which we explained could be shown by proof of "reduction to practice" or "drawings or other descriptions of the invention that were sufficiently specific to enable a person skilled in the art to practice the invention." *Id*., at 67-68.

Although this Court has never addressed the precise question presented in this case, our precedents suggest that a sale or offer of sale need not make an invention available to the public. For instance, we held in *Pfaff* that an offer for sale could cause an inventor to lose the right to patent, without regard to whether the offer discloses each detail of the invention. E.g., *id*., at 67. Other cases focus on whether the invention had been sold, not whether the details of the invention had been made available to the public or whether the sale itself had been publicly disclosed. E.g., *Consolidated Fruit-Jar Co. v. Wright*, 94 U. S. 92, 94 (1877) ("[A] single instance of sale or of use by the patentee may, under the circumstances, be fatal to the patent . . . "); cf. *Smith & Griggs Mfg. Co. v. Sprague*, 123 U. S. 249, 257 (1887) ("A single sale to another . . . would certainly have defeated his right to a patent . . . "); *Elizabeth v. Pavement Co.*, 97 U. S. 126, 136 (1878) ("It is not a public knowledge of his invention that precludes the inventor from obtaining a patent for it, but a public use or sale of it").

The Federal Circuit—which has "exclusive jurisdiction" over patent appeals, 28 U. S. C. §1295(a)—has made explicit what was implicit in our precedents. It has long held that "secret sales" can invalidate a patent. *E.g., Special Devices, Inc. v. OEA, Inc*., 270 F. 3d 1353, 1357 (2001) (invalidating patent claims based on "sales for the purpose of the commercial stockpiling of an invention" that "took place in secret"); *Woodland Trust v. Flowertree Nursery, Inc.*, 148 F. 3d 1368, 1370 (1998) ("Thus an inventor's own prior commercial use, albeit kept secret, may constitute a public use or sale under §102(b), barring him from obtaining a patent").

In light of this settled pre-AIA precedent on the meaning of "on sale," we presume that when Congress reenacted the same language in the AIA, it adopted the earlier judicial construction of that phrase. See *Shapiro v. United States*, 335 U. S. 1, 16 (1948) ("In adopting the language used in the earlier act, Congress 'must be considered to have adopted also the construction given by this Court to such language, and made it a part of the enactment'"). The new §102 retained the exact language used in its predecessor statute ("on sale") and, as relevant here, added only a new catchall clause ("or otherwise available to the public"). As *amicus* United States noted at oral argument, if "on sale" had a settled meaning before the AIA was adopted, then adding the phrase "or otherwise available to the public" to the statute "would be a fairly oblique way of attempting to overturn" that "settled body of law." Tr. of Oral Arg. 28. The addition of "or otherwise available to the public" is simply not enough of a change for us to conclude that Congress intended to alter the meaning of the reenacted term "on sale."

Helsinn disagrees, arguing that our construction reads "otherwise" out of the statute. Citing *Paroline v. United States*, 572 U. S. 434 (2014), and *Federal Maritime Comm'n v. Seatrain Lines, Inc.*, 411 U. S. 726 (1973), Helsinn contends that the associated-words canon requires us to read "otherwise available to the public" to limit the preceding terms in §102 to disclosures that make the claimed invention available to the public.

As an initial matter, neither of the cited decisions addresses the reenactment of terms that had acquired a well-settled judicial interpretation. And Helsinn's argument places too much weight on §102's catchall phrase. Like other such phrases, "otherwise available to the public" captures material that does not fit neatly into the statute's enumerated categories but is nevertheless meant to be covered. Given that the phrase "on sale" had acquired a well-settled meaning when the AIA was enacted, we decline to read the addition of a broad catchall phrase to upset that body of precedent.

III

Helsinn does not ask us to revisit our pre-AIA interpretation of the on-sale bar. Nor does it dispute the Federal Circuit's determination that the invention claimed in the '219 patent was "on sale" within the meaning of the pre-AIA statute. Because we determine that Congress did not alter the meaning of "on sale" when it enacted the AIA, we hold that an inventor's sale of an invention to a third party who is obligated to keep the invention confidential can qualify as prior art under §102(a). We therefore affirm the judgment of the Federal Circuit.

It is so ordered.

NOTES ON *HELSINN*

1. Why Was Helsinn's Patent Application Subject to the AIA Even Though It Had Its Priority of Filing Date in 2003? As discussed in the casebook's introduction to Chapter 5, the general rule concerning the application of the AIA is that the new statute applies to all patent applications with effective filing dates on or after March 16, 2013. The older first-to-invent version of § 102 generally applies to applications with effective filing dates before that date. Those are only the general rules, however. As explained in the introduction, there's a complex exception, and that very exception allowed Helsinn to have an effective filing date in 2003 and yet still be subject to the AIA.

The exception is that, where an applicant files a continuation-in-part (CIP) application (an application containing additional material that could be used to support additional patent claims) on or after March 16, 2013, and at least one claim in that CIP application is entitled to an AIA priority of filing date, then *the whole of the application* becomes subject to the AIA. This rule applies even though some or even most of the claims in the new application do not rely on the newly added material and thus can claim a priority of filing date before March 16, 2013.

That exception was used by Helsinn. On May 23, 2013 (approximately nine weeks after the AIA's effective date of March 16, 2013), Helsinn filed its CIP application containing all of its prior disclosure of inventions plus a new "Example 8" and a new claim directed to that example. Because that one single claim was had a post-March 16, 2013, priority of filing date, it was subject to the AIA, and thus all other claims became subject to the AIA too. And once an application is subject to the AIA, there's no going back. Indeed, Helsinn soon deleted its new claim so that, by the time the 2013 CIP application issued, it contained only claims with a 2003 priority of filing date.

Why did Helsinn go through all of that trouble to get into the AIA priority system? The answer is that the company knew about the problem with its 2001 sales agreement and thought that the reenacted "on sale" language in the AIA's version of § 102 might possibly be interpreted differently than the same language in the pre-AIA version of the statute. Helsinn's lawyers were ultimately wrong of course, but it was perhaps a good gamble. After all, the Helsinn won in district court, and it was able to get the U.S. government as an amicus supporting its view.

In light of the Court's decision in *Helsinn*, however, it is unlikely that many more inventors will try to engage the same exception to transform an application governed by pre-AIA § 102 into one governed by post-AIA § 102. In general, the pre-AIA § 102 is structurally more favorable to patent applicants than the older version of the statute. If the addition of the phrase "otherwise available to the public" had narrowed the "on sale" and "public use" categories of art, then perhaps other patent applicants would follow Helsinn's lead. With the Supreme Court now holding that the pre-existing prior art categories did not change when they were reenacted in the AIA, few and perhaps even no other patent applicants entitled to the pre-AIA system are going to be eager to have the AIA system applied to their applications.

2. Continuity in Patent Law. As stated in the casebook on page 331, most commentators (including both authors of this casebook) previously believed that, where Congress reenacted prior

art categories in the same language found in the pre-AIA version of § 102 (i.e., the categories of "printed publication," "patented," "in public use," and "on sale"), the courts were likely to maintain prior interpretations of those categories. Indeed, the entire structure of Chapter 5 in the casebook generally makes that assumption, for it uses pre-AIA cases to demonstrate the scope of categories of prior art in the AIA version of § 102. *Helsinn* confirms the validity of that assumption.

Two passages from the Court's unanimous opinion are key. First, the Court noted that "Congress enacted the AIA in 2011 against the backdrop of a substantial body of law interpreting §102's on-sale bar." That's true not only for the on-sale bar, but for the other major categories of prior art in § 102(a)(1). The second passage states that the Court would "presume that when Congress reenacted the same language in the AIA, it adopted the earlier judicial construction of that phrase." The Court's approach here is highly sensible. By carrying forward established meanings for statutory language in the absence of clear statutory indication for change, the Court maintains continuity between modern patent law and more than 200 years of precedents providing wisdom about how to maintain a well-functioning patent system.

Although the Court's unanimous opinion makes the outcome in the case appear easy, the case looked much more up-for-grabs while it was being litigated. Not only the government, but also the largest U.S. intellectual property associations (including the Intellectual Property Owners' Association and the American Intellectual Property Law Association) and major trade associations in the pharmaceutical and biotechnology industries all supported the view that the secret sales were not part of the prior art under the AIA's version of § 102. Those amici all pointed to several passages of the legislative history in which sponsors of the AIA appeared to interpret the phrase "otherwise available to the public" in the new version of § 102 as indicating a congressional intent to limit all categories of the prior art only to things that are non-secret. Furthermore, Helsinn's position did not rely solely on legislative history; it was supported also by a textual argument, which was well summarized by Justice Alito during the oral argument:

> JUSTICE ALITO: [S]uppose that the statute had been amended to read just the way it does, except -- so it would -- with one exception. So it says the -- the claimed invention was patented, described in a printed publication, or in public use, on sale publicly or on sale privately, or otherwise available to the public.
>
> That would be nonsense, wouldn't it? …
>
> [I]t would be nonsense because the meaning of "otherwise" is in the same -- in some other manner, to do the same thing in some other manner.
>
> And you have -- what we have now after this change is an enumerated -- is an enumeration of a number of things that are public, a printed publication in public use, two things that are obviously public.
>
> Then we have on sale. And then it says, "or otherwise available to the public." And I find it very difficult to get over the idea that this means that all of the things that went before are public.

Obviously, Justice Alito and all the other Justices were able "to get over the idea" that the text and legislative history indicated that all of the prior art categories in the new § 102 must be publicly available. Still, the strength of the arguments on Helsinn's side demonstrates the degree to which the Court is willing to maintain continuity through a strong presumption that reenacted statutory terms carry their traditional meanings.

The Court's decision in *Helsinn* echoes another of the Court's recent patent decision. In *TC Heartland v. Kraft Foods Group*, 137 S.Ct. 1514 (2017), the Court instructed that, when Congress wants to change the settled meaning of a statutory provision, "it ordinarily provides a relatively clear

indication of its intent in the text of the amended provision." *Id*. at 1520. The issue in *Heartland* was whether the Court should change its longstanding interpretation of a statute governing venue specifically in patent cases in light of Congress's action in amending the statutory provisions generally in civil litigation. In *Heartland* as in *Helsinn*, the Court found too little of a congressional signal to supply the "relatively clear indication" necessary to disrupt the continuity of precedential law. Quoting a work on statutory interpretation co-authored by the late Justice Scalia, the *Heartland* Court endorsed the view that "[a] clear, authoritative judicial holding on the meaning of a particular provision should not be cast in doubt and subjected to challenge whenever a related though not utterly inconsistent provision is adopted in the same statute … ." *Id.* at 1520 (quoting A. Scalia & B. Garner, Reading Law 331 (2012)).

Together *Helsinn* and *Heartland* demonstrate the Court's fairly strong preference for continuity over disruption in the interpretation of the Patent Act.

3. The Breadth of the Supreme Court's Decision. As noted in the introduction to the Supreme Court's opinion, the Federal Circuit held that a sale could qualify as "on sale" prior art "if the existence of the sale is public" even the details of the technology are not publicly disclosed. The Supreme Court's decision seems broader. The emphasized that the crucial issue is "whether the invention had been sold, *not whether the details of the invention had been made available to the public or whether the sale itself had been publicly disclosed*." (Emphasis added.) Thus, under the Court's decision, the reporting of the sale in documents filed with the Securities and Exchange Commission is legally irrelevant to the outcome of the case. Helsinn would have lost even if all information about the sale was kept in the strictest of confidence.

4. Secret Sales by a Third Party. *Helsinn* involved sales by patent owner. Would the outcome change if the sales had been by a third party—someone having no interest in the patent rights?

The logic of the Supreme Court's opinion suggests that question should be answered "no." The Court reasoned that, under *Pfaff*, an invention is "on sale" under § 102 if the invention is subject to a commercial offer for sale and ready for patenting, and the Court explicitly rejected the notion that a sale must be in some measure "public" in order to count as prior art. Nothing in *Pfaff*, *Helsinn* or in the text of § 102 suggests that the analysis should change based on the identity of the party offering the invention for sale.

Prior to both *Pfaff* and *Helsinn*, however, the Court of Federal Claims in *MDS Associates, Ltd. Partnership v. United States*, 37 Fed. Cl. 611 (1997), *aff 'd without opin.*, 135 F.3d 778 (Fed. Cir. 1998), held that secret sales by third parties were not "on sale" prior art under the pre-AIA version of § 102. The relevant patent covered certain automated systems designed to avoid collisions between ships, and prior to the critical date, a similar system was independently developed by the United States military and secretly sold to Germany. In facts similar to those in *Helsinn*, the fact of the sale was public, but not the technical details of the technology, which were classified and disclosed only to the Germans. The court reasoned that such a secret sale fell into an exception "created" by the Federal Circuit.

> As a general rule, the on-sale bar applies to sales made by third parties, as well as to sales made by the inventor. *In re Epstein*, 32 F.3d 1559, 1564 (Fed. Cir. 1994). "An exception to this general rule exists where a patented method is kept secret and remains secret after a sale of the unpatented product of the method. Such a sale prior to the critical date is a bar if engaged in by the patentee or patent applicant, but not if engaged in by another." *In re Caveney*, 761 F.2d 671, 675 (Fed. Cir, 1985) (citing *W.L Gore & Assocs., Inc. v. Garlock, Inc*., 721 F.2d 1540, 1550 (Fed. Cir. 1983)). The Federal Circuit created the third-party-secret-method exception because the sale of a product, where the method is kept secret, prevents the public from learning of the invention.

37 Fed. Cl. at 632. Is that reasoning still sound after *Pfaff* and *Helsinn*? Would the Supreme Court accept the Federal Circuit's power to "create" an exception to statutory text?

Recently, S*chlumberger Tech. Corp. v. Bico Drilling Tools, Inc*., 2019 U.S. Dist. LEXIS 98509 (June 12, 2019), also held that secret third party sales do not count as "on sale" prior art and that such sale "should be analyzed under the public use prong" of § 102(a). *Id*. at *28. The issue seems likely to be bound for appellate review in the near future.

5. Contingent Sales. The Federal Circuit's opinion in *Helsinn* also contained an important holding about "contingent" sales: Sales contingent on future events *do* qualify as prior art, provided that the contract is binding on the party making the sale. Helsinn's sales contract obligated Helsinn to supply its newly formulated drug to MGI but only if the FDA approved the drug for marketing. Holding such future sales to qualify as "on sale" makes good sense given the blackletter law that a mere "offer" to sell (which is contingent upon the future acceptance of a buyer) is sufficient to place an invention "on sale."

6. New Pharmaceutical Formulations. The claimed invention in *Helsinn* was not a new active ingredient (i.e., not a new chemical molecule) but instead a new pharmaceutical formulation. The claims at issue covered a previously known active ingredient in a different dosage range combined with other ingredients to make the allegedly improved pharmaceutical product. Patents covering such innovations have recently begun to generate some controversy.

The major criticism of such patents are that they help pharmaceutical companies to engage in so-called "evergreening" of previously patented pharmaceuticals—where "evergreening" is defined as seeking new patents to cover very slight changes in existing pharmaceuticals to extend (or "evergreen") exclusive rights beyond the normal 20-year patent term. The major defense of such patents is that almost all technological progress is incremental, and version 1.0 of a new technology is usually inferior to version 2.0. The patent system is very much designed to foster not only pioneering inventions, but also incremental advances. The facts of *Helsinn* show one reason why such incremental patents might be necessary: Each new formulation of an existing pharmaceutical needs regulatory approval from the FDA. That regulatory approval process can be uncertain and expensive as the FDA tries to assure that the new product is safe and effective for human use.

For present purposes, however, we should note only that the novelty doctrine of patent law does not attempt to prevent the patenting of slight tweaks of existing technology. If the claimed invention is even slightly new (not identical to the prior art), it passes the novelty requirement. The nonobviousness requirement, which will be discussed in Chapter 7, is the major patent law doctrine that attempts to prevent patents issuing on trivial changes.

e. "Otherwise Available to the Public"

On page 377-78, delete the first two paragraphs of section "e" and replace with this single paragraph:

> The Supreme Court's opinion in *Helsinn* provides a definitive answer to the question whether the "otherwise available to the public" language constricts the preexisting interpretations of the prior art categories in § 102(a)(1)—it does not. With that controversy resolved, there remains the issue of how to interpret the new "otherwise available to the public" language in § 102(a)(1), which plainly establishes a new category of prior art distinct from the other prior art categories. What might fall into this new category and not into any of the others?

Chapter 7: Nonobviousness

Chap. 7.C.2. Obviousness at the Federal Circuit After *KSR*

On page 600, add the following notes:

7. *Samsung v. Apple*—Future Supreme Court Review on Obviousness? The Federal Circuit's first *en banc* decision on obviousness since the Supreme Court's *KSR* decision came in *Apple Inc. v. Samsung Elecs. Co., Ltd.*, 839 F.3d 1034 (Fed. Cir. 2016) (en banc). While the majority opinion claimed to be making no new law on obviousness, the decision drew strong dissents from Chief Judge Prost and Judges Dyk and Reyna. Judge Dyk's dissent, in particular, was sharply worded and accused the majority of "lower[ing] the bar for nonobviousness" in a way that is "contrary to *KSR*." 839 F.3d at 1076-77.

