Chapter 2

PATENTABLE SUBJECT MATTER

The best ideas are common property.

—Lucius Annaeus Seneca *Epistles* 12, 11

A. INTRODUCTION TO THE PATENT ACT

This chapter deals with an issue generally known as "patentable subject matter" or "patent eligibility": that is, the issue of which *types* of inventions are eligible for patent protection. Our inquiry in the chapter will focus on general classes of inventions. We shall consider, for example, whether patents can ever cover such things as living organisms, mathematical algorithms, laws of nature and business methods. Doctrines governing whether any *particular* organism, algorithm or method deserves a patent—what are known as "patentability" requirements—are reserved for Chapters 3 through 7 (which cover the utility, disclosure, novelty and nonobviousness requirements).

Though patentable subject matter is conventionally treated (and will be treated here) as a distinct issue, it has significant connections to the history, thought and policies underlying the more specific patentability requirements mentioned above. Thus, this chapter will introduce policy considerations that will also be relevant in later chapters covering specific patentability doctrines.

The statutory provisions relevant to patentable subject matter are quite brief; they are contained in only two sections of the statute. Section 101 of the statute provides:

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

This provision has been part of U.S. law for over two centuries; it descends directly from language enacted into law in 1793. *See* Patent Act of 1793, § 1, 1 Stat. 318, 319 (authorizing patents for "any new and useful art, machine, manufacture, or composition of matter, or any new and useful improvement on any art, machine, manufacture, or composition of matter"). In addition to § 101, the first two subsections of § 100 provides important definitions necessary for understanding the reach of § 101:

> **§ 100. Definitions**
>
> When used in [the Patent Act] unless the context otherwise indicates —
>
> (a) The term "invention" means invention or discovery.

> (b) The term "process" means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material.

At first glance, applying these statutory provisions might seem quite straightforward: simply ask whether an "invention" fits one of the listed categories in § 101—"process, machine, manufacture, or composition of matter"; if it does, the invention is eligible for a patent. Furthermore, the definitions in § 100(a) & (b) might seem to point toward a broad interpretation of the crucial words "invention" (which covers even a "discovery") and "process" (which covers the older term "art" and extends even a "new use" of existing technologies).

The approach taken by the courts, however, has not always been so simple. To take one example, a researcher who "discovers … [a] new and useful … composition of matter" — a pine needle with medicinal properties, for example — may be denied a patent on the grounds that the pine needle is merely a product of nature, not a human invention or discovery. In this and many other examples, the broadly worded provisions of the Patent Act must be read in light of the many cases over 200 years interpreting the statute. Thus, even though the law is ultimately based on statute, it has acquired a distinctly common law feel.

In reading this chapter, you should be aware that patentable subject matter or patent eligibility doctrines are distinctly different in at least three ways from the patentability issues that will be covered in Chapters 3 through 7.

First, as compared to the doctrines of patentability, patent subject matter is controlled much more by judge-made common law than by statutory law. While the patentability doctrines discussed in later chapters also have extensive case law that helps define the requirements of the law, each patentability doctrine can be tied back to fairly specific statutory text. That's not true for patentable subject matter. The law of patentable subject matter is pretty much entirely judge-made, and indeed the Supreme Court has only occasionally attempted to reconcile its patentable subject matter case law with the text and structure of the Patent Act. Patentable subject matter thus raises an important question of power and institutional competence — specifically, whether Congress or the courts should have the predominant role in fashioning law of patents.

Second, patentable subject matter law has a much broader focus than the individual patentability doctrines introduced in later chapters. While patentability doctrines tend to ask rather specific questions (e.g., Is the claimed invention new? Is it useful? Is it disclosed sufficiently well?), patentable subject matter tends to ask the much more basic and holistic question of whether the invention is the sort of thing that should be subject to exclusive rights. That more general focus of patentable subject matter could be seen as both a weakness and a strength of the doctrine. It's a weakness because the generality of the inquiry can make the law in the area seem standardless and indefinite. But it also could be seen as a strength in that patentable subject matter allows courts to consider the complete aggregation of problems with a particular patent and to determine whether, on balance, permitting patentable eligibility advances or retards the goals of the statute.

Third, at least in current practice, issues of patentable subject matter are treated as threshold issues to be decided by the PTO at the beginning of the administrative process to obtain a patent and by courts very early in infringement litigation (sometimes even as early as a motion

to dismiss). By contrast, the patentability issues tend to be decided—at least under current lower court doctrine—towards the end of proceedings. It is questionable whether there should be such a dramatic procedural difference between patent eligibility and other patent validity doctrines, but the difference is a real one especially in current lower court practice. Given that difference, defendants in patent infringement litigation have strong incentives to raise patentable subject matter issues because success on them can invalidate the patent at the very beginning of litigation, saving months or years of litigation costs. Thus, patentable subject matter issues have been raised with dramatically increasing frequency in recent years.

One of the most interesting and debated questions in current patent law—a question you should consider constantly as you proceed through this book—is to what extent issues of patent law and policy should be addressed through generalized, judge-made doctrines applied at the threshold of administrative or judicial proceedings, or alternatively, through more specific, statutory inquires to be addressed after administrative or judicial proceedings have developed a more detailed factual record.

The following two opinions — one from 1980 and the other from 2010 — provide an excellent introduction to patentable subject matter doctrine. Though the decisions reach different outcomes in terms of whether the relevant subject matter is patentable, the two are more similar than they might at first seem. The opinions are presented below, with case notes after the two.

DIAMOND v. CHAKRABARTY

447 U.S. 303 (1980)

MR. CHIEF JUSTICE BURGER delivered the opinion of the Court.

We granted certiorari to determine whether a live, human-made micro-organism is patentable subject matter under 35 U.S.C. § 101.

I

In 1972, respondent Chakrabarty, a microbiologist, filed a patent application, assigned to the General Electric Co. The application asserted 36 claims related to Chakrabarty's invention of "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."[1] This human-made, genetically engineered bacterium is capable of breaking down multiple components of crude oil. Because of this property, which is possessed by no naturally occurring bacteria, Chakrabarty's invention is believed to have significant value for the treatment of oil spills.

---

[1] Plasmids are hereditary units physically separate from the chromosomes of the cell. In prior research, Chakrabarty and an associate discovered that plasmids control the oil degradation abilities of certain bacteria. In particular, the two researchers discovered plasmids capable of degrading camphor and octane, two components of crude oil. In the work represented by the patent application at issue here, Chakrabarty discovered a process by which four different plasmids, capable of degrading four different oil components, could be transferred to and maintained stably in a single *Pseudomonas* bacterium, which itself has no capacity for degrading oil.

Chakrabarty's patent claims were of three types: first, process claims for the method of producing the bacteria; second, claims for an inoculum comprised of a carrier material floating on water, such as straw, and the new bacteria; and third, claims to the bacteria themselves. The patent examiner allowed the claims falling into the first two categories, but rejected claims for the bacteria. His decision rested on two grounds: (1) that micro-organisms are "products of nature," and (2) that as living things they are not patentable subject matter under 35 U.S.C. § 101.

Chakrabarty appealed the rejection of these claims to the Patent Office Board of Appeals, and the Board affirmed the examiner on the second ground.[3] Relying on the legislative history of the 1930 Plant Patent Act, in which Congress extended patent protection to certain asexually reproduced plants, the Board concluded that § 101 was not intended to cover living things such as these laboratory created micro-organisms.

The Court of Customs and Patent Appeals, by a divided vote, reversed on the authority of its prior decision in *In re Bergy*, 563 F.2d 1031, 1038 (1977), which held that "the fact that microorganisms … are alive … [is] without legal significance" for purposes of the patent law… .

[W]e granted [certiorari] as to both *Bergy* and *Chakrabarty*. Since then, *Bergy* has been dismissed as moot, leaving only *Chakrabarty* for decision.

II

The Constitution grants Congress broad power to legislate to "promote the Progress of Science and useful Arts … ." The patent laws promote this progress by offering inventors exclusive rights for a limited period as an incentive for their inventiveness and research efforts. The authority of Congress is exercised in the hope that "[t]he productive effort thereby fostered will have a positive effect on society through the introduction of new products and processes of manufacture into the economy, and the emanations by way of increased employment and better lives for our citizens."

The question before us in this case is a narrow one of statutory interpretation requiring us to construe 35 U.S.C. § 101. Specifically, we must determine whether respondent's micro-organism constitutes a "manufacture" or "composition of matter" within the meaning of the statute.

III

[T]his Court has read the term "manufacture" in § 101 in accordance with its dictionary definition 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." *American Fruit Growers, Inc. v. Brogdex Co*., 283 U.S. 1, 11 (1931). Similarly, "composition of matter" has been construed consistent with its common usage to include "all compositions of two or more substances and … all composite articles, whether they be the results of chemical union, or of mechanical mixture, or whether they be gases, fluids, powders or solids."

---

[3] The Board concluded that the new bacteria were not "products of nature," because *Pseudomonas* bacteria containing two or more different energy-generating plasmids are not naturally occurring.

Shell Development Co. v. Watson, 149 F. Supp. 279, 280 (D.D.C. 1957). In choosing such expansive terms as "manufacture" and "composition of matter," modified by the comprehensive "any," Congress plainly contemplated that the patent laws would be given wide scope.

The relevant legislative history also supports a broad construction. The Patent Act of 1793, authored by Thomas Jefferson, defined statutory subject matter as "any new and useful art, machine, manufacture, or composition of matter, or any new or useful improvement [thereof]." Act of Feb. 21, 1793, § 1, 1 Stat. 319. The Act embodied Jefferson's philosophy that "ingenuity should receive a liberal encouragement." 5 Writings of Thomas Jefferson 75–76 (Washington ed. 1871). Subsequent patent statutes in 1836, 1870, and 1874 employed this same broad language. In 1952, when the patent laws were recodified, Congress replaced the word "art" with "process," but otherwise left Jefferson's language intact. The Committee Reports accompanying the 1952 Act inform us that Congress intended statutory subject matter to "include anything under the sun that is made by man." S. Rep. No. 1979, 82d Cong., 2d Sess., 5 (1952); H.R. Rep. No. 1923, 82d Cong., 2d Sess., 6 (1952).

This is not to suggest that § 101 has no limits or that it embraces every discovery. The laws of nature, physical phenomena, and abstract ideas have been held not patentable. *See Parker v. Flook*, 437 U. S. 584 (1978); *Gottschalk v. Benson*, 409 U. S. 63, 409 U. S. 67 (1972); ….Thus, a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E = mc^2$; nor could Newton have patented the law of gravity. Such discoveries are "manifestations of … nature, free to all men and reserved exclusively to none."

Judged in this light, respondent's micro-organism plainly qualifies as patentable subject matter. His claim is not to a hitherto unknown natural phenomenon, but to a nonnaturally occurring manufacture or composition of matter — a product of human ingenuity "having a distinctive name, character [and] use." The point is underscored dramatically by comparison of the invention here with that in *Funk* [*Bros. Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948)]. There, the patentee had discovered that there existed in nature certain species of root-nodule bacteria which did not exert a mutually inhibitive effect on each other. He used that discovery to produce a mixed culture capable of inoculating the seeds of leguminous plants. Concluding that the patentee had discovered "only some of the handiwork of nature," the Court ruled the product nonpatentable:

> Each of the species of root-nodule bacteria contained in the package infects the same group of leguminous plants which it always infected. No species acquires a different use. The combination of species produces no new bacteria, no change in the six species of bacteria, and no enlargement of the range of their utility. Each species has the same effect it always had. The bacteria perform in their natural way. Their use in combination does not improve in any way their natural functioning. They serve the ends nature originally provided and act quite independently of any effort of the patentee.

333 U.S., at 131.

Here, by contrast, the patentee has produced a new bacterium with markedly different characteristics from any found in nature and one having the potential for significant utility. His

discovery is not nature's handiwork, but his own; accordingly it is patentable subject matter under § 101.

IV

Two contrary arguments are advanced, neither of which we find persuasive.

The petitioner's first argument rests on the enactment of the 1930 Plant Patent Act, which afforded patent protection to certain asexually reproduced plants, and the 1970 Plant Variety Protection Act, which authorized protection for certain sexually reproduced plants but excluded bacteria from its protection.[7] In the petitioner's view, the passage of these Acts evidences congressional understanding that the terms "manufacture" or "composition of matter" do not include living things; if they did, the petitioner argues, neither Act would have been necessary.

We reject this argument. Prior to 1930, two factors were thought to remove plants from patent protection. The first was the belief that plants, even those artificially bred, were products of nature for purposes of the patent law. This position appears to have derived from the decision of the Patent Office in *Ex parte Latimer*, 1889 Dec. Com. Pat. 123, in which a patent claim for fiber found in the needle of the *Pinus australis* was rejected. The Commissioner reasoned that a contrary result would permit "patents [to] be obtained upon the trees of the forest and the plants of the earth, which of course would be unreasonable and impossible." *Id.*, at 126. The *Latimer* case, it seems, came to "se[t] forth the general stand taken in these matters" that plants were natural products not subject to patent protection. Thorne, Relation of Patent Law to Natural Products, 6 J. Pat. Off. Soc. 23, 24 (1923).[8] The second obstacle to patent protection for plants was the fact that plants were thought not amenable to the "written description" requirement of the

---

[7] The Plant Patent Act of 1930, 35 U.S.C. § 161, provides in relevant part:

> Whoever invents or discovers and asexually reproduces any distinct and new variety of plant, including cultivated sports, mutants, hybrids, and newly found seedlings, other than a tuber propagated plant or a plant found in an uncultivated state, may obtain a patent therefor… .

The Plant Variety Protection Act of 1970, provides in relevant part:

> The breeder of any novel variety of sexually reproduced plant (other than fungi, bacteria, or first generation hybrids) who has so reproduced the variety, or his successor in interest, shall be entitled to plant variety protection therefor … .

84 Stat. 1547, 7 U.S.C. § 2402(a). *See generally*, 3 A. Deller, Walker on Patents, ch. IX (2d ed. 1964); R. Allyn, The First Plant Patents (1934).

[8] Writing three years after the passage of the 1930 Act, R. Cook, Editor of the Journal of Heredity, commented:

> "It is a little hard for plant men to understand why [Art. I, § 8] of the Constitution should not have been earlier construed to include the promotion of the art of plant breeding. The reason for this is probably to be found in the principle that natural products are not patentable."

Florists Exchange and Horticultural Trade World, July 15, 1933, p. 9.

patent law. *See* 35 U.S.C. § 112. Because new plants may differ from old only in color or perfume, differentiation by written description was often impossible.

In enacting the Plant Patent Act, Congress addressed both of these concerns. It explained at length its belief that the work of the plant breeder "in aid of nature" was patentable invention. S. Rep. No. 315, 71st Cong., 2d Sess., 6–8 (1930); H.R. Rep. No. 1129, 71st Cong., 2d Sess., 7–9 (1930). And it relaxed the written description requirement in favor of "a description … as complete as is reasonably possible." 35 U.S.C. § 162. No committee or Member of Congress, however, expressed the broader view, now urged by the petitioner, that the terms "manufacture" or "composition of matter" exclude living things. The sole support for that position in the legislative history of the 1930 Act is found in the conclusory statement of Secretary of Agriculture Hyde, in a letter to the Chairmen of the House and Senate Committees considering the 1930 Act, that "the patent laws … at the present time are understood to cover only inventions or discoveries in the field of inanimate nature." See S. Rep. No. 315, *supra*, at Appendix A; H.R. Rep. No. 1129, *supra*, at Appendix A. Secretary Hyde's opinion, however, is not entitled to controlling weight. His views were solicited on the administration of the new law and not on the scope of patentable subject matter — an area beyond his competence. Moreover, there is language in the House and Senate Committee Reports suggesting that to the extent Congress considered the matter it found the Secretary's dichotomy unpersuasive. The Reports observe:

> There is a clear and logical distinction *between the discovery of a new variety of plant and of certain inanimate things*, such, for example, as a new and useful natural mineral. The mineral is created wholly by nature unassisted by man …. On the other hand, a plant discovery resulting from cultivation is unique, isolated, and is not repeated by nature, nor can it be reproduced by nature unaided by man… .

S. Rep. No. 315, *supra*, at 6; H.R. Rep. No. 1129, *supra*, at 7 (emphasis added). Congress thus recognized that the relevant distinction was not between living and inanimate things, but between products of nature, whether living or not, and human-made inventions. Here, respondent's micro-organism is the result of human ingenuity and research. Hence, the passage of the Plant Patent Act affords the Government no support.

Nor does the passage of the 1970 Plant Variety Protection Act support the Government's position. As the Government acknowledges, sexually reproduced plants were not included under the 1930 Act because new varieties could not be reproduced true-to-type through seedlings. By 1970, however, it was generally recognized that true-to-type reproduction was possible and that plant patent protection was therefore appropriate. The 1970 Act extended that protection. There is nothing in its language or history to suggest that it was enacted because § 101 did not include living things.

In particular, we find nothing in the exclusion of bacteria from plant variety protection to support the petitioner's position. The legislative history gives no reason for this exclusion. As the Court of Customs and Patent Appeals suggested, it may simply reflect congressional agreement with the result reached by that court in deciding *In re Arzberger*, 112 F.2d 834, 27 C.C.P.A. (Pat.) 1315 (1940), which held that bacteria were not plants for the purposes of the 1930 Act. Or it may reflect the fact that prior to 1970 the Patent Office had issued patents for bacteria under § 101. In any event, absent some clear indication that Congress "focused on [the] issues … directly related

to the one presently before the Court," there is no basis for reading into its actions an intent to modify the plain meaning of the words found in § 101.

The petitioner's second argument is that micro-organisms cannot qualify as patentable subject matter until Congress expressly authorizes such protection. His position rests on the fact that genetic technology was unforeseen when Congress enacted § 101. From this it is argued that resolution of the patentability of inventions such as respondent's should be left to Congress. The legislative process, the petitioner argues, is best equipped to weigh the competing economic, social, and scientific considerations involved, and to determine whether living organisms produced by genetic engineering should receive patent protection. In support of this position, the petitioner relies on our recent holding in *Parker v. Flook*, 437 U.S. 584 (1978), and the statement that the judiciary "must proceed cautiously when … asked to extend patent rights into areas wholly unforeseen by Congress." *Id*., at 596.

It is, of course, correct that Congress, not the courts, must define the limits of patentability; but it is equally true that once Congress has spoken it is "the province and duty of the judicial department to say what the law is." *Marbury v. Madison*, 1 Cranch 137, 177 (1803). Congress has performed its constitutional role in defining patentable subject matter in § 101; we perform ours in construing the language Congress has employed. In so doing, our obligation is to take statutes as we find them, guided, if ambiguity appears, by the legislative history and statutory purpose. Here, we perceive no ambiguity. The subject-matter provisions of the patent law have been cast in broad terms to fulfill the constitutional and statutory goal of promoting "the Progress of Science and the useful Arts" with all that means for the social and economic benefits envisioned by Jefferson. Broad general language is not necessarily ambiguous when congressional objectives require broad terms.

Nothing in *Flook* is to the contrary. The Court carefully scrutinized the claim at issue to determine whether it was precluded from patent protection under "the principles underlying the prohibition against patents for 'ideas' or phenomena of nature." *Id*., at 593. We have done that here. *Flook* did not announce a new principle that inventions in areas not contemplated by Congress when the patent laws were enacted are unpatentable *per se*.

To read that concept into *Flook* would frustrate the purposes of the patent law. This is especially true in the field of patent law. A rule that unanticipated inventions are without protection would conflict with the core concept of the patent law that anticipation undermines patentability. Mr. Justice Douglas reminded that the inventions most benefiting mankind are those that "push back the frontiers of chemistry, physics, and the like." *Great A.&P. Tea Co. v. Supermarket Corp.*, 340 U.S. 147, 154 (1950) (concurring opinion). Congress employed broad general language in drafting § 101 precisely because such inventions are often unforeseeable.[10]

To buttress his argument, the petitioner, with the support of *amicus*, points to grave risks that may be generated by research endeavors such as respondent's. The briefs present a gruesome parade of horribles. Scientists, among them Nobel laureates, are quoted suggesting that genetic

---

[10] Even an abbreviated list of patented inventions underscores the point: telegraph (Morse, No. 1,647); telephone (Bell, No. 174,465); electric lamp (Edison, No. 223,898); airplane (the Wrights, No. 821,393); transistor (Bardeen & Brattain, No. 2,524,035); neutronic reactor (Fermi & Szilard, No. 2,708,656); laser (Schawlow & Townes, No. 2,929,922)… .

research may pose a serious threat to the human race, or, at the very least, that the dangers are far too substantial to permit such research to proceed apace at this time. We are told that genetic research and related technological developments may spread pollution and disease, that it may result in a loss of genetic diversity, and that its practice may tend to depreciate the value of human life. These arguments are forcefully, even passionately, presented; they remind us that, at times, human ingenuity seems unable to control fully the forces it creates — that, with Hamlet, it is sometimes better "to bear those ills we have than fly to others that we know not of."

It is argued that this Court should weigh these potential hazards in considering whether respondent's invention is patentable subject matter under § 101. We disagree. The grant or denial of patents on micro-organisms is not likely to put an end to genetic research or to its attendant risks. The large amount of research that has already occurred when no researcher had sure knowledge that patent protection would be available suggests that legislative or judicial fiat as to patentability will not deter the scientific mind from probing into the unknown any more than Canute could command the tides. Whether respondent's claims are patentable may determine whether research efforts are accelerated by the hope of reward or slowed by want of incentives, but that is all.

What is more important is that we are without competence to entertain these arguments — either to brush them aside as fantasies generated by fear of the unknown, or to act on them. The choice we are urged to make is a matter of high policy for resolution within the legislative process after the kind of investigation, examination, and study that legislative bodies can provide and courts cannot. That process involves the balancing of competing values and interests, which in our democratic system is the business of elected representatives. Whatever their validity, the contentions now pressed on us should be addressed to the political branches of the Government, the Congress and the Executive, and not to the courts.[11]

Accordingly, the judgment of the Court of Customs and Patent Appeals is [a]ffirmed.

MR. JUSTICE BRENNAN, with whom MR. JUSTICE WHITE, MR. JUSTICE MARSHALL, and MR. JUSTICE POWELL join, dissenting.

I agree with the Court that the question before us is a narrow one. Neither the future of scientific research, nor even the ability of respondent Chakrabarty to reap some monopoly profits from his pioneering work, is at stake. Patents on the processes by which he has produced and employed the new living organism are not contested. The only question we need decide is whether Congress intended that he be able to secure a monopoly on the living organism itself, no matter how produced or how used. Because I believe the Court has misread the applicable legislation, I dissent.

---

[11] We are not to be understood as suggesting that the political branches have been laggard in the consideration of the problems related to genetic research and technology. They have already taken action. In 1976, for example, the National Institutes of Health released guidelines for NIH-sponsored genetic research which established conditions under which such research could be performed. 41 Fed. Reg. 27902. In 1978 those guidelines were revised and relaxed. 43 Fed. Reg. 60080, 60108, 60134. And Committees of the Congress have held extensive hearings on these matters. [Citing three congressional subcommittee hearings from 1975 and 1977.]