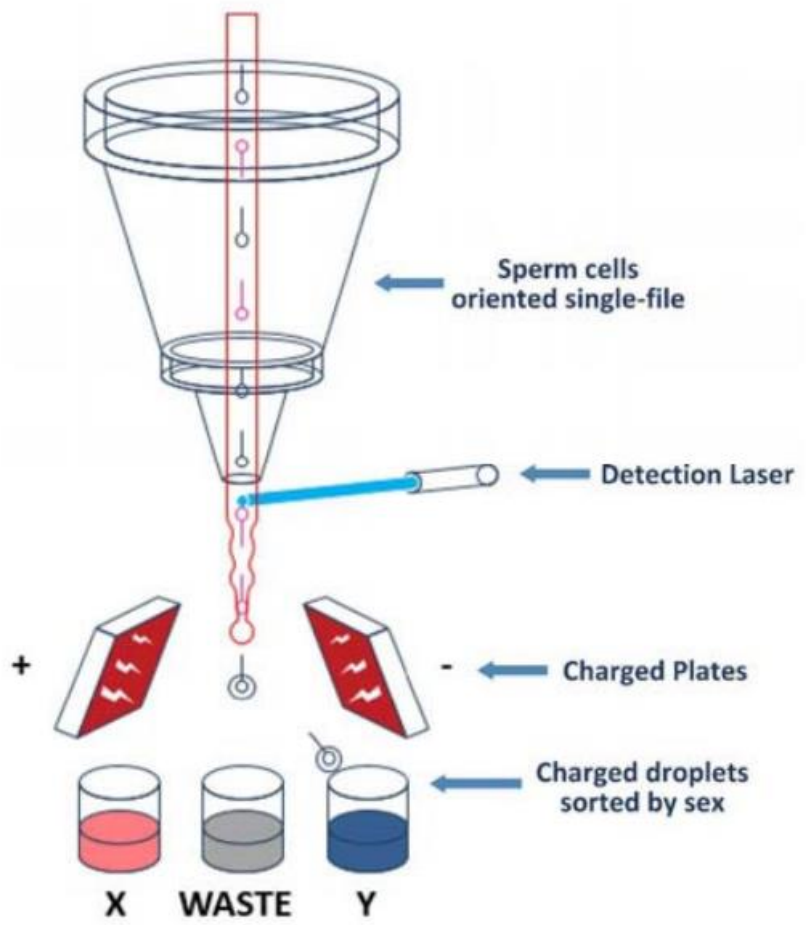
Samsung—the accused infringer and the losing party in the case—petitioned the Supreme Court for certiorari on several issues, including whether the Federal Circuit's approach to obviousness was wrong. In response to the petition, the Supreme Court called for the views of the Solicitor General (CVSG) concerning whether certiorari should be granted.

The SG urged the Court to deny certiorari for multiple reasons, including that the case had a number of procedural problems that might prevent the Court from resolving the issues presented in the petition. Significantly, however, the government agreed with Samsung that there is "some reason for concern that the Federal Circuit may be drifting back toward 'rigid and mandatory formulas' of the type this Court rejected in *KSR*." SG Br. at 16. In particular, the government's brief asserted that the Federal Circuit case law on obviousness "is at least in tension with" *KSR* in cases where the court has asserted "that a showing of obviousness 'requires finding *both* "that a skilled artisan would have been motivated to combine the teachings of the prior art . . . *and* that the skilled artisan would have had a reasonable expectation of success in doing so."'" SG Br. at 16-17 (quoting *In re Stepan Co.*, 868 F.3d 1342, 1345-46 (Fed. Cir. 2017); emphases added by the SG).

While the Court followed the SG's recommendation and denied certiorari in *Apple v. Samsung*, the SG's criticism of the Federal Circuit's post-*KSR* obviousness case law means that the door may be open to some future litigant obtaining Supreme Court review in an obviousness case.

8. A Circuit Split? While almost all patent cases are subject to the exclusive nationwide jurisdiction of the Federal Circuit, a very small number of cases are not. For example, the recent case of *ABS Global, Inc. v. Inguran, LLC*, 914 F.3d 1054 (7th Cir. 2019), was not subject to the Federal Circuit's jurisdiction because the initial complaint in the case did not "arise under" the patent law (it stated an antitrust cause of action) and the defendant's counterclaim for patent infringement was a permissive, not mandatory, counterclaim. *See id.* at 1063-64 (deciding that the court had appellate jurisdiction because the case falls outside the Federal Circuit's jurisdiction under 28 U.S.C. § 1295(a)(1)). The Seventh Circuit's reasoning on obviousness seems to mark out a circuit split with the Federal Circuit on the precise point identified in the Solicitor General's brief in *Samsung*: whether a showing of obviousness *requires* a finding that a person skilled in the art would have a "motivation to combine" the prior art in the same way as disclosed in the patent at issue.

The patent in *ABS* covers technology for sorting individual bull semen cells based on whether the cell contains an X chromosome (which will produce female offspring) or a Y chromosome (which will produce male offspring). (The sorted cells can then be used to select the biological sex of the bull's offspring.) A diagram of the system is below:



As the court opinion describes the technology:

> [The] process begins with a sample of stained sperm cells suspended in liquid. The stain allows the sorter to distinguish X-bearing cells from Y-bearing cells based on differences in their DNA content. The stained fluid is forced through a stream, spacing out the cells and orienting them single-file. Next, a laser identifies each cell as bearing either an X or Y chromosome. By this time, each sperm cell is contained in an individual droplet, and a different charge is applied to each droplet depending on whether it contains an X- or Y-bearing sperm cell [the apparatus for imparting the charge is not shown in the above figure]. The individually charged cells are then passed through charged plates, which redirect the cells into three batches: X-bearing cells, Y-bearing cells, and waste.

914 F.3d at 1061.

Like many modern patent infringement cases, the matter was tried to a jury, which was instructed on the law of obviousness. The jury returned a verdict upholding the validity of the patent, meaning that the jury was unable to find clear and convincing evidence (the relevant standard for invalidating an issued patent in an infringement action) that the invention was obvious. In reviewing that verdict, the patentee argued that, in light of the jury verdict, the court could not invalidate the patent if there existed any a factual dispute concerning whether a person skilled in the art would have been "motivated to combine" the relevant pieces of prior art to make the claimed invention (and like *KSR* and many other patent cases, the claimed invention was arguably a combination of prior art elements). Taking a position quite different from the Federal Circuit's approach to the importance of

motivation to combine, the Seventh Circuit reasoned that a dispute over such a motive would not prevent the court from holding the patent invalid as a matter of law:

> ABS [the accused infringer] argues that "for the most part the relevant facts were not disputed.' Sexing Tech [the patentee] takes the opposite position, contending that factual disputes abounded. It asserts that whether an artisan would have been "motivated to combine" the prior art is itself a factual question. Sexing Tech asserts that the jury implicitly concluded that the prior art "teaches away" from the '987 patent's use of a photo-damage method. But that is hard to say, especially in a case such as this one, where the jury rendered only a general verdict. Special verdicts are the only reliable way to nail down such findings. See Fed. R. Civ. P. 49(a); *Roberts v. Sears, Roebuck & Co.*, 723 F.2d 1324, 1341-42 (7th Cir. 1983) (*en banc*).
>
> The mystery question concerns what the jury might have thought about the motivation to combine [the prior art] Johnson's droplet sorter with a photo-damage method. In the Federal Circuit, motivation to combine is always a factual question that is "[s]ubsumed within the Graham factors." *Pfizer, Inc. v. Apotex, Inc*., 480 F.3d 1348, 1361 (Fed. Cir. 2007); *see also Wyers v. Master Lock Co.*, 616 F.3d 1231, 1238-39 (Fed. Cir. 2010). That court asks "whether there is a known reason a skilled artisan would have been motivated to combine elements to arrive at a claimed combination." *Arctic Cat Inc. v. Bombardier Recreational Prods. Inc*., 876 F.3d 1350, 1359 (Fed. Cir. 2017). Here, to the extent that there are disputes about the existence of something that would give an artisan a "known reason" to combine prior art elements, the jury's verdict indicates that it resolved those factual questions in favor of Sexing Tech.
>
> Nevertheless, it does not follow, as Sexing Tech contends, that the existence of factual disputes by itself makes judgment as a matter of law inappropriate. Sexing Tech's position overstates the importance of a motivation to combine or "teaching away" after *KSR*. *KSR* recognizes that "expert testimony ... may resolve or keep open certain questions of fact," but "[t]hat is not the end of the issue." 550 U.S. at 427. Some factors might point away from obviousness and other factors might point toward it, yet judgment as a matter of law might be appropriate. That is because the jury does not have the last word on obviousness; as we noted earlier, it is the court that must resolve the ultimate legal issue.

914 F.3d at 1066-67.

Thus, while the Federal Circuit gives a preeminent position to the presence or absence of a "motivation to combine," the Seventh Circuit views such a motivation as merely one of several "factors" that could point towards or away from a legal conclusion of obviousness. In other words, the Seventh Circuit views a "motivation to combine" much like "teaching away" in the *Graham* framework: they are both merely examples "secondary considerations" that serve as "indicia of obviousness or nonobviousness," *Graham*, 383 U.S. at 17-18, with a finding of a "motivation to combine" pointing toward obviousness and a finding of prior art that "teaches away" from the patented combination pointing toward nonobviousness.

Chapter 8: Infringement

Chap. 8.B.4. Joint and Divided Infringement.

On page 694, add the following new note following note 4 in the section on "Notes and Comments on Limelight":

5. Multiple Parties and System Claims. The Federal Circuit's jurisprudence on "divided" infringement seems to apply only to method or process claims, which are typically claimed as a series of steps. The Federal Circuit has not applied its "divided" infringement precedents to system claims, even though many or most process claims could be rewritten to claim a system with components that perform steps in a process. The reason that such system claims have not been subject to the divided infringement precedents is the basic rule that a person can "use" a machine (and a system is a type of machine) even though that person did not construct the machine.

Recently, however, the Federal Circuit has announced a new doctrine that limits the scope of infringement for system claims. *Intellectual Ventures I v. Motorola Mobility*, 870 F.3d 1320, 1329 (Fed. Cir. 2017), holds that "proof of an infringing 'use' of the claimed system under § 271(a) requires the patentee to demonstrate that the direct infringer obtained 'benefit' from each and every element of the claimed system." In a subsequent unpublished decision, the Federal Circuit restated the holding of *Intellectual Ventures I* as a hard-and-fast rule:

> In our recent case, *Intellectual Ventures I LLC v. Motorola Mobility LLC*, 870 F.3d 1320, 1329 (Fed. Cir. 2017), we rejected the notion that to find direct infringement, an accused infringer needs only to "benefit from the system as a whole" by deriving a benefit from "any claimed component of the claimed system." Rather, we clarified that the infringer must "benefit from each claimed component," i.e., from "each and every element of the claimed system." Id.

Grecia v. McDonald's Corp., 724 Fed. Appx. 942, 946-47 (Fed. Cir. 2018).

Like the divided infringement doctrine, this new benefit-from-each-element rule means that parties can successfully employ a divide-and-conquer strategy to defeat claims of infringement. For example, it is possible under the Federal Circuit's rule that no party is liable for infringement where a patented system being used by two parties, where each party benefits from some, but not all, of the elements of the system. Thus, like the divided infringement doctrine, the Federal Circuit's benefit-from-each-element rule creates the seemingly odd result that no one is liable for infringement even though the patented invention is being used in commerce. Also like the divided infringement doctrine, the benefit-from-each-element rule has no textual foundation in the infringement statute.

Chap. 8.H. Infringement and Foreign Activity.

On page 790, add the following note:

6. § 271(f) and Single Components. In early 2017, the Supreme Court decided another case on § 271(f), *Life Technologies Corp. v. Promega Corp.*, 137 S. Ct. 734 (2017). The case presented the narrow issue whether the statutory phrase "all or a substantial portion of the components of a patented invention" in § 271(f)(1)) can refer to a *single* component of a multicomponent invention. Not surprisingly, the Court unanimously answered that question "no."

The Court had two good reasons for reaching that result. First, the Court looked to the text of § 271(f)(1):

> [Section 271(f)(1)] is targeted toward the supply of all or a substantial portion "of the components," where "such components" are uncombined, in a manner that actively induces the combination of "such components" outside the United States. Text specifying a substantial portion of "components," plural, indicates that multiple components constitute the substantial portion.

137 S.Ct. at 741. Second, the Court considered the relationship between paragraphs (1) and (2) of § 271(f):

> Reading §271(f)(1) to refer to more than one component allows the two provisions to work in tandem. Whereas §271(f)(1) refers to "components," plural, §271(f)(2) refers to "any component," singular. And, whereas §271(f)(1) speaks to whether the components supplied by a party constitute a substantial portion of the components, §271(f)(2) speaks to whether a party has supplied "any" noncommodity component "especially made or especially adapted for use in the invention."

137 S.Ct. at 741-42. Thus, the Court's reading makes sense of the statute's structure.

The Court's ruling—that a single component never qualifies as a "substantial portion" of the components under paragraph (1) of § 271(f)—also tends to curb the extraterritorial effects of Section 271(f), and that result is sensible given that the baseline rule of U.S. patent law is still a principle of territoriality. Section 271(f) is an exception, and the courts usually balk at endorsing broad readings of statutes that create exceptions to fundamental principles that have long governed a field of law. Of course, supplying a single component could still generate liability under § 271(f)(2), but that provision requires that the component (i) is not a "commodity of commerce" and (ii) "is especially made or especially adapted for use in the invention"—requirements that tend to limit the scope of exporters' responsibility for extraterritorial infringement.

7. § 271(f) and Damages: The Court's *WesternGeco* Ruling. In contrast with the ruling in *Life Technologies*, which tends to curb the extraterritorial effects of U.S. patent law, the Court's decision in *WesternGeco LLC v. ION Geophysical Corp*., 138 S. Ct. 2129 (2018), expands the extraterritorial effect of domestic patent law. The patentee in the case, WesternGeco, successfully sued ION for infringement under § 271(f)(2) because ION manufactured components "especially made or especially adapted for use" in WesternGeco's patented invention. The issue addressed by the Supreme Court dealt with the permissible damages that WesternGeco could obtain—specifically whether WesternGeco could obtain lost profits that, but for ION's infringement, WesternGeco would have earned from foreign work using its invention.

In a 7-2 decision, the Court ruled that WesternGeco could seek lost profits for work it would have performed overseas. The Court's theory was that ION's liability stemmed from its *domestic* action in manufacturing components of the patented invention within the United States in violation of § 271(f)(2). Once ION's violation of § 271(f)(2) was established, WesternGeco was entitled to a complete remedy—one that compensated for all damage suffered by WesternGeco that flowed from ION's unlawful acts, even if that damage occurred outside of the United States.

Because the Court's ruling in *WesternGeco* centers on the law of remedies, the decision is discussed in more detail in Chapter 9 of this supplement.

Chapter 9: Remedies

Chap. 9.C. Lost Profits.

Insert on page 877 the following two new subchapters (Chaps. 9.C.4 & 9.C.5) before subchapter D:

4. Obtaining the Infringer's Profits under Design Patent Law.

While most of this subchapter has addressed the lost profits remedy available under § 284 for infringement of a *utility* patent, § 289 of the Patent Act grants a special remedy for infringement of a *design* patent:

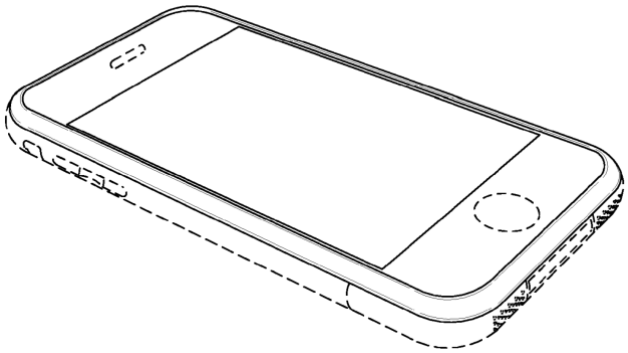
> Whoever during the term of a patent for a design, without license of the owner, (1) applies the patented design, or any colorable imitation thereof, to any article of manufacture for the purpose of sale, or (2) sells or exposes for sale any article of manufacture to which such design or colorable imitation has been applied shall be liable to the owner to the extent of his total profit, but not less than $250, recoverable in any United States district court having jurisdiction of the parties.
>
> Nothing in this section shall prevent, lessen, or impeach any other remedy which an owner of an infringed patent has under the provisions of this title, but he shall not twice recover the profit made from the infringement.

The remedy granted under that section is what's known as a *disgorgement* remedy: It requires the *infringer* to disgorge *its* "total profit" to the design patent holder. The focus of the remedy is what *the infringer made in its profits* rather than what *the patentee lost in its profits* due to the infringement. Thus, the remedy applies even if the patentee cannot prove any damages to its business. For example, a design patentee incapable of producing even one more article of manufacture and thus incapable of proving any lost profits due to infringement would still be entitled by the statute to recover the "total profit" made by the infringer.