The patent laws attempt to reconcile this Nation's deep-seated antipathy to monopolies with the need to encourage progress. Given the complexity and legislative nature of this delicate task, we must be careful to extend patent protection no further than Congress has provided. In particular, were there an absence of legislative direction, the courts should leave to Congress the decisions whether and how far to extend the patent privilege into areas where the common understanding has been that patents are not available.

In this case, however, we do not confront a complete legislative vacuum. The sweeping language of the Patent Act of 1793, as re-enacted in 1952, is not the last pronouncement Congress has made in this area. In 1930 Congress enacted the Plant Patent Act affording patent protection to developers of certain asexually reproduced plants. In 1970 Congress enacted the Plant Variety Protection Act to extend protection to certain new plant varieties capable of sexual reproduction. Thus, we are not dealing — as the Court would have it — with the routine problem of "unanticipated inventions." In these two Acts Congress has addressed the general problem of patenting animate inventions and has chosen carefully limited language granting protection to some kinds of discoveries, but specifically excluding others. These Acts strongly evidence a congressional limitation that excludes bacteria from patentability.[2]

First, the Acts evidence Congress' understanding, at least since 1930, that § 101 does not include living organisms. If newly developed living organisms not naturally occurring had been patentable under § 101, the plants included in the scope of the 1930 and 1970 Acts could have been patented without new legislation. Those plants, like the bacteria involved in this case, were new varieties not naturally occurring. Although the Court rejects this line of argument, it does not explain why the Acts were necessary unless to correct a pre-existing situation. I cannot share the Court's implicit assumption that Congress was engaged in either idle exercises or mere correction of the public record when it enacted the 1930 and 1970 Acts. And Congress certainly thought it was doing something significant. The Committee Reports contain expansive prose about the previously unavailable benefits to be derived from extending patent protection to plants. H.R. Rep. No. 91-1605, pp. 1-3 (1970); S. Rep. No. 315, 71st Cong., 2d Sess., 1-3 (1930). Because Congress thought it had to legislate in order to make agricultural "human-made inventions" patentable and because the legislation Congress enacted is limited, it follows that Congress never meant to make items outside the scope of the legislation patentable.

Second, the 1970 Act clearly indicates that Congress has included bacteria within the focus of its legislative concern, but not within the scope of patent protection. Congress specifically excluded bacteria from the coverage of the 1970 Act. 7 U.S.C. § 2402(a). The Court's attempts to supply explanations for this explicit exclusion ring hollow. It is true that there is no mention in the legislative history of the exclusion, but that does not give us license to invent

---

[2] But even if I agreed with the Court that the 1930 and 1970 Acts were not dispositive, I would dissent. This case presents cogent reasons not to extend the patent monopoly in the face of uncertainty. At the very least, these Acts are signs of legislative attention to the problems of patenting living organisms, but they give no affirmative indication of congressional intent that bacteria be patentable. The caveat of *Parker v. Flook*, 437 U.S. 584, 596 (1978), an admonition to "proceed cautiously when we are asked to extend patent rights into areas wholly unforeseen by Congress," therefore becomes pertinent. I should think the necessity for caution is that much greater when we are asked to extend patent rights into areas Congress has foreseen and considered but has not resolved.

reasons. The fact is that Congress, assuming that animate objects as to which it had not specifically legislated could not be patented, excluded bacteria from the set of patentable organisms.

The Court protests that its holding today is dictated by the broad language of § 101, which cannot "be confined to the 'particular application[s] … contemplated by the legislators.' " But as I have shown, the Court's decision does not follow the unavoidable implications of the statute. Rather, it extends the patent system to cover living material even though Congress plainly has legislated in the belief that § 101 does not encompass living organisms. It is the role of Congress, not this Court, to broaden or narrow the reach of the patent laws. This is especially true where, as here, the composition sought to be patented uniquely implicates matters of public concern.

BILSKI v. KAPPOS

561 U.S. 593 (2010)

JUSTICE KENNEDY delivered the opinion of the Court, except as to Parts II-B-2 and II-C-2. [Chief Justice Roberts and JUSTICES ALITO and THOMAS joined the opinion in its entirety. JUSTICE SCALIA joined the opinion except for Parts II-B-2 and II-C-2.]

The question in this case turns on whether a patent can be issued for a claimed invention designed for the business world. The patent application claims a procedure for instructing buyers and sellers how to protect against the risk of price fluctuations in a discrete section of the economy. Three arguments are advanced for the proposition that the claimed invention is outside the scope of patent law: (1) it is not tied to a machine and does not transform an article; (2) it involves a method of conducting business; and (3) it is merely an abstract idea. The Court of Appeals ruled that the first mentioned of these, the so-called machine-or-transformation test, was the sole test to be used for determining the patentability of a "process" under the Patent Act, 35 U.S.C. § 101.

I

Petitioners' application seeks patent protection for a claimed invention that explains how buyers and sellers of commodities in the energy market can protect, or hedge, against the risk of price changes. The key claims are claims 1 and 4. Claim 1 describes a series of steps instructing how to hedge risk. Claim 4 puts the concept articulated in claim 1 into a simple mathematical formula. Claim 1 consists of the following steps:

> "(a) initiating a series of transactions between said commodity provider and consumers of said commodity wherein said consumers purchase said commodity at a fixed rate based upon historical averages, said fixed rate corresponding to a risk position of said consumers;
>
> "(b) identifying market participants for said commodity having a counter-risk position to said consumers; and
>
> "(c) initiating a series of transactions between said commodity provider and said market participants at a second fixed rate such that said series of

market participant transactions balances the risk position of said series of consumer transactions." App. 19–20.

The remaining claims explain how claims 1 and 4 can be applied to allow energy suppliers and consumers to minimize the risks resulting from fluctuations in market demand for energy.

The patent examiner rejected petitioners' application, explaining that it " 'is not implemented on a specific apparatus and merely manipulates [an] abstract idea and solves a purely mathematical problem without any limitation to a practical application, therefore, the invention is not directed to the technological arts.' " App. to Pet. for Cert. 148a. The Board of Patent Appeals and Interferences affirmed ….

The United States Court of Appeals for the Federal Circuit heard the case en banc and affirmed. …

This Court granted certiorari.

II

A

Section 101 defines the subject matter that may be patented under the Patent Act:

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

Section 101 thus specifies four independent categories of inventions or discoveries that are eligible for protection: processes, machines, manufactures, and compositions of matter. "In choosing such expansive terms … modified by the comprehensive 'any,' Congress plainly contemplated that the patent laws would be given wide scope." *Diamond v. Chakrabarty*, 447 U.S. 303, 308 (1980). Congress took this permissive approach to patent eligibility to ensure that " 'ingenuity should receive a liberal encouragement.' " *Id.*, at 308–309, 100 S.Ct. 2204 (quoting 5 Writings of Thomas Jefferson 75–76 (H. Washington ed. 1871)).

The Court's precedents provide three specific exceptions to § 101's broad patent-eligibility principles: "laws of nature, physical phenomena, and abstract ideas." *Chakrabarty*, *supra*, at 309. While these exceptions are not required by the statutory text, they are consistent with the notion that a patentable process must be "new and useful." And, in any case, these exceptions have defined the reach of the statute as a matter of statutory *stare decisis* going back 150 years. See *Le Roy v. Tatham*, 14 How. 156, 174–175 (1853). The concepts covered by these exceptions are "part of the storehouse of knowledge of all men … free to all men and reserved exclusively to none." *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948).

The § 101 patent-eligibility inquiry is only a threshold test. Even if an invention qualifies as a process, machine, manufacture, or composition of matter, in order to receive the Patent Act's protection the claimed invention must also satisfy "the conditions and requirements of this title." § 101. Those requirements include that the invention be novel, see § 102, nonobvious, see § 103, and fully and particularly described, see § 112.

The present case involves an invention that is claimed to be a "process" under § 101. Section 100(b) defines "process" as:

> "process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material."

The Court first considers two proposed categorical limitations on "process" patents under § 101 that would, if adopted, bar petitioners' application in the present case: the machine-or-transformation test and the categorical exclusion of business method patents.

B

1

Under the Court of Appeals' formulation, an invention is a "process" only if: "(1) it is tied to a particular machine or apparatus, or (2) it transforms a particular article into a different state or thing." 545 F.3d, at 954. This Court has "more than once cautioned that courts 'should not read into the patent laws limitations and conditions which the legislature has not expressed.' " *Diamond v. Diehr*, 450 U.S. 175, 182 (1981) (quoting *Chakrabarty*, *supra*, at 308, 100 S.Ct. 2204; some internal quotation marks omitted). In patent law, as in all statutory construction, "[u]nless otherwise defined, 'words will be interpreted as taking their ordinary, contemporary, common meaning.' " *Diehr*, *supra*, at 182. The Court has read the § 101 term "manufacture" in accordance with dictionary definitions, see *Chakrabarty*, *supra*, at 308, and approved a construction of the term "composition of matter" consistent with common usage, see *Chakrabarty*, *supra*, at 308.

Any suggestion in this Court's case law that the Patent Act's terms deviate from their ordinary meaning has only been an explanation for the exceptions for laws of nature, physical phenomena, and abstract ideas. See *Parker v. Flook*, 437 U.S. 584, 588–589 (1978). This Court has not indicated that the existence of these well-established exceptions gives the Judiciary *carte blanche* to impose other limitations that are inconsistent with the text and the statute's purpose and design. Concerns about attempts to call any form of human activity a "process" can be met by making sure the claim meets the requirements of § 101.

Adopting the machine-or-transformation test as the sole test for what constitutes a "process" (as opposed to just an important and useful clue) violates these statutory interpretation principles. Section 100(b) provides that "[t]he term 'process' means process, art or method, and includes a new use of a known process, machine, manufacture, composition of matter, or material." The Court is unaware of any " 'ordinary, contemporary, common meaning,' " *Diehr*, *supra*, at 182, of the definitional terms "process, art or method" that would require these terms to be tied to a machine or to transform an article. Respondent urges the Court to look to the other patentable categories in § 101 — machines, manufactures, and compositions of matter — to confine the meaning of "process" to a machine or transformation, under the doctrine of *noscitur a sociis*. Under this canon, "an ambiguous term may be given more precise content by the neighboring words with which it is associated." *United States v. Stevens*, 559 U.S. ___, ___, 130 S.Ct. 1577, 1587 (2010) (internal quotation marks omitted). This canon is inapplicable here, for § 100(b) already explicitly defines the term "process." See *Burgess v. United States*, 553 U.S.

124, 130 (2008) ("When a statute includes an explicit definition, we must follow that definition" (internal quotation marks omitted)).

The Court of Appeals incorrectly concluded that this Court has endorsed the machine-or-transformation test as the exclusive test. It is true that *Cochrane v. Deener*, 94 U.S. 780, 788 (1877), explained that a "process" is "an act, or a series of acts, performed upon the subject-matter to be transformed and reduced to a different state or thing." More recent cases, however, have rejected the broad implications of this dictum; and, in all events, later authority shows that it was not intended to be an exhaustive or exclusive test. …

This Court's precedents establish that the machine-or-transformation test is a useful and important clue, an investigative tool, for determining whether some claimed inventions are processes under § 101. The machine-or-transformation test is not the sole test for deciding whether an invention is a patent-eligible "process."

2

[Part B.2 is an opinion for JUSTICE KENNEDY and three other Justices.]

It is true that patents for inventions that did not satisfy the machine-or-transformation test were rarely granted in earlier eras, especially in the Industrial Age, as explained by Judge Dyk's thoughtful historical review. See 545 F.3d, at 966–976 (concurring opinion). But times change. Technology and other innovations progress in unexpected ways. For example, it was once forcefully argued that until recent times, "well-established principles of patent law probably would have prevented the issuance of a valid patent on almost any conceivable computer program." *Diehr*, 450 U.S., at 195 (STEVENS, J., dissenting). But this fact does not mean that unforeseen innovations such as computer programs are always unpatentable. See *id.*, at 192–193 (majority opinion) (holding a procedure for molding rubber that included a computer program is within patentable subject matter). Section 101 is a "dynamic provision designed to encompass new and unforeseen inventions." *J.E.M. Ag Supply, Inc. v. Pioneer Hi-Bred Int'l, Inc.*, 534 U.S. 124, 135 (2001). A categorical rule denying patent protection for "inventions in areas not contemplated by Congress … would frustrate the purposes of the patent law." *Chakrabarty*, 447 U.S., at 315.

The machine-or-transformation test may well provide a sufficient basis for evaluating processes similar to those in the Industrial Age — for example, inventions grounded in a physical or other tangible form. But there are reasons to doubt whether the test should be the sole criterion for determining the patentability of inventions in the Information Age. As numerous *amicus* briefs argue, the machine-or-transformation test would create uncertainty as to the patentability of software, advanced diagnostic medicine techniques, and inventions based on linear programming, data compression, and the manipulation of digital signals. …

C

1

Section 101 similarly precludes the broad contention that the term "process" categorically excludes business methods. The term "method," which is within § 100(b)'s definition of "process," at least as a textual matter and before consulting other limitations in the Patent Act and this Court's precedents, may include at least some methods of doing business. See, *e.g.*,

Webster's New International Dictionary 1548 (2d ed.1954) (defining "method" as "[a]n orderly procedure or process … regular way or manner of doing anything; hence, a set form of procedure adopted in investigation or instruction"). The Court is unaware of any argument that the " 'ordinary, contemporary, common meaning,' " *Diehr*, *supra*, at 182, of "method" excludes business methods. Nor is it clear how far a prohibition on business method patents would reach, and whether it would exclude technologies for conducting a business more efficiently. See, *e.g.*, Hall, Business and Financial Method Patents, Innovation, and Policy, 56 Scottish J. Pol. Econ. 443, 445 (2009) ("There is no precise definition of … business method patents").

The argument that business methods are categorically outside of § 101's scope is further undermined by the fact that federal law explicitly contemplates the existence of at least some business method patents. Under 35 U.S.C. § 273(b)(1), if a patent-holder claims infringement based on "a method in [a] patent," the alleged infringer can assert a defense of prior use. For purposes of this defense alone, "method" is defined as "a method of doing or conducting business." § 273(a)(3). In other words, by allowing this defense the statute itself acknowledges that there may be business method patents. Section 273's definition of "method," to be sure, cannot change the meaning of a prior-enacted statute. But what § 273 does is clarify the understanding that a business method is simply one kind of "method" that is, at least in some circumstances, eligible for patenting under § 101.

A conclusion that business methods are not patentable in any circumstances would render § 273 meaningless. This would violate the canon against interpreting any statutory provision in a manner that would render another provision superfluous. See *Corley v. United States*, 556 U.S. 303, 129 S.Ct. 1558 (2009). This principle, of course, applies to interpreting any two provisions in the U.S.Code, even when Congress enacted the provisions at different times. See, *e.g.*, *Hague v. Committee for Industrial Organization*, 307 U.S. 496, 529-530 (1939) (opinion of Stone, J.). This established rule of statutory interpretation cannot be overcome by judicial speculation as to the subjective intent of various legislators in enacting the subsequent provision. Finally, while § 273 appears to leave open the possibility of some business method patents, it does not suggest broad patentability of such claimed inventions.

2

[Part C.2 is an opinion for JUSTICE KENNEDY and three other Justices.]

Interpreting § 101 to exclude all business methods simply because business method patents were rarely issued until modern times revives many of the previously discussed difficulties. See *supra*, at ___ - ___. At the same time, some business method patents raise special problems in terms of vagueness and suspect validity. See *eBay Inc. v. MercExchange, L.L. C.*, 547 U.S. 388, 397 (2006) (KENNEDY, J., concurring). The Information Age empowers people with new capacities to perform statistical analyses and mathematical calculations with a speed and sophistication that enable the design of protocols for more efficient performance of a vast number of business tasks. If a high enough bar is not set when considering patent applications of this sort, patent examiners and courts could be flooded with claims that would put a chill on creative endeavor and dynamic change.

In searching for a limiting principle, this Court's precedents on the unpatentability of abstract ideas provide useful tools. See *infra*, at ___ - ___. Indeed, if the Court of Appeals were to

succeed in defining a narrower category or class of patent applications that claim to instruct how business should be conducted, and then rule that the category is unpatentable because, for instance, it represents an attempt to patent abstract ideas, this conclusion might well be in accord with controlling precedent. See *ibid.* But beyond this or some other limitation consistent with the statutory text, the Patent Act leaves open the possibility that there are at least some processes that can be fairly described as business methods that are within patentable subject matter under § 101.

Finally, even if a particular business method fits into the statutory definition of a "process," that does not mean that the application claiming that method should be granted. In order to receive patent protection, any claimed invention must be novel, § 102, nonobvious, § 103, and fully and particularly described, § 112. These limitations serve a critical role in adjusting the tension, ever present in patent law, between stimulating innovation by protecting inventors and impeding progress by granting patents when not justified by the statutory design.

III

Even though petitioners' application is not categorically outside of § 101 under the two broad and atextual approaches the Court rejects today, that does not mean it is a "process" under § 101. Petitioners seek to patent both the concept of hedging risk and the application of that concept to energy markets. App. 19-20. Rather than adopting categorical rules that might have wide-ranging and unforeseen impacts, the Court resolves this case narrowly on the basis of this Court's decisions in *Benson* [*Gottschalk v. Benson*, 409 U.S. 63 (1972)], *Flook* [*Parker v. Flook*, 437 U.S. 584 (1978)], and *Diehr*, which show that petitioners' claims are not patentable processes because they are attempts to patent abstract ideas. Indeed, all members of the Court agree that the patent application at issue here falls outside of § 101 because it claims an abstract idea.

In *Benson*, the Court considered whether a patent application for an algorithm to convert binary-coded decimal numerals into pure binary code was a "process" under § 101. 409 U.S., at 64–67. The Court first explained that " '[a] principle, in the abstract, is a fundamental truth; an original cause; a motive; these cannot be patented, as no one can claim in either of them an exclusive right.' " *Id.*, at 67, 93 S.Ct. 253 (quoting *Le Roy*, 14 How., at 175). The Court then held the application at issue was not a "process," but an unpatentable abstract idea. "It is conceded that one may not patent an idea. But in practical effect that would be the result if the formula for converting … numerals to pure binary numerals were patented in this case." 409 U.S., at 71, 93 S.Ct. 253. A contrary holding "would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself." *Id.*, at 72.

In *Flook*, the Court considered the next logical step after *Benson*. The applicant there attempted to patent a procedure for monitoring the conditions during the catalytic conversion process in the petrochemical and oil-refining industries. The application's only innovation was reliance on a mathematical algorithm. 437 U.S., at 585–586. *Flook* held the invention was not a patentable "process." The Court conceded the invention at issue, unlike the algorithm in *Benson*, had been limited so that it could still be freely used outside the petrochemical and oil-refining industries. 437 U.S., at 589–590. Nevertheless, *Flook* rejected "[t]he notion that post-solution activity, no matter how conventional or obvious in itself, can transform an unpatentable principle into a patentable process." *Id.*, at 590. The Court concluded that the process at issue there was "unpatentable under § 101, not because it contain[ed] a mathematical algorithm as one component, but because once that algorithm [wa]s assumed to be within the prior art, the

application, considered as a whole, contain[ed] no patentable invention." *Id.*, at 594. As the Court later explained, *Flook* stands for the proposition that the prohibition against patenting abstract ideas "cannot be circumvented by attempting to limit the use of the formula to a particular technological environment" or adding "insignificant postsolution activity." *Diehr*, 450 U.S., at 191–192.

Finally, in *Diehr*, the Court established a limitation on the principles articulated in *Benson* and *Flook*. The application in *Diehr* claimed a previously unknown method for "molding raw, uncured synthetic rubber into cured precision products," using a mathematical formula to complete some of its several steps by way of a computer. 450 U.S., at 177. *Diehr* explained that while an abstract idea, law of nature, or mathematical formula could not be patented, "an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection." *Id.*, at 187. *Diehr* emphasized the need to consider the invention as a whole, rather than "dissect[ing] the claims into old and new elements and then … ignor[ing] the presence of the old elements in the analysis." *Id.*, at 188. Finally, the Court concluded that because the claim was not "an attempt to patent a mathematical formula, but rather [was] an industrial process for the molding of rubber products," it fell within § 101's patentable subject matter. *Id.*, at 192–193.

In light of these precedents, it is clear that petitioners' application is not a patentable "process." Claims 1 and 4 in petitioners' application explain the basic concept of hedging, or protecting against risk: "Hedging is a fundamental economic practice long prevalent in our system of commerce and taught in any introductory finance class." 545 F.3d, at 1013 (Rader, J., dissenting); see, *e.g.*, D. Chorafas, Introduction to Derivative Financial Instruments 75-94 (2008); C. Stickney, R. Weil, K. Schipper, & J. Francis, Financial Accounting: An Introduction to Concepts, Methods, and Uses 581–582 (13th ed.2010); S. Ross, R. Westerfield, & B. Jordan, Fundamentals of Corporate Finance 743–744 (8th ed.2008). The concept of hedging, described in claim 1 and reduced to a mathematical formula in claim 4, is an unpatentable abstract idea, just like the algorithms at issue in *Benson* and *Flook*. Allowing petitioners to patent risk hedging would pre-empt use of this approach in all fields, and would effectively grant a monopoly over an abstract idea.

Petitioners' remaining claims are broad examples of how hedging can be used in commodities and energy markets. *Flook* established that limiting an abstract idea to one field of use or adding token postsolution components did not make the concept patentable. That is exactly what the remaining claims in petitioners' application do. These claims attempt to patent the use of the abstract idea of hedging risk in the energy market and then instruct the use of well-known random analysis techniques to help establish some of the inputs into the equation. Indeed, these claims add even less to the underlying abstract principle than the invention in *Flook* did, for the *Flook* invention was at least directed to the narrower domain of signaling dangers in operating a catalytic converter.

Today, the Court once again declines to impose limitations on the Patent Act that are inconsistent with the Act's text. The patent application here can be rejected under our precedents on the unpatentability of abstract ideas. The Court, therefore, need not define further what constitutes a patentable "process," beyond pointing to the definition of that term provided in § 100(b) and looking to the guideposts in *Benson*, *Flook*, and *Diehr*.

And nothing in today's opinion should be read as endorsing interpretations of § 101 that

the Court of Appeals for the Federal Circuit has used in the past. See, *e.g.*, [*State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368, 1373 (C.A.Fed.1998)]. It may be that the Court of Appeals thought it needed to make the machine-or-transformation test exclusive precisely because its case law had not adequately identified less extreme means of restricting business method patents, including (but not limited to) application of our opinions in *Benson*, *Flook*, and *Diehr*. In disapproving an exclusive machine-or-transformation test, we by no means foreclose the Federal Circuit's development of other limiting criteria that further the purposes of the Patent Act and are not inconsistent with its text.

The judgment of the Court of Appeals is affirmed.

It is so ordered.

JUSTICE STEVENS, with whom JUSTICE GINSBURG, JUSTICE BREYER and JUSTICE SOTOMAYOR join, concurring in the judgment.

In the area of patents, it is especially important that the law remain stable and clear. The only question presented in this case is whether the so-called machine-or-transformation test is the exclusive test for what constitutes a patentable "process" under 35 U.S.C. § 101. It would be possible to answer that question simply by holding, as the entire Court agrees, that although the machine-or-transformation test is reliable in most cases, it is not the *exclusive* test.

I agree with the Court that, in light of the uncertainty that currently pervades this field, it is prudent to provide further guidance. But I would take a different approach. Rather than making any broad statements about how to define the term "process" in § 101 or tinkering with the bounds of the category of unpatentable, abstract ideas, I would restore patent law to its historical and constitutional moorings.

For centuries, it was considered well established that a series of steps for conducting business was not, in itself, patentable. In the late 1990's, the Federal Circuit and others called this proposition into question. Congress quickly responded to a Federal Circuit decision with a stopgap measure designed to limit a potentially significant new problem for the business community. It passed the First Inventors Defense Act of 1999 (1999 Act), 113 Stat. 1501A-555 (codified at 35 U.S.C. § 273), which provides a limited defense to claims of patent infringement, see § 273(b), for "method[s] of doing or conducting business," § 273(a)(3). Following several more years of confusion, the Federal Circuit changed course, overruling recent decisions and holding that a series of steps may constitute a patentable process only if it is tied to a machine or transforms an article into a different state or thing. This "machine-or-transformation test" excluded general methods of doing business as well as, potentially, a variety of other subjects that could be called processes.

The Court correctly holds that the machine-or-transformation test is not the sole test for what constitutes a patentable process; rather, it is a critical clue.[1] But the Court is quite wrong, in

[1] Even if the machine-or-transformation test may not define the scope of a patentable process, it would be a grave mistake to assume that anything with a "'useful, concrete and tangible result,'" *State Street Bank & Trust v. Signature Financial Group, Inc*., 149 F. 3d 1368, 1373 (CA Fed. 1998), may be patented.

my view, to suggest that any series of steps that is not itself an abstract idea or law of nature may constitute a "process" within the meaning of § 101. The language in the Court's opinion to this effect can only cause mischief. The wiser course would have been to hold that petitioners' method is not a "process" because it describes only a general method of engaging in business transactions — and business methods are not patentable. More precisely, although a process is not patent-ineligible simply because it is useful for conducting business, a claim that merely describes a method of doing business does not qualify as a "process" under § 101. …

JUSTICE BREYER with whom JUSTICE SCALIA joins as to Part II, concurring in the judgment.

…

II

In addition to the Court's unanimous agreement that the claims at issue here are unpatentable abstract ideas, it is my view that the following four points are consistent with both the opinion of the Court and Justice Stevens' opinion concurring in the judgment:

First, although the text of § 101 is broad, it is not without limit. "[T]he underlying policy of the patent system [is] that 'the things which are worth to the public the embarrassment of an exclusive patent,' … must outweigh the restrictive effect of the limited patent monopoly." *Graham v. John Deere Co. of Kansas City*, 383 U.S. 1, 10–11 (1966) (quoting Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813), in 6 Writings of Thomas Jefferson 181 (H. Washington ed.)). The Court has thus been careful in interpreting the Patent Act to "determine not only what is protected, but also what is free for all to use." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 151. In particular, the Court has long held that "[p]henomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable" under § 101, since allowing individuals to patent these fundamental principles would "wholly pre-empt" the public's access to the "basic tools of scientific and technological work." *Gottschalk v. Benson*, 409 U.S. 63, 67, 72 (1980).

Second, in a series of cases that extend back over a century, the Court has stated that "[t]ransformation and reduction of an article to a different state or thing is *the clue* to the patentability of a process claim that does not include particular machines." *Diehr*, *supra*, at 184 (emphasis added; internal quotation marks omitted). Application of this test, the so-called "machine-or-transformation test," has thus repeatedly helped the Court to determine what is "a patentable 'process.' " *Flook*, *supra*, at 589.

Third, while the machine-or-transformation test has always been a "useful and important clue," it has never been the "sole test" for determining patentability. *Benson*, *supra*, at 71 (rejecting the argument that "no process patent could ever qualify" for protection under § 101 "if it did not meet the [machine-or-transformation] requirements"). Rather, the Court has emphasized that a process claim meets the requirements of § 101 when, "considered as a whole," it "is performing a function which the patent laws were designed to protect (*e.g.*, transforming or reducing an article to a different state or thing)." *Diehr*, *supra*, at 192. The machine-or-transformation test is thus an *important example* of how a court can determine patentability under § 101, but the Federal Circuit erred in this case by treating it as the *exclusive test*.

Fourth, although the machine-or-transformation test is not the only test for patentability, this by no means indicates that anything which produces a " 'useful, concrete, and tangible result,' " *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368, 1373

(C.A.Fed.1998), is patentable. "[T]his Court has never made such a statement and, if taken literally, the statement would cover instances where this Court has held the contrary." *Laboratory Corp. of America Holdings v. Metabolite Laboratories, Inc.*, 548 U.S. 124, 136 (2006) (Breyer, J., dissenting from dismissal of certiorari as improvidently granted). Indeed, the introduction of the "useful, concrete, and tangible result" approach to patentability, associated with the Federal Circuit's *State Street* decision, preceded the granting of patents that "ranged from the somewhat ridiculous to the truly absurd." *In re Bilski*, 545 F.3d 943, 1004 (C.A.Fed.2008) (Mayer, J., dissenting) (citing patents on, *inter alia*, a "method of training janitors to dust and vacuum using video displays," a "system for toilet reservations," and a "method of using color-coded bracelets to designate dating status in order to limit 'the embarrassment of rejection' ").

In sum, it is my view that, in reemphasizing that the "machine-or-transformation" test is not necessarily the *sole* test of patentability, the Court intends neither to de-emphasize the test's usefulness nor to suggest that many patentable processes lie beyond its reach.

NOTES ON *CHAKRABARTY* AND *BILSKI*

1. The "expansive terms" of the statute vs. the judicial exclusions for "laws of nature, physical phenomena, and abstract ideas." Two passages set forth originally in *Chakrabarty* and repeated verbatim in *Bilski* state the basic thesis and antithesis that, for better or worse, define the currently dominant approach to defining patentability under § 101. In both cases, the Court begins its analysis with the acknowledgement that Congress chose "expansive terms" to define patentable subject matter in § 101 and that such language should "be given wide scope." Yet in both cases, the Court immediately qualifies its broad statement with the declaration that "laws of nature, physical phenomena, and abstract ideas" are not patentable.

This point and counterpoint—what might be called the yin and yang of patentable subject matter—will be the major focus of this chapter. In deciding the right balance between these two opposing forces, courts have invoked virtually every policy consideration relevant to patent law and policy. The debate over patentable subject matter is thus a microcosm of all patent law and provides an appropriate, if intellectually challenging, starting point for the study of patents.

2. The Rejection of "Categorical" Exclusions from Patentable Subject Matter and the Rules vs. Standards Distinction. Scholars frequently note that legal norms can be established either through more hard-edged rules or through more general standards that require the consideration and balancing of several factors. In both *Chakrabarty* and *Bilski*, the Supreme Court rejected opportunities to impose *per se* or "categorical" rules limiting the scope of patentable subject matter and instead opted to evaluate patentable subject matter by more open-ended standards. In *Chakrabarty*, the Court rejected a rule that would limit patentable subject matter to inanimate objects only. In *Bilski*, the Court rejected both a rule limiting process patents to inventions that pass a "machine-or-transformation" test, and a rule that would exclude all business methods from patentability.

Rejection of per se limits on patentable subject matter does seem to be a theme in the case law. In a dissent authored 29 years prior to *Bilski*, Justice Stevens also unsuccessfully argued for a categorical exclusion of computer programs from patentable subject matter. *See Diamond v. Diehr*, 450 U.S. 175, 219 (1981) (Stevens, J., dissenting) (arguing for "an unequivocal holding

that no program-related invention is a patentable process under § 101 unless it makes a contribution to the art that is not dependent entirely on the utilization of a computer"). As in *Bilski*, Justice Stevens' proposed categorical exclusion garnered four of nine votes—just one short of becoming the law. Other historical examples of failed attempts to limit patentable subject matter with categorical rules are provided in John F. Duffy, *Rules and Standards on the Forefront of Patentability*, 51 Wm. & Mary L. Rev. 609 (2009). Though the historical trend appears to be against categorical rules, the issue remains a matter of active debate, with the deep division of the Justices in *Bilski* demonstrating the appeal of categorical rules.[1] Are these more general standards better for the development of patent law? Does a "standards-based" approach breed the very uncertainty that all the Justices in *Bilski* seem to decry?

3. Textualism vs. A Common-Law Approach to Statutory Interpretation. The proper approach to statutory interpretation has long been one of the most important sub-issues in the debate about patentable subject matter. Prior to *Bilski*, cases such as *Chakrabarty* had simultaneously (i) embraced a broad, textualist interpretation of § 101, and (ii) recognized traditional exceptions that prior Supreme Court precedents have read into the statute ("laws of nature, physical phenomena, and abstract ideas"). The Supreme Court case law had, however, not even attempted to explain how the exceptions could be reconciled with the statutory text. The majority opinion in *Bilski* finally attempts to provide an answer.

Although acknowledging that the three case law exceptions "are not required by the statutory text," the Court tied the exceptions to a specific phrase in § 101, noting that the exceptions are "consistent with the notion that a patentable process must be 'new and useful.'" Does this provide a satisfying reconciliation between the statutory text and the exceptions to patentable subject matter recognized in the case law? If the three exceptions are grounded in the language "new and useful," does that statutory basis provide guidance as to how courts Court should apply the exceptions in the future?

In an omitted portion of his lengthy dissent in *Bilski*, Justice Stevens suggested that the broad language in § 101 of the Patent Act should not be interpreted using the "ordinary, contemporary, common meaning" of the words in the statute but should instead be interpreted more like the Sherman Antitrust Act. The reference to the Sherman Act was a brilliant gambit, for that statute is a celebrated instance in which even relatively conservative textualist judges have been willing to read a statute as authorizing the courts to develop a judge-made common law unconstrained by the statutory text. *See, e.g.*, Frank H. Easterbrook, *Statutes' Domains*, 50 U. Chi. L. Rev. 533, 544 (1983) (recognizing the Sherman Act as an example where Congress has authorized courts to create judge-made federal law). Nevertheless, the majority rejected taking the Patent Act all the way down the path of the Sherman Act. Would it be better for the Supreme Court to interpret § 101 of the Patent Act as authorizing judges to control patentable eligibility entirely through judge-made law?

---

[1] Indeed, a majority of Justices in *Bilski* might have initially voted in favor of a categorical exclusion for business methods. Many sophisticated observers of Supreme Court practice believe that Justice Stevens had originally been assigned to write the majority opinion. (Among the reasons for this belief is that Justice Stevens' opinion includes a lengthy recitation of the facts in the case, which is unnecessary and not typically found in concurrences or dissents.) At some point after the drafting of the opinion, Justice Stevens probably did "lose the Court," possibly by losing the vote of Justice Scalia.

4. The Relevance of Other Statutory Provisions. Though both *Chakrabarty* and *Bilski* focus primarily on § 101 (and also § 100 in *Bilski*), the Court's opinions also consider the implications of other provisions in statutory law. In *Chakrabarty*, the dissent interprets the two special statutes, the 1930 Plant Act and the 1970 Plant Variety Protection Act, as providing the exclusive means for obtaining patent protection for any animate organism. For the majority, those two statutes are merely alternatives that help certain inventors (i.e., plant breeders) to obtain exclusive rights where they might otherwise be unable to satisfy the disclosure and other requirements of the general patent statute. In *Bilski*, the majority relied in part on a special provision in the Patent Act (§ 273) that limited the rights granted in "business method" patents but also may have had the effect of entrenching the patentability of business methods. In an omitted portion of his dissent, Justice Stevens unsuccessfully argued that § 273 should not be viewed as supporting the patentability of business methods because, in enacting § 273, Congress did not have the "motivation" to ratify business method patents.

Whether the majority or the dissent had the better view in each case is less important than the larger lesson that, in defining the scope of patentable subject matter, the Supreme Court will look to indications from the structure of the entire Patent Act as well as other relevant statutes. This approach is consistent with the much more general point that, even if patentable subject matter appears to be judge-made law to a certain extent, the law of patents is ultimately statutory law, and thus the courts will search within federal statutory law for any indications of congressional intent on the scope of the statute.

5. "Push[ing] back the frontiers of chemistry, physics, and the like." The opinion in *Chakrabarty* also introduces a subordinate theme found in some cases defining patent eligibility — that "the inventions most benefitting mankind are those that 'push back the frontiers of chemistry, physics, and the like.'" At least two cautionary points should be mentioned about this theme. First, any approach to defining patentability that exalts advances in "chemistry, physics, and the like" seems hard to reconcile with the doctrine that precludes patents on newly discovered laws of nature. *Chakrabarty* itself casually states that $E=mc^2$ would not have been patentable, but that formula clearly pushed back the frontiers of physics, didn't it? Second, the theme also suggests that patent protection might be denied for many inventions—such as new games or even clever mechanical contrivances—that have long been treated as patentable by the courts and the Patent Office.

6. The patentability of Chakrabarty's process claims. As the dissent in *Chakrabarty* notes, the inventor's process claims are not contested because the PTO allowed those claims. Thus, even if the dissenters had carried the day, Dr. Chakrabarty would have received a patent, albeit one without claims drawn to the bacterium itself. This raises an important and general point: Even where inventors are precluded from obtaining certain types of patent rights by patent subject matter doctrine, they may be able to obtain other rights. Thus, as we will see, a researcher may not be able to patent a newly discovered DNA sequence but may patent the complimentary or "cDNA" sequence that is derived from the DNA. Similarly, a researcher who succeeds in cloning an animal might not get a patent on the clone (because it's identical to the natural animal), but may get a patent on the process of cloning. In reading this chapter (and later in advising clients), you should consider the extent to which inventors can obtain significant patent rights despite the limits on patent eligibility.

7. The Practical Importance of *Chakrabarty*. On a narrow level, *Chakrabarty* decided that living organisms are the proper subjects of utility patents notwithstanding Congress's enactment of two statutes that provide special forms of patent protection for certain living organisms. Even if it contained only that holding, *Chakrabarty* would still be highly significant. Not only does the holding — that life itself can be patented — capture the imagination, but the decision was also extremely important for the then-nascent biotechnology industry because it established that the fruits of the industry's research, whether classified as living or not, would be eligible for patenting. *See* David G. Scalise and Daniel Nugent, *Patenting Living Matter in the European Community: Diriment of the Draft Directive*, 16 FORDHAM INT'L L.J. 990, 1005-1006 (1993) (noting that Chakrabarty "opened a new world of opportunity to U.S. industry" and that, as a result of the decision, "U.S. industry greatly expanded its commitment to genetic engineering, establishing an early position of world dominance, which it has yet to yield").

8. The Practical Importance of *Bilski* for Business Method Patents. The practical importance of the *Bilski* decision for business method patents remains a matter of debate. Prior to *Bilski*, the Federal Circuit's decision in *Street Bank & Trust Co. v. Signature Financial Group, Inc.*, 149 F.3d 1368 (1998), became famous (or infamous) for holding in quite clear terms that there was no business method exception to patentable subject matter. The case was not so dramatic an event as its fame might suggest. The specific patent in the case had been issued years earlier. Moreover, the PTO had been issuing similar business method patents for several years, and three years prior *State Street*, the agency had also removed from the Manual of Patent Examining Procedure (the agency's "Bible" on patent law) any suggestion that patent law contained a "business method exception" to patentability.

All of the Justices who authored opinions in *Bilski* went out of their way to disavow or at least to distance themselves from the reasoning in *State Street*. The majority stated that it was not "endorsing interpretations of § 101 that the Court of Appeals for the Federal Circuit has used in the past," with a citation to *State Street*. The concurrence by Justice Breyer (joined by Justice Scalia) disavowed the "useful, concrete and tangible" test for patent eligibility applied by *State Street*. And, obviously, Justice Stevens and the three other Justices who joined his opinion would have barred all business method patents.

Still, the holdings of the *Bilski* majority were a split decision for business method patents. The Court rejected a categorical exclusion of business methods from patentable subject matter but affirmed the ineligibility of the particular business method on the grounds that it is abstract.

The post-*Bilski* experience of business method patents can be seen in the following charts, which provide the number of patents issued each year from 2000 to 2014 in the PTO's general business method category (class 705) and in the sub-category for financial and banking patents (class 705 / sub-class 35). (Data after 2014 is harder to obtain because the PTO changed its entire classification system.) Even after *Bilski*, the PTO continued to issue thousands of business method patents per year, with about a thousand per year devoted just to finance and banking. The vast majority of these patents continue to include claims to methods, though the titles of the patents seem less likely to advertise that methods are being claimed.

Patents in PTO Class 705 (Inventions concerning "Financial, Business Practice, Management, or Cost/Price Determination")[2]

Year	Total	Percent with "Method" in a Patent Claim	Percent with "Method" in the Patent Title
2014	7018	89%	37%
2013	7905	89%	39%
2012	6657	88%	43%
2011	5472	88%	46%
2010	5260	88%	47%
2009	2936	88%	50%
2008	2525	88%	53%
2007	1937	87%	52%
2006	2119	86%	52%
2005	1356	87%	54%
2004	900	84%	55%
2003	868	83%	50%
2002	835	82%	51%
2001	818	84%	49%
2000	1020	84%	50%

[2] This is the label that the PTO has given to this class of inventions. For the complete description of the class, see http://www.uspto.gov/web/patents/classification/uspc705/defs705.htm.

Patents in Class 705 / Subclass 35 (Inventions concerning "Finance (e.g., banking, investment or credit)")[3]

Year	Total in 705/35	Percent with "Method" in a Patent Claim	Percent with "Method" in the Patent Title
2014	957	0.86938	0.41588
2013	1324	0.88973	0.40559
2012	1033	0.89642	0.4395
2011	982	0.88187	0.47963
2010	1009	0.89891	0.49058
2009	503	0.90258	0.50099
2008	365	0.92055	0.54247
2007	213	0.93897	0.51174
2006	243	0.8642	0.46914
2005	79	0.91139	0.48101
2004	46	0.86957	0.45652
2003	49	0.87755	0.36735
2002	50	0.82	0.54
2001	57	0.78947	0.45614
2000	94	0.81915	0.45745

More recent data published by the PTO suggest that *applications* for business method patents (the figures above are for *issued* patents) have fallen by about 30-40% since peaking in 2013-2014. Still, even that data shows that, throughout 2015 and the early months of 2016, the PTO was continuing to receive more than 600 patent applications *per month*, with the total some months exceeding 1000. The data on *allowance* rates for patent applications on business methods suggests a much larger effect of *Bilski* (and subsequent cases). Data released by the PTO in 2015 shows the allowance rate for applications in class 705 to be about 10%, roughly 1/5th the agency's reported allowance rate of about 54% for all patent applications. In releasing that data, however, the agency cautioned that the recent drop in the allowance rate was in part due to the law in area being "in flux" and suggested that the agency might be taking more time in evaluating business method applications (which could lead to a short-term drop in allowance rates larger than the ultimate long-term drop).

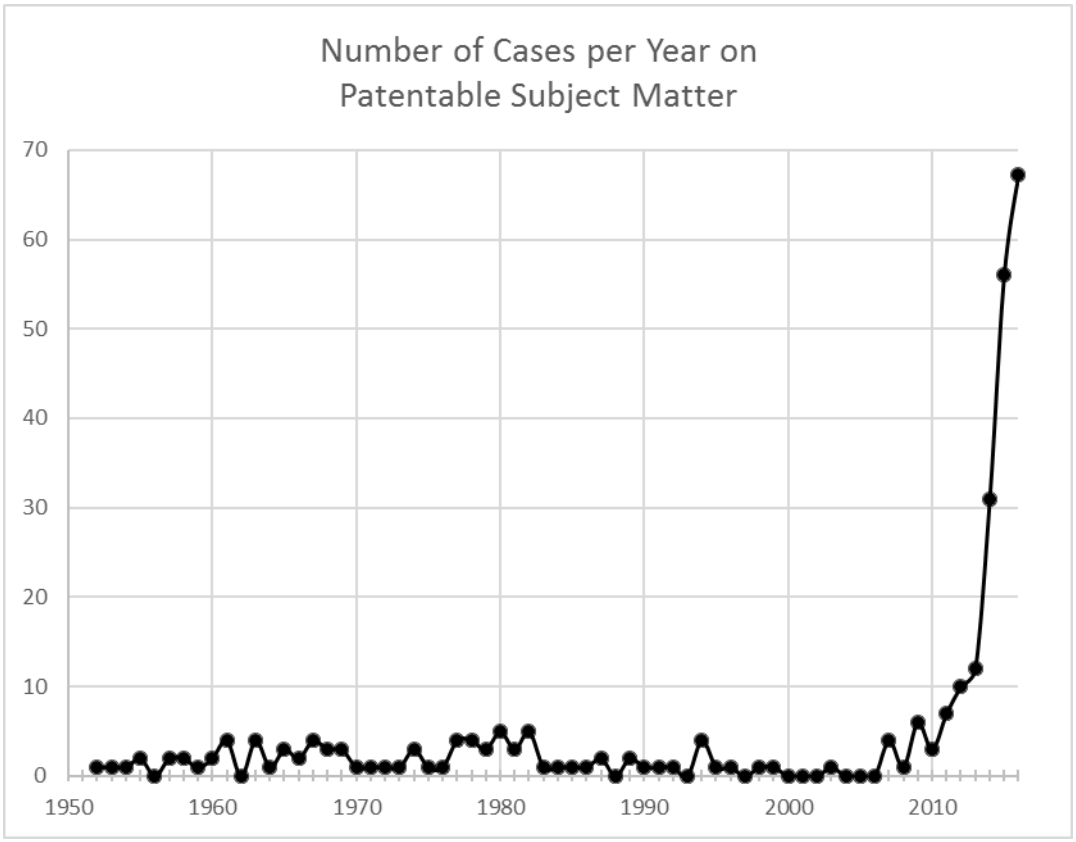
---

[3] For the full description of the PTO's class 705, subclass 35, see http://www.uspto.gov/web/patents/classification/uspc705/defs705.htm#C705S035000

9. *Bilski* and the Patentable Subject Matter Revolution. Immediately after *Bilski*, scholars debated its likely broader effects. One group of scholars suggested that *Bilski*'s holding on abstract ideas should be read as an effort to prevent patent applicants from claiming inventions too broadly. According to these scholars, "[r]ecasting the abstract ideas doctrine as an over claiming test eliminates the constraints of the artificial machine-or-transformation test, as well as the pointless effort to fit inventions into permissible or impermissible categories." *See* Mark A. Lemley, Michael Risch, Ted Sichelman & R. Polk Wagner, *Life After* Bilski, 63 STAN. L. REV. 1315 (2011). Other scholars such as Josh Sarnoff argued that *Bilski* heralded a much more general move toward protecting the "public domain of science, nature and ideas while simultaneously improving the patent system." *See* Joshua D. Sarnoff, *Patent-Eligible Inventions After* Bilski: *History and Theory*, 63 HASTINGS L.J. 53 (2011).