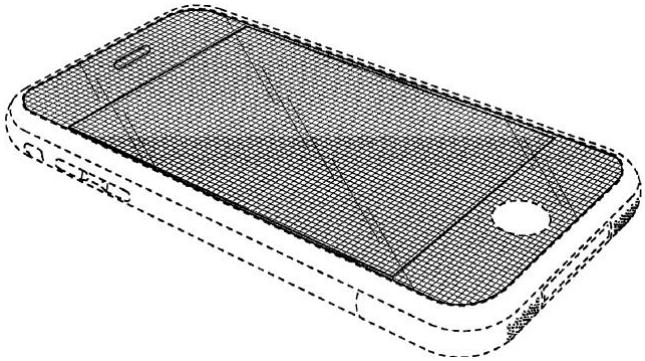
A crucial question, however, is: total profit on what? The statute cannot mean that an infringer's full corporate profits are subject to disgorgement even if the corporation infringed merely one design patent on only one of many products sold by the corporation.

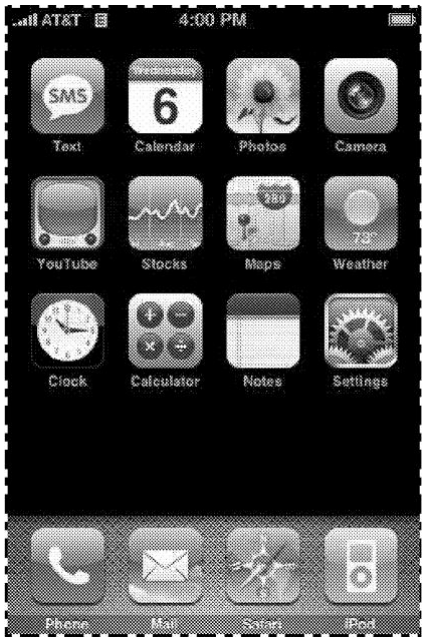
The statutory structure suggests that the "total profit" refers to the profits on the "article of manufacture" to which the design was applied. That interpretive step still leaves another issue: which article of manufacture? For example, if a design patent covers the exterior shape of a car, should the infringer be forced to disgorge all profits earned on the car or only the portion of the profits attributable to the body of the car?

This issue became important in patent infringement litigation brought by Apple against Samsung. Apple's iPhone was covered by several design patents including, for example, U.S. Patent No. D593,087 (May 26, 2009), which covers the bezel of the iPhone (the rim surrounding the glass face). The solid lines in the following drawing illustrate the patented design (design patents are claimed via drawings with a convention that only the solid lines—not the broken lines—claim the design):



Two other design patents covered the dark glass face of the original iPhone (D618,677), and the appearance of icons on the phone's screen (D604,305):





Some of Samsung's smartphones were found to infringe each of these three design patents. As a remedy for that infringement, Apple elected to seek Samsung's "total profits" under § 289, and both the district court and the Federal Circuit held that Apple was entitled to the entirety of Samsung

profits on the infringing smartphones—a total of $399 million. The Supreme Court unanimously reversed:

Samsung Electronics Co. v. Apple Inc.
137 S. Ct. 429 (2016)

Justice SOTOMAYOR delivered the opinion of the Court.

…

II

Section 289 allows a patent holder to recover the total profit an infringer makes from the infringement. It does so by first prohibiting the unlicensed "appli[cation]" of a "patented design, or any colorable imitation thereof, to any article of manufacture for the purpose of sale" or the unlicensed sale or exposure to sale of "any article of manufacture to which [a patented] design or colorable imitation has been applied." 35 U. S. C. § 289. It then makes a person who violates that prohibition "liable to the owner to the extent of his total profit, but not less than $250." *Ibid.* "Total," of course, means all. See American Heritage Dictionary 1836 (5th ed. 2011) ("[t]he whole amount of something; the entirety"). The "total profit" for which § 289 makes an infringer liable is thus all of the profit made from the prohibited conduct, that is, from the manufacture or sale of the "article of manufacture to which [the patented] design or colorable imitation has been applied."

Arriving at a damages award under § 289 thus involves two steps. First, identify the "article of manufacture" to which the infringed design has been applied. Second, calculate the infringer's total profit made on that article of manufacture.

This case requires us to address a threshold matter: the scope of the term "article of manufacture." The only question we resolve today is whether, in the case of a multicomponent product, the relevant "article of manufacture" must always be the end product sold to the consumer or whether it can also be a component of that product. Under the former interpretation, a patent holder will always be entitled to the infringer's total profit from the end product. Under the latter interpretation, a patent holder will sometimes be entitled to the infringer's total profit from a component of the end product.

A

The text resolves this case. The term "article of manufacture," as used in § 289, encompasses both a product sold to a consumer and a component of that product.

"Article of manufacture" has a broad meaning. An "article" is just "a particular thing." J. Stormonth, A Dictionary of the English Language 53 (1885) (Stormonth); see also American Heritage Dictionary, at 101 ("[a]n individual thing or element of a class; a particular object or item"). And "manufacture" means "the conversion of raw materials by the hand, or by machinery, into articles suitable for the use of man" and "the articles so made." Stormonth 589; see also American Heritage Dictionary, at 1070 ("[t]he act, craft, or process of manufacturing products, especially on a large scale" or "[a] product that is manufactured"). An article of manufacture, then, is simply a thing made by hand or machine.

So understood, the term "article of manufacture" is broad enough to encompass both a product sold to a consumer as well as a component of that product. A component of a product, no

less than the product itself, is a thing made by hand or machine. That a component may be integrated into a larger product, in other words, does not put it outside the category of articles of manufacture.

This reading of article of manufacture in § 289 is consistent with 35 U. S. C. §171(a), which makes "new, original and ornamental design[s] for an article of manufacture" eligible for design patent protection. The Patent Office and the courts have understood §171 to permit a design patent for a design extending to only a component of a multicomponent product. See, *e.g.*, *Ex parte Adams*, 84 Off. Gaz. Pat. Office 310, 311 (1898) ("The several articles of manufacture of peculiar shape which when combined produce a machine or structure having movable parts may each separately be patented as a design . . . "); *Application of Zahn*, 617 F. 2d 261, 268 (CCPA 1980) ("Section 171 authorizes patents on ornamental designs for articles of manufacture. While the design must be *embodied* in some articles, the statute is not limited to designs for complete articles, or 'discrete' articles, and certainly not to articles separately sold . . . ").

This reading is also consistent with 35 U. S. C. § 101, which makes "any new and useful . . . manufacture . . . or any new and useful improvement thereof" eligible for utility patent protection. Cf. 8 D. Chisum, Patents § 23.03[2], pp. 23-12 to 23-13 (2014) (noting that "article of manufacture" in § 171 includes "what would be considered a 'manufacture' within the meaning of Section 101"). "[T]his Court has read the term 'manufacture' in §101 . . . to mean 'the production of articles for use from raw or prepared materials by giving to these materials new forms, qualities, properties, or combinations, whether by hand-labor or by machinery.'" *Diamond* v. *Chakrabarty*, 447 U. S. 303, 308 (1980) (quoting *American Fruit Growers, Inc.* v. *Brogdex Co.*, 283 U. S. 1, 11 (1931)). The broad term includes "the parts of a machine considered separately from the machine itself." 1 W. Robinson, The Law of Patents for Useful Inventions § 183, p. 270 (1890).

B

The Federal Circuit's narrower reading of "article of manufacture" cannot be squared with the text of § 289. The Federal Circuit found that components of the infringing smartphones could not be the relevant article of manufacture because consumers could not purchase those components separately from the smartphones. See 786 F. 3d, at 1002 (declining to limit a § 289 award to a component of the smartphone because "[t]he innards of Samsung's smartphones were not sold separately from their shells as distinct articles of manufacture to ordinary purchasers"); see also *Nordock, Inc.* v. *Systems Inc.*, 803 F. 3d 1344, 1355 (CA Fed. 2015) (declining to limit a § 289 award to a design for a "'lip and hinge plate'" because it was "welded together" with a leveler and "there was no evidence" it was sold "separate[ly] from the leveler as a complete unit"). But, for the reasons given above, the term "article of manufacture" is broad enough to embrace both a product sold to a consumer and a component of that product, whether sold separately or not. Thus, reading "article of manufacture" in § 289 to cover only an end product sold to a consumer gives too narrow a meaning to the phrase.

The parties ask us to go further and resolve whether, for each of the design patents at issue here, the relevant article of manufacture is the smartphone, or a particular smartphone component. Doing so would require us to set out a test for identifying the relevant article of manufacture at the first step of the § 289 damages inquiry and to parse the record to apply that test in this case. The United States as *amicus curiae* suggested a test, see Brief for United States as *Amicus Curiae* 27-29, but Samsung and Apple did not brief the issue. We decline to lay out a test for the first step of the § 289 damages inquiry in the absence of adequate briefing by the parties. Doing so is not necessary to resolve the question presented in this case, and the Federal Circuit may address any remaining issues on remand.

III

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

It is so ordered.

NOTES ON *SAMSUNG v. APPLE*

1. Damages for Infringements in Multicomponent Devices. Though the Supreme Court decides this case as a narrow matter of interpreting rather specific statutory text, the Court frames the case in a very particular way—stating the issue in the case is "whether, in the case of a multicomponent product, the relevant 'article of manufacture' must always be the end product sold to the consumer or whether it can also be a component of that product." That framing helps to explain the greater significance of this case, for it is another situation in which the courts have been confronted with patent infringement of a few particular patents within the context of a much larger multicomponent device.

One great achievement of modern technology industries is the ability to combine numerous advances into a single highly functional product. For example, a smartphone encompasses a large number of creative contributions in electronics, communications protocols, batteries, cameras, software and design. The end product is enormously useful, but the combination of creative efforts makes calculating patent damages enormously difficult. The goal is to provide reasonable remedies (to maintain incentives for innovation) but to avoid overcompensation (so as not to foster litigation).

2. What's Next? The *Samsung* Court rejected the Federal Circuit's approach—which required the "article of manufacture" to be something that was sold separately to consumers—but the Court did not decide the correct method for assessing the infringer's profits. What is the best way to do so? Note that the Federal Circuit's approach, whatever its flaws, was easy to administer because businesses typically do have some idea of how much profit is made on each product they sell.

The Supreme Court's approach will lead to some difficult decisions. For example, how much of Samsung's profits should be attributable to the bezel or the arrangement of the icons of the smartphone (which appear only when the phone is in use and then only when the phone is showing a "home screen")? Should it be a percentage of how much it cost to make that part of the phone? Should consumers be surveyed (e.g., by asking "how much more do you value your phone because the icons on the home screen are squares not circles")? The Supreme Court leaves all such questions for the lower courts on remand.

5. Obtaining Lost Profits from Overseas Activities.

WesternGeco LLC v. ION Geophysical Corp.
138 S. Ct. 2129 (2018)

JUSTICE THOMAS delivered the opinion of the Court.

Under the Patent Act, a company can be liable for patent infringement if it ships components of a patented invention overseas to be assembled there. See 35 U. S. C. §271(f)(2). A patent owner who proves infringement under this provision is entitled to recover damages. §284. The question in this case is whether these statutes allow the patent owner to recover for lost foreign profits. We hold that they do.

I

The Patent Act gives patent owners a "civil action for infringement." §281. Section 271 outlines several types of infringement. The general infringement provision, §271(a), covers most infringements that occur "within the United States." The subsection at issue in this case, §271(f), "expands the definition of infringement to include supplying from the United States a patented invention's components." *Microsoft Corp.* v. *AT&T Corp.*, 550 U. S. 437, 444-445 (2007). It contains two provisions that "work in tandem" by addressing "different scenarios." *Life Technologies Corp.* v. *Promega Corp.*, 580 U. S. ___, ___ (2017). Section 271(f)(1) addresses the act of exporting a substantial portion of an invention's components:

> "Whoever without authority supplies or causes to be supplied in or from the United States all or a substantial portion of the components of a patented invention, where such components are uncombined in whole or in part, 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, shall be liable as an infringer."

Section 271(f)(2), the provision at issue here, addresses the act of exporting components that are specially adapted for an invention:

> "Whoever without authority supplies or causes to be supplied in or from the United States any component of a patented invention that is especially made or especially adapted for use in the invention and not a staple article or commodity of commerce suitable for substantial noninfringing use, where such component is uncombined in whole or in part, knowing that such component is so made or adapted and intending that such component will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States, shall be liable as an infringer."

Patent owners who prove infringement under §271 are entitled to relief under §284, which authorizes "damages adequate to compensate for the infringement, but in no event less than a reasonable royalty for the use made of the invention by the infringer."

II

Petitioner WesternGeco LLC owns four patents relating to a system that it developed for surveying the ocean floor. The system uses lateral-steering technology to produce higher quality data than previous survey systems. WesternGeco does not sell its technology or license it to competitors. Instead, it uses the technology itself, performing surveys for oil and gas companies. For several years, WesternGeco was the only surveyor that used such lateral-steering technology.
In late 2007, respondent ION Geophysical Corporation began selling a competing system. It manufactured the components for its competing system in the United States and then shipped them to companies abroad. Those companies combined the components to create a surveying system indistinguishable from WesternGeco's and used the system to compete with WesternGeco.

WesternGeco sued for patent infringement under §§271(f)(1) and (f)(2). At trial, WesternGeco proved that it had lost 10 specific survey contracts due to ION's infringement. The jury found ION liable and awarded WesternGeco damages of $12.5 million in royalties and $93.4 million in lost profits. ION filed a post-trial motion to set aside the verdict, arguing that WesternGeco could not recover damages for lost profits because §271(f) does not apply extraterritorially. The District Court denied the motion. 953 F. Supp. 2d 731, 755-756 (SD Tex. 2013).

On appeal, the Court of Appeals for the Federal Circuit reversed the award of lost-profits damages. *WesternGeco LLC* v. *ION Geophysical Corp*., 791 F. 3d 1340, 1343 (2015). The Federal Circuit had previously held that §271(a), the general infringement provision, does not allow patent owners to recover for lost foreign sales. See *id.*, at 1350-1351 (citing *Power Integrations, Inc.* v. *Fairchild Semiconductor Int'l, Inc.*, 711 F. 3d 1348 (CA Fed. 2013)). Section 271(f) should be interpreted the same way, the Federal Circuit reasoned, because it was "designed" to put patent infringers "in a similar position." *WesternGeco*, 791 F. 3d, at 1351. Judge Wallach dissented. See *id.*, at 1354-1364. WesternGeco petitioned for review in this Court. … We now reverse.

III

Courts presume that federal statutes "apply only within the territorial jurisdiction of the United States." *Foley Bros., Inc.* v. *Filardo*, 336 U. S. 281, 285 (1949). This principle, commonly called the presumption against extraterritoriality, has deep roots. See A. Scalia & B. Garner, Reading Law: The Interpretation of Legal Texts §43, p. 268 (2012) (tracing it to the medieval maxim *Statuta suo clauduntur territorio, nec ultra territorium disponunt*). The presumption rests on "the commonsense notion that Congress generally legislates with domestic concerns in mind." *Smith* v. *United States*, 507 U. S. 197, 204, n. 5 (1993). And it prevents "unintended clashes between our laws and those of other nations which could result in international discord." *EEOC* v. *Arabian American Oil Co.*, 499 U. S. 244, 248 (1991).

This Court has established a two-step framework for deciding questions of extraterritoriality. The first step asks "whether the presumption against extraterritoriality has been rebutted." *RJR Nabisco, Inc.* v. *European Community*, 579 U. S. ___, ___ (2016). It can be rebutted only if the text provides a "clear indication of an extraterritorial application." *Morrison* v. *National Australia Bank Ltd.*, 561 U. S. 247, 255 (2010). If the presumption against extraterritoriality has not been rebutted, the second step of our framework asks "whether the case involves a domestic application of the statute." *RJR Nabisco*, 579 U. S., at ___. Courts make this determination by identifying "the statute's 'focus'" and asking whether the conduct relevant to that focus occurred in United States territory. *Ibid.* If it did, then the case involves a permissible domestic application of the statute. See *ibid.*

We resolve this case at step two. While "it will usually be preferable" to begin with step one, courts have the discretion to begin at step two "in appropriate cases." See *id.*, at ___, n. 5 L. Ed. 2d 476 (citing *Pearson* v. *Callahan*, 555 U. S. 223, 236-243 (2009)). One reason to exercise that discretion is if addressing step one would require resolving "difficult questions" that do not change "the outcome of the case," but could have far-reaching effects in future cases. See *id.*, at 236-237. That is true here. WesternGeco argues that the presumption against extraterritoriality should never apply to statutes, such as §284, that merely provide a general damages remedy for conduct that Congress has declared unlawful. Resolving that question could implicate many other statutes besides the Patent Act. We therefore exercise our discretion to forgo the first step of our extraterritoriality framework.