Both perspectives were right to a degree, though perhaps Professor Sarnoff was more accurate in his prediction. *Bilski* did seem to end attempts to define categorical rules for patent eligible and ineligible inventions. The lack of categorical exclusions or inclusions, however, meant that the judicial exclusions from patentable subject matter were free to operate broadly, against every claimed invention. Thus *Bilski*, along with three subsequent Supreme Court cases (each to be examined in the subsequent subchapters), did produce a profound revolution in patent law, with the judge-made exclusions to patentable subject matter becoming more important topics of litigation than they had been at least since the enactment of the Patent Act of 1952 (and perhaps ever). The graph below shows the number of decided federal cases per year categorized by Westlaw as relevant to the exclusions to patentable subject matter.[4]

[4] The cases are all those in Westlaw's class 291 (Patents) with "keycite" number 450-454 (which Westlaw defines to cover "ineligible subject matter" for patents). The data point for 2016 is an estimated annualized number based on data from the first five months of the year.



As the graph demonstrates, recent Supreme Court decisions have transformed patentable subject matter into a major area of litigation. Prior to 2009 (which the year *Bilski* was argued in the Supreme Court), no year had more than five cases classified as involving the exclusions to patentable subject matter. By early 2016, the number of cases involving patentable subject matter exceeded five *per month*. Thus, while *Bilski* did not signal an end to business method patents, it was the start of a revolution in patentable subject matter doctrine.

B. NATURAL LAWS AND NATURAL PRINCIPLES

Both *Chakrabarty* and *Bilski* describe the judge-made law as excluding from patentable subject matter "laws of nature, physical phenomena, and abstract ideas." Other cases have also followed this tripartite description of the exclusions from patentable subject matter, although the practice has not been uniform. Sometimes the Court has referred to the exclusions as "[p]henomena of nature, … mental processes, and abstract intellectual concepts." *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972). In other cases, the Court has stressed that a "principle" or "fundamental truth" is unpatentable. *Parker v. Flook*, 437 U.S. 584, 589 (1978) (quoting *Le Roy v. Tatham*, 55 U.S. (14 How.) 156, 175 (1853)). Elsewhere the Court has asserted simply and boldly that "[a]n idea of itself is not patentable." *Rubber-Tip Pencil Co. v. Howard*, 87 U.S. (20 Wall.) 498, 507 (1874).

Because more recent cases tend to follow *Chakrabarty* and *Bilski* in describing the exclusions, this casebook has organized its discussion to track that description. It should be noted, however, that the doctrine could be organized in a different way. While both the Supreme Court and the lower courts have organized the law into three subject matter exclusions, the courts also freely cite cases from one exclusion in deciding the scope of the other exclusions. For example, our first case for study—*Mayo v. Prometheus Labs.*—has become a canonical case that the courts now frequently cite as supplying a generally applicable test for deciding the scope of all three exclusions. Thus, the exclusions for patentable subject matter could be taught as a single doctrine. Nonetheless, this book separates the doctrine into three parts because, as you will see, each part seems to address slightly different fact patterns.

MAYO COLLAB. SERVICES *v.* PROMETHEUS LABS, INC.

566 U.S. ____ (2012)

JUSTICE BREYER delivered the opinion of the Court.

Section 101 of the Patent Act defines patentable subject matter. It says:

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

The Court has long held that this provision contains an important implicit exception. "[L]aws of nature, natural phenomena, and abstract ideas" are not patentable. *Diamond v. Diehr*, 450 U.S. 175, 185 (1981); see also *Bilski v. Kappos*, 561 U.S. ___, ___, (2010); *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980); *Le Roy v. Tatham*, 55 U.S. 156, 175 (1853); *O'Reilly v. Morse*, 56 U.S. 62, 112-120 (1854); cf. *Neilson v. Harford*, Webster's Patent Cases 295, 371 (1841) (English case discussing same). Thus, the Court has written that "a new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter. Likewise, Einstein could not patent his celebrated law that $E=mc^2$; nor could Newton have patented the law of gravity. Such discoveries are 'manifestations of . . . nature, free to all men and reserved exclusively to none.'" *Chakrabarty*, supra, at 309 (quoting *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127, 130 (1948)).

"Phenomena of nature, though just discovered, mental processes, and abstract intellectual concepts are not patentable, as they are the basic tools of scientific and technological work." *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972). And monopolization of those tools through the grant of a patent might tend to impede innovation more than it would tend to promote it.

The Court has recognized, however, 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. Thus, in *Diehr* the Court pointed out that "'a process is not unpatentable simply because it contains a law of nature or a mathematical algorithm.'" 450 U.S., at 187 (quoting *Parker v. Flook*, 437 U.S. 584, 590 (1978)).

It added that "an *application* of a law of nature or mathematical formula to a known structure or process may well be deserving of patent protection." *Diehr, supra*, at 187. And it emphasized Justice Stone's similar observation in *Mackay Radio & Telegraph Co. v. Radio Corp. of America*, 306 U.S. 86 (1939):

> "'While a scientific truth, or the mathematical expression of it, is not a patentable invention, a novel and useful structure created with the aid of knowledge of scientific truth may be.'" 450 U.S., at 188 (quoting *Mackay Radio, supra*, at 94).

See also *Funk Brothers, supra*, at 130 ("If there is to be invention from [a discovery of a law of nature], it must come from the application of the law of nature to a new and useful end").

Still, as the Court has also made clear, to transform an unpatentable law of nature into a patent-eligible *application* of such a law, one must do more than simply state the law of nature while adding the words "apply it." See, *e.g.*, *Benson, supra*, at 71-72.

The case before us lies at the intersection of these basic principles. It concerns patent claims covering processes that help doctors who use thiopurine drugs to treat patients with autoimmune diseases determine whether a given dosage level is too low or too high. The claims purport to apply natural laws describing the relationships between the concentration in the blood of certain thiopurine metabolites and the likelihood that the drug dosage will be ineffective or induce harmful side-effects. We must determine whether the claimed processes have transformed these unpatentable natural laws into patent-eligible applications of those laws. We conclude that they have not done so and that therefore the processes are not patentable.

Our conclusion rests upon an examination of the particular claims before us in light of the Court's precedents. Those cases warn us against interpreting patent statutes in ways that make patent eligibility "depend simply on the draftsman's art" without reference to the "principles underlying the prohibition against patents for [natural laws]." *Flook, supra*, at 593. They warn us against upholding patents that claim processes that too broadly preempt the use of a natural law. *Morse, supra*, at 112-120; *Benson, supra*, at 71-72. And they insist that a process that focuses upon the use of a natural law also contain other elements or a combination of elements, sometimes referred to as an "inventive concept," sufficient to ensure that the patent in practice amounts to significantly more than a patent upon the natural law itself. *Flook, supra*, at 594; see also *Bilski, supra*, at ___ ("[T]he prohibition against patenting abstract ideas 'cannot be circumvented by attempting to limit the use of the formula to a particular technological environment' or adding 'insignificant post solution activity'" (quoting *Diehr, supra*, at 191-192)).

We find that the process claims at issue here do not satisfy these conditions. In particular, the steps in the claimed processes (apart from the natural laws themselves)

involve well-understood, routine, conventional activity previously engaged in by researchers in the field. At the same time, upholding the patents would risk disproportionately tying up the use of the underlying natural laws, inhibiting their use in the making of further discoveries.

I

A

The patents before us concern the use of thiopurine drugs in the treatment of autoimmune diseases, such as Crohn's disease and ulcerative colitis. When a patient ingests a thiopurine compound, his body metabolizes the drug, causing metabolites to form in his bloodstream. Because the way in which people metabolize thiopurine compounds varies, the same dose of a thiopurine drug affects different people differently, and it has been difficult for doctors to determine whether for a particular patient a given dose is too high, risking harmful side effects, or too low, and so likely ineffective.

At the time the discoveries embodied in the patents were made, scientists already understood that the levels in a patient's blood of certain metabolites, including, in particular, 6-thioguanine and its nucleotides (6-TG) and 6-methyl-mercaptopurine (6-MMP), were correlated with the likelihood that a particular dosage of a thiopurine drug could cause harm or prove ineffective. But those in the field did not know the precise correlations between metabolite levels and likely harm or ineffectiveness. …

[T]he patents—U.S. Patent No. 6,355,623 ('623 patent) and U.S. Patent No. 6,680,302 ('302 patent)—embody findings that concentrations in a patient's blood of 6-TG or of 6-MMP metabolite beyond a certain level (400 and 7000 picomoles per $8x10^8$ red blood cells, respectively) indicate that the dosage is likely too high for the patient, while concentrations in the blood of 6-TG metabolite lower than a certain level (about 230 picomoles per $8x10^8$ red blood cells) indicate that the dosage is likely too low to be effective.

The patent claims seek to embody this research in a set of processes. Like the Federal Circuit we take as typical claim 1 of the '623 Patent, which describes one of the claimed processes as follows:

> "A method of optimizing therapeutic efficacy for treatment of an immune-mediated gastrointestinal disorder, comprising:
>
> "(a) administering a drug providing 6-thioguanine to a subject having said immune-mediated gastrointestinal disorder; and

> "(b) determining the level of 6-thioguanine in said subject having said immune-mediated gastrointestinal disorder,
>
> "wherein the level of 6-thioguanine less than about 230 pmol per $8x10^8$ red blood cells indicates a need to increase the amount of said drug subsequently administered to said subject and
>
> "wherein the level of 6-thioguanine greater than about 400 pmol per $8x10^8$ red blood cells indicates a need to decrease the amount of said drug subsequently administered to said subject." '623 patent, col. 20, ll. 10-20, 2 App. 16.

For present purposes we may assume that the other claims in the patents do not differ significantly from claim 1.

B

Respondent, Prometheus Laboratories, Inc. (Prometheus), is the sole and exclusive licensee of the '623 and '302 patents. It sells diagnostic tests that embody the processes the patents describe. For some time petitioners, Mayo Clinic Rochester and Mayo Collaborative Services (collectively Mayo), bought and used those tests. But in 2004 Mayo announced that it intended to begin using and selling its own test—a test using somewhat higher metabolite levels to determine toxicity (450 pmol per $8x10^8$ for 6-TG and 5700 pmol per $8x10^8$ for 6-MMP). Prometheus then brought this action claiming patent infringement.

[The district court invalided the patents as effectively claiming natural laws or natural phenomena. The Federal Circuit reversed, sustaining the validity of the patents under § 101. The Supreme Court granted certiorari.]

II

Prometheus' patents set forth laws of nature—namely, relationships between concentrations of certain metabolites in the blood and the likelihood that a dosage of a thiopurine drug will prove ineffective or cause harm. Claim 1, for example, states that *if* the levels of 6-TG in the blood (of a patient who has taken a dose of a thiopurine drug) exceed about 400 pmol per $8x10^8$ red blood cells, then the administered dose is likely to produce toxic side effects. While it takes a human action (the administration of a thiopurine drug) to trigger a manifestation of this relation in a particular person, the relation itself exists in principle apart from any human action. The relation is a consequence of the ways in which thiopurine compounds are metabolized by the body—entirely natural processes. And so a patent that simply describes that relation sets forth a natural law.

The question before us is whether the claims do significantly more than simply describe these natural relations. To put the matter more precisely, do the patent claims add *enough* to their statements of the correlations to allow the processes they describe to qualify as patent-eligible processes that *apply* natural laws? We believe that the answer to this question is no.

A

If a law of nature is not patentable, then neither is a process reciting a law of nature, unless that process has additional features that provide practical assurance that the process is more than a drafting effort designed to monopolize the law of nature itself. A patent, for example, could not simply recite a law of nature and then add the instruction "apply the law." Einstein, we assume, could not have patented his famous law by claiming a process consisting of simply telling linear accelerator operators to refer to the law to determine how much energy an amount of mass has produced (or vice versa). Nor could Archimedes have secured a patent for his famous principle of flotation by claiming a process consisting of simply telling boat builders to refer to that principle in order to determine whether an object will float.

What else is there in the claims before us? The process that each claim recites tells doctors interested in the subject about the correlations that the researchers discovered. In doing so, it recites an "administering" step, a "determining" step, and a "wherein" step. These additional steps are not themselves natural laws but neither are they sufficient to transform the nature of the claim.

First, the "administering" step simply refers to the relevant audience, namely doctors who treat patients with certain diseases with thiopurine drugs. That audience is a pre-existing audience; doctors used thiopurine drugs to treat patients suffering from autoimmune disorders long before anyone asserted these claims. In any event, the "prohibition against patenting abstract ideas 'cannot be circumvented by attempting to limit the use of the formula to a particular technological environment.'" *Bilski*, *supra*, at ___ (quoting *Diehr*, 450 U.S., at 191–192).

Second, the "wherein" clauses simply tell a doctor about the relevant natural laws, at most adding a suggestion that he should take those laws into account when treating his patient. That is to say, these clauses tell the relevant audience about the laws while trusting them to use those laws appropriately where they are relevant to their decisionmaking (rather like Einstein telling linear accelerator operators about his basic law and then trusting them to use it where relevant).

Third, the "determining" step tells the doctor to determine the level of the relevant metabolites in the blood, through whatever process the doctor or the laboratory wishes to use. As the patents state, methods for determining metabolite levels were well known in the art. '623 patent, col. 9, ll. 12-65, 2 App. 11. Indeed, scientists routinely measured metabolites as part of their investigations into the relationships between metabolite levels

and efficacy and toxicity of thiopurine compounds. '623 patent, col. 8, ll. 37-40, *id.*, at 10. Thus, this step tells doctors to engage in well-understood, routine, conventional activity previously engaged in by scientists who work in the field. 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. *Flook*, 437 U.S., at 590; see also *Bilski*, 561 U.S., at ___ ("[T]he prohibition against patenting abstract ideas 'cannot be circumvented by' . . . adding 'insignificant post-solution activity'" (quoting *Diehr*, *supra*, at 191–192)).

Fourth, to consider the three steps as an ordered combination adds nothing to the laws of nature that is not already present when the steps are considered separately. See *Diehr*, *supra*, at 188 ("[A] new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made"). Anyone who wants to make use of these laws must first administer a thiopurine drug and measure the resulting metabolite concentrations, and so the combination amounts to nothing significantly more than an instruction to doctors to apply the applicable laws when treating their patients.

The upshot is that the three steps simply tell doctors to gather data from which they may draw an inference in light of the correlations. To put the matter more succinctly, the claims inform a relevant audience about certain laws of nature; any additional steps consist of well understood, routine, conventional activity already engaged in by the scientific community; and those steps, when viewed as a whole, add nothing significant beyond the sum of their parts taken separately. For these reasons we believe that the steps are not sufficient to transform unpatentable natural correlations into patentable applications of those regularities.

B

1

A more detailed consideration of the controlling precedents reinforces our conclusion. The cases most directly on point are *Diehr* and *Flook*, two cases in which the Court reached opposite conclusions about the patent eligibility of processes that embodied the equivalent of natural laws. The *Diehr* process (held patent eligible) set forth a method for molding raw, uncured rubber into various cured, molded products. The process used a known mathematical equation, the Arrhenius equation, to determine when (depending upon the temperature inside the mold, the time the rubber had been in the mold, and the thickness of the rubber) to open the press. It consisted in effect of the steps of: (1) continuously monitoring the temperature on the inside of the mold, (2) feeding the resulting numbers into a computer, which would use the Arrhenius equation to continuously recalculate the mold-opening time, and (3) configuring the computer so that at the appropriate moment it would signal "a device" to open the press. *Diehr*, 450 U.S., at 177-179.

The Court pointed out that the basic mathematical equation, like a law of nature, was not patentable. But it found the overall process patent eligible because of the way the additional steps of the process integrated the equation into the process as a whole. Those steps included "installing rubber in a press, closing the mold, constantly determining the temperature of the mold, constantly recalculating the appropriate cure time through the use of the formula and a digital computer, and automatically opening the press at the proper time." *Id.*, at 187. It nowhere suggested that all these steps, or at least the combination of those steps, were in context obvious, already in use, or purely conventional. And so the patentees did not "seek to pre-empt the use of [the] equation," but sought "only to foreclose from others the use of that equation in conjunction with all of the other steps in their claimed process." *Ibid*. These other steps apparently added to the formula something that in terms of patent law's objectives had significance—they transformed the process into an inventive application of the formula.

The process in *Flook* (held not patentable) provided a method for adjusting "alarm limits" in the catalytic conversion of hydrocarbons. Certain operating conditions (such as temperature, pressure, and flow rates), which are continuously monitored during the conversion process, signal inefficiency or danger when they exceed certain "alarm limits." The claimed process amounted to an improved system for updating those alarm limits through the steps of: (1) measuring the current level of the variable, *e.g.*, the temperature; (2) using an apparently novel mathematical algorithm to calculate the current alarm limits; and (3) adjusting the system to reflect the new alarm limit values. 437 U.S., at 585-587.

The Court, as in *Diehr*, pointed out that the basic mathematical equation, like a law of nature, was not patentable. But it characterized the claimed process as doing nothing other than "provid[ing] a[n unpatentable] formula for computing an updated alarm limit." *Flook*, *supra*, at 586. Unlike the process in *Diehr*, it did not "explain how the variables used in the formula were to be selected, nor did the [claim] contain any disclosure relating to chemical processes at work or the means of setting off an alarm or adjusting the alarm limit." *Diehr*, *supra*, at 192, n. 14; see also *Flook*, 437 U.S., at 586. And so the other steps in the process did not limit the claim to a particular application. Moreover, "[t]he chemical processes involved in catalytic conversion of hydrocarbons[,] . . . the practice of monitoring the chemical process variables, the use of alarm limits to trigger alarms, the notion that alarm limit values must be recomputed and readjusted, and the use of computers for 'automatic monitoring-alarming'" were all "well known," to the point where, putting the formula to the side, there was no "inventive concept" in the claimed application of the formula. *Id.*, at 594. "[P]ost solution activity" that is purely "conventional or obvious," the Court wrote, "can[not] transform an unpatentable principle into a patentable process." *Id.*, at 589, 590.

The claim before us presents a case for patentability that is weaker than the (patent-eligible) claim in *Diehr* and no stronger than the (unpatentable) claim in *Flook*. Beyond picking out the relevant audience, namely those who administer doses of thiopurine drugs, the claim simply tells doctors to: (1) measure (somehow) the current

level of the relevant metabolite, (2) use particular (unpatentable) laws of nature (which the claim sets forth) to calculate the current toxicity/inefficacy limits, and (3) reconsider the drug dosage in light of the law. These instructions add nothing specific to the laws of nature other than what is well-understood, routine, conventional activity, previously engaged in by those in the field. And since they are steps that must be taken in order to apply the laws in question, the effect is simply to tell doctors to apply the law somehow when treating their patients. The process in *Diehr* was not so characterized; that in *Flook* was characterized in roughly this way.

2

Other cases offer further support for the view that simply appending conventional steps, specified at a high level of generality, to laws of nature, natural phenomena, and abstract ideas cannot make those laws, phenomena, and ideas patentable. This Court has previously discussed in detail an English case, *Neilson*, which involved a patent claim that posed a legal problem very similar to the problem now before us. The patent applicant there asserted a claim

> "for the improved application of air to produce heat in fires, forges, and furnaces, where a blowing apparatus is required. [The invention] was to be applied as follows: The blast or current of air produced by the blowing apparatus was to be passed from it into an air vessel or receptacle made sufficiently strong to endure the blast; and through or from that vessel or receptacle by means of a tube, pipe, or aperture into the fire, the receptacle be kept artificially heated to a considerable temperature by heat externally applied." *Morse*, 15 How., at 114-115.

The English court concluded that the claimed process did more than simply instruct users to use the principle that hot air promotes ignition better than cold air, since it explained how the principle could be implemented in an inventive way. Baron Parke wrote (for the court):

> "It is very difficult to distinguish [Neilson's claim] from the specification of a patent for a principle, and this at first created in the minds of some of the court much difficulty; but after full consideration, we think that the plaintiff does not merely claim a principle, but a machine embodying a principle, and a very valuable one. We think the case must be considered as if the principle being well known, the plaintiff had first invented a mode of applying it by a mechanical apparatus to furnaces; and his invention then consists in this—by interposing a receptacle for heated air between the blowing apparatus and the furnace. In this receptacle he directs the air to be heated by the application of heat externally to the receptacle, and thus he accomplishes the object of applying the blast, which was before of cold air, in a heated state to the furnace." *Neilson v. Harford*, Webster's Patent Cases, at 371.

Thus, the claimed process included not only a law of nature but also several unconventional steps (such as inserting the receptacle, applying heat to the receptacle externally, and blowing the air into the furnace) that confined the claims to a particular, useful application of the principle. …

3

The Court has repeatedly emphasized … a concern that patent law not inhibit further discovery by improperly tying up the future use of laws of nature. …

These statements reflect the fact that, even though rewarding with patents those who discover new laws of nature and the like might well encourage their discovery, those laws and principles, considered generally, are "the basic tools of scientific and technological work." *Benson*, *supra*, at 67. And so there is a danger that the grant of patents that tie up their use will inhibit future innovation premised upon them, a danger that becomes acute when a patented process amounts to no more than an instruction to "apply the natural law," or otherwise forecloses more future invention than the underlying discovery could reasonably justify. …

The laws of nature at issue here are narrow laws that may have limited applications, but the patent claims that embody them nonetheless implicate this concern. They tell a treating doctor to measure metabolite levels and to consider the resulting measurements in light of the statistical relationships they describe. In doing so, they tie up the doctor's subsequent treatment decision whether that treatment does, or does not, change in light of the inference he has drawn using the correlations. And they threaten to inhibit the development of more refined treatment recommendations (like that embodied in Mayo's test), that combine Prometheus' correlations with later discovered features of metabolites, human physiology or individual patient characteristics. The "determining" step too is set forth in highly general language covering all processes that make use of the correlations after measuring metabolites, including later discovered processes that measure metabolite levels in new ways.

We need not, and do not, now decide whether were the steps at issue here less conventional, these features of the claims would prove sufficient to invalidate them. For here, as we have said, the steps add nothing of significance to the natural laws themselves. Unlike, say, a typical patent on a new drug or a new way of using an existing drug, the patent claims do not confine their reach to particular applications of those laws. The presence here of the basic underlying concern that these patents tie up too much future use of laws of nature simply reinforces our conclusion that the processes described in the patents are not patent eligible, while eliminating any temptation to depart from case law precedent.

III

… Prometheus argues that, because the particular laws of nature that its patent claims embody are narrow and specific, the patents should be upheld. … But the underlying functional concern here is a *relative* one: how much future innovation is foreclosed relative to the contribution of the inventor. A patent upon a narrow law of nature may not inhibit future research as seriously as would a patent upon Einstein's law of relativity, but the creative value of the discovery is also considerably smaller. And, as we have previously pointed out, even a narrow law of nature (such as the one before us) can inhibit future research.

[T]he Government argues that virtually any step beyond a statement of a law of nature itself should transform an unpatentable law of nature into a potentially patentable application sufficient to satisfy §101's demands. The Government does not necessarily believe that claims that (like the claims before us) extend just minimally beyond a law of nature should receive patents. But in its view, other statutory provisions—those that insist that a claimed process be novel, 35 U.S.C. §102, that it not be "obvious in light of prior art," §103, and that it be "full[y], clear[ly], concise[ly], and exact[ly]" described, § 112—can perform this screening function. In particular, it argues that these claims likely fail for lack of novelty under §102.

This approach, however, would make the "law of nature" exception to §101 patentability a dead letter. The approach is therefore not consistent with prior law. The relevant cases rest their holdings upon section 101, not later sections.

We recognize that, in evaluating the significance of additional steps, the §101 patent-eligibility inquiry and, say, the §102 novelty inquiry might sometimes overlap. But that need not always be so. And to shift the patent eligibility inquiry entirely to these later sections risks creating significantly greater legal uncertainty, while assuming that those sections can do work that they are not equipped to do.

What role would laws of nature, including newly discovered (and "novel") laws of nature, play in the Government's suggested "novelty" inquiry? Intuitively, one would suppose that a newly discovered law of nature is novel. The Government, however, suggests in effect that the novelty of a component law of nature may be disregarded when evaluating the novelty of the whole. But §§102 and 103 say nothing about treating laws of nature as if they were part of the prior art when applying those sections. Cf. *Diehr*, 450 U.S., at 188 (patent claims "must be considered as a whole"). And studiously ignoring *all* laws of nature when evaluating a patent application under §§102 and 103 would "make all inventions unpatentable because all inventions can be reduced to underlying principles of nature which, once known, make their implementation obvious." *Id.*, at 189, n. 12. …

Prometheus, supported by several *amici*, argues that a principle of law denying patent coverage here will interfere significantly with the ability of medical researchers to

make valuable discoveries, particularly in the area of diagnostic research. That research, which includes research leading to the discovery of laws of nature, is expensive; it "ha[s] made the United States the world leader in this field"; and it requires protection. Brief for Respondent 52.

Other medical experts, however, argue strongly against a legal rule that would make the present claims patent eligible, invoking policy considerations that point in the opposite direction. The American Medical Association, the American College of Medical Genetics, the American Hospital Association, the American Society of Human Genetics, the Association of American Medical Colleges, the Association for Molecular Pathology, and other medical organizations tell us that if "claims to exclusive rights over the body's natural responses to illness and medical treatment are permitted to stand, the result will be a vast thicket of exclusive rights over the use of critical scientific data that must remain widely available if physicians are to provide sound medical care." Brief for American College of Medical Genetics et al. as *Amici Curiae* 7; see also App. to Brief for Association Internationale pour la Protection de la Propriété Intellectuelle et al. as *Amici Curiae* A6, A16 (methods of medical treatment are not patentable in most of Western Europe).

We do not find this kind of difference of opinion surprising. Patent protection is, after all, a two-edged sword. On the one hand, the promise of exclusive rights provides monetary incentives that lead to creation, invention, and discovery. On the other hand, that very exclusivity can impede the flow of information that might permit, indeed spur, invention, by, for example, raising the price of using the patented ideas once created, requiring potential users to conduct costly and time-consuming searches of existing patents and pending patent applications, and requiring the negotiation of complex licensing arrangements. At the same time, patent law's general rules must govern inventive activity in many different fields of human endeavor, with the result that the practical effects of rules that reflect a general effort to balance these considerations may differ from one field to another.

In consequence, we must hesitate before departing from established general legal rules lest a new protective rule that seems to suit the needs of one field produce unforeseen results in another. And we must recognize the role of Congress in crafting more finely tailored rules where necessary. Cf. 35 U.S.C. §§161–164 (special rules for plant patents). We need not determine here whether, from a policy perspective, increased protection for discoveries of diagnostic laws of nature is desirable.

* * *

For these reasons, we conclude that the patent claims at issue here effectively claim the underlying laws of nature themselves. The claims are consequently invalid. And the Federal Circuit's judgment is reversed.

It is so ordered.

NOTES ON MAYO

1. "Too Broad an Interpretation of this Exclusionary Principle Could Eviscerate Patent Law." In *Mayo*, the Supreme Court acknowledges that the "implicit exception" read into the text of § 101 could eviscerate patent law because "all inventions at some level embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." Though the Supreme Court's § 101 case law remains deeply controversial, nearly everyone in the debate believes that this statement in *Mayo* is clearly correct. This truth might also explain why, in the last half century, the Supreme Court has granted review and decided more cases involving § 101 (nine case in total) than cases involving any other patent law doctrine. The judge-made exceptions to § 101 provide a general throttle on the entirety of the patent system, and because the exceptions are not based on any statutory text, the courts—especially the Supreme Court—can exercise control over the statutory system based on judicial assessments of good patent policy.

2. "The Draftsman's Art." Repeating a phrase from its earlier precedents, the Court cautions that patentable subject matter should not depend on the "draftsman's art" in choosing particular language for patent claims. That statement, however, has to be read in the context of the entire opinion and should not be read as meaning that patentable subject matter cases can be decided without reading the claims in a patent. After all, the *Mayo* Court quotes claim 1 of the patent in full, focuses attention on the precise language used in the claim (including, for example, "highly general language covering all processes that make use of the correlations after measuring metabolites"), and eschews any opinion on what the outcome would be if the steps in the claims were different. The overall thrust of the Court's precedents is that the prohibition on patenting natural laws cannot be evaded by adding conventional elements as window-dressing. Thus, Einstein could not patent a method of teaching physics using $E=mc^2$ even if his patent attorney were to add to the claim elements such a blackboard, chalk, a textbook, homework problems and other conventional items used in teaching.

3. Einstein, $E=mc^2$ and Enablement. Einstein and his famous equation are mentioned so frequently in modern court opinions precisely because they provide good examples of the limits of patentability. One bedrock requirement of patent law, which will be examined in more detail in Chapter 4, is that an inventor seeking patent rights must "enable" the use of his claimed technology—i.e., must include in the patent application a complete description "of the manner and process of making and using" the invention to enable any person skilled in the art … to make and use the same." 35 U.S.C. § 112(a).

In the modern world, the formula $E=mc^2$ helps to explain the behavior and physics of things such as nuclear bombs, nuclear reactors and linear accelerators (Justice Breyer's example). But when Einstein formulated his equation in 1905, none of those things existed. Einstein might have been able to guess that nuclear reactors and atomic bombs would eventually be possible (two implications of Einstein's formula). *See* RICHARD RHODES, THE MAKING OF THE ATOMIC BOMB 172 (1986) (noting that Einstein understood as early as 1907 that "there was vast energy stored in matter, though he was not at all sure that it could be released, even experimentally").[1]

---

[1] Einstein was not even the first to realize this. As early as 1904, future Nobel laureate Frederick Soddy understood that the energy released from radioactive decay was "at least twenty-thousand times, and may be a million times, as great as the energy of any [chemical] change," and that "[t]he man who put his hand

But he could not patent those inventions because he could not "enable" the construction and operation of them. The technical knowledge to build reactors, bombs and accelerators would not exist until decades later.[2] The doctrinal bar against patenting scientific principles and the enablement requirement thus work toward the same end, which is to control the *timing* and *scope* of patenting. This point also reinforces the *Bilski* Court's statement that the exclusions from patentable subject matter "are consistent with the notion that a patentable process must be 'new and useful.'" To the extent it describes nature, $E=mc^2$ is not new, and at the time Einstein formulated it, no one could yet use it in any practical way.

4. The "Wherein" Clauses of the Patent. One of the weaknesses in the patentee's case in *Mayo* was that the claims included only two conventional, non-novel process steps (the "administering" and "determining" steps), coupled with enigmatic "wherein" clauses that state certain newly discovered truths. One problem with this structure—a problem that made it easy for the Supreme Court to conclude that patent was trying to cover a natural law—is that, to the extent the facts stated in the "wherein" clauses are true, they have always been true. Thus, the traditional wisdom of sophisticated patent attorneys had long been that a "wherein," "whereby" and similar clause "adds nothing that aids patentability as it is purely explanatory of the modus operandi of the structure claimed." Ridsdale Ellis, Patent Claims § 271 at p. 358 (1949).

5. Natural Laws, Applications of Natural Laws and the *Neilson* Case. The *Mayo* Court follows earlier Supreme Court precedent by distinguishing between natural laws, which are not patentable, and *applications* of natural laws, which are. The Court also gives a good example of a case that falls on the "application" side of the line: *Neilson v. Harford*, Webster's Patent Cases 295 (1841). In that case, Neilson discovered a basic natural principle: for igniting fuel of the sort used in nineteenth century furnaces, "hot air promotes ignition better than cold air." Neilson did not try to patent that natural principle, rather he patented a furnace that was designed to take advantage of that new natural principle—a furnace with a heated receptacle through which the air supplying ignition would blow. That was an unconventional design for a furnace, even though such a design might seem relatively easy to devise once the newly discovered natural principle is known and even though Neilson's patent described the design in very general terms (it covered any furnace with a "receptacle" capable of pre-heating the air prior to ignition).

The result and reasoning in the *Neilson* case—which the *Mayo* Court endorses—suggests one limit on the bar against patenting natural laws: Changing prior technology in unconventional ways can be a patentable invention even if the motivation to make those changes arises in a straightforward way from the inventor's discovery a natural principle. The *Mayo* Court

---

on the level by which a parsimonious nature regulates so jealously the output of this store of energy would possess a weapon by which he could destroy the earth if he chose." RHODES, *supra*, at 43–44 (quoting Soddy).

[2] Linear accelerators would not be developed until the late 1920s. See M. Stanley Livingston, *Early History of Particle Acclerators*, in 50 ADVANCES IN ELECTRONICS AND ELECTRONIC PHYSICS 2, 3-5, 49-51 (1980). The first nuclear reactor was built in 1942 in an abandoned squash court at the University of Chicago, see RHODES, *supra*, at 433–442, and was subsequently patented. See, e.g., U.S. Patent No. 2,708,656, available at http://www.uspto.gov (patent on the "Neutronic Reactor" issued in 1955 on the application by Enrico Fermi and Leo Szilard filed in 1944). The first atomic bomb was possible only after the completion of the enormously expensive "Manhattan Project" in 1945.

underscores this point later in its opinion when it differentiates the inquiry under § 101 from the statutory "obviousness" inquiry under § 103 (a subject covered in Chapter 7, infra). The Court recognizes that "all inventions can be reduced to underlying principles of nature which, once known, make their implementation obvious," but that fact does not make all inventions unpatentable under § 101.

6. *Mayo*'s Two-Step "Framework"? Two years after *Mayo*, the Supreme Court in *Alice Corp. v. CLS Bank Int'l*, 134 S. Ct. 2347, 2355 (2014), described *Mayo* as having established a two-step "framework" for evaluating the exceptions to patentable subject matter. The first step, according to the *Alice* Court, requires a court to determine "whether the claims at issue are directed to one of [the] patent-ineligible concepts" (which the Court described as "laws of nature, natural phenomena, and abstract ideas"). *Id.* In "step two," a court "must examine the elements of the claim to determine whether it contains an 'inventive concept' sufficient to 'transform' the claimed [patent-ineligible concept] into a patent-eligible application." *Id.* at 2357 (quoting *Mayo*).

Subchapter 2.D, *infra*, will cover *Alice* in more detail, but for now you should review *Mayo* and ask whether such a "framework" is articulated in Justice Breyer's opinion for the Court. The *Alice* Court cited the introductory portion of part II of *Mayo* as the basis for the first step of the framework. As the basis for step two, the Court relied on the penultimate paragraph in the opening portion of the *Mayo* opinion (the portion before part I), plus the last paragraph of part II.A. Do these portions of the *Mayo* opinion support a two-part framework?

The case below provides a good example of how the Federal Circuit is applying this two-part framework and also illustrates three limiting principles derived from Supreme Court precedents. First, a claimed invention is not "directed to" a law of nature, natural phenomenon or abstract idea merely because it is based on, or exploits, such ineligible subject matter. Second, an unconventional combination or ordering of conventional steps can mean that the claim as a whole is unconventional and thus patentable. Third, an application of a newly discovered natural law is not rendered unpatentable merely because the application is easy to devise once the natural law is known.

Rapid Litigation Mgmt. v. CellzDirect, Inc., ___ F.3d ___ (Fed. Cir. July 5, 2016) (Prost, C.J.) (joined by Moore and Stoll, JJ.).

[Liver cells called "hepatocytes" are useful for medical research and treatment. The cells are harvested from donated organs and must be stored until they are needed. Storage of the cells is difficult because the cells must still be alive or "viable" when they are eventually used. One known method of storing the cells is a "cryopreservation" technique that freezes the cells in liquid nitrogen. Cryopreservation, however, damages the cells, leading to a substantial fraction of the cells being nonviable after they are thawed. Thus, once cells are thawed after cryopreservation, the viable cells have to be separated from the nonviable using a prior art sorting process called "density gradient fractionation." Given the damage done to the cells and the difficulty of recovering viable cells after cryopreservation, the prevailing wisdom in the prior art had been that the cells could be frozen only once and then had to be either used or discarded.

The inventors in the case discovered that some fraction of cells are capable of surviving multiple freeze-thaw cycles. As one of the inventors testified, "the unexpected outcome was that cells twice frozen behaved like cells that were once frozen."

With this discovery, the inventors obtained U.S. Patent No. 7,604,929 (the '929 patent) on an improved process of preserving the cells, comprising: (A) subjecting previously frozen and thawed cells to density gradient fractionation to separate viable cells from non-viable ones; (B) recovering the viable cells; and (C) refreezing the viable cells. The claims specify that the resulting cells, when subsequently thawed, will exhibit 70% viability (which is considered an acceptably high level of viability) even without performing a second gradient fractionation to separate the viable from the nonviable cells.[1]]

A

We begin with step one [of the *Mayo* test]: whether the claims here are "directed to" a patent-ineligible concept. The district court concluded that they were: that "the patent is directed to an ineligible law of nature: the discovery that hepatocytes are capable of surviving multiple freeze-thaw cycles." We disagree.

[T]he claims are simply not directed to the ability of hepatocytes to survive multiple freeze-thaw cycles. Rather, the claims of the '929 patent are directed to a new and useful laboratory technique for preserving hepatocytes. This type of constructive process, carried out by an artisan to achieve "a new and useful end," is precisely the type of claim that is eligible for patenting. *Alice*, 134 S. Ct. at 2354 (quoting *Gottschalk v. Benson*, 409 U.S. 63, 67 (1972)). The inventors certainly discovered the cells' ability to survive multiple freeze-thaw cycles, but that is not where they stopped, nor is it what they patented. Rather, "as the first party with knowledge of" the cells' ability, they were "in an excellent position to claim applications of that knowledge." *Ass'n for Molecular Pathology v. Myriad Genetics, Inc.*, 133 S. Ct. 2107, 2120 (2013) (quoting *Ass'n for Molecular Pathology v. U.S. Patent & Trademark Office*, 689 F.3d 1303, 1349 (Fed. Cir. 2012) (Bryson, J., concurring in part and dissenting in part)). That is precisely what they did. They employed their natural discovery to create a new and improved way of preserving hepatocyte cells for later use. …

The '929 patent claims are like thousands of others that recite processes to achieve a desired outcome, e.g., methods of producing things, or methods of treating disease. That one way of describing the process is to describe the natural ability of the subject matter to undergo the

---

[1] Claim 1 of the patent recites:

> 1. A method of producing a desired preparation of multi-cryopreserved hepatocytes, said hepatocytes being capable of being frozen and thawed at least two times, and in which greater than 70% of the hepatocytes of said preparation are viable after the final thaw, said method comprising:
>
> (A) subjecting hepatocytes that have been frozen and thawed to density gradient fractionation to separate viable hepatocytes from nonviable hepatocytes,
>
> (B) recovering the separated viable hepatocytes, and
>
> (C) cryopreserving the recovered viable hepatocytes to thereby form said desired preparation of hepatocytes without requiring a density gradient step after thawing the hepatocytes for the second time, wherein the hepatocytes are not plated between the first and second cryopreservations, and wherein greater than 70% of the hepatocytes of said preparation are viable after the final thaw.

process does not make the claim "directed to" that natural ability. If that were so, we would find patent-ineligible methods of, say, producing a new compound (as directed to the individual components' ability to combine to form the new compound), treating cancer with chemotherapy (as directed to cancer cells' inability to survive chemotherapy), or treating headaches with aspirin (as directed to the human body's natural response to aspirin). …

As the Supreme Court has made clear, "an invention is not rendered ineligible for patent simply because it involves" one of the patent-ineligible concepts. *Alice*, 134 S. Ct. at 2354. Indeed, to preclude the patenting of an invention simply because it touches on something natural would "eviscerate patent law." *Mayo*, 132 S. Ct. at 1293.

At 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." Here, the plain claim language shows that it is not. The '929 patent does not simply claim hepatocytes' ability to survive multiple freeze-thaw cycles. The '929 patent instead claims a "method of producing a desired preparation of multi-cryopreserved hepatocytes." '929 patent col. 19 l. 56-col. 20 l. 20. This 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.

B

Even if [the patent were] "directed to" hepatocytes' natural ability to survive multiple freeze-thaw cycles, and that we must proceed to step two, we would find the claims patent-eligible at that point as well. Under step two, claims that are "directed to" a patent-ineligible concept, yet also "improve[] an existing technological process," are sufficient to "transform[] the process into an inventive application" of the patent-ineligible concept. *Alice*, 134 S. Ct. at 2358 (quoting *Mayo*, 132 S. Ct. at 1299) (discussing *Diamond v. Diehr*, 450 U.S. 175 (1981). The claims of the '929 patent do precisely that: they recite an improved process for preserving hepatocytes for later use. …

That each of the claims' individual steps (freezing, thawing, and separating) were known independently in the art does not make the claim unpatentable. It is true that, at step two, a claim that recites only "well-understood, routine, conventional activity already engaged in by the scientific community" will not be patent eligible. *Mayo*, 132 S. Ct. at 1298. … That is not to say, however, that all process claims that employ only independently known steps will be unpatentable. To the contrary, in examining claims under step two, we must view them as a whole, considering their elements "both individually and 'as an ordered combination.'" *Alice*, 134 S. Ct. at 2355 (quoting *Mayo*, 132 S. Ct. at 1298). Thus, "a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made." *Diehr*, 450 U.S. at 188.

Here, the claimed process involves freezing and thawing hepatocytes twice. The individual steps of freezing and thawing were well known, but a process of preserving hepatocytes by repeating those steps was itself far from routine and conventional. …

Repeating a step that the art taught should be performed only once can hardly be considered routine or conventional. This is true even though it was the inventor's discovery of

something natural that led them to do so. Just as in *Diehr*, it is the particular "combination of steps" that is patentable here. 450 U.S. at 188.

[T]he crux of [the defendant's] argument seems to be that, once it was discovered that hepatocytes could survive multiple freeze-thaw cycles, it would have been a simple task to repeat the known freeze-thaw process to arrive at the claimed invention. But patent-eligibility does not turn on ease of execution or obviousness of application. Those are questions that are examined under separate provisions of the Patent Act. *Mayo*, 132 S. Ct. at 1304.[2]

NOTE ON O'REILLY v. MORSE, THE TELEPHONE CASES AND NINETEENTH CENTURY VIEWS ON PATENT ELIGIBILITY

The doctrines of patent eligibility have very old roots, and they have also historically generated substantial debate. Two nineteenth century cases are important for understanding the historical debate, and those cases involved two of the most famous inventions ever: Samuel F. B. Morse's telegraph and Alexander Graham Bell's telephone.

1. Morse's Telegraph Patent and *O'Reilly v. Morse*. Samuel Morse was an extremely successful inventor and patentee, and for patent lawyers, he is also inextricably bound to the Supreme Court case frequently cited as the earliest U.S. case on patentable subject matter, *O'Reilly v. Morse*, 56 U.S. 62 (1854).

a. The Context of the Case: Revolutionary Times. *O'Reilly v. Morse* is an important case for a variety of reasons. The telegraph was one of the most significant inventions of the nineteenth century; it began a revolution in communications that has swept the world with dizzying speed.[1] The next century and a half would see an ever-increasing appetite for more wires, cables, satellites and fibers to carry electronic communications.

Yet Morse's invention also occurred at the beginning of a revolution in patent law as significant as the one in communications. Prior to 1836, the U.S. patent system had compiled an uneven record in protecting intellectual property rights. For example, the system failed meritorious inventors such as Eli Whitney, who was famously unsuccessful in profiting from the

---

[2] Indeed, the obviousness of the '929 patent claims under 35 U.S.C. § 103 has been addressed in prior proceedings. During original examination, and then again during post-grant reexamination, the U.S. Patent and Trademark Office found the claims non-obvious given the knowledge that cryopreservation damages cells and the prior art's lack of experimentation with multi-cryopreserved cells. On a preliminary record, we made similar observations in affirming the district court's entry of preliminary injunction. See [*Celsis In Vitro, Inc. v. CellzDirect, Inc.*, 664 F.3d 922, 928 (Fed. Cir. 2012)], (noting that "the prior art taught away from multiple freezings").

[1] Just fourteen years after a primitive telegraph system built by Morse succeeded in transmitting the question "What hath God wrought?" from Baltimore to Washington, the first transoceanic cable began relaying signals from Europe to North America in 1858. *See* BERN DIBNER, THE ATLANTIC CABLE 66 (1964). Although the 1858 transatlantic cable ceased working within a few days, transatlantic telegraph service was restored in 1866.

cotton gin despite massive infringement of his patents.[2] Furthermore, the system sometimes rewarded the unscrupulous. Like England, the U.S. followed a registration approach under which the executive branch had no discretion to deny a patent to any applicant complying with certain formalities, and that approach led to the issuance of numerous fraudulent patents.

Morse invented just as the patent law was changing, and changing dramatically. Two years before Morse applied for his patent, the Patent Act of 1836 abandoned the primitive registration system and established the current system for administrative examination of all patent applications. Moreover, the patent claim, which had been unknown at the beginning of the nineteenth century, was evolving into the essential legal instrument for defining a patentee's rights.[3] These and other developments were rapidly increasing the reliability, value and precision of patent rights.

b. The Prior Art. Like all inventors, Morse was not working on a clean slate. His telegraph was based on a progression of technological advances over the prior decades. Previous investigators had already realized that the natural phenomenon of electromagnetism could be harnessed for communications purposes. Consider the following abridged history of the invention:[4]

1753:	An author identified only as "C.M." publishes "An Expeditious Method of Conveying Intelligence" in a Scottish journal. The article suggests stringing between distant points wires equal in number to the letters of the alphabet; communications could then be made by imparting sufficient electric charge to move a small ball or bell at the other end of the wire.
1774:	George Louis Le Sage of Geneva constructs a telegraph with separate wires corresponding to the letters of the alphabet. The device is similar to that suggested by the earlier Scottish writer; electrical charge imparted on one end of the wire moves small pith balls on the other end. Le Sage's device functions but is not commercialized.
1816:	Dr. John Redmond Coxe, a chemistry professor at the University of Pennsylvania, publishes an article suggesting that the power of electric current to decompose water could be harnessed for communications.
	Danish scientist Hans Christian Oersted discovers the relationship between electricity

[2] *See* CONSTANCE MCLAUGHLIN GREEN, ELI WHITNEY AND THE BIRTH OF AMERICAN TECHNOLOGY 63-96 (Oscar Handlin ed., 1956) (describing Whitney's difficulty in enforcing his cotton gin patent against Southern cotton planters); JEANNETTE MIRSKY & ALLAN NEVINS, THE WORLD OF ELI WHITNEY 111-127 (1952) (same).