A

Under the second step of our framework, we must identify "the statute's 'focus.'" *RJR Nabisco, supra*, at ___. The focus of a statute is "the objec[t] of [its] solicitude," which can include the conduct it "seeks to 'regulate,'" as well as the parties and interests it "seeks to 'protec[t]'" or vindicate. *Morrison, supra*, at 267 (quoting *Superintendent of Ins. of N. Y.* v. *Bankers Life & Casualty Co.*, 404 U. S. 6, 12, 10 (1971)). "If the conduct relevant to the statute's focus occurred in the United States, then the case involves a permissible domestic application" of the statute, "even if other conduct occurred abroad." *RJR Nabisco*, 579 U. S., at ___. But if the relevant conduct occurred

in another country, "then the case involves an impermissible extraterritorial application regardless of any other conduct that occurred in U. S. territory." *Ibid.*

When determining the focus of a statute, we do not analyze the provision at issue in a vacuum. See *Morrison, supra,* at 267-269. If the statutory provision at issue works in tandem with other provisions, it must be assessed in concert with those other provisions. Otherwise, it would be impossible to accurately determine whether the application of the statute in the case is a "domestic application." *RJR Nabisco*, 579 U. S., at ___, 136 S. Ct. 2090, 195 L. Ed. 2d 476, 493). And determining how the statute has actually been applied is the whole point of the focus test. See *ibid.*

Applying these principles here, we conclude that the conduct relevant to the statutory focus in this case is domestic. We begin with §284. It provides a general damages remedy for the various types of patent infringement identified in the Patent Act. The portion of §284 at issue here states that "the court shall award the claimant damages adequate to compensate for the infringement." We conclude that "the infringement" is the focus of this statute. As this Court has explained, the "overriding purpose" of §284 is to "affor[d] patent owners complete compensation" for infringements. *General Motors Corp.* v. *Devex Corp.,* 461 U. S. 648, 655 (1983). …

But that observation does not fully resolve this case, as the Patent Act identifies several ways that a patent can be infringed. See §271. To determine the focus of §284 in a given case, we must look to the type of infringement that occurred. We thus turn to §271(f)(2), which was the basis for WesternGeco's infringement claim and the lost-profits damages that it received.

Section 271(f)(2) focuses on domestic conduct. It provides that a company "shall be liable as an infringer" if it "supplies" certain components of a patented invention "in or from the United States" with the intent that they "will be combined outside of the United States in a manner that would infringe the patent if such combination occurred within the United States." The conduct that §271(f)(2) regulates—*i.e.,* its focus—is the domestic act of "suppl[ying] in or from the United States." As this Court has acknowledged, §271(f) vindicates domestic interests: It "was a direct response to a gap in our patent law," *Microsoft Corp.,* 550 U. S., at 457, and "reach[es] components that are manufactured in the United States but assembled overseas," *Life Technologies*, 580 U. S., at ___. As the Federal Circuit explained, §271(f)(2) protects against "domestic entities who export components . . . from the United States." 791 F. 3d, at 1351.

In sum, the focus of §284, in a case involving infringement under §271(f)(2), is on the act of exporting components from the United States. In other words, the domestic infringement is "the objec[t] of the statute's solicitude" in this context. *Morrison,* 561 U. S., at 267. The conduct in this case that is relevant to that focus clearly occurred in the United States, as it was ION's domestic act of supplying the components that infringed WesternGeco's patents. Thus, the lost-profits damages that were awarded to WesternGeco were a domestic application of §284.

B

ION's arguments to the contrary are not persuasive. ION contends that the statutory focus here is "self-evidently on the award of damages." Brief for Respondent 22. While §284 does authorize damages, what a statute authorizes is not necessarily its focus. Rather, the focus is "the objec[t] of the statute's solicitude"—which can turn on the "conduct," "parties," or interests that it regulates or protects. *Morrison, supra,* at 267. Here, the damages themselves are merely the means by which the statute achieves its end of remedying infringements. Similarly, ION is mistaken to assert that this case involves an extraterritorial application of §284 simply because "lost-profits damages occurred extraterritorially, and foreign conduct subsequent to [ION's] infringement was

necessary to give rise to the injury." Brief for Respondent 22. Those overseas events were merely incidental to the infringement. In other words, they do not have "primacy" for purposes of the extraterritoriality analysis. *Morrison, supra,* at 267.

Two of our colleagues contend that the Patent Act does not permit damages awards for lost foreign profits. *Post,* at 1 (Gorsuch, J., joined by Breyer, J., dissenting). Their position wrongly conflates legal injury with the damages arising from that injury. See *post,* at 2-3. And it is not the better reading of "the plain text of the Patent Act." *Post,* at 9. Taken together, §271(f)(2) and §284 allow the patent owner to recover for lost foreign profits. Under §284, damages are "adequate" to compensate for infringement when they "plac[e] [the patent owner] in as good a position as he would have been in" if the patent had not been infringed. *General Motors Corp., supra,* at 655, 103 S.. Specifically, a patent owner is entitled to recover "'the difference between [its] pecuniary condition after the infringement, and what [its] condition would have been if the infringement had not occurred.'" *Aro Mfg. Co., supra,* at 507. This recovery can include lost profits. And, as we hold today, it can include lost foreign profits when the patent owner proves infringement under §271(f)(2).[3]

* * *

We hold that WesternGeco's damages award for lost profits was a permissible domestic application of §284. The judgment of the Federal Circuit is reversed, and the case is remanded for further proceedings consistent with this opinion.

It is so ordered.

JUSTICE GORSUCH, with whom JUSTICE BREYER joins, dissenting.

The Court holds that WesternGeco's lost profits claim does not offend the judicially created presumption against the extraterritorial application of statutes. With that much, I agree. But I cannot subscribe to the Court's further holding that the terms of the Patent Act permit awards of this kind. In my view the Act's terms prohibit the lost profits sought in this case, whatever the general presumption against extraterritoriality applicable to all statutes might allow. So while the Federal Circuit may have relied in part on a mistaken extraterritoriality analysis, I respectfully submit it reached the right result in concluding that the Patent Act forecloses WesternGeco's claim for lost profits.

The reason is straightforward. A U. S. patent provides a lawful monopoly over the manufacture, use, and sale of an invention within this country only. Meanwhile, WesternGeco seeks lost profits for uses of its invention beyond our borders. Specifically, the company complains that it lost lucrative foreign surveying contracts because ION's customers used its invention overseas to steal that business. In measuring its damages, WesternGeco assumes it could have charged monopoly rents abroad premised on a U. S. patent that has no legal force there. Permitting damages of this sort would effectively allow U. S. patent owners to use American courts to extend their monopolies to foreign markets. That, in turn, would invite other countries to use their own patent laws and courts to assert control over our economy. Nothing in the terms of the Patent Act supports that result and much militates against it. …

[Remainder of the dissent omitted.]

[3] In reaching this holding, we do not address the extent to which other doctrines, such as proximate cause, could limit or preclude damages in particular cases.

NOTES ON *WESTERNGECO*

1. The Scope of *WesternGeco*. On the surface, the *WesternGeco* decision appears narrow as it involves only infringement liability under § 271(f) and only a claim concerning foreign lost profits. Furthermore, the case involves the unusual setting where the patentee's strategy for profiting from its invention was not to sell or license the invention but instead to keep the invention exclusively for its own use and sell its services in using the invention. Yet the Court's reasoning appears easy to extend to other situations. Consider the following two possible extensions:

a. Other Subsections of § 271. The Court reasoned that § 284 had a domestic application in this case because the statutory focus was ION's acts of supplying components of the patented invention from the United States in violation of § 271(f). Can that holding be extended to other subsections of § 271? The answer would seem to be "yes." Each of the subsections in § 271 spell out infringement liability based on activity in the United States. Thus, for example, if ION had manufactured the entirety of WesternGeco's invention within the United States (a violation of § 271(a)), and then sold that infringing product to someone overseas whose use of the invention harmed WesternGeco, it would seem that the Court's rationale would dictate that WesternGeco could recover lost profits just as much as it was able to do so in the actual case.

b. Reasonable Royalties. The Court did not consider how its ruling might apply to cases involving reasonable royalties because, even under the Federal Circuit's more restrictive approach, WesternGeco's award for reasonable royalties did not involve any component that was arguably extraterritorial. But what if a reasonable royalties award did include such a component?

For example, consider a case where a patentee licenses its technology and does not practice it. Assume that, in the relevant industry, all technologies are licensed on a worldwide basis. The patentee had licensed other companies to its technology at a rate of $1.00 per unit for any unit made or sold anywhere throughout the world. (Such a license might be viewed as convenient for both parties—the licensor might be able to monitor the licensee's worldwide sales more easily than just U.S. sales, and the licensee gains the ability to manufacture and market anywhere.) If the patentee proves infringement within the United States (e.g., from U.S. sales), can it legitimately seek a reasonable royalty remedy based on worldwide sales on the theory that a worldwide license is the appropriate hypothetical license in that industry? If instead the court excludes non-U.S. activity, should the royalty rate be greater than $1.00?

2. Proximate Cause Limitations. Footnote 3 of the *WesternGeco* opinion suggests an important limitation on the ability of patentees to obtain overseas damages due to infringement in the United States: the foreign damages must be "proximately" caused by the U.S. acts of infringement. Often that element might be hard to satisfy. For example, if a defendant manufactured copies of a patented invention within the United States (thereby committing acts of infringement under § 271(a)) and sold the copies in a foreign country in competition with the patentee, the patentee might claim that it lost sales due to the defendant's infringing U.S. manufacturing. Still, the defendant's infringement might not be a "proximate" cause if the foreign market has a competitive price and the sales could just have easily been made by another competitor that manufactured outside of the United States.

Causation questions are likely to loom large in future litigation, and as any law student knows, proximate causation is a murky area. Would the dissenting position be a reasonable rule for avoiding the complex litigation likely to accompany such causation inquiries even if the rule sometimes undercompensates patentees? Or should courts strive to provide full compensation even if that approach complicates litigation?

Chapter 10: The Legal Process of the Patent System

Chap. 10.A.5. The Jurisdictional Structure of the Federal Courts.

On page 923, after the note on the Federal Circuit and the Supreme Court, add the following note:

NOTES ON VENUE IN PATENT INFRINGEMENT CASES

1. Federal Circuit vs. Supreme Court Precedent on Patent Venue. While the prior note provides some background and academic commentary about the relationship between the Federal Circuit and the Supreme Court, this note provides a real-world example of the degree to which diverging views between the two courts can dramatically affect the legal process of the patent system.

In patent infringement cases, "venue"—the procedural rules governing in which federal district courts a plaintiff may properly file suit—has long been a subject of controversy. In 1897, the Congress passed a special statute, only two sentences long, that governed venue in patent infringement cases and, in the statute's second sentence, authorized federal service of process in patent cases. The venue sentence, now separately codified, is at 28 U.S.C. § 1400(b) and reads:

> Any civil action for patent infringement may be brought in the judicial district [i] where the defendant resides, or [ii] where the defendant has committed acts of infringement and has a regular and established place of business.

As the language of that statute makes clear, patent infringement actions may properly be brought in only two types of districts: [i] the district where the defendant's resides; and [ii] districts where the defendant has a "regular and established place of business" and has committed acts of infringement.

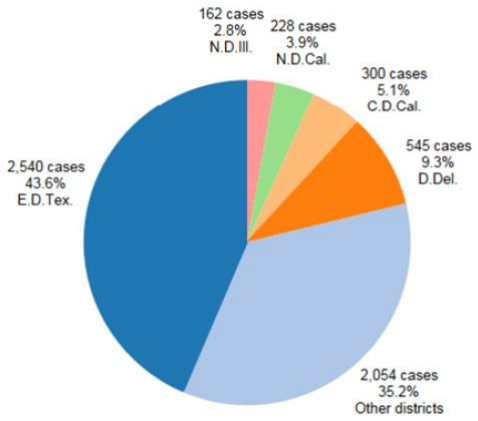
In 1942 and again in 1957, the Supreme Court held that the patent venue statute was the sole statute governing venue in patent infringement cases and that the statute should not be supplemented by provisions in general venue statutes. *See Stonite Products Co. v. Melvin Lloyd Co.*, 315 U.S. 561, 566 (1942) (holding that the patent venue statute "was intended to define the exact limits of venue in patent infringement suits" and that "Congress did not intend the [patent venue statute] to dovetail with the general provisions relating to the venue of civil suits, but rather that it alone should control venue in patent infringement proceedings"); *Fourco Glass Co. v. Transmirra Products Corp.*, 353 U.S. 222, 229 (1957) (holding that the patent venue statute "is the sole and exclusive provision controlling venue in patent infringement actions" and that "it is not to be supplemented by the provisions of" the general venue statute).

In 1990, after Congress enacted a slight wording change to the general venue statute, the Federal Circuit held that the patent venue statute now *could be supplemented* by the provisions of the general venue statute. *See VE Holding Corp. v. Johnson Gas Appliance Co.*, 917 F.2d 1574 (Fed. Cir. 1990). Specifically, the *VE Holding* court held that the concept of "where the defendant resides" in the patent venue statute could be supplemented by the definition of residence in the general venue statute, which provided that a corporate defendant "shall be deemed to reside in any judicial district in which it is subject to personal jurisdiction at the time the action is commenced." 28 U.S.C. § 1391(c) (1990). That result was particularly surprising because the issue in *VE Holding*—whether the corporate residence definition in § 1391(c) should define residence in the patent venue statute

(§ 1400(b))—was the exact same issue that the Supreme Court had decided the opposite way in its 1957 *Fourco* decision.

The Federal Circuit's holding in *VE Holding* effectively destroyed the defense of venue for all corporate defendants in patent infringement suits and rendered the patent venue statute a dead letter in almost all cases. Plaintiffs in patent infringement suits were free to sue corporate defendants in any district having personal jurisdiction, and that rule meant suit could usually be brought in almost every judicial district.

The Federal Circuit's *VE Holding* precedent soon led to a great deal of forum shopping by plaintiffs. Eventually, a few districts—most notably the Eastern District of Texas—became favorities for plaintiffs to bring their suits. By 2006, the Eastern District of Texas had captured about 9% of all patent infringement cases (even though it is only one of 94 federal judicial districts), and the *New York Times* ran a story entitled "So Small a Town, So Many Patent Suits" (available at http://www.nytimes.com/2006/09/24/business/24ward.html) that documented the extraordinary rise in patent filings in the district. By 2015, that district's share of patent litigation swelled to over 43% of all patent infringement cases in the country:



See Brian Howard, Lex Machina 2015 End-of-Year Trends Fig.3 (Jan. 7, 2016), available at http://www.lexmachina.com/lex-machina-2015-en.

In 2016, a party argued to the Federal Circuit that Supreme Court precedent should control the interpretation of the patent venue statute, but the court found the argument "to be utterly without merit or logic." *In re TC Heartland LLC*, 821 F.3d 1338, 1342 (Fed. Cir. 2016). The Supreme Court granted certiorari and unanimously reversed. *TC Heartland LLC v. Kraft Food Brands LLC*, 137 S. Ct. 1514 (2017). (Full disclosure: One coauthor of this casebook—Professor Duffy—served as counsel to TC Heartland, the losing party in the Federal Circuit and the prevailing party in the Supreme Court.)

Because of its prior precedents interpreting the patent venue statute, the Supreme Court viewed the case as turning on "whether Congress changed the meaning of [patent venue statute] when it amended [the general venue statute]." 137 S.Ct. at 1520. The Court reasoned that "[w]hen Congress intends to effect a change of that kind, it ordinarily provides a relatively clear indication of its intent in the text of the amended provision." *Id.* The Court concluded that "[t]he current version of § 1391 [the general venue statute] does not contain any indication that Congress intended to alter the meaning of § 1400(b) [the patent venue statute] as interpreted in *Fourco*." *Id.*

In sum, the Supreme Court seemed to see the issue as clear cut, even though the Federal Circuit had seen the issue as clear cut in the other direction for over a quarter century. Cases like *TC Heartland* will likely provide more fuel to the academic debate over the relationship between the Federal Circuit and the Supreme Court.

2. Practical Consequences and Open Questions. In addition to its academic significance, *TC Heartland* also has enormous practical consequences for litigators across the country, who now must pay attention to the patent venue statute that was viewed as a dead letter for more than two decades. Several important practical questions have arisen, including:

a. Did *TC Heartland* change the law? An objection to improper venue has to be raised at a very early stage in litigation or else the objection is waived. Because the patent venue statute had been interpreted so broadly under Federal Circuit precedent, many attorneys for defendants did not raise timely objections even though venue was improper under the older Supreme Court precedents. Lower court precedent on procedural default sometimes excuses a failure to make a timely objection if there is *a change in the law*. Thus, many attorneys who failed to make a proper objection to venue in patent infringement cases found themselves litigating a seemingly paradoxical question: Did *TC Heartland* change the law?

As a practical matter, the answer to that question may seem obvious: Of course, the Supreme Court's decision changed the law governing patent venue law in a major way—certainly that was the practical effect. On the other hand, the whole theory of the Supreme Court's *TC Heartland* opinion is that the 1957 *Fourco* decision had always been binding and that, as Justice Kagan commented in oral argument, the Federal Circuit had just "been ignoring [the Court's] decision."[2] To some extent, answering the question whether *TC Heartland* changed the law requires an answer to a philosophical question: Is the law how the courts were actually ruling for years or was the law really the "correct" view as eventually established by the Supreme Court?