[3] Robert Fulton's 1811 patent on the steamboat is generally credited with the "first examples of real patent claims in the modern sense." William Redin Woodward, *Definiteness and Particularity in Patent Claims*, 46 MICH. L. REV. 755, 758 (1948); *see also id.* (humorously noting that "Fulton might more properly be credited with the invention of the 'claim' than of the steamboat"); Karl B. Lutz, *Evolution of the Claims of U. S. Patents*, 20 J. PAT. OFF. SOC'Y 134, 136 (1938) (crediting Fulton's patent with "the first real 'claims,' in the modern patent meaning"). The Patent Act of 1836 codified the statutory requirement for claims. *See* Act of July 4, 1836, chap. 157, § 5, 5 Stat. 117, 119; Woodward, *supra*, at 759–60 (noting codification); Lutz, *supra*, 142–143 (same).

[4] The history is derived from the Court's opinion in *Morse*, supplemented BY ALVIN F. HARLOW, OLD WIRES AND NEW WAVES 35-57 (1936).

1820:	and magnetism. Soon thereafter, "it was believed by men of science that this newly-discovered power might be used to communicate intelligence to distant places." *Morse*, 56 U.S. at 107.
1823:	French physicist Andre Ampere proposes using electromagnetic effects for communication, but his proposal is never reduced to practice.
1824:	Russian Baron Paul Ludovitch Schilling constructs a working model of a telegraph that uses electric current in a circuit to deflect needles.
1831:	In Albany, New York, Professor Joseph Henry constructs an electric device that rings a bell at the end of a mile-long length of copper wire. Henry mentions to his classes that the bell could be used for signaling and publishes an article discussing the possibility of electric telegraphs.[5]
1832:	On a transatlantic voyage, Morse first considers the possibility of using electric current for long distance communication. Morse apparently believes his idea to be original even though by this time, as the Supreme Court notes, "the conviction was general among men of science everywhere" that an electromagnetic telegraph could be produced. *Morse*, 56 U.S. at 107.
1837 - 1839:	Four inventors, Morse, Steinheil (German), Wheatstone and Davy (both English), invent "so nearly simultaneously, that neither inventor can justly be accused of having derived any aid from the discoveries of the other." *Id.*, at 108.

c. Morse's Invention, Patent and Infringement Litigation. While Morse was certainly not the first to realize that electricity could carry information, he did produce a practical and effective machine for carrying out the idea. His telegraph consisted of a main circuit with battery, a key with signal lever and local circuit plus battery, a receiver with electromagnet, and a register with electro-magnet, pen lever, and grooved roller (see Figure 2-1). Morse's patent (U.S. Reissue Pat. No. 117 (June 13, 1848)) included eight claims that, with the exception of the two claims discussed below, were directed toward the details of his telegraph machinery.

Morse assigned his patents to companies which had laid down telegraph lines between several American cities, such as New York and Boston, New Orleans and Boston, and several other cities. While most of the telegraph companies were operating under license from Morse, some refused, leading Morse to file suit for patent infringement. The trial court ruled entirely in favor of Morse. The defendants then filed an appeal to the Supreme Court, which ultimately ruled mostly in favor of Morse. Two of Morse's claims are worth attention.

---

[5] CARLETON MABEE, THE AMERICAN LEONARDO: A LIFE OF SAMUEL F. B. MORSE 191 (1943) (noting that "if sound telegraphs are to be considered telegraphs — and they were the common forms at Morse's death — Henry's [bell ringing device] *was* a telegraph").

No. 117. REISSUED JUNE 13, 1848.

S. F. B. MORSE.

ELECTROMAGNETIC TELEGRAPH.

4 SHEETS—SHEET 4.

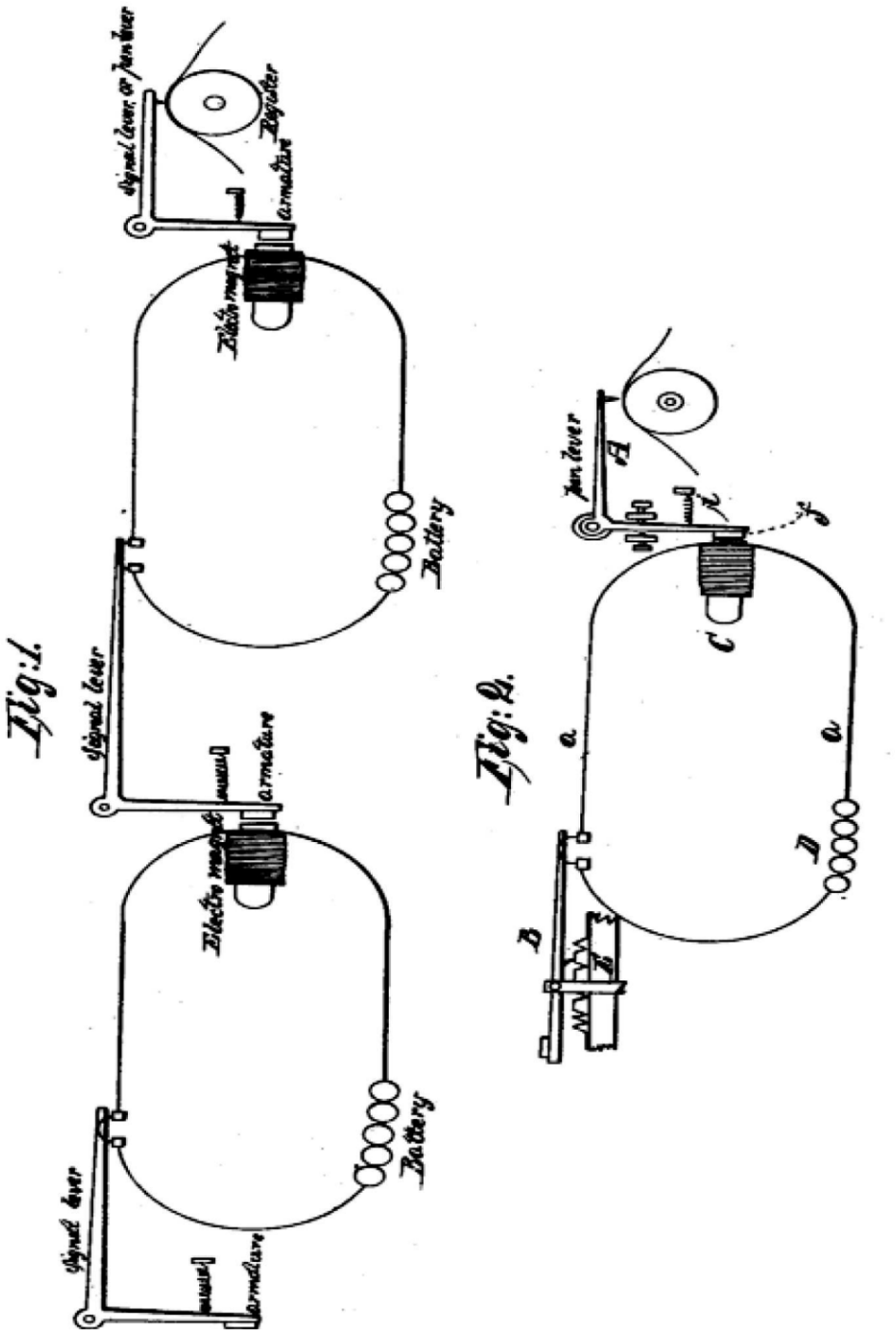


Figure 2-1: The Morse Telegraph

d. Morse Code and Claim 5. In addition to his telegraphic machinery, Morse also developed and patented his own communications code. Claim 5 of his patent covered:

> 5. The system of signs consisting of dots and spaces, and of dots, spaces, and horizontal lines, for numerals, letters, words, or sentences, substantially as herein set forth and illustrated, for telegraphic purposes.

At the Supreme Court, the defendants challenged that claim as unpatentable subject matter, arguing that "such an arrangement of an alphabet" could not be "the subject of a patent." Transcript of Record in O'Reilly v. Morse (S.Ct. No. 224) (filed Aug. 3, 1850), at 35. Morse submitted evidence acknowledging that claim 5 covered an alphabet, id. at 121, 122-23 (setting forth an affidavit of a chief examiner at the U.S. Patent Office who, testifying in support Morse, repeatedly describes Morse as having obtained a claim to an "alphabet"), but he nonetheless defended the propriety of such a claim. The Supreme Court sided with Morse, finding "no well-founded objection to … [Morse's] right to a patent for the first seven inventions set forth in the specification of his claims." 56 U.S. at 112.

The Court's validating of claim 5 is consistent with the *Bilski* Court's rejection of the "machine-or-transformation" test. A useful code need not be bound to a particular machine or a particular transformation of physical objects to be patentable. Indeed, the PTO's traditional patent classification system includes an entire category devoted to cryptography (class 380), including subcategories covering coding systems for data compression such as MPEP (subclass 217). See http://www.uspto.gov/web/patents/classification/uspc380/defs380.htm.

e. Morse's Claim 8. Though it sustained all of Morse's other claims (and thus allowed him to prevail in his infringement suit), the Court invalidated claim 8, which read:

> 8th. I do not propose to limit myself to the specific machinery or parts of machinery described in the foregoing specification and claims, the essence of my invention being the use of the motive power of the electric or galvanic current, which I call electro-magnetism, however developed, for marking or printing intelligible characters, signs, or letters, at any distances, being a new application of that power, of which I claim to be the first inventor or discoverer.

As the Court correctly recognized, that claim sought to give Morse exclusive rights "to every improvement where the motive power is the electric or galvanic current, and the result is the marking or printing intelligible characters, signs, or letters at a distance." 56 U.S. at 112.[6] The

---

[6] An oft-repeated, but inaccurate, assertion is that Morse's eighth claim would have covered "electronic communications of all types." Mark F. Grady & Jay I. Alexander, Patent Law and Rent Dissipation, 78 VA. L. REV. 305, 323 (1992); see also Brief for Petitioner at 22, in Dann v. Johnston, No. 74-1033 (filed July 31, 1975) (brief for the Patent Office asserting that "Morse's idea of transmitting information at a distance by means of electromagnetic force … cannot be patented"). The claim covers only the use of electric "current" for "marking or printing." Thus, a telephone used for voice communications but not printing would not infringe. Wireless electronic communications, such as radio, television and cellular telephones,

Court rejected such a sweeping claiming, holding it to be "too broad and not warranted by law." Id. at 113.

The Court relied on two reasons. First, citing the *Neilson* case, the Court embraced the view that "the discovery of a principle in natural philosophy or physical science, is not patentable." *Id.* at 116. Second, the Court quoted and relied upon the portion of the Patent Act requiring a disclosure of the "the manner and process of making, constructing, [and] using" the invention (the enablement requirement, which is now codified in § 112(a) of the Act). *Id.* at 118. From that statutory language, the Court reasoned that Congress intended to give an inventor "the exclusive right to use the means he specifies to produce the result or effect he describes, and nothing more." Id. at 119. Thus, to the Court, the structure of the Patent Act reinforced the conclusion that patent claims could not be directed more generally to principles of nature, but instead had to be limited to the technology specified by the inventor for applying natural principles to useful ends.

2. Bell's Patent and *The Telephone Cases*. Like Morse, Alexander Graham Bell was also extremely successful inventor and patentee, and he also is liked to a famous piece of Supreme Court litigation, *The Telephone Cases*, 126 U.S. 1 (1888). That litigation involved five consolidated lawsuits, and it was a cause célèbre in its day. Oral arguments at the Supreme stretched over 12 days, and the Court ultimately filed a report of the case filling the entire volume 126 of the U.S. Reports.

a. The Prior Art. Like the telegraph, the telephone did not suddenly spring into being through the efforts of a single inventor; it evolved over a period of two decades. Both the concept and the general principle of the telephone were described at least as early as 1854 (twenty-one years prior to Bell's invention) by the Frenchman Charles Bourseul, who thought that "it is certain that in a more or less distant future speech will be transmitted by electricity." *The Telephone Cases*, 126 U.S. at 32–33.

The earliest electric device capable of conveying sounds was constructed fourteen years before Bell's invention by the German inventor Phillip Reis, who also coined the word "telephone" (spelled "Telefon," in German). Reis's telephone could reproduce musical tones, but not intelligible speech. Prior to Bell, persons skilled in art did not know why Reis's telephone distorted speech to such a degree as to render it unintelligible, but they assumed that the distortions were attributable "to the imperfect mechanism of the apparatus used, rather than to any fault in the principle" of the phone. *Id.* at 544.

---

also do not infringe because those technologies rely on electromagnetic waves, not an electric "current." In fact, if Morse had meant to claim any transmission of information by electromagnetism generally, his claim would have been plainly anticipated. One form of electromagnetic waves — light — had already been used for centuries to transmit information across distances. In addition to the famous light code used by Paul Revere in 1775 ("one if by land, and two if by sea"), light signals have been used to communicate information since at least 1100 B.C. See GERALD J. HOLZMANN & BJÖRN PEHRSON, THE EARLY HISTORY OF DATA NETWORK 15 (1995). In fact, an elaborate network of optical or "semaphore" telegraphs was constructed in France beginning in the 1790's. See id. at 59–79 (describing the construction of the French system and its expansion to other countries). See also GEOFFREY WILSON, THE OLD TELEGRAPHS (1976) (tracing the development of semaphore telegraphs in Europe and the United States)

Bell proved that this assumption was wrong and that Reis's failure was due "not to [his] workmanship but to [his] principle." *Id.* Reis's telephone relied on an *intermittent* current: the vibrations of sound would alternately open and close a circuit. Bell found that the intermittent current was the source of the distortions. He thus constructed his telephone so that the electrical circuit was never broken and the current flowed *continuously*. To transport sounds, Bell's telephone varied the intensity of the current. Bell called this arrangement an "undulatory current" because the undulations of the current would track the vibrations of the sound. As the Supreme Court concluded, this "was his discovery, and it was new. Reis never thought of it, and he failed to transmit speech telegraphically. Bell did, and he succeeded." *Id.* at 545.

b. Bell's Patent. Bell sought and obtained a U.S. Pat. No. 174,465 (March 7, 1876), modestly entitled "Improvement in Telegraphy" (See Figure 2-2.).

Bell's patent included five claims and, as in Morse's patent, the final claim was the broadest:

> 5: The method of, and apparatus for, transmitting vocal or other sounds telegraphically, as herein described, by causing electrical undulation, similar in form to the vibrations of the air accompanying the said vocal or other sounds, substantially as set forth.

Obviously, Bell avoided using the capacious language found in Morse's claim 8 ("I do not propose to limit myself," etc.) and included some apparently restrictive phrases in his claim ("as herein described" and "substantially as set forth"). Still, the Supreme Court interpreted the claim broadly to include the entire "art" (or process) invented by Bell, not just "the particular means" disclosed in his patent. 126 U.S. at 533. Bell's "art," according to the Court, encompassed using "changes of intensity in a continuous current of electricity … for sending and receiving articulate speech telegraphically." *Id*. at 533-34.

Despite that broad interpretation, the Court sustained the validity of Bell's claim 5 and explained how it was different from the invalid Claim 8 in Morse's patent:

> In the present case the claim is not for the use of a current of electricity in its natural state as it comes from the battery, but for putting a continuous current in a closed circuit into a certain specified condition suited to the transmission of vocal and other sounds, and using it in that condition for that purpose. So far as at present known, without this peculiar change in its condition it will not serve as a medium for the transmission of speech, but with the change it will. Bell was the first to discover this fact, and how to put such a current in such a condition, and what he claims is its use in that condition for that purpose …. It may be that electricity cannot be used at all for the transmission of speech except in the way Bell has discovered, and that therefore, practically, his patent gives him its exclusive use for that purpose, but that does not make his claim one for the use of electricity distinct from the particular process with which it is connected in his patent. It will, if true, show more clearly the great importance of his discovery, but it will not invalidate his patent.

Id. at 534-535.

A. G. BELL.

TELEGRAPHY.

No. 174,465. Patented March 7, 1876.

Fig. 4.

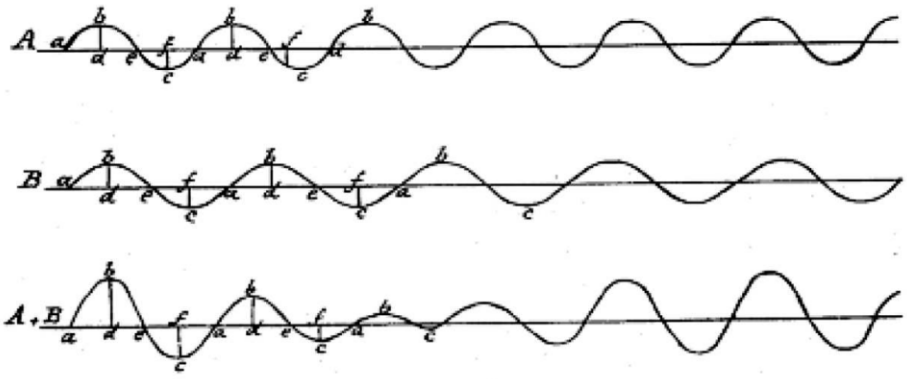


Fig. 5.

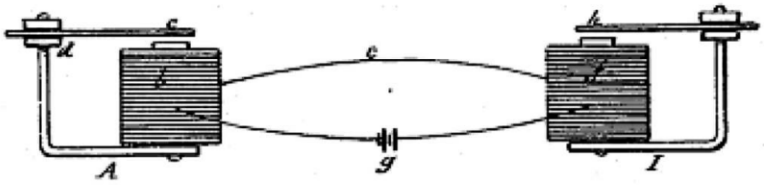
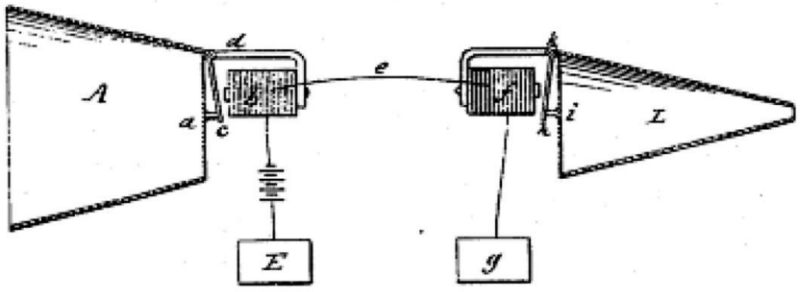


Fig. 7



Witnesses

Ewell & Dick.

W. J. Hutchinson

Inventor:

a. Graham Bell

by atty Pollock & Bailey

Figure 2-2: The Bell Telephone

Thus, the key to sustaining Bell's broad claim was that, though the claim was potentially quite broad, it was still tightly correlated to Bell's own inventive contribution, for the claim was expressly limited to transmitting sound by means of "electrical undulations"—gradual changes to a continuous electric current. As the Court explained:

> In this art — or, what is the same thing under the patent law, this process, this way of transmitting speech — electricity, one of the forces of nature, is employed; but electricity, left to itself, will not do what is wanted. The art consists in so controlling the force as to make it accomplish the purpose. It had long been believed that if the vibrations of air caused by the voice in speaking could be reproduced at a distance by means of electricity, the speech itself would be reproduced and understood. How to do it was the question.
>
> Bell discovered that it could be done by gradually changing the intensity of a continuous electric current, so as to make it correspond exactly to the changes in the density of the air caused by the sound of the voice. This was his art.

Id. at 532. Because Bell's broadest claim was still limited to "his art," it was valid.

3. Nineteenth Century Views on the Patenting of Principles. Like their twentieth century counterparts, nineteenth century commentators also struggled to distinguish between patentable subject matter and unpatentable principles of nature. They saw the matter as a "very difficult question," CURTIS TREATISE, *supra*, § 124, at 140, on which "[t]he opinions of professional men are far from being settled." S.H.H., *Patenting a Principle*, 7 (n.s.) AM. L. REG. & U. PENN. L. REV. 129 (1868). Yet despite the difficulty of the problem, most commentators did agree on three crucial points.

First, they agreed that the discoverer of a new rule or force of nature could not obtain a patent unless and until he also discovered a useful *application* of the natural law or principle. *See* 1 WILLIAM C. ROBINSON, THE LAW OF PATENTS § 136, 195–196 (1890) (hereinafter ROBINSON TREATISE); CURTIS TREATISE, *supra*, § 136, at 149. Indeed, one commentator elevated utility to primary importance in the area, declaring that "[e]very discoverer of a new and useful application of any law of nature, any quality of matter, or any mathematical principle, is entitled to a patent for it." *Patenting a Principle*, *supra*, at 143.

Second, the commentators also noted that ambiguity in the term "principle" accounted for at least some of the confusion in the area. The problem was best summarized in 1890 by Professor Robinson of Yale Law School: "No proposition has been more frequently or positively stated by the courts than that a principle is not a patentable invention, and yet with almost equal positiveness and frequency they have declared that the subject-matter covered by a patent is the principle of the invention." 1 ROBINSON TREATISE § 134, at 190–191. *See also* CURTIS TREATISE, § 124, at 140.

The best resolution of this ambiguity had been set forth in 1813 by Justice Story, who distinguished between "the original elementary principles of motion, which philosophy and science have discovered," and the principle of the inventor's creation, meaning "the modus operandi, the peculiar device or manner of producing any given effect." *Whittemore v. Cutter*, 29

F. Cas. 1123, 1124 (C.C. D.Mass. 1813). The former was not patentable; the latter was. *See Barrett v. Hall*, 2 F. Cas. 914, 923 (C.C. D.Mass. 1818) (Story, J.); *see also Patenting a Principle*, *supra*, at 137 (endorsing Story's view). Resolving this ambiguity focused the patentability inquiry on the inventor's contribution because it was that type of principle that was patentable.

Third and finally, the commentators recognized that the cases on the patentability of principles turned less on metaphysical distinctions and more on the fit between the inventor's claims and his inventive contribution, as disclosed in the patent specification. George Curtis provided the best analysis on the subject. Curtis stressed that the patentability was closely "connected with the construction of particular [patent] specifications." CURTIS TREATISE, § 124, at 140. He did not read *Morse* as "establishing that a patent cannot extend to the application of a newly discovered truth in physics" but instead thought "the decision turned entirely upon a view taken of [Morse's] general claim, which gave it an extent that divested it of all conditions and made it an abstraction." *Id.* § 159, at 184–85. Once the *Morse* Court interpreted the eighth claim to have no connection to "the means used and described by the patentee," the claim had to be invalidated. *Id.* § 166, at 191. Curtis recognized that, although "Morse's specification furnished the means for saving his eighth claim from this fatal defect, it cannot be denied that [the claim] was so drawn as to expose it to the force of this objection." *Id.*

In sum, the nineteenth century law on the patentability of natural principles was mainly concerned with insuring (1) that the inventor specified a practical application, and (2) that the patent claims bore some relation to the inventor's contribution to the useful arts. These pragmatic inquiries, and not metaphysical distinctions between natural and artificial principles, were at the heart of the law governing patent eligibility.

C. NATURAL PRODUCTS AND NATURAL PHENOMENA

The law has long been clear that a purely natural product is not patentable subject matter under § 101. As the majority opinion in *Bilski* suggests, the unpatentability of natural products is supported by the text of § 101, which requires patentable subject matter to be "new." Naturally occurring products are not "new" in the sense that they have existed long before any human invention or discovery.

Yet all human creations are ultimately composed of, and based on, naturally occurring products. Even the most elaborate integrated circuit is ultimately composed of naturally occurring substances that have undergone human manipulation (a lot of it). Similarly, the artificial bacterium in *Chakrabarty* was composed of a naturally occurring bacterium into which the inventor inserted four naturally occurring plasmids found in "donor" bacteria, with each of the four donor plasmids capable of degrading a particular component of oil. *See* U.S. Pat. No. 4,259,444 cols. 5-8 (1981) (Dr. Chakrabarty's patent, issued after the Supreme Court decision). Thus, the crucial question then is one of *degree*: How much human intervention and manipulation is necessary before a naturally-occurring product is recognized as patentable?

One frequently recurring sub-issue associated with that general question is whether the isolation of a "pure" form of a naturally occurring substance is a sufficient degree of human intervention for patent eligibility. This issue dates back to at least 1873, when the Patent Office

issued Louis Pasteur a patent on an "improvement in the manufacture of beer and yeast" that claimed "[y]east, free from organic germs of disease, as an article of manufacture." U.S. Pat. No. 141,072 (July 22, 1873) (patent title and claim 2).

Pasteur's patent on purified yeast does not seem to have generated controversy at the time, perhaps because Pasteur dedicated all of his patents to the public domain. *See Pasteur's Patents*, 20 J. PAT. OFF. SOC'Y 642 (1938).[1] One year after Pasteur's patent issued, however, the Supreme suggested that things merely "extracted" from natural substances are not patentable:

> There are many things well known and valuable in medicine or in the arts which may be extracted from divers substances. But the extract is the same, no matter from what it has been taken. A process to obtain it from a subject from which it has never been taken may be the creature of invention, but the thing itself when obtained cannot be called a new manufacture.

American Wood Paper Co. v. Fibre Disintegrating Co., 90 U.S. 566, 593–94 (1874). The Court's comments in that case were, however, dicta because the Court held that the extract in the case (i.e., wood pulp for use in making paper) could not be patented because it "had been produced and used in the manufacture of paper long before" the patentee's work. *Id.* at 594. Because the inventor claimed *all* pulps suitable for making paper, the Court expressly reserved judgment as to whether a new pulp could be patented if there was "a slight difference in the degree of purity" between it and the prior art pulps.

Later in *Ex parte Latimer*, 1889 Dec. Com. Pat. 123 (also discussed in *Chakrabarty*, *supra*), the Commissioner of Patents rejected a patent claim for "the cellular tissues" of a particular species of pine needle separated from "the silicious, resinous, and pulpy parts" of the needle. *Id.* at 123. That decision acknowledged that the patent applicant may have discovered that these particular pine needles were very valuable because they "possess more or less strength or fineness" than known fibers. *Id.* at 125. But if they were, it was because "[n]ature made them so," and the discovery of these properties no more entitled the applicant to a patent on them "than to find a new gem or jewel in the earth would entitle the discoverer to patent all gems which should be subsequently found." *Id.* Still, the *Latimer* decision equivocated, noting that "[n]atural fibers, hair, and many other substances have been allowed as patentable products" where the substance had been "treated and [had] become something new or different from what it [was] in its natural state." *Id.* The Commissioner suggested that a patent could have issued to Latimer if he had changed the pine needle from "its natural state … either by curling it or giving it some new quality or function which it does not possess in its natural condition as fiber." *Id.*

In 1911, Learned Hand (then a district judge) issued an influential opinion in *Parke-Davis & Co. v. H.K. Mulford & Co.*, 189 F. 95 (S.D.N.Y. 1911), *aff'd*, 196 F. 496 (2d Cir. 1912), which sustained the patentability of claims to purified forms of adrenaline—a substance naturally

---

[1] Later, however, P. J. Federico — a leading commentator of the era (and later examiner-in-chief at the Patent Office and a principal drafter of the 1952 Patent Act) — opined that a claim such as Pasteur's on yeast "would now probably be refused by the examiner, since it is doubted that the subject matter is capable of being patented." P. J. Federico, *Louis Pasteur's Patents*, 86 SCI. 327 (1937), reprinted in 19 J. PAT. OFF. SOC'Y 966, 967 (1937). It is unclear whether Federico thought the patent claim questionable because its subject matter was living or because it was a purified version of a naturally occurring product.

produced in humans and animals. Some of the claims at issue in that case were to a chemical "base" of adrenaline, not a "salt" (a salt consists of an acid and base bound together). The base claims were sustained on the grounds that "no one had ever isolated a substance which was not in salt form" and even the defendant's expert conceded that the substance "exist[s] as a natural salt, and that the base was an original production of Takamine's." 189 F. at 103 (referring to the inventor, Jokichi Takamine).

Other claim in *Parke-Davis* were, however, to a purified salt of adrenaline, and Judge Hand sustained the validity of those claims too. He wrote:

> [E]ven if it were merely an extracted product without change, there is no rule that such products are not patentable. Takamine was the first to make it available for any use by removing it from the other gland-tissue in which it was found, and, while it is of course possible logically to call this a purification of the principle, it became for every practical purpose a new thing commercially and therapeutically. That was a good ground for a patent. *Kuehmsted v. Farbenfabriken*, 179 Fed. 701 [(7th Cir. 1910)]; *Union Carbide Co. v. American Carbide Co.*, 181 Fed. 106 [(2d Cir. 1910)]. That the change here resulted in ample practical differences is fully proved. Everyone, not already saturated with scholastic distinctions, would recognize that Takamine's crystals were not merely the old dried glands in a purer state, nor would his opinion change if he learned that the crystals were obtained from the glands by a process of eliminating the inactive organic substances. The line between different substances and degrees of the same substance is to be drawn rather from the common usages of men than from nice considerations of dialectic.

189 F. at 103.

Judge Hand's opinion in *Parke-Davis* (which was affirmed on appeal by the Second Circuit) became a standard citation to support the patentability of purified natural products. Thus, for example, the PTO in 2001 relied on *Parke-Davis* to support the proposition that "[p]atenting compositions or compounds isolated from nature follows well established principles, and is not a new practice." See U.S. Patent and Trademark Office, *Utility Examination Guidelines*, 66 Fed. Reg. 1092, 1093 (Jan. 5, 2001). Throughout the 1990s and 2000s, the agency relied on *Parke-Davis* and other lower court authority to issue thousands of patents on isolated and purified fragments of DNA, reasoning that "[a]n isolated and purified DNA molecule that has the same sequence as a naturally occurring gene is eligible for a patent because (1) an excised DNA molecule does not occur in that isolated form in nature, or (2) [the] purified state is different from the naturally occurring compound." *Id*.

Until the following case, however, the Supreme Court had never passed upon the validity of patenting isolated and purified DNA.

Assn. for Molecular Pathology, Inc. v. Myriad Genetics, Inc.

133 S.Ct. 2107 (2013)

JUSTICE THOMAS delivered the opinion of the Court.

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

I

A

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

Creation of proteins from DNA involves two principal steps, known as transcription and translation. In transcription, the bonds between DNA nucleotides separate, and the DNA helix unwinds into two single strands. A single strand is used as a template to create a complementary ribonucleic acid (RNA) strand. The nucleotides on the DNA strand pair naturally with their counterparts, with the exception that RNA uses the nucleotide base uracil (U) instead of thymine (T). Transcription results in a single

strand RNA molecule, known as pre-RNA, whose nucleotides form an inverse image of the DNA strand from which it was created. Pre–RNA still contains nucleotides corresponding to both the exons and introns in the DNA molecule. The pre-RNA is then naturally "spliced" by the physical removal of the introns. The resulting product is a strand of RNA that contains nucleotides corresponding only to the exons from the original DNA strand. The exons-only strand is known as messenger RNA (mRNA), which creates amino acids through translation. In translation, cellular structures known as ribosomes read each set of three nucleotides, known as codons, in the mRNA. Each codon either tells the ribosomes which of the 20 possible amino acids to synthesize or provides a stop signal that ends amino acid production.

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

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

B

This case involves patents filed by Myriad after it made one such medical breakthrough. Myriad discovered the precise location and sequence of what are now known as the BRCA1 and BRCA2 genes. Mutations in these genes can dramatically increase an individual's risk of developing breast and ovarian cancer. The average American woman has a 12– to 13–percent risk of developing breast cancer, but for women with certain genetic mutations, the risk can range between 50 and 80 percent for breast cancer and between 20 and 50 percent for ovarian cancer. Before Myriad's discovery of the BRCA1 and BRCA2 genes, scientists knew that heredity played a role in establishing a woman's risk of developing breast and ovarian cancer, but they did not know which genes were associated with those cancers.

Myriad identified the exact location of the BRCA1 and BRCA2 genes on chromosomes 17 and 13. Chromosome 17 has approximately 80 million nucleotides, and chromosome 13 has approximately 114 million. Within those chromosomes, the BRCA1 and BRCA2 genes are each about 80,000 nucleotides long. If just exons are counted, the BRCA1 gene is only about 5,500 nucleotides long; for the BRCA2 gene, that number is about 10,200. Ibid. Knowledge of the location of the BRCA1 and BRCA2 genes allowed Myriad to determine their typical nucleotide sequence.[1] That information, in turn, enabled Myriad to develop medical tests that are useful for detecting mutations in a patient's BRCA1 and BRCA2 genes and thereby assessing whether the patient has an increased risk of cancer.

Once it found the location and sequence of the BRCA1 and BRCA2 genes, Myriad sought and obtained a number of patents. [Though nine different claims from three patents were at issue in the case, the Court focused on four representative claims—claims 1, 2, 5, 6, and 7 of U.S. Patent 5,747,282 (the '282 patent).] The first claim asserts a patent on "[a]n isolated DNA coding for a BRCA1 polypeptide," which has "the amino acid sequence set forth in SEQ ID NO:2." SEQ ID NO:2 sets forth a list of 1,863 amino acids that the typical BRCA1 gene encodes. Put differently, claim 1 asserts a patent claim on the DNA code that tells a cell to produce the string of BRCA1 amino acids listed in SEQ ID NO:2.

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

Claim 5 of the '282 patent claims a subset of the data in claim 1. In particular, it claims "[a]n isolated DNA having at least 15 nucleotides of the DNA of claim 1." The practical effect of claim 5 is to assert a patent on any series of 15 nucleotides that exist in the typical BRCA1 gene. Because the BRCA1 gene is thousands of nucleotides long, even BRCA1 genes with substantial mutations are likely to contain at least one segment of 15 nucleotides that correspond to the typical BRCA1 gene. Similarly, claim 6 of the '282 patent claims "[a]n isolated DNA having at least 15 nucleotides of the DNA of claim 2." Ibid. This claim operates similarly to claim 5, except that it references the cDNA-based claim 2. …

---

[1] Technically, there is no "typical" gene because nucleotide sequences vary between individuals, sometimes dramatically. Geneticists refer to the most common variations of genes as "wild types."

C

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

But isolation is necessary to conduct genetic testing, and [thus Myriad was able to] solidif[y] its position as the only entity providing BRCA testing.

[The petitioners, a group of doctors, researchers, patients and advocacy groups, filed suit to have Myriad's patents on isolated DNA and cDNA declared invalid. The district court granted that relief, but a panel of the Federal Circuit reversed, with each judge writing a separate opinion.] The central dispute among the [Federal Circuit] panel members was whether the act of *isolating* DNA—separating a specific gene or sequence of nucleotides from the rest of the chromo-some—is an inventive act that entitles the individual who first isolates it to a patent. Each of the judges on the panel had a different view on that question. Judges Lourie and Moore agreed that Myriad's claims were patent eligible under § 101 but disagreed on the rationale. Judge Lourie relied on the fact that the entire DNA molecule is held together by chemical bonds and that the covalent bonds at both ends of the segment must be severed in order to isolate segments of DNA. This process technically creates new molecules with unique chemical compositions. Judge Lourie found this chemical alteration to be dispositive, because isolating a particular strand of DNA creates a nonnaturally occurring molecule, even though the chemical alteration does not change the information-transmitting quality of the DNA.

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

Finally, Judge Bryson concurred in part and dissented in part, concluding that isolated DNA is not patent eligible. …

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

II

A

[After quoting § 101 of the Patent Act, the Court continued:] We have "long held that this provision contains an important implicit exception[:] Laws of nature, natural phenomena, and abstract ideas are not patentable." Mayo, 566 U.S., at ___. Rather, " 'they are the basic tools of scientific and technological work' " that lie beyond the domain of patent protection. Id., at ___. As the Court has explained, without this exception, there would be considerable danger that the grant of patents would "tie up" the use of such tools and thereby "inhibit future innovation premised upon them." Id., at ___. This would be at odds with the very point of patents, which exist to promote creation.

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

B

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

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

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

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

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

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

Finally, Myriad argues that the PTO's past practice of awarding gene patents is entitled to deference, citing J.E.M. Ag Supply, Inc. v. Pioneer Hi–Bred Int'l, Inc., 534 U.S. 124 (2001). We disagree. *J.E.M.* held that new plant breeds were eligible for utility patents under §101 notwithstanding separate statutes providing special protections for plants. After analyzing the text and structure of the relevant statutes, the Court mentioned that the Board of Patent Appeals and Interferences had determined that new plant breeds were patent eligible under §101 and that Congress had recognized and endorsed that position in a subsequent Patent Act amendment. In this case, however, Congress has not endorsed the views of the PTO in subsequent legislation. While Myriad relies on Judge Moore's view that Congress endorsed the PTO's position in a single sentence in the

Consolidated Appropriations Act of 2004, that Act does not even mention genes, much less isolated DNA.

Further undercutting the PTO's practice, the United States argued in the Federal Circuit and in this Court that isolated DNA was not patent eligible under § 101, Brief for United States as Amicus Curiae 20–33, and that the PTO's practice was not "a sufficient reason to hold that isolated DNA is patent-eligible." Id., at 26. See also id., at 28–29. These concessions weigh against deferring to the PTO's determination.[7]

C

cDNA does not present the same obstacles to patentability as naturally occurring, isolated DNA segments. As already explained, creation of a cDNA sequence from mRNA results in an exons-only molecule that is not naturally occurring.[8] Petitioners concede that cDNA differs from natural DNA in that "the non-coding regions have been removed." They nevertheless argue that cDNA is not patent eligible because "[t]he nucleotide sequence of cDNA is dictated by nature, not by the lab technician." That may be so, but the lab technician unquestionably creates something new when cDNA is made. cDNA retains the naturally occurring exons of DNA, but it is distinct from the DNA from which it was derived. As a result, cDNA is not a "product of nature" and is patent eligible under § 101, except insofar as very short series of DNA may have no intervening introns to remove when creating cDNA. In that situation, a short strand of cDNA may be indistinguishable from natural DNA.

III

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

---

[7] Myriad also argues that we should uphold its patents so as not to disturb the reliance interests of patent holders like itself. Concerns about reliance interests arising from PTO determinations, insofar as they are relevant, are better directed to Congress.

[8] Some viruses rely on an enzyme called reverse transcriptase to reproduce by copying RNA into cDNA. In rare instances, a side effect of a viral infection of a cell can be the random incorporation of fragments of the resulting cDNA, known as a pseudogene, into the genome. Such pseudogenes serve no purpose; they are not expressed in protein creation because they lack genetic sequences to direct protein expression. See J. Watson et al., Molecular Biology of the Gene 142, 144, fig. 7-5 (6th ed. 2008). Perhaps not surprisingly, given pseudogenes' apparently random origins, petitioners "have failed to demonstrate that the pseudogene consists of the same sequence as the BRCA1 cDNA." *Association for Molecular Pathology v. United States Patent and Trademark Office*, 689 F. 3d 1303, 1356, n. 5 (CA Fed. 2012). The possibility that an unusual and rare phenomenon might randomly create a molecule similar to one created synthetically through human ingenuity does not render a composition of matter nonpatentable.

understood by geneticists at the time of Myriad's patents … and are not at issue in this case.

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

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

* * *

For the foregoing reasons, the judgment of the Federal Circuit is affirmed in part and reversed in part.

It is so ordered.

JUSTICE SCALIA, concurring in part and concurring in the judgment.

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

NOTES ON *MYRIAD*

1. The Limits of Judicial Scientific Knowledge. Justice Scalia's concurrence highlights the limited ability of judges to understand the complex science often involved in patent cases. His concurrence harks back to the penultimate paragraph in Learned Hand's opinion in *Parke-Davis*—a passage that has become fairly famous for its commentary on the limits of judicial knowledge:

> I cannot stop without calling attention to the extraordinary condition of the law which makes it possible for a man without any knowledge of even the rudiments of

> chemistry to pass upon such questions as these. The inordinate expense of time is the least of the resulting evils, for only a trained chemist is really capable of passing upon such facts …. In Germany, where the national spirit eagerly seeks for all the assistance it can get from the whole range of human knowledge, they do quite differently. The court summons technical judges to whom technical questions are submitted and who can intelligently pass upon the issues without blindly groping among testimony upon matters wholly out of their ken. How long we shall continue to blunder along without the aid of unpartisan and authoritative scientific assistance in the administration of justice, no one knows; but all fair persons not conventionalized by provincial legal habits of mind ought, I should think, unite to effect some such advance.

Do the opinions of Justice Scalia and Judge Hand suggest that our legal system should create more specialized courts to handle complex patent cases? Or does Justice Scalia's opinion demonstrate instead that even apparently complex cases can be resolved by judges who understand certain basic and undisputed facts?

2. Is Longstanding Administrative Practice Unreliable? As discussed in the opening note of this subchapter, the PTO had issued thousands of patents on isolated and purified DNA over the course of decades prior to *Myriad*. *See, e.g.*, U.S. Patent No. 4,703,008 (1987) ("DNA sequences encoding erythropoietin"). The Supreme Court dismisses the argument that reliance on those administrative decisions should influence judicial decision. Does this approach provide insight into future legal strategies?

Recall that in *Bilski*, the Court sustained the patentability of business method patents in part because Congress had enacted a specific statute, 35 U.S.C. § 273, that addressed and *restricted* the scope of business method patents. Should industries in need of certainty seek special statutes that regulate, in some way, particular classes of patents so as to solidify the legal basis for such patents?

3. What Is an "Act of Invention"? Early in its legal analysis, the Court's announces its conclusion that "separating [the BRCA] gene from its surrounding genetic material is not an act of invention." Should this holding be read generally—as a statement that *any* separation or isolation of naturally occurring material is always unpatentable? Or is the conclusion more limited?

In its statement of the case, the Court notes that scientists could "extract DNA from cells using well known laboratory methods" that "allow scientists to isolate specific segments of DNA." And the opinion also makes clear that Myriad's achievement was not in separating or isolating the BRCA genes, but in painstakingly finding and mapping the genes—i.e., in "uncovering the precise location and genetic sequence of the BRCA1 and BRCA2 genes." Would the result be different if the act of isolation itself were inventive? Note that, in sustaining the patents at issue in *Parke-Davis*, Judge Hand relied on the fact that, prior to the patentee's work in that case, "the best experts were trying to get a practicable form of the active [ingredient]" in the gland tissue, but those experts were unable to separate that active ingredient. *Parke-Davis* was obviously read too broadly to mean that *any* isolation and separation was patentable. Is it too broad a reading of *Myriad* to say that any isolation and separation is unpatentable?

4. The Patentability of cDNA. The Court ruled that cDNA sequences are patentable even though the Court also (correctly) notes that, at the time Myriad sought its patents, synthetically created DNA such as cDNA could be created through processes "well known in the field of genetics." What then is the "act of invention" associated with creating the cDNA sequences associated with the BRCA gene? Isolating the BRCA gene isn't invention under the Court holding, and once that gene is isolated, the cDNA sequence can be created through well known, conventional techniques. The Court reasons that "the lab technician unquestionably creates something new when cDNA is made." Is that sufficient for the cDNA to be patent eligible?

5. Funk Brothers. The *Myriad* Court relies heavily on *Funk Brothers Seed Co. v. Kalo Inoculant Co.*, 333 U.S. 127 (1948), which involved the combination of certain strains of naturally-occurring bacteria into a single package. The prior art relevant to that case understood that certain agricultural crops needed to be inoculated with particular strains of bacteria to assist the crops in their growth. Different crops, however, needed to be inoculated with different strains of the bacteria and, prior to the discovery at issue in the case, it was thought that the different strains of bacteria could not be packaged together because they would be "mutually inhibiting" on each other. The patentee in the case had discovered that some strains of the bacteria were not mutually inhibiting and thus could be packaged together into an inoculant that would work on several crops.

In invalidating the patent, the *Funk Brothers* Court decided first that the "[d]iscovery of the fact that certain strains of each species of these bacteria can be mixed without harmful effect … is no more than the discovery of some of the handiwork of nature, and hence is not patentable." *Id.* at 131. That first step in reasoning did not, however, decide the case because the patentee had claimed the bacteria strains combined into a commercial "inoculant"—i.e., "placed in a powder or liquid base and packaged for sale." *Id.* at 129. Yet the Court found that such a new commercial product was also not patentable because it was "simple" to make that product once the principle of nature was known. The Court reasoned:

> There is, of course, an advantage in the combination [of different bacteria]. The farmer need not buy six different packages for six different crops. He can buy one package and use it for any or all of his crops …. [T]he packages of mixed inoculants also hold advantages for the dealers and manufacturers by reducing inventory problems and the like. But a product must be more than new and useful to be patented; it must also satisfy the requirements of invention or discovery. *Cuno Engineering Corp. v. Automatic Devices Corp.*, 314 U. S. 84, 314 U. S. 90-91, and cases cited. The application of this newly discovered natural principle to the problem of packaging of inoculants may well have been an important commercial advance. But once nature's secret of the noninhibitive quality of certain strains of the species of Rhizobium was discovered, the state of the art made the production of a mixed inoculant a simple step. Even though it may have been the product of skill, it certainly was not the product of invention. There is no way in which we could call it such unless we borrowed invention from the discovery of the natural principle itself. That is to say, there is no invention here unless the discovery that certain strains of the several species of these bacteria are noninhibitive, and may thus be safely mixed, is invention. But we cannot so hold without allowing a patent to issue on one of the ancient secrets of nature now disclosed.

Id. at 131-132. Is the *Myriad* Court's sustaining of cDNA patent claims consistent with this reasoning? Once the BRCA gene sequences are known, the cDNA sequences could be produced by well-known techniques. Are some steps inherently not simple even if they are well known in the prior art?

6. The Patent Ineligibility of Clones. In 1996, the birth of the first successful cloned mammal—a sheep named "Dolly"—was considered a huge scientific breakthrough. The development was widely covered in the press of the era, and Dolly eventually rose to the true pinnacle of modern fame: her life is covered in its own Wikipedia page, see https://en.wikipedia.org/wiki/Dolly_(sheep).

Despite the magnitude of the breakthrough and the fame of the subject, patent claims to the clone were held patent ineligible in In re Roslin Institute, 750 F.3d 1333 (Fed. Cir. 2014) (opinion by Dyk, J., joined by Moore and Wallach, JJ.). The reasoning in this case is straightforward even if the outcome seems counterintuitive: the clone Dolly was patent ineligible precisely because she was an exact copy of a naturally occurring sheep. Of course, the whole goal of the researchers was to imitate nature precisely, but the achievement of that goal was fatal to their patent claim to the resulting clones. The Court reasoned:

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

Id. at 1337. *Roslin* is thus a good counterpoint to *Chakrabarty*. Where inventors artificially create an unnatural living thing (an oil-eating bacterium), they can obtain patents on their new organisms, but if they artificially duplicate nature, those artificial organisms will be unpatentable because they are identical to naturally-occurring things.