District courts quickly split on the issue,[3] and the issue soon made its way to the Federal Circuit. The court in *In re Micron*, 875 F.3d 1091 (Fed. Cir. 2017), resolved the issue by siding with the district courts that had found a change in law. The *Micron* court first explained why, under the Federal Rules of Civil Procedure, the state of the law at the time the defendant should have objected to venue was important to deciding whether the defendant had waived the objection:

> [Federal] Rule [of Civil Procedure] 12(g)(2), in relevant part, states that "a party that makes a motion under this rule must not make another motion under this rule raising a defense or objection that was available to the party but omitted from its earlier motion." In particular, subject to one crucial condition, Rule 12(g)(2) covers a situation in which a defendant has made a Rule 12(b) motion to dismiss but omitted from that motion a venue objection under Rule 12(b)(3)—which is what Micron did in August 2016. The crucial condition for Rule 12(g)(2) to apply, and hence for the unmade venue objection to be waived

[2] Transcript of Oral Argument at 11 (statement of Justice Kagan) (https://www.supremecourt.gov/oral_arguments/argument_transcripts/2016/16-341_8njq.pdf).

[3] *See Westech Aerosol Corp. v. 3M Company*, 2017 U.S. Dist. LEXIS 95768 (W.D. Wash. June 21, 2017) (allowing a late challenge to patent venue on the grounds that *TC Heartland* was a "sea change" in the law of patent venue that could not have been "reasonably anticipated" by the defendant's counsel); *compare Cobalt Boats, LLC v. Sea Ray Boats, Inc*., 2017 U.S. Dist. LEXIS 90728 (E.D. Va. June 7, 2017) (refusing to allow a late challenge to venue because the Supreme Court's *Fourco* decision was always "binding law" and was "available to every defendant since 1957").

> under Rule 12(h)(1)(A), is that the venue defense had to be "available to the [defendant]" when the defendant made the initial Rule 12(b) motion.
>
> Accordingly, the Rule 12 waiver question presented here is whether the venue defense was "available" to Micron in August 2016. We conclude as a matter of law that it was not.

875 F.3d at 1096.

The court then explained that the venue defense was "unavailable" because the Federal Circuit's precedent in *VE Holding* would have precluded the defense:

> [I]f *V.E. Holding* is taken as a binding precedent, [it] would plainly have barred the district court from adopting a venue objection had Micron made one before the Supreme Court decided *TC Heartland*. The 1957 *Fourco* decision had not (and could not have) addressed the post-1988 versions of § 1391(c), and no intervening Supreme Court decision had undermined *V.E. Holding* before the Court decided *TC Heartland*. The *V.E. Holding* precedent, applied to the 2011 version of § 1391(c), therefore precluded the district court in this case from finding venue improper until the Court decided *TC Heartland*. …
>
> The Supreme Court changed the controlling law when it decided *TC Heartland* in May 2017. The Court observed that Congress "has amended § 1391 twice" since *Fourco*, 137 S. Ct. at 1517, and the Court described both the 1988 and 2011 amendments, *id.* at 1519–20. The Court then encompassed both amendments within its statement of its holding: "We conclude that the amendments to § 1391 did not modify the meaning of § 1400(b) as interpreted by *Fourco*." *Id.* at 1517. Similarly, the Court did not distinguish the two amendments when, having stated the *Fourco*-declared meaning of § 1400(b), it said that "the only question [it] must answer is whether Congress changed the meaning of § 1400(b) when it amended § 1391." *Id.* at 1520. The answer was no. *Id.* at 1520–21. The Court thus clearly (if not quite expressly) rejected *V.E. Holding* and concluded that the definition of "resides" in § 1391(c) does not apply to § 1400(b).
>
> That change of law, by severing § 1400(b) from § 1391(c), made available to Micron in this case the objection that it does not come within the meaning of "resides" for purposes of venue under § 1400(b). That position was not available for the district court to adopt before the Court decided *TC Heartland*, because controlling precedent precluded adoption of the position. For that reason, the objection was not "available" under Rule 12(g)(2) when Micron made its motion to dismiss in 2016. Accordingly, contrary to the district court's conclusion, Rule 12(h)(1)(A)'s waiver rule is inapplicable here.

875 F.3d at 1099-1100.

Though the court's conclusion helped patent infringement defendants to escape Rule 12(h)(1)(A)'s *per se* waiver rule, the Federal Circuit's decision was not entirely favorable to tardy defendants. The court held that district courts possess "inherent power" outside of Rule 12(h)(1)(A) "to find forfeiture of a venue objection" that comes too late. *Id.* at 1101. While the court refused to define with specificity all of the circumstances that might justify such an inherent power to find waiver, the court suggested that district courts could consider not only "the sheer time from when the defense becomes available to when it is asserted," but also "factors such as how near is the trial."[4]

[4] *Id.* at 1102.

The court noted that, even after the Supreme Court's *TC Heartland* decision, it had "denied mandamus, finding no clear abuse of discretion, in several cases involving venue objections based on *TC Heartland* that were presented close to trial." *Id*.

The end result is sensible: Tardy defendants *may* be able to escape a procedural default due to a change in the law, but there's no guarantee. It's still better to raise defenses, even those that may conflict with Federal Circuit precedent, in a timely fashion.

The larger lesson here is that attorneys rely on the solidity of Federal Circuit precedent at their peril. Now that the Supreme Court is frequently reviewing Federal Circuit decisions, counsel must be aware of the extent to which Federal Circuit precedent might conflict with Supreme Court case law. Otherwise, counsel could miss out on objections later shown to be as meritorious and will be in the unenviable position of explaining to clients why a timely objection was not raised.

b. Where does a defendant company reside if a state has multiple districts? In the past, the answer to this question was relatively clear: The defendant company resided at the address shown in its articles of incorporation as its legal address within the state (its exact place of incorporation), and thus was a resident of the federal judicial district containing that location. 15 Wright, Miller and Cooper, Jurisdiction and Related Matters § 3823, at 222 (2nd 1986) (opining that, under the patent venue statute, "[a] corporation resides at the place of incorporation").

After *TC Heartland*, however, the Eastern District of Texas opined that corporations should be treated as resident in *every district* within their state of incorporation. *See Diem LLC v. BigCommerce, Inc.*, 2017 U.S. Dist. LEXIS 117602 (E.D. Tex. 2017). Under that view, every Texas corporation would be viewed as residing in the E.D. of Texas, even if it has no operations there whatsoever.

That decision was, however, swiftly overturned by the Federal Circuit. *See In re BigCommerce, Inc*., 890 F.3d 978 (Fed. Cir. 2018). The Federal Circuit did, however, modify the traditional approach—it held that a corporation would be deemed to reside "only in the single judicial district within that state where it maintains a principal place of business, or, failing that, the judicial district in which its registered office is located." *Id.* at 986. In most cases, the Federal Circuit's modification of the traditional rule is not likely to make a difference, as the corporation's legal address on its articles of incorporation typically is the corporation's principal place of business, if that is located in the state. The most important part of the Federal Circuit's ruling is its restoration of the rule that a corporation could reside, for purposes of patent venue, only in a single judicial district.

c. In which districts can non-resident defendants be sued? A defendant not resident in a particular district will be subject to suit in the district only if "the defendant [*a*] has committed acts of infringement and [*b*] has a regular and established place of business" in the district.

The first requirement (labeled "*a*" above) is that the defendant have committed acts of infringement "in" the district. In many instances, it is easy to determine the location of infringement—e.g., where a manufacturing plant produces an infringing product at a particular location or where a retail store sells an infringing product to a customer. In other instances, it can be difficult to define the location of infringement. For example, if a computer process is patented, some steps in the process may occur in one judicial district while others occur on the other side of the country. If all steps of a process have to occur within the judicial district, there may be no district in which the infringement occurs (this problem is analogous to the so-called divided infringement studied in Chapter 8.B.4). Induced or contributory infringement presents another issue: If a potential

defendant takes actions *outside* the district inducing others to infringe *inside* the district, it would seem that the defendant has not committed acts of infringement "in" the district even though the induced parties have.

The second requirement is that the defendant needs to have a regular and established place of business in the district. Note first that this requirement is textually decoupled from the "acts of infringement" analysis. Thus, if a defendant commits no acts of infringement at its regular and established place of business but does infringe at another location in the district (e.g., at a trade show), the defendant should be subject to suit in the district.

What constitutes a "regular" and "established" place of business? The controversies usually center around employees—often salespeople—who work out of their homes. Circuit court case law is split, with pre-*TC Heartland* Federal Circuit precedent taking a more pro-patentee position than the regional circuits. *See Grantham v. ChallengeCook Bros., Inc*., 420 F.2d 1182 (7th Cir. 1969) (holding employee's home office is not a regular and established place of business); *American Cyanamid Co. v. Nopco Chem. Co*., 388 F.2d 818 (4th 1968) (also holding home office is not a regular and established place of business even though the home office contained company brochures, invoices and communications); *compare In re Cordis Corp.*, 769 F.2d 733 (Fed. Cir. 1985) (holding a home office is a regular and established place of business where the home contained company sales literature, copies of communications and the company's products).

Shortly after the decision in *TC Heartland*, the Eastern District of Texas issued an opinion broadly defining the concept of "regular and established place of business" so that many home offices would qualify (and thus preserving for the E.D. Tex. a bigger share of patent litigation than it would have under a narrower definition). *See Raytheon Co. v. Cray, Inc.*, 2017 U.S. Dist. LEXIS 100887 (June 29, 2017 E.D. Tex.). That decision drew significant criticism, including a comment from Rep. Darrell Issa (R-Cal.) that the court was essentially "reject[ing] the Supreme Court's unanimous decision." *See https://arstechnica.com/tech-policy/2017/07/will-east-texas-be-able-to-keep-patent-cases-despite-the-supreme-court/*.

In *In re Cray Inc*., 871 F.3d 1355 (Fed. Cir. 2017), the Federal Circuit reversed the district court and embraced a much more limited view that excludes many home offices:

> The statutory language we need to interpret is "where the defendant ... has a regular and established place of business." 28 U.S.C. § 1400(b). The noun in this phrase is "place," and "regular" and "established" are adjectives modifying the noun "place." The following words, "of business," indicate the nature and purpose of the "place," and the preceding words, "the defendant," indicate that it must be that of the defendant. Thus, § 1400(b) requires that "a defendant has" a "place of business" that is "regular" and "established." All of these requirements must be present. The district court's four-factor test is not sufficiently tethered to this statutory language and thus it fails to inform each of the necessary requirements of the statute.
>
> In deciding whether a defendant has a regular and established place of business in a district, no precise rule has been laid down and each case depends on its own facts. The "requirements" listed above and discussed below inform whether there exist the necessary elements, but do not supplant the statutory language. We stress that the analysis must be closely tied to the language of the statute.
>
> As noted above, when determining venue, the first requirement is that there "must be a physical place in the district." The district court erred as a matter of law in holding that "a

fixed physical location in the district is not a prerequisite to proper venue." Transfer Order, 258 F.Supp.3d at 795. This interpretation impermissibly expands the statute. The statute requires a "place," *i.e.*, "[a] building or a part of a building set apart for any purpose" or "quarters of any kind" from which business is conducted. William Dwight Whitney, The Century Dictionary, 732 (Benjamin E. Smith, ed. 1911); *see also Place*, Black's Law Dictionary (1st ed. 1891) (defining place as a "locality, limited by boundaries"). The statute thus cannot be read to refer merely to a virtual space or to electronic communications from one person to another. But such "places" would seemingly be authorized under the district court's test.

While the "place" need not be a "fixed physical presence in the sense of a formal office or store," *Cordis*, 769 F.2d at 737, there must still be a physical, geographical location in the district from which the business of the defendant is carried out. …

The second requirement for determining venue is that the place "must be a regular and established place of business." The district court's test fails to recognize that the place of business must be "regular." A business may be "regular," for example, if it operates in a "steady[,] uniform[,] orderly [, and] methodical" manner, Whitney, *supra*, at 5050. In other words, sporadic activity cannot create venue. *See Phillips v. Baker*, 121 F.2d 752, 756 (9th Cir. 1941) ("A 'regular place of business' is, obviously, a place where such business is carried on 'regularly' and not merely temporarily, or for some special work or particular transaction." (quoting *Winterbottom v. Casey*, 283 F. 518, 521 (E.D. Mich. 1922))). Indeed, "[t]he doing of a single act pertaining to a particular business will not be considered engaging in or carrying on the business; yet a series of such acts would be so considered." *Regular*, Black's Law Dictionary (1st ed. 1891).

The "established" limitation bolsters this conclusion. The word contains the root "stable," indicating that the place of business is not transient. It directs that the place in question must be "settle[d] certainly, or fix[ed] permanently." *Establish*, Black's Law Dictionary (1st ed. 1891). To make "permanent" clearly accords with the "main purpose" identified in the predecessor statute's legislative history. *See* 29 Cong. Rec. 1900 (1987) (statement of Rep. Lacey). Indeed, court decisions have stressed the importance of sufficient permanence. *See, e.g.*, *Phillips*, 121 F.2d at 756 (explaining that where the defendant's "establishment [in the district] was just a location for a particular transaction," "the necessary element of permanency is lacking" (internal quotation marks omitted)). …

Accordingly, while a business can certainly move its location, it must for a meaningful time period be stable, established. On the other hand, if an employee can move his or her home out of the district at his or her own instigation, without the approval of the defendant, that would cut against the employee's home being considered a place of business of the defendant.

Finally, the third requirement when determining venue is that "the regular and established place of business" must be "the place of the defendant." As the statute indicates, it must be a place *of the defendant*, not solely a place of the defendant's employee. Employees change jobs. Thus, the defendant must establish or ratify the place of business. It is not enough that the employee does so on his or her own.

871 F.3d at 1362-63.

The Federal Circuit holding in *Clay* seems correct, and perhaps more importantly, it shows that the appellate court appears to be trying rather faithfully to implement the Court's ruling in *TC Heartland*.

Chap. 10.C.1. Adversarial Administrative Review.

Add the following new note to Chapter 10.C.1, page 947:

NOTES ON NEW DEVELOPMENTS IN *INTER PARTES* REVIEW

In 2018 and 2019, five significant developments occurred concerning *inter partes* review, three at the Supreme Court, one at the PTO and one at the Federal Circuit. Each are covered in the notes below.

1. *Inter Partes* Review Does Not Violate Article III of the Constitution. One of the most watched patent case in recent years was *Oil States Energy Servs., LLC v. Greene's Energy Grp.,* 138 S. Ct. 1365 (2018), in which the Supreme Court was presented with a constitutional challenge to the entire structure of the administrative review. The Petitioner in the case, Oil States Energy Services, argued that once the PTO issues a patent, the validity of the issued patent cannot be challenged in an administrative forum, or at least it cannot be challenged administratively without the consent of the patentee. As the Petitioner framed it, the question presented in the case was:

> Whether inter partes review, an adversarial process used by the Patent and Trademark Office (PTO) to analyze the validity of existing patents, violates the Constitution by extinguishing private property rights through a non-Article III forum without a jury.

By a 7-2 vote, the Court rejected the constitutional challenge. Writing for the Court, Justice Thomas had to determine whether Article III courts have the exclusive power to decide the validity of issued patents:

> Article III vests the judicial power of the United States "in one supreme Court, and in such inferior Courts as the Congress may from time to time ordain and establish." §1. Consequently, Congress cannot "confer the Government's 'judicial Power' on entities outside Article III." *Stern* v. *Marshall*, 564 U. S. 462, 484 (2011). When determining whether a proceeding involves an exercise of Article III judicial power, this Court's precedents have distinguished between "public rights" and "private rights." *Executive Benefits Ins. Agency* v. *Arkison*, 573 U. S. ___, ___ (2014) (internal quotation marks omitted). Those precedents have given Congress significant latitude to assign adjudication of public rights to entities other than Article III courts. See *ibid.*; *Stern*, *supra*, at 488-492.
>
> This Court has not "definitively explained" the distinction between public and private rights, *Northern Pipeline Constr. Co.* v. *Marathon Pipe Line Co.*, 458 U. S. 50, 69 (1982), and its precedents applying the public-rights doctrine have "not been entirely consistent," *Stern*, 564 U. S., at 488. But this case does not require us to add to the "various formulations" of the public-rights doctrine. *Ibid*. Our precedents have recognized that the doctrine covers matters "which arise between the Government and persons subject to its authority in connection with the performance of the constitutional functions of the executive or legislative departments." *Crowell* v. *Benson*, 285 U. S. 22, 50 (1932). In other words, the public-rights doctrine applies to matters "'arising between the government and others, which from their nature do not require judicial determination and yet are susceptible of it.'" *Ibid.* (quoting *Ex parte Bakelite Corp.*, 279 U. S. 438, 451 (1929)). Inter partes

review involves one such matter: reconsideration of the Government's decision to grant a public franchise.

A

Inter partes review falls squarely within the public-rights doctrine. This Court has recognized, and the parties do not dispute, that the decision to *grant* a patent is a matter involving public rights—specifically, the grant of a public franchise. Inter partes review is simply a reconsideration of that grant, and Congress has permissibly reserved the PTO's authority to conduct that reconsideration. Thus, the PTO can do so without violating Article III.

1

This Court has long recognized that the grant of a patent is a "'matte[r] involving public rights.'" *United States* v. *Duell*, 172 U. S. 576, 582-583 (1899) (quoting *Murray's Lessee* v. *Hoboken Land & Improvement Co.*, 59 U.S. 272, 284 (1856)). It has the key features to fall within this Court's longstanding formulation of the public-rights doctrine.

Ab initio, the grant of a patent involves a matter "arising between the government and others." *Ex parte Bakelite Corp.*, *supra*, at 451. As this Court has long recognized, the grant of a patent is a matter between "'the public, who are the grantors, and . . . the patentee.'" *Duell*, *supra*, at 586 (quoting *Butterworth* v. *United States ex rel. Hoe*, 112 U. S. 50, 59 (1884)). By "issuing patents," the PTO "take[s] from the public rights of immense value, and bestow[s] them upon the patentee." *United States* v. *American Bell Telephone Co.*, 128 U. S. 315, 370 (1888). Specifically, patents are "public franchises" that the Government grants "to the inventors of new and useful improvements." *Seymour* v. *Osborne*, 78 U.S. 516, 533 (1871); accord, *Pfaff* v. *Wells Electronics, Inc.*, 525 U. S. 55, 63-64 (1998). The franchise gives the patent owner "the right to exclude others from making, using, offering for sale, or selling the invention throughout the United States." 35 U. S. C. §154(a)(1). That right "did not exist at common law." *Gayler* v. *Wilder*, 51 U.S. 477, 494 (1851). Rather, it is a "creature of statute law." *Crown Die & Tool Co.* v. *Nye Tool & Machine Works*, 261 U. S. 24, 40 (1923).

Additionally, granting patents is one of "the constitutional functions" that can be carried out by "the executive or legislative departments" without "'judicial determination.'" *Crowell*, *supra*, at 50-51 (quoting *Ex parte Bakelite Corp.*, *supra*, at 452). Article I gives Congress the power "[t]o promote the Progress of Science and useful Arts, by securing for limited Times to Authors and Inventors the exclusive Right to their respective Writings and Discoveries." §8, cl. 8. Congress can grant patents itself by statute. See, *e.g.*, *Bloomer* v. *McQuewan*, 55 U.S. 539, 548-550 (1853). And, from the founding to today, Congress has authorized the Executive Branch to grant patents that meet the statutory requirements for patentability. See 35 U. S. C. §§2(a)(1), 151; see also Act of July 8, 1870, §31, 16 Stat. 202; Act of July 4, 1836, §7, 5 Stat. 119-120; Act of Apr. 10, 1790, ch. 7, §1, 1 Stat. 109-110. When the PTO "adjudicate[s] the patentability of inventions," it is "exercising the executive power." *Freytag* v. *Commissioner*, 501 U. S. 868, 910 (1991) (Scalia, J., concurring in part and concurring in judgment) (emphasis deleted).

Accordingly, the determination to grant a patent is a "matte[r] involving public rights." *Murray's Lessee*, *supra*, at 284. It need not be adjudicated in Article III court.

> Inter partes review involves the same basic matter as the grant of a patent. So it, too, falls on the public-rights side of the line.
>
> Inter partes review is "a second look at an earlier administrative grant of a patent." *Cuozzo*, 579 U. S., at ___. The Board considers the same statutory requirements that the PTO considered when granting the patent. See 35 U. S. C. §311(b). Those statutory requirements prevent the "issuance of patents whose effects are to remove existent knowledge from the public domain." *Graham* v. *John Deere Co. of Kansas City*, 383 U. S. 1, 6 (1966). So, like the PTO's initial review, the Board's inter partes review protects "the public's paramount interest in seeing that patent monopolies are kept within their legitimate scope," *Cuozzo, supra*, at ___ (internal quotation marks and alterations omitted). Thus, inter partes review involves the same interests as the determination to grant a patent in the first instance. See *Duell*, *supra*, at 586.
>
> The primary distinction between inter partes review and the initial grant of a patent is that inter partes review occurs *after* the patent has issued. But that distinction does not make a difference here. Patent claims are granted subject to the qualification that the PTO has "the authority to reexamine—and perhaps cancel—a patent claim" in an inter partes review. See *Cuozzo, supra*, at ___. Patents thus remain "subject to [the Board's] authority" to cancel outside of an Article III court. *Crowell*, 285 U. S., at 50.
>
> This Court has recognized that franchises can be qualified in this manner. For example, Congress can grant a franchise that permits a company to erect a toll bridge, but qualify the grant by reserving its authority to revoke or amend the franchise. See, *e.g., Louisville Bridge Co.* v. *United States*, 242 U. S. 409, 421 (1917) (collecting cases). Even after the bridge is built, the Government can exercise its reserved authority through legislation or an administrative proceeding. See, *e.g., id.,* at 420-421; *Hannibal Bridge Co.* v. *United States*, 221 U. S. 194, 205 (1911); *Bridge Co.* v. *United States*, 105 U. S. 470, 478-482 (1882). The same is true for franchises that permit companies to build railroads or telegraph lines. See, *e.g., United States* v. *Union Pacific R. Co.*, 160 U. S. 1, 24-25, 37-38 (1895).
>
> Thus, the public-rights doctrine covers the matter resolved in inter partes review. The Constitution does not prohibit the Board from resolving it outside of an Article III court.

The Court's characterization of patents as public franchises may seem to demote patents to a status below constitutionally protected property rights. The Court, however, cautioned that its "decision should not be misconstrued as suggesting that patents are not property for purposes of the Due Process Clause or the Takings Clause." Would it be inconsistent for the Court to hold that patents are constitutionally protected property even though the grant is a "public franchise"? Note that, under the Court's current precedent, statutory benefits such as welfare benefits are protected under the Due Process Clause even though such benefits are not traditional property. *See* Goldberg v. Kelly, 397 U.S. 254 (1970).

2. Ending Partial Grants of *Inter Partes* Review. While the *Oil States* case was the most momentous Supreme Court patent decision of the year, the Court's ruling in *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348 (2018), might have much greater practical implications. Prior to *SAS*, the PTO believed that it had discretion to grant *inter partes* review in part—in other words, it could

grant review limited to assessing the validity of only some of the claims challenged by the Petitioner.

SAS Institute—a statistical software company—filed a petition for *inter partes* review challenging 16 claims in a patent owned by ComplementSoft. The PTO's Patent Trial and Appeal Board (the PTAB) instituted review on 9 claims but declined to institute on the other 7 challenged claims. After winning invalidation of most of the 9 claims on which the PTAB instituted review, SAS continued to press its view that, once the agency institutes *inter partes* review, the PTAB is statutorily required to decide the validity of all claims challenged in the petition.

The Federal Circuit rejected SAS's argument, but a five-Justice majority of the Supreme Court reversed. Writing for the Court, Justice Gorsuch summed up the Court's holding succinctly:

> When the Patent Office initiates an inter partes review, must it resolve *all* of the claims in the case, or may it choose to limit its review to only *some* of them? The statute, we find, supplies a clear answer: the Patent Office must "issue a final written decision with respect to the patentability of *any* patent claim challenged by the petitioner." 35 U. S. C. §318(a) (emphasis added). In this context, as in so many others, "any" means "every." The agency cannot curate the claims at issue but must decide them all.

138 S.Ct. at 1352-53.

While the *SAS* decision was a win for a particular party challenging the validity of an issued patent, the future effect of the decision may not be entirely favorable to patent challengers. The Court's decision gives the PTO an all-or-nothing choice in deciding whether to grant *inter partes* review. Sometimes the agency might choose nothing—i.e., to deny review entirely—rather than to be forced into granting review over all challenged claims.

Moreover, if the PTAB does not want to grant review of particular patent claims because it believes the challenges to those claims are weak, is the challenger really better off forcing the PTAB to decide the validity of such claims? Might the PTAB be likely to sustain such claims? Wouldn't the challenger be better off adjudicating the validity of such claims in a district court that might have a different view about the validity of the claims? Or is it the case that the PTAB is still the best forum for a party challenging the validity of any patent claim because the PTAB, unlike a court, does not afford the issued patent claims any presumption of validity?

3. The United States and Its Agencies Cannot Seek IPR. A third development at the Supreme Court came in *Return Mail, Inc. v. United States Postal Service*, 139 S.Ct. 1853 (2019). It is quite a bit less significant than the first two developments covered above.

The statute authorizing IPRs allows any "person who is not the [patent] owner" to file a petition seeking IPR. 35 U.S.C. § 311(a). A nonlawyer might thus reasonably think that any legal "person" could seek to initiate an IPR, with the sole exception being the owner of the patent. Interpreting statutes can, however, be a tricky business, for the law often contains presumptions about how words should be interpreted in special circumstances. One such presumption is that "'[i]n the absence of an express statutory definition, [the word] "person" [is presumed] not [to] include the sovereign,' and thus excludes a federal agency like the Postal Service." *Return Mail*, 139 S.Ct. at 1861-62 (quoting *Vermont Agency of Natural Resources v. United States ex rel. Stevens*, 529 U. S. 765, 780–781(2000)).

The Court recognized that the presumption excluding the sovereign from the meaning of "person" could be overcome if the statutory "context indicates otherwise," *id.*, at 1863, but the Court did not find sufficient statutory indicia in the AIA to overcome the presumption. The Court did not find any "oddity" in excluding federal agencies from the ability to seek IPR because such agencies enjoy special limits on their liability for patent infringement:

> Most notably, [28 U.S.C.] § 1498 restricts a patent owner who sues the Government to her "reasonable and entire compensation" for the Government's infringing use; she cannot seek an injunction, demand a jury trial, or ask for punitive damages, all of which are available in infringement suits against nongovernmental actors under § 271(e)(4). Thus, although federal agencies remain subject to damages for impermissible uses, they do not face the threat of preliminary injunctive relief that could suddenly halt their use of a patented invention, and they enjoy a degree of certainty about the extent of their potential liability that ordinary accused infringers do not.

139 S.Ct. at 1867.

4. Ending the Broadest Reasonable Interpretation of Patent Claims in Post-Issuance Proceedings. As mentioned in the 7th edition of the casebook (pp. 846-47), the Supreme Court's decision in *Cuozzo* made clear that the PTO has the legal authority to accept or reject policy arguments in favor of changing its rule requiring claims challenged in post-issuance proceedings to be given their broadest reasonable interpretation (BRI). The casebook speculated that a new Administration would be "free to reconsider this issue."

The PTO is now under new administration and, on May 9, 2018, new Director Andrei Iancu published a notice proposing to eliminate BRI in each of the three post-issuance proceedings authorized in the America Invents Act (*inter partes* review, post grant review, and review for covered business methods). Under the proposed new rule, claims challenged in those three post-issuance proceedings would "be construed using the same claim construction standard that would be used to construe such claim in a civil action to invalidate a patent …." The notice proposing the rule change explained:

> [A]lthough the BRI standard is consistent with longstanding agency practice, the fact that the Office uses a claim construction standard that is different from that used by federal district courts and the ITC means that decisions construing the same or similar claims in those fora may be different from those in AIA trial proceedings and vice versa. Minimizing differences between claim construction standards used in the various fora could lead to greater uniformity and predictability of the patent grant. …
>
> Having AIA trial proceedings use the same claim construction standard that is applied in federal district courts and ITC proceedings also addresses the concern that potential unfairness could result from using an arguably broader standard in AIA trial proceedings. According to some patent owners, the same claim construction standard should apply to both validity (or patentability) determination and infringement determination. Because the BRI standard potentially reads on a broader universe of prior art than does the [standard applied in court], a patent claim could be found unpatentable in an AIA trial on account of claim scope that the patent owner would not be able to assert in an infringement proceeding.

83 Fed. Reg. 21221, 21222-23 (2018). The agency finalized the rule on October 11, 2018. *See Changes to the Claim Construction Standard for Interpreting Claims in Trial Proceedings Before*

the Patent Trial and Appeal Board, 83 Fed. Reg. 51,340 (2019) (amending 37 CFR § 42.100(b)). The final text of the rule is:

> [§ 42.100](b) In an inter partes review proceeding, a claim of a patent, or a claim proposed in a motion to amend under § 42.121, shall be construed using the same claim construction standard that would be used to construe the claim in a civil action under 35 U.S.C. 282(b), including construing the claim in accordance with the ordinary and customary meaning of such claim as understood by one of ordinary skill in the art and the prosecution history pertaining to the patent. Any prior claim construction determination concerning a term of the claim in a civil action, or a proceeding before the International Trade Commission, that is timely made of record in the inter partes review proceeding will be considered.

Parallel rules apply ordinary principles of claim construction to the other two post-issuance adversarial proceedings created by the AIA. *See* 37 CFR § 42.200(b) (the rule for post-grant review) & § 42.300(b) (the rule for covered business method review proceedings).

5. Standing to Seek Review of Agency Decisions. As previously mentioned, any "person" other than the patent owner (and, in light of the *Return Mail* decision, other than a federal agency) can seek to initiate an IPR and, if the agency agrees to initiate, can participate in the adversarial IPR proceedings at the agency. If the PTAB invalidates the patent, then the patent owner can seek judicial review of the agency's decision in the Federal Circuit. If the PTAB sustains the validity of the patent, however, the person challenging the patent—known as the IPR "petitioner"—might not be able to seek judicial review. What accounts for that asymmetry?

The answer lies in the constitutional doctrine of "Article III standing," or simply "standing." To initiate litigation in a federal court, a person must have standing to do so. Under current Supreme Court precedent, such standing exists if (i) the party has an "injury in fact" that is concrete, particularized and imminent, not conjectural or hypothetical; (ii) there is a causal connection between the injury and the challenged conduct of the defendant; and (iii) the injury is likely to be redressed by a favorable decision. *See Lujan v. Defenders of Wildlife*, 504 US 555, 560-61 (1992). In a string of recent decisions, the Federal Circuit has found a variety of parties to lack the requisite "injury in fact" that would support Article III standing. The result in such cases is that the agency's decision stands and the attempt to seek judicial review is dismissed for want of jurisdiction.

It should be emphasized, of course, that most parties seeking review of adverse PTAB decisions *do* have standing. All patent owners who are seeking to defend their patent rights have standing; they can plead as their "injury in fact" the imminent loss of the property rights if the adverse PTAB decision stands. Also, many IPR challengers are simultaneously defendants in patent infringement litigation; they too have an obvious "injury in fact" if the PTAB decision adverse to them is affirmed: They will have to continue defend themselves against charges of infringing the patent claims that they unsuccessfully challenged in the IPR process.

On the other hand, some parties lack any demonstrable injury. For example, in *RPX Corp. v. Chanbond LLC*, 780 Fed. Appx. 866 (Fed. Cir. 2018) (unpublished), the court denied standing to the RPX corporation, which described to the court its "core business" as being "acquiring patent rights on the open market and in litigation to achieve peaceful resolution of patent disputes through rationally negotiated transactions." *Id.* at 867. RPX also, however, challenges "weak patents" through the IPR process as a means of gaining "enhanced reputational goodwill generated by its successful IPR challenges." *Id.* RPX conceded, however, that it "typically realizes no direct monetary benefit" through its IPRs. *Id.* The corporation also did not claim to be a consumer of the

technologies covered in the challenged patents, nor did it claim to be potential competitor of the patentee in the technology covered by the patent. Thus, the Federal Circuit rejected RPX's claim to standing, holding that RPX's general claims about the reputational harm it was suffering from the adverse IPR decision were "insufficient evidence [to demonstrate] a concrete and particularized harm." *Id.* at 869.

While *RPX* appears to be an easy (and correct) decision, more recent decisions are more controversial. In decisions such as *General Electric Company v. United Technologies Corporation*, 928 F.3d 1349 (Fed. Cir. 2019), *AVX Corp. v. Presidio Components, Inc.*, 923 F.3d 1357 (Fed. Cir. 2019), and *JTEKT Corp. v. GKN Automotive Ltd*., 898 F.3d 1217 (Fed. Cir. 2018), the Federal Circuit has denied standing to *competitors* of the patentee even though the agency's decision to sustain the patent rights of one firm in a particular field of technology would seem to reduce the freedom of the other firms to compete in the field. The Federal Circuit has explained this line of decisions on the grounds that the appellants in the cases "lacked Article III standing because [they] had 'no present or nonspeculative interest in engaging in conduct even arguably covered by the patent claims at issue.'" *General Electric*, 928 F.3d at 1354 (quoting *AVX*, 923 F.3d at 1363).

A patent's power to constrain competitors' ability to "engag[e] in conduct" covered by the patent claims is surely one sort of concrete injury that can generate standing for party challenging the patent, but aren't there others too? For example, suppose a jet-engine manufacturer like General Electric alleges as its injury the costs of paying its lawyers to interpret the patent claims so that its engineers can then design around the patent's claims. Aren't such "design-around" costs another type of injury? And if so, wouldn't invaliding the patent remedy the injury? Note that a firm could suffer "design-around" costs in trying to avoid a patented technology even if it has "no present or nonspeculative interest in engaging in conduct even arguably covered by the patent claims at issue." *AVX*, 923 F.3d at 1363.

One last important point about standing: The burden to produce evidence establishing standing is always on the party seeking to invoke federal court jurisdiction. That seemingly minor procedural point can loom large because many attorneys seeking to "appeal" an adverse PTAB decision to the Federal Circuit may wrongly view the Federal Circuit as exercising something like an appellate function over the PTAB. In fact, however, the Federal Circuit in such circumstances is a court of "first instance"—the Federal Circuit in such cases is more akin to a federal district court because it is the first Article III court in which the matter is being adjudicated. If there is any question about standing, the circuit court must receive evidence about the issue, and of course, the attorneys for the party seeking review of the PTAB decision must have affidavits and other evidence at hand to demonstrate standing.

In concrete terms, consider the "design-around" costs discussed in the earlier paragraph. What should the Federal Circuit do if a party seeking to challenge a patent *could have demonstrated*, but did not in fact demonstrate, that it was suffering from such "design-around" costs? The right answer is that the Court should deny standing because the party seeking to invoke Article III jurisdiction failed to meet its burden of proof.

6. No Judicial Review of PTO Decisions to Institute IPRs. Section 314(d) of the Patent Act provides that any PTO decision "whether to institute an inter partes review under this section shall be final and nonappealable." In the 2016 case of *Cuozzo Speed Technologies v. Lee*, the Supreme Court interpreted Section 314(d) as providing the agency some degree of unreviewable discretion concerning IPR-institution decisions. But then in *SAS Institute, Inc. v. Iancu*, 138 S. Ct. 1348 (2018) (discussed above), the Court did review—and hold unlawful—the PTO's decision to grant *partial* review in IPRs (granting review as to some challenges while denying review on

others). Those two cases left uncertain the exact scope of the § 314(d)'s bar against courts' ability to review the PTO's decisions to institute an IPR.

In *Thryv Inc. v. Click-To-Call Techs., LP*, 140 S. Ct. 1367 (2020), the Court clarified the scope of § 314(d) by giving the section a broad sweep. The underlying issue in the case was whether the PTO instituted an IPR in violation of a rule found in § 315(b) of the Patent Act, which forbids instituting an IPR if the petition for the IPR is "filed more than 1 year after the date on which the petitioner [or a predecessor in interest] was served with a complaint alleging infringement of the patent." The predecessor in interest to IPR petitioner in *Thryv* was served with an infringement complaint in 2001 and the IPR petition was not filed until 2013—more than decade too late for lawfully instituting an IPR. Nonetheless, the PTO did institute an IPR and eventually held the patent invalid. On appeal, the patentee argued that the institution of the IPR was illegal and that the court could review enforce the one-year time bar found in § 315(b) because § 314(d)'s prohibition of judicial review foreclosed judicial review only of PTO decisions made "under this section"—i.e., decisions made under *§ 314*, not agency's incorrect decision about the one-year time bar in *§ 315*. The Federal Circuit agreed that the issue was subject to judicial review and vacated the results of the IPR.

At the Supreme Court, the PTO argued that its decision to institute the IPR was contrary to law but nonetheless argued that the result of the IPR should stand because § 314(d) broadly precluded any judicial review of the PTO's institution decisions. The Court majority agreed with the agency:

> Because §315(b) expressly governs institution and nothing more, a contention that a petition fails under §315(b) is a contention that the agency should have refused "to institute an inter partes review." §314(d). A challenge to a petition's timeliness under §315(b) thus raises "an ordinary dispute about the application of " an institution-related statute. *Cuozzo*, 579 U. S., at ___. In this case as in *Cuozzo*, therefore, §314(d) overcomes the presumption favoring judicial review.

140 S.Ct. at 1373-74. The end result is quite simple to state: The preclusion of review in § 314(d) will be interpreted broadly and therefore PTO decisions to institute an IPR are essentially immune from judicial review.

7. Are Administrative Patent Judges Unconstitutional … Again? In 2007, one of this casebook's authors published a short paper on a popular blog asserting that Administrative Patent Judges were unconstitutionally appointed. *See* John F. Duffy, *Are Administrative Patent Judges Constitutional?*, 2007 Patently—O Patent L.J. 21, 25 (2007), *revised and reprinted in* 77 G.W. L. Rev. 904 (2009). The basic argument was that (i) administrative patent judges exercised significant authority under the laws of the United States and thus had to be counted as "Officers" for purposed of the Constitution's Appointments Clause (art. II, § 2, cl. 2); (ii) the Appointments Clause permits officers to be appointed in only four ways (by the President with the advice and consent of the Senate; by the President alone; by a Head of Department; or by the Courts of Law); and (iii) the then-existing appointment system for administrative patent judges—appointment by the Director of the PTO, who is an Assistant Secretary of Commerce and thus clearly not a Head of Department—was constitutionally impermissible.

That short piece generated significant media coverage, *see, e.g.*, Adam Liptak, *In One Flaw, Questions on Validity of 46 Judges*, N.Y. Times, May 6, 2008, at A18, available at http://www.nytimes.com/2008/05/06/washington/06bar.html, and eventually led to legislation changing the appointment process for administrative patent judges. The new legislation lodged the

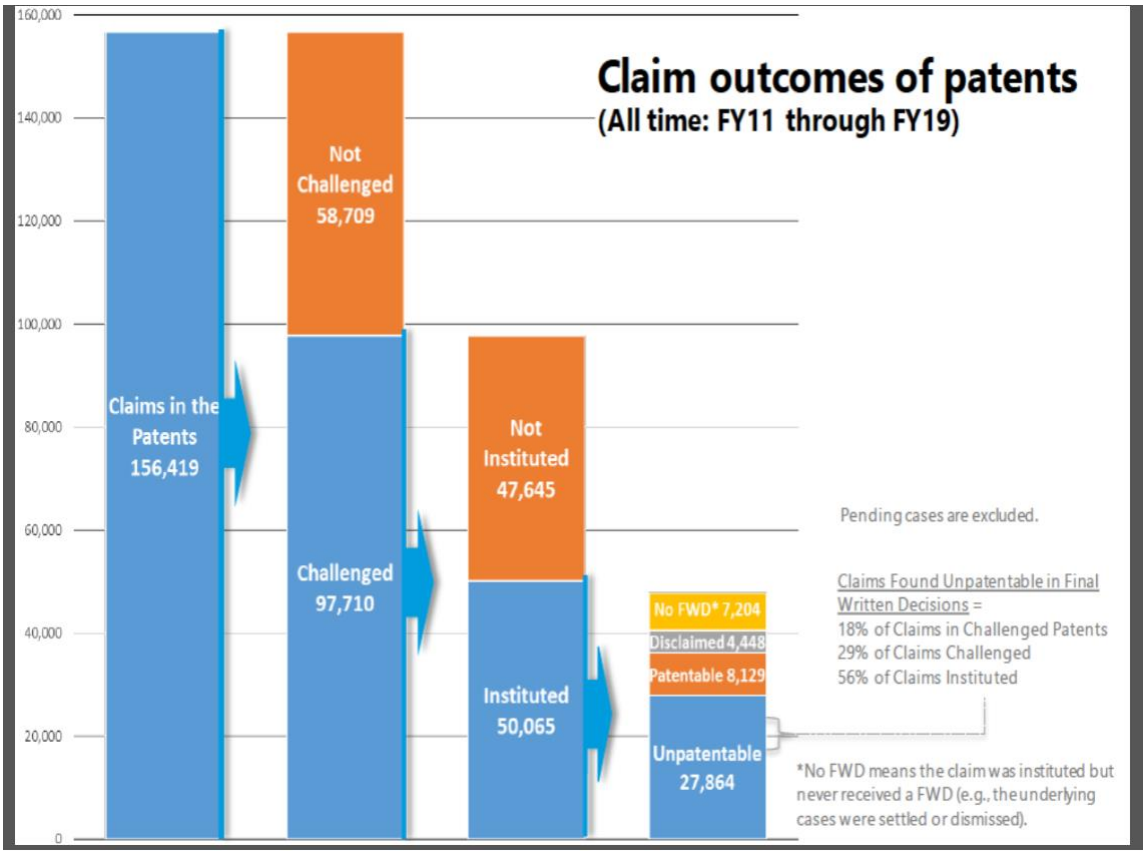
appointment power in the Secretary of Commerce, who is a "Head of Department." *See* Pub. L. No. 110-313, § 1(a)(1), 122 Stat. 3014, 3014 (2008) (35 U.S.C. § 6). The legislative change at least made administrative patent judges appointed in one of the ways that is *a* constitutionally permissible way to appoint officers, but there's one further catch: The Appointments Clause allows that method of appointment only if the officer is a so-called "inferior" officer.

Are the PTAB's administrative patent judges or "APJs" "inferior" officers? Under the Supreme Court precedents on the Appointments Clause, that question requires a complex legal analysis of the degree to which the judges are supervised by, and subordinate to, some superior officer. In the years since Congress's 2008 statutory change, two developments have cast doubt on whether the patent judges can be viewed as sufficiently supervised by, and subordinate to, a superior officer (such as the PTO Director) to qualify as "inferior" officers. First, the PTO has read various statutory provisions in the Patent Act and in title 5 of the United States Code (which governs, among other things, federal employment practices generally) as providing patent judges with a significant degree of tenure protection. Second, the AIA's revision of *inter partes* procedures have generally diminished the role that the agency head plays in the proceedings. The end result is that the administrative patent judges might not be "inferior" officers and thus their appointments would once again be unconstitutional under the Appointments Clause.

In *Arthrex, Inc. v. Smith & Nephew, Inc.*, 941 F.3d 1320 (2019), the Federal Circuit concluded that administrative patent judges were unconstitutionally appointed because the judges could not be considered "inferior" officers. *See id.* at 1335 (concluding that "the current structure of the [PTAB] violates the Appointments Clause"). The court also decided, however, that the statutory structure could be made consistent with the Constitution by severing one small piece of the statute: the provisions in the statutory law that arguably provide the judges tenure protection. *See id.* at 1338 ("Accordingly, we hold unconstitutional the statutory removal provisions as applied to APJs, and sever that application."). The court then remanded the case back to the PTAB with instructions "that a new panel of APJs must be designated and a new hearing granted." *Id.* at 1340.

That outcome seems to please exactly no one, so that the government, Arthrex, and Smith & Nephew have all three filed petitions for certiorari at the Supreme Court. Arthrex believes the Federal Circuit was right in holding the APJs unconstitutional but thinks the remedy is wrong. Arthrex believes the entire statutory appointment structure must be held unconstitutional, which would put the PTAB out of business until Congress changed the appointment process. The government and Smith & Nephew think that Federal Circuit erred in holding the existing appointment process unconstitutional. All three petitions for certiorari are currently pending at the Court (Nos. 19-1434, 19-1452, 19-1458 on the Court's docket), and all parties support the granting of the three petitions—i.e., no party seems to be opposing certiorari. Thus, it seems likely that the Court will grant one or more of the petitions in September, and it may very well grant all three and consolidate the petitions for argument. In the meanwhile, the constitutional status of the PTAB remains in doubt.

8. Data on Adversarial PTAB Proceedings Authorized under the AIA. Below is a graph published by the PTO (on page 15 of the presentation available at https://www.uspto.gov/sites/default/files/documents/PTAB_boardside_chat_new_trial_stats_sas_and_operational_faqs_06_11_2020.pdf). It shows the outcomes, on a claim-by-claim basis, of all AIA PTAB proceedings (which can include *inter partes* review, post-grant reviews, and so-called "covered business method" reviews):



The chart could be viewed as supporting different views. The text in the bottom right hand is written by the PTO and begins with the point that the PTAB has invalidated only 18% of the claims in patents challenged by petitioners in the AIA-authorized post-issuance proceedings. That number sounds small, but it is probably not the most relevant figure because it includes in the denominator many claims that no one challenged. Another way of looking at the data is to emphasize that the PTAB upholds only about 16% of the patent claims it adjudicates (8,129 ÷ 50,065). That too is probably not such a relevant figure because it excludes from consideration the many claims that the PTAB chooses not to review (and thus leaves as presumptively valid).

Probably the best way to look at the data is to consider only claims challenged and then to find the percentage of those claims for which the PTAB process produces a relatively positive result, which would include (i) refusing to institute on the challenge to the claim *or* (ii) upholding the claim. That figure is 57% ((47,645 + 8,129) ÷ 97,710). In more than 40% of the cases, the outcome is fairly negative, with claims invalidated, disclaimed or the case settled (the settlements are likely on terms favorable to the challengers given that only a minority of claims are sustained once the PTAB institutes the proceeding). That perspective is a glass-half-full vs. glass-half-empty situation. A majority of the patent claims challenged at the PTAB are likely to survive the challenge, but if the PTAB does agree to institute full proceedings on the challenged claim, then the Board is quite unlikely to uphold the claim as patentable.

* * *

Add the following new note 2A after note 2 in the "***Note on Post-Grant Review***," page 948:

2A. Scope of the Initiated Process. Unlike *inter partes* review, which is limited to reviewing challenges involving only novelty and nonobviousness and only where such challenges are based on prior art references of patents and printed publications, the post-grant review process is open to all patent validity challenges that could be raised as defenses in patent infringement litigation. *See, e.g., Grunenthal Gmbh v. Antecip Bioventures II LLC*, Case PGR2017–00008, 2017 WL 2901321 (P.T.A.B. July 7, 2017) (considering a petition to institute post-grant review based on written description and enablement challenges to a pharmaceutical patent, U.S. Patent No. 9,283,239, and ultimately granting review on the written description challenges only); *Grunenthal Gmbh v. Antecip Bioventures II LLC*, Case PGR2017–00008, 2018 WL 3105488 (June 22, 2018) (invalidating all of the challenged claims for failure to comply with the written description requirement).

Chap. 10.E.2. Laches

On pages 999-1000, the following paragraphs should replace the second paragraph in note 5:

In *SCA Hygiene Prods. v. First Quality Baby Prods.*, LLC, 137 S.Ct. 954 (2017), the Supreme Court extended its holding in *Petrella* to patent cases. The Court held that "*Petrella*'s reasoning easily fits" the patent statute, which also contains a statute of limitations (albeit one affording six years to bring suit, not just three). *See* 35 U.S.C. § 286.

Importantly, the Court rejected the Federal Circuit's view that § 282(b)(1) of the Patent Act codified the laches doctrine by providing that "unenforceability" is a defense to infringement. The Court reasoned:

> Section 282(b), which does not specifically mention laches, provides in relevant part as follows:
>
> > "The following shall be defenses in any action involving the validity or infringement of a patent and shall be pleaded:
> >
> > "(1) Noninfringement, absence of liability for infringement or unenforceability."
>
> The en banc majority below never identified which word or phrase in § 282 codifies laches as a defense, but First Quality argues that laches falls within § 282(b)(1) because laches is a defense based on "unenforceability."
>
> SCA disputes this interpretation of § 282(b)(1), arguing that laches does not make a patent categorically unenforceable. Reply Brief 6-8; see *Aukerman*, 960 F. 2d, at 1030 ("Recognition of laches as a defense . . . does not affect the general enforceability of the patent against others"). We need not decide this question. Even if we assume for the sake of argument that § 282(b)(1) incorporates a laches defense *of some dimension*, it does not necessarily follow that this defense may be invoked to bar a claim for damages incurred within the period set out in § 286. Indeed, it would be exceedingly unusual, if not unprecedented, if Congress chose to include in the Patent Act both a statute of limitations for damages and a laches provision applicable to a damages claim. Neither the Federal Circuit, nor First Quality, nor any of First Quality's *amici* has identified a single federal statute that provides such dual protection against untimely claims.

137 S.Ct. at 963.

Does the Supreme Court's reasoning undermine the availability of prosecution laches where an infringement suit is brought outside of equity? Or does a case like *Symbol Tech.* show a proper use of laches even where a case is brought at law not in equity? Note that, of the two Supreme Court cases relied upon by the court in *Symbol Tech.*, one was a suit in equity (*Webster Electric*) and the other (*Woodbridge*) was a suit in the Court of Claims to recover "the amount of compensation which was due in equity and justice" for patent infringement by the United States.

Chapter 12: Antitrust and Patent Misuse

Chap. 12.C. Exhaustion and the "First Sale" Doctrine: In place of note 6 on page 1158 and the long note concerning *Lexmark v. Impression Products* on pages 1158 - 61, add the following case:

Impression Products v. Lexmark Int'l, Inc.
137 S. Ct. 1523 (2017)

Chief Justice Roberts delivered the opinion of the Court.

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

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

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

I

The underlying dispute in this case is about laser printers—or, more specifically, the cartridges that contain the powdery substance, known as toner, that laser printers use to make an image appear on paper. Respondent Lexmark International, Inc. designs, manufactures, and sells toner cartridges to consumers in the United States and around the globe. It owns a number of patents that cover components of those cartridges and the manner in which they are used.
When toner cartridges run out of toner they can be refilled and used again. This creates an opportunity for other companies—known as remanufacturers—to acquire empty Lexmark cartridges from purchasers in the United States and abroad, refill them with toner, and then resell them at a lower price than the new ones Lexmark puts on the shelves.

Not blind to this business problem, Lexmark structures its sales in a way that encourages customers to return spent cartridges. It gives purchasers two options: One is to buy a toner cartridge at full price, with no strings attached. The other is to buy a cartridge at roughly 20-percent off through Lexmark's "Return Program." A customer who buys through the Return Program still owns the cartridge but, in exchange for the lower price, signs a contract agreeing to use it only once and to refrain from transferring the empty cartridge to anyone but Lexmark. To enforce this single-use/no-resale restriction, Lexmark installs a microchip on each Return Program cartridge that prevents reuse once the toner in the cartridge runs out.

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

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

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

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

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

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

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

II

A

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

The Patent Act grants patentees the "right to exclude others from making, using, offering for sale, or selling [their] invention[s]." 35 U. S. C. §154(a). For over 160 years, the doctrine of patent exhaustion has imposed a limit on that right to exclude. See *Bloomer* v. *McQuewan*, 55 U.S. 539 (1853). The limit functions automatically: When a patentee chooses to sell an item, that product "is no longer within the limits of the monopoly" and instead becomes the "private, individual property" of the purchaser, with the rights and benefits that come along with ownership. *Id.*, at 549-550. A patentee is free to set the price and negotiate contracts with purchasers, but may not, "*by virtue of his patent*, control the use or disposition" of the product after ownership passes to the purchaser. *United States* v. *Univis Lens Co.*, 316 U. S. 241, 250 (1942) (emphasis added). The sale "terminates all patent rights to that item." *Quanta Computer, Inc.* v. *LG Electronics, Inc.*, 553 U. S. 617, 625 (2008).

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

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

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

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

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

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

It is true that *Boston Store* and *Univis* involved resale price restrictions that, at the time of those decisions, violated the antitrust laws. But in both cases it was the sale of the items, rather than the illegality of the restrictions, that prevented the patentees from enforcing those resale price agreements through patent infringement suits. And if there were any lingering doubt that patent exhaustion applies even when a sale is subject to an express, otherwise lawful restriction, our recent decision in *Quanta Computer, Inc.* v. *LG Electronics, Inc.* settled the matter. In that case, a technology company—with authorization from the patentee—sold microprocessors under contracts requiring purchasers to use those processors with other parts that the company manufactured. One buyer disregarded the restriction, and the patentee sued for infringement. Without so much as

mentioning the lawfulness of the contract, we held that the patentee could not bring an infringement suit because the "authorized sale . . . took its products outside the scope of the patent monopoly." 553 U. S., at 638.

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

B

The Federal Circuit reached a different result largely because it got off on the wrong foot. The "exhaustion doctrine," the court believed, "must be understood as an interpretation of" the infringement statute, which prohibits anyone from using or selling a patented article "without authority" from the patentee. 816 F. 3d, at 734 (quoting 35 U. S. C. §271(a)). Exhaustion reflects a default rule that a patentee's decision to sell an item "*presumptively* grant[s] 'authority' to the purchaser to use it and resell it." 816 F. 3d, at 742. But, the Federal Circuit explained, the patentee does not have to hand over the full "bundle of rights" every time. *Id.*, at 741 (internal quotation marks omitted). If the patentee expressly withholds a stick from the bundle—perhaps by restricting the purchaser's resale rights—the buyer never acquires that withheld authority, and the patentee may continue to enforce its right to exclude that practice under the patent laws.

The misstep in this logic is that the exhaustion doctrine is not a presumption about the authority that comes along with a sale; it is instead a limit on "the scope of the *patentee's rights*." *United States* v. *General Elec. Co.*, 272 U. S. 476, 489 (1926) (emphasis added). The right to use, sell, or import an item exists independently of the Patent Act. What a patent adds—and grants exclusively to the patentee—is a limited right to prevent others from engaging in those practices. See *Crown Die & Tool Co.* v. *Nye Tool & Machine Works*, 261 U. S. 24, 35 (1923). Exhaustion extinguishes that exclusionary power. See *Bloomer*, 55 U.S. 539 at 549 (the purchaser "exercises no rights created by the act of Congress, nor does he derive title to [the item] by virtue of the . . . exclusive privilege granted to the patentee"). As a result, the sale transfers the right to use, sell, or import because those are the rights that come along with ownership, and the buyer is free and clear of an infringement lawsuit because there is no exclusionary right left to enforce.

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

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

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

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

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

III

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

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

Applying patent exhaustion to foreign sales is just as straightforward. Patent exhaustion, too, has its roots in the antipathy toward restraints on alienation, see *supra*, at 6-8, and nothing in the text or history of the Patent Act shows that Congress intended to confine that borderless common law principle to domestic sales. In fact, Congress has not altered patent exhaustion at all; it remains an unwritten limit on the scope of the patentee's monopoly. See *Astoria Fed. Sav. & Loan Ass'n* v. *Solimino*, 501 U.S. 104, 108 (1991) ("[W]here a common-law principle is well established, . . . courts may take it as given that Congress has legislated with an expectation that the principle will apply except when a statutory purpose to the contrary is evident" (internal quotation marks omitted)). And differentiating the patent exhaustion and copyright first sale doctrines would make little theoretical or practical sense: The two share a "strong similarity . . . and identity of purpose," *Bauer & Cie* v. *O'Bauer & Cie*, 229 U.S. 1, 13 (1913), and many everyday products—"automobiles, microwaves, calculators, mobile phones, tablets, and personal computers"—are subject to both patent and copyright protections, see *Kirtsaeng*, 568 U. S., at 545; Brief for Costco Wholesale Corp. et al. as *Amici Curiae* 14-15. There is a "historic kinship between patent law and copyright law," *Sony Corp. of America* v. *Universal City Studios, Inc.*, 464 U. S. 417, 439 (1984), and the bond between the two leaves no room for a rift on the question of international exhaustion.

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

The territorial limit on patent rights is, however, no basis for distinguishing copyright protections; those protections "do not have any extraterritorial operation" either. 5 M. Nimmer & D. Nimmer, Copyright §17.02, p. 17-26 (2017). Nor does the territorial limit support the premise of Lexmark's argument. Exhaustion is a separate limit on the patent grant, and does not depend on the patentee receiving some undefined premium for selling the right to access the American market. A purchaser buys an item, not patent rights. And exhaustion is triggered by the patentee's decision to give that item up and receive whatever fee it decides is appropriate "for the article and the invention which it embodies." *Univis*, 316 U. S., at 251. The patentee may not be able to command the same amount for its products abroad as it does in the United States. But the Patent Act does not guarantee

a particular price, much less the price from selling to American consumers. Instead, the right to exclude just ensures that the patentee receives one reward—of whatever amount the patentee deems to be "satisfactory compensation," *Keeler*, 157 U. S., at 661—for every item that passes outside the scope of the patent monopoly.

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

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

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

The Government has little more than "long ago" on its side. In the 1890s, two circuit courts—in cases involving the same company—did hold that patentees may use express restrictions to reserve their patent rights in connection with foreign sales. See *Dickerson* v. *Tinling*, 84 F. 192, 194-195 (CA8 1897); *Dickerson* v. *Matheson*, 57 F. 524, 527 (CA2 1893). But no "coalesc[ing]" ever took place: Over the following hundred-plus years, only a smattering of lower court decisions mentioned this express-reservation rule for foreign sales. See, *e.g.*, *Sanofi, S. A.* v. *Med-Tech Veterinarian Prods., Inc.*, 565 F. Supp. 931, 938 (NJ 1983). And in 2001, the Federal Circuit adopted its blanket rule that foreign sales do not trigger exhaustion, even if the patentee fails to expressly reserve its rights. *Jazz Photo*, 264 F. 3d, at 1105. These sparse and inconsistent decisions provide no basis for any expectation, let alone a settled one, that patentees can reserve patent rights when they sell abroad.

The theory behind the Government's express-reservation rule also wrongly focuses on the likely expectations of the patentee and purchaser during a sale. Exhaustion does not arise because of the parties' expectations about how sales transfer patent rights. More is at stake when it comes to patents than simply the dealings between the parties, which can be addressed through contract law.

Instead, exhaustion occurs because, in a sale, the patentee elects to give up title to an item in exchange for payment. Allowing patent rights to stick remora-like to that item as it flows through the market would violate the principle against restraints on alienation. Exhaustion does not depend on whether the patentee receives a premium for selling in the United States, or the type of rights that buyers expect to receive. As a result, restrictions and location are irrelevant; what matters is the patentee's decision to make a sale.

* * *

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

It is so ordered.

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

Justice GINSBURG, concurring in part and dissenting in part.

I concur in the Court's holding regarding domestic exhaustion—a patentee who sells a product with an express restriction on reuse or resale may not enforce that restriction through an infringement lawsuit, because the U. S. sale exhausts the U. S. patent rights in the product sold. See *ante*, at 5-13. I dissent, however, from the Court's holding on international exhaustion. A foreign sale, I would hold, does not exhaust a U. S. inventor's U. S. patent rights.

Patent law is territorial. When an inventor receives a U. S. patent, that patent provides no protection abroad. See *Deepsouth Packing Co.* v. *Laitram Corp.*, 406 U. S. 518, 531 (1972) ("Our patent system makes no claim to extraterritorial effect."). See also 35 U. S. C. §271(a) (establishing liability for acts of patent infringement "within the United States" and for "import[ation] into the United States [of] any patented invention"). A U. S. patentee must apply to each country in which she seeks the exclusive right to sell her invention. *Microsoft Corp.* v. *AT&T Corp.*, 550 U. S. 437, 456 (2007). And patent laws vary by country; each country's laws "may embody different policy judgments about the relative rights of inventors, competitors, and the public in patented inventions." *Microsoft*, 550 U. S., at 455 (internal quotation marks omitted).

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

The majority disagrees, in part because this Court decided, in *Kirtsaeng* v. *John Wiley & Sons, Inc.*, 568 U. S. 519, 525 (2013), that a foreign sale exhausts U. S. *copyright* protections. Copyright and patent exhaustion, the majority states, "share a strong similarity." *Ante*, at 14 (internal quotation marks omitted). I dissented from our decision in *Kirtsaeng* and adhere to the view that a foreign sale should not exhaust U. S. copyright protections. See 568 U. S., at 557.

But even if I subscribed to *Kirtsaeng*'s reasoning with respect to copyright, that decision should bear little weight in the patent context. Although there may be a "historical kinship" between patent law and copyright law, *Sony Corp. of America* v. *Universal City Studios, Inc.*, 464 U. S. 417, 439 (1984), the two "are not identical twins," *id*, at 439, n. 19. The Patent Act contains no analogue to 17 U. S. C. §109(a), the Copyright Act first-sale provision analyzed in *Kirtsaeng*. See *ante*, at 13-

14. More importantly, copyright protections, unlike patent protections, are harmonized across countries. Under the Berne Convention, which 174 countries have joined,[1] members "agree to treat authors from other member countries as well as they treat their own." *Golan* v. *Holder*, 565 U. S. 302, 308 (2012) (citing Berne Convention for the Protection of Literary and Artistic Works, Sept. 9, 1886, as revised at Stockholm on July 14, 1967, Arts. 1, 5(1), 828 U. N. T. S. 225, 231-233). The copyright protections one receives abroad are thus likely to be similar to those received at home, even if provided under each country's separate copyright regime.

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

NOTES ON *IMPRESSION PRODUCTS v. LEXMARK*

1. A Simple But Powerful Exhaustion Doctrine. The Supreme Court's decision provides a simple to understand, and quite powerful, exhaustion doctrine: Any authorized sale by the patentee, anywhere in the world, exhausts U.S. patent rights with respect to that article. The result of such an authorized sale is that the purchaser may use, sell, offer to sell or import the patented article into the United States without triggering any liability under U.S. *patent law.*

The ruling does not, however, hold that authorized sales free purchasers *generally* to use, sell, offer to sell or import the patented article. Indeed, the Court expressly notes that an authorized purchaser could be liable under contract law if the patentee sold the article with a binding contract restricting subsequent uses, sales or importations.

In addition to contract law, other bodies of law might also restrict the freedom of purchasers and others. For example, regulation by the Food & Drug Administration (FDA) generally prevents the importation into the United States of drugs produced in foreign countries, "including foreign-made versions of U.S. approved drugs, that have not been manufactured in accordance with and pursuant to an FDA approval." *See Information on Importation of Drugs Prepared by the Division of Import Operations and Policy, FDA*, available at https://www.fda.gov/forindustry/importprogram/ucm173751.htm (citing 21 U.S.C. § 331). Consider, for example, a pharmaceutical patentee that produces in a Canadian manufacturing plant a Canadian version of a U.S. approved drug. If the manufacturing plant has not been approved by the FDA (even if Canadian authorities have approved it), the Canadian version of the drug might be barred from importation into the United States not by patent law, but by the Food & Drug and Cosmetics Act (the statute enforced by the FDA).

2. Exhaustion as a Limit on Statutory Scope. The *Impressions Product* decision also provides a fairly clear theoretical basis for the exhaustion doctrine: It is a "a limit on 'the scope of the *patentee's rights*'" (emphasis by the Court). Thus, the basis for the exhaustion doctrine is an implied limit on the grant of patent rights in 35 U.S.C. § 154(a)(1), which confers on patentees the "right to exclude others from making, using, offering for sale, or selling the invention throughout the United States or importing the invention into the United States." Though that grant of rights appears unqualified, the exhaustion doctrine operates to restrict the scope of the grant so that patent law does not interfere with other legal principles, including, most prominently, the general common law hostility to restraints on alienation, but also the law governing tortious interference with contract, security interests, personal property servitudes, etc. The exhaustion doctrine rests not so much on a

[1] See WIPO-Administered Treaties: Contracting Parties: Berne Convention, www.wipo.int/treaties/en/ShowResults.jsp?lang=en&treaty_ id=5 (as last visited May 25, 2017).

policy forbidding contractual conditions or property-based encumbrances, but on a policy of making sure that any such conditions are enforced through other areas of law.

Consider, for example, a patentee who wants to sell patented lasers both (i) for 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 a remedy against the downstream commercial entity that bought from the first purchaser? Commercial law provides several ways to get such a remedy. 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 to impose binding conditions on property that is being sold into commerce, to enforce those conditions using the same general 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. 1 (2016). (http://ssrn.com/abstract=2599074).

3. Ambiguity about Licenses. The Supreme Court leaves open one crucial ambiguity about the exhaustion doctrine, which is whether the patent owner can escape the exhaustion doctrine entirely by describing a transaction not as a "sale," but merely as a transfer of possession of the patented article coupled with a "license" to use it. In other words, can the patentee escape the exhaustion doctrine merely by refusing to characterize the transaction as a "sale"? That issue was not presented in *Impression Products* because both parties stipulated that Lexmark sold cartridges to its customers. But if in the future Lexmark told its customers that Lexmark continued to own the cartridges and that the customers were merely using the cartridges subject to a one-use-only-no-refill license, would the exhaustion doctrine apply?

One possible source of law to answer this question is the Uniform Commercial Code, which generally provides that any attempt to retain title in goods notwithstanding shipment or delivery to a buyer "is limited in effect to a reservation of a 'security interest.'" UCC § 1-201(b)(35). In other words, an attempt to retain title despite the transfer of possession is treated as a sale, with the

possible reservation of a security interest in the goods. *See* Duffy & Hynes, *supra*, at 71; Brian W. Carver, *Why License Agreements Do Not Control Copy Ownership: First Sales and Essential Copies*, 25 Berkeley Tech. L.J. 1887, 1914-15 (2010); John A. Rothchild, *The Incredible Shrinking First-Sale Rule:Are Software Resale Limits Lawful?*, 57 Rutgers L. Rev. 1, 39, 62 (2004).

If the UCC applies (perhaps a big "if"), then the transaction would constitute a sale and the exhaustion doctrine would apply—although Lexmark would still have contractual rights and perhaps also a security interest to enforce those contractual rights.

For the contrary position arguing that the licensing of software is not a sale and does not trigger exhaustion under *Impression Products* (at least in the context of software), see Robert W. Gomulkiewicz, *Is the License Still the Product?* https://papers.ssrn.com/sol3/papers.cfm?abstract_id=3021895.

All of this is, however, speculation because such cases have not yet arisen. Prior to *Impression Products*, firms like Lexmark could characterize transactions as sales and still enforce their contractual conditions with patent infringement remedies. *Impression Products* now creates incentives for firms to use alternative formulations (e.g., calling the transaction a license or a lease). Such transactions are bound to occur and bound to generate litigation.

4. What's Good Public Policy? The Supreme Court asserts that, without the exhaustion doctrine, the "smooth flow of commerce would sputter" because it would be burdensome to keep track of all the conditions imposed on patented goods. Is that true?

Here are three arguments to the contrary. First, the Federal Circuit's precedent in *Mallinckrodt, Inc.* v. *Medipart, Inc.* had been in place for a quarter century prior to *Impression Products* and conditions on patented products did not seem to cause the flow of commerce in the United States to sputter in any obvious way.

Second, commercial law often does allow parties to place encumbrances such as security interests on personal property, and the enforceability of those encumbrances is generally viewed as a net positive economically, not a negative. Of course, commercial law typically requires that parties have notice of encumbrances that are enforced against them, but couldn't patent law be adjusted to require such notice?

Third, enforceable conditions on sales might foster economic efficiency by allowing producers to provide discounts to certain classes of consumers who may not be able to afford the good at full price. Thus, for example, Lexmark gave a 20% discount for consumers who agreed to the conditions of the "Return Program" cartridge. For an argument that the mandatory exhaustion is bad economic policy, *see* Jonathan Barnett & Ted Sichelman, *An Economic Argument Against Mandatory Patent Exhaustion*, https://patentlyo.com/patent/2017/03/economic-mandatory-exhaustion.html (concluding that "a mandatory, 'per se' rule [of exhaustion] assumes all downstream limitations are pernicious, when the economics show otherwise").