If the result of *Roslin* seems a bit unfair, it must be noted that the researchers were allowed to patent their *process* for cloning. *See* U.S. Patent No. 7,514,258 (2009). Under modern law, the holder of such a process patent has some rights that extend even to the *products* produced by the patented process. *See* 35 U.S.C. § 271(g) (defining infringement to include the importation into the U.S., or the use, sale, or offer to sell in the U.S., of any product produced by process patented in the U.S.).

7. Sequenom's Invalid Patent for Fetal Testing. Pre-natal fetal DNA testing can determine a number of fetal characteristics including, for example, fetal gender. Prior to 1996, the widely-used techniques for such testing required taking small samples from the fetus or placenta, but such invasive testing techniques carried significant health risks (e.g., miscarriage). In 1996, two researchers discovered that maternal blood samples contain "cell-free fetal DNA" ("cffDNA"), which is non-cellular fetal DNA that circulates freely in the blood stream of a pregnant woman. With that discovery, the researchers were able to combine a set of known

laboratory techniques to produce a new process for fetal testing using the small fraction of paternally inherited cffDNA in maternal blood, without the need for fetal or placental tissue samples. (Prior to this discovery, maternal blood samples were typically discarded as medical waste.)

The two researchers obtained U.S. Patent No. 6,258,540 (2001) ("the '540 patent") and exclusively licensed the patent to Sequenom. Claim 1 of the patent was directed to a "method for detect paternally inherited" fetal DNA:

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

Another claim in the patent was directed to a method for "prenatal diagnosis on a maternal blood sample":

> 25. A method for performing a prenatal diagnosis on a maternal blood sample, which method comprises
>
> obtaining a non-cellular fraction of the blood sample
>
> amplifying a paternally inherited nucleic acid from the non-cellular fraction
>
> and performing nucleic acid analysis on the amplified nucleic acid to detect paternally inherited fetal nucleic acid.

In *Ariosa Diagnostics, Inc. v. Sequenom, Inc.*, 788 F.3d 1371 (Fed. Cir. 2015) (opinion by Renya, J., joined by Linn and Wallach, JJ.), *cert. denied*, 126 S.Ct. ___ (June 2016), the court held all asserted claims ineligible for patenting on the grounds that the claims were "directed to a naturally occurring thing or natural phenomenon." Id. at 1376. While the court acknowledged that, "patent does not claim cffDNA or paternally inherited cffDNA," it still claimed unpatentable subject matter. The court reasoned:

> In this case, the asserted claims of the '540 patent are directed to a multistep method that starts with cffDNA taken from a sample of maternal plasma or serum — a naturally occurring non-cellular fetal DNA that circulates freely in the blood stream of a pregnant woman. It is undisputed that the existence of cffDNA in maternal blood is a natural phenomenon. Sequenom does not contend that [the two researchers named as inventors in the patent] created or altered any of the genetic information encoded in the cffDNA, and it is undisputed that the location of the nucleic acids existed in nature before [the researchers] found them. The method ends with paternally inherited cffDNA, which is also a natural phenomenon. The method therefore begins and ends with a natural phenomenon. Thus, the claims are directed to matter that is naturally occurring.

> The written description supports the conclusion that the claims of the '540 patent are directed to a naturally occurring thing or natural phenomenon. In the Summary and Objects of the Invention section of the '540 patent, the patent states that "[i]t has now been discovered that foetal DNA is detectable in maternal serum or plasma samples." The patent goes on to state that "[t]his is a surprising and unexpected finding; maternal plasma is the very material that is routinely discarded by investigators studying noninvasive prenatal diagnosis using foetal cells in maternal blood." … The patent also states: "[t]he most important observation in this study is the very high concentration of foetal DNA in maternal plasma and serum." Thus, the claims at issue, as informed by the specification, are generally directed to detecting the presence of a naturally occurring thing or a natural phenomenon, cffDNA in maternal plasma or serum. As we noted above, the claimed method begins and ends with a naturally occurring phenomenon.

Id. at 1376.

Relying on *Mayo*, the court rejected the argument that the patent was an "application" rather than a "natural phenomenon":

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

Id. at 1377. The court also noted that, while it was true that the two researchers "combined and utilized man-made tools of biotechnology in a new way that revolutionized prenatal care," that achievement was insufficient to justify patent eligibility under the Supreme Court's teaching in *Myriad* that "even brilliant discovery" may be unpatentable. Id. at 1379.

Can the *Ariosa* be reconciled with the Supreme Court's holding in *Myriad* that cDNA was patentable, even though cDNA could be easily produced once the relevant DNA was isolated? Also, consider once again the Federal Circuit holding in *Rapid Litigation Management* (*supra*) that a process involving freezing liver cells twice was patentable subject matter even though "once it was discovered that [the liver cells] could survive multiple freeze-thaw cycles, it would have been a simple task to repeat the known freeze-thaw process to arrive at the claimed invention." Are *Ariosa* and *Rapid Litigation Management* reconcilable? Does it make a difference that *Ariosa* involved (at some level) the discovery of "a naturally occurring thing" whereas *Rapid Litigation Management* involved the discovery of a new natural principle? Is there something wrong with the claims in *Ariosa*—all of which end merely with "detecting the presence of a paternally inherited" fetal DNA without further steps directed to the determination of fetal characteristics?

8. Diagnostic Patents Generally. Do decisions such as *Mayo* and *Ariosa* spell the end of diagnostic tests generally, or at least for diagnostic tests where the underlying components of the test were measureable with prior technology? Imagine that current technology can detect substances A, B and C in the human body and can measure the levels of those substances. Now a researcher discovers that people having high levels of A, B and C substances are in the early stages of Disease Z, which can be treated if detected in such early stages.

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

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

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

D. ABSTRACT IDEAS

ALICE CORP. v. CLS BANK INT'L

134 S. Ct. 2347 (2014)

JUSTICE THOMAS delivered the opinion of the Court.

The patents at issue in this case disclose a computer-implemented scheme for mitigating "settlement risk" (*i.e.*, the risk that only one party to a financial transaction will pay what it owes) by using a third-party intermediary. The question presented is whether these claims are patent eligible under 35 U.S.C. § 101, or are instead drawn to a patent-ineligible abstract idea. We hold that the claims at issue are drawn to the abstract idea of intermediated settlement, and that merely requiring generic computer implementation fails to transform that abstract idea into a patent-eligible invention. We therefore affirm the judgment of the United States Court of Appeals for the Federal Circuit.

I
A

Petitioner Alice Corporation is the assignee of several patents that disclose schemes to manage certain forms of financial risk.[1] According to the specification largely shared by the patents, the invention "enabl[es] the management of risk relating to specified, yet unknown, future events." The specification further explains that the "invention relates to methods and apparatus, including electrical computers and data processing systems applied to financial matters and risk management."

The claims at issue relate to a computerized scheme for mitigating "settlement risk"—*i.e.*, the risk that only one party to an agreed-upon financial exchange will satisfy its obligation. In particular, the claims are designed to facilitate the exchange of financial obligations between two parties by using a computer system as a third-party intermediary.[2] The intermediary creates "shadow" credit and debit records (*i.e.*, account ledgers) that mirror the balances in the parties' real-world accounts at "exchange institutions" (*e.g.*, banks). The intermediary updates the shadow records in real time as transactions are entered, allowing "only those transactions for which the parties' updated shadow records indicate sufficient resources to satisfy their mutual obligations." 717 F.3d 1269, 1285 (C.A.Fed.2013) (Lourie, J., concurring). At the end of the day, the intermediary instructs the relevant financial institutions to carry out the "permitted" transactions in accordance with the updated shadow records, *ibid.*, thus mitigating the risk that only one party will perform the agreed-upon exchange.

In sum, the patents in suit claim (1) the foregoing method for exchanging obligations (the method claims), (2) a computer system configured to carry out the

---

[1] The patents at issue are United States Patent Nos. 5,970,479 (the '479 patent), 6,912,510, 7,149,720, and 7,725,375.

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

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

method for exchanging obligations (the system claims), and (3) a computer-readable medium containing program code for performing the method of exchanging obligations (the media claims). All of the claims are implemented using a computer; the system and media claims expressly recite a computer, and the parties have stipulated that the method claims require a computer as well.

B

[CLS Bank, a major financial institution that facilitates global currency transactions, filed suit against Alice, seeking declaratory judgment that the claims at issue are invalid, unenforceable, or not infringed. Alice counterclaimed for infringement. After the decision in *Bilski v. Kappos*, 561 U.S. 593 (2010), the parties filed cross-motions for summary judgment concerning the validity of the relevant patent claims under § 101. The district court held the claims to be patent ineligible abstract ideas. Sitting en banc, the Federal Circuit affirmed the district court's judgment of ineligibility in a one-paragraph *per curiam* opinion. 717 F.3d, at 1273. Seven of the ten participating judges agreed that petitioner's method and media claims are patent ineligible. With respect to petitioner's system claims, the en banc Federal Circuit affirmed the District Court's judgment by an equally divided vote. Judge Lourie wrote the controlling opinion for a five-member plurality of the court. Alice successfully sought a grant of certiorari.]

II

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

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

At the same time, we tread carefully in construing this exclusionary principle lest it swallow all of patent law. *Mayo*, 566 U.S., at —— . At some level, "all inventions ...

embody, use, reflect, rest upon, or apply laws of nature, natural phenomena, or abstract ideas." *Id.,* at ——. Thus, an invention is not rendered ineligible for patent simply because it involves an abstract concept. See *Diamond v. Diehr,* 450 U.S. 175, 187 (1981). "[A]pplication[s]" of such concepts "'to a new and useful end,'" we have said, remain eligible for patent protection. *Gottschalk v. Benson,* 409 U.S. 63, 67 (1972).

Accordingly, in applying the § 101 exception, we must distinguish between patents that claim the "'buildin[g] block[s]'" of human ingenuity and those that integrate the building blocks into something more, *Mayo,* 566 U.S., at ——, thereby "transform[ing]" them into a patent-eligible invention, *id.,* at ——. The former "would risk disproportionately tying up the use of the underlying" ideas, *id.,* at ——, and are therefore ineligible for patent protection. The latter pose no comparable risk of pre-emption, and therefore remain eligible for the monopoly granted under our patent laws.

III

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

A

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

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

We most recently addressed the category of abstract ideas in *Bilski v. Kappos*, 561 U.S. 593 (2010). … "[A]ll members of the Court agree[d]" that the patent at issue in *Bilski* claimed an "abstract idea." *Id.*, at 609; see also *id.*, at 619 (Stevens, J., concurring in judgment). Specifically, the claims described "the basic concept of hedging, or protecting against risk." *Id.*, at 611. The Court explained that "'[h]edging is a fundamental economic practice long prevalent in our system of commerce and taught in any introductory finance class.'" *Ibid.* "The concept of hedging" as recited by the claims in suit was therefore a patent-ineligible "abstract idea, just like the algorithms at issue in *Benson* and *Flook." Ibid.*

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

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

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

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

any special significance to that fact, much less the sort of talismanic significance petitioner claims. Instead, the Court grounded its conclusion that all of the claims at issue were abstract ideas in the understanding that risk hedging was a "'fundamental economic practice.'" 561 U.S., at 611.

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

B

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

1

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

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

The introduction of a computer into the claims does not alter the analysis at *Mayo* step two. In *Benson,* for example, we considered a patent that claimed an algorithm implemented on "a general-purpose digital computer." 409 U.S., at 64. Because the algorithm was an abstract idea, see *supra,* at 8, the claim had to supply a "'new and useful'" application of the idea in order to be patent eligible. 409 U.S., at 67. But the

computer implementation did not supply the necessary inventive concept; the process could be "carried out in existing computers long in use." *Ibid.* We accordingly "held that simply implementing a mathematical principle on a physical machine, namely a computer, [i]s not a patentable application of that principle." *Mayo, supra,* at —— (citing *Benson, supra,* at 64).

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

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

These cases demonstrate that the mere recitation of a generic computer cannot transform a patent-ineligible abstract idea into a patent-eligible invention. Stating an abstract idea "while adding the words 'apply it' " is not enough for patent eligibility. *Mayo, supra,* at ——. Nor is limiting the use of an abstract idea " 'to a particular technological environment.' " *Bilski, supra,* at 610–611. Stating an abstract idea while adding the words "apply it with a computer" simply combines those two steps, with the same deficient result. Thus, if a patent's recitation of a computer amounts to a mere instruction to "implemen[t]" an abstract idea "on ... a computer," *Mayo, supra,* at ——, that addition cannot impart patent eligibility. This conclusion accords with the pre-emption concern that undergirds our § 101 jurisprudence. Given the ubiquity of computers, see 717 F.3d, at 1286 (Lourie, J., concurring), wholly generic computer implementation is not generally the sort of "additional featur[e]" that provides any

"practical assurance that the process is more than a drafting effort designed to monopolize the [abstract idea] itself." *Mayo,* 566 U.S., at ——.

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

2

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

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

Taking the claim elements separately, the function performed by the computer at each step of the process is "[p]urely conventional." *Mayo, supra,* at —— (internal quotation marks omitted). Using a computer to create and maintain "shadow" accounts amounts to electronic recordkeeping—one of the most basic functions of a computer. See, *e.g., Benson,* 409 U.S., at 65 (noting that a computer "operates ... upon both new and previously stored data"). The same is true with respect to the use of a computer to obtain data, adjust account balances, and issue automated instructions; all of these computer functions are "well-understood, routine, conventional activit[ies]" previously known to the industry. *Mayo,* 566 U.S., at ——. In short, each step does no more than require a generic computer to perform generic computer functions.

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

C

Petitioner's claims to a computer system and a computer-readable medium fail for substantially the same reasons. Petitioner conceded below that its media claims rise or fall with its method claims. As to its system claims, petitioner emphasizes that those claims recite "specific hardware" configured to perform "specific computerized functions." Brief for Petitioner 53. But what petitioner characterizes as specific hardware—a "data processing system" with a "communications controller" and "data storage unit," for example — is purely functional and generic. Nearly every computer will include a "communications controller" and "data storage unit" capable of performing the basic calculation, storage, and transmission functions required by the method claims. See 717 F.3d, at 1290 (Lourie, J., concurring). As a result, none of the hardware recited by the system claims "offers a meaningful limitation beyond generally linking 'the use of the [method] to a particular technological environment,' that is, implementation via computers." *Id.,* at 1291 (quoting *Bilski,* 561 U.S., at 610–611).

Put another way, the system claims are no different from the method claims in substance. The method claims recite the abstract idea implemented on a generic computer; the system claims recite a handful of generic computer components configured to implement the same idea. This Court has long "warn[ed] ... against" interpreting § 101 "in ways that make patent eligibility 'depend simply on the draftsman's art.'" *Mayo, supra,* at —— (quoting *Flook,* 437 U.S., at 593). Holding that the system claims are patent eligible would have exactly that result.

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

* * *

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

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

I adhere to the view that any "claim that merely describes a method of doing business does not qualify as a 'process' under § 101." *Bilski v. Kappos*, 561 U.S. 593, 614 (2010) (Stevens, J., concurring in judgment). As in *Bilski*, however, I further believe that the method claims at issue are drawn to an abstract idea. I therefore join the opinion of the Court.

NOTES ON *ALICE*

1. Rubber-Tip Pencil and the Prohibition on Patenting Abstract Ideas. *Rubber-Tip Pencil Co. v. Howard*, 87 U.S. 498, 507 (1874), is one of the earliest cases cited by the *Alice* Court to support a prohibition on the patenting of ideas in the abstract. The patent in the case covered a rubber tip or cap that could be inserted over the end of a pencil. See Figure 2-3. The patent claim was only to the "elastic erasive pencil head" (marked "B" in the figure); the pencil itself (marked "A") was not part of the alleged invention. An erasive cap or head for a pencil may not seem like an "idea" in the abstract. After all, such eraser caps are pretty definite things that can be readily touched, perceived and used.

In holding the alleged invention to be an unpatentable idea, the Court seems to rest on two factors. First, the alleged invention was claimed in general terms, covering "'broadly any form which would enable the rubber to encompass a pencil, ink eraser, or other articles of like character.'" 87 U.S. at 501 (statement of case quoting the trial court's construction of the patent claim). Second, the alleged invention was exceptionally simple—a trivial application of well-known principles.

The holding of unpatentability appears to flow from the combination of those two aspects of the patent. Thus, because of the breadth of the claim, the Court reasoned that the invention covered "any convenient external form," so thus "the external form was not a part of the invention." *Id*. at 505. Yet the remaining aspects of the claimed invention were so trivial that they could not be considered inventive. Rubber and its "naturally erasive" ability "had long been known," *id.*, and so there was nothing inventive about the material of the erasive head. All that was left of the idea was then the inner cavity of the eraser head, which was formed to grip the end of the pencil. The Court, however, found that last aspect of the invention also to be trivial, writing:

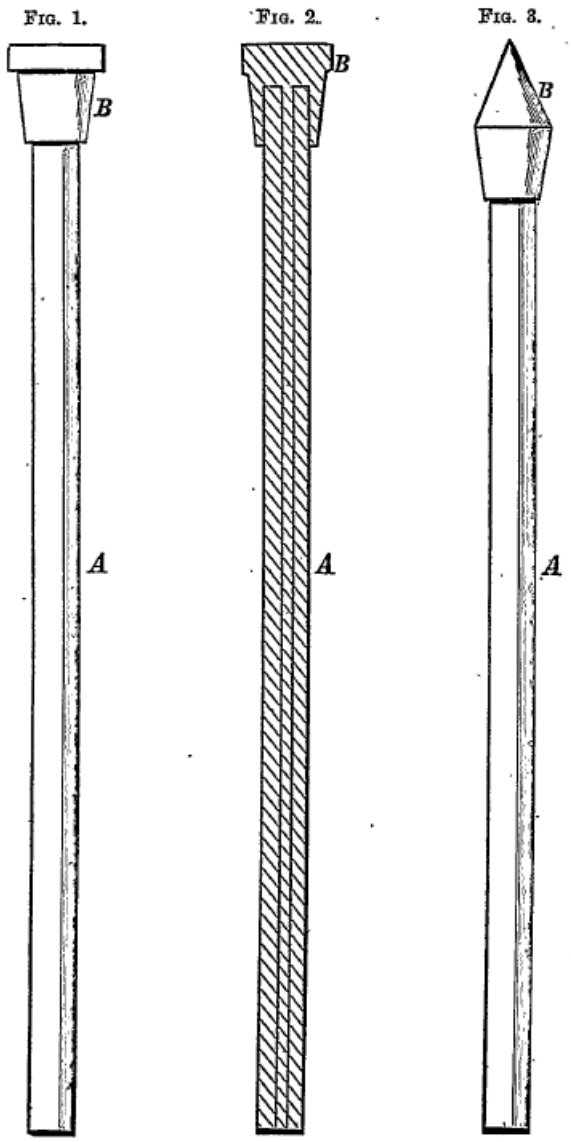


Figure 2-3: Drawings of the Eraser Cap ("B") from *Rubber-Tip Pencil*

[T]he cavity [of the eraser head] must be made smaller than the pencil and so constructed as to encompass its sides and be held thereon by the inherent elasticity of the rubber. This adds nothing to the patentable character of the invention. Everybody knew when the patent was applied for that if a solid substance was inserted into a cavity in a piece of rubber smaller than itself, the rubber would cling to it. The small opening in the piece of rubber not limited in form or shape, was not patentable, neither was the elasticity of the rubber. What, therefore, is left for this patentee but the idea that if a pencil is inserted into a cavity in a piece of rubber smaller than itself the rubber will attach itself to the pencil, and when so attached become convenient for use as an eraser?

> An idea of itself is not patentable, but a new device by which it may be made practically useful is. The idea of this patentee was a good one, but his device to give it effect, though useful, was not new. Consequently he took nothing by his patent.

Id. at 507.

As we will see in later Chapters, modern patent law includes specific statutory provisions designed to restrict the permissible degree of generality or breadth of patent claims (§ 112, covered in Chapter 4) and to prevent patents from claiming trivial or "obvious" developments (§ 103, covered in Chapter 7). The prohibition against patenting abstract ideas seems to reinforce those statutory provisions by eliminating patent claims that have problems with both generality and triviality.

2. *Benson, Flook* and *Diehr* and Software Patents. Part III.B.1 of the *Alice* opinion briefly recounts three Supreme Court cases decided in the nine years between 1972 and 1981. From 1981 until the *Alice* decision in 2014—a full third of a century—those three opinions were the complete set of Supreme Court opinions concerning the patentability of software. The three are worth covering in a bit more detail.

a. *Benson*. Although the first electronic computers, assembled sometime in the 1930s, were built on mathematical ideas that originated in the nineteenth century, the programs they ran were quite primitive. Not until the general purpose computer reached the stage where it could run a wide variety of programs did the field of computer science begin to blossom. Only slowly did the designers of programs (software) separate themselves from the designers of the machines they ran on (hardware). At this early stage, not many people really understood the nature of software.

With the growth of the field came an early crop of patent applications. *Gottschalk v. Benson*, 409 U. S. 63 (1972)—the Supreme Court's first case concerning the patentability of a computer program—involved a patent application filed in 1963. The application addressed a way to convert "binary coded decimal" numbers into true binary form. Computers themselves are fundamentally binary machines, containing millions or billions of electronic elements that can be either on ("1") or off ("0"). The binary system of representing numbers is therefore perfect for a computer, and in that system, each digit in a number represents a power of 2. Thus, the number ten in binary could be represented as 00001010 (see Figure 2-4).

0	0	0	0	1	0	1	0
128's	64's	32's	16's	8's	4's	2's	1's

Figure 2-4: The Number "10" in True Binary (Place Value of Digits Shown)

Because humans, however, read and write numbers in a decimal or base-ten number system (wherein each digit in a number represents a power of ten), many early computers used a mixed numbering system—"binary coded decimal" or "BCD"—in which four binary digits were assigned to code for each digit in a base-ten number. Thus, the number ten in binary coded decimal is written 0001 0000 (see Figure, 2-5), with each group of four binary digits coding for a single digit in a decimal number.

10's				1's			
0	0	0	1	0	0	0	0
80's	40's	20's	10's	8's	4's	2's	1's

Figure 2-5: The Number "10" in Binary-Code Decimal (Place Value of Digits Shown)

The process at issue in *Benson* provided an iterative series of steps for converting BCD numbers into true binary. Claim 8 of the patent application read:

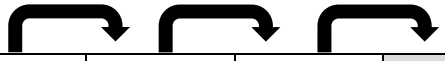
> 8. The method of converting signals from binary coded decimal form into binary which comprises the steps of
>
> (1) storing the binary coded decimal signals in a reentrant shift register,
>
> (2) shifting the signals to the right by at least three places, until there is a binary '1' in the second position of said register,
>
> (3) masking out said binary '1' in said second position of said register,
>
> (4) adding a binary '1' to the first position of said register,
>
> (5) shifting the signals to the left by two positions,
>
> (6) adding a '1' to said first position, and
>
> (7) shifting the signals to the right by at least three positions in preparation for a succeeding binary '1' in the second position of said register.

While that might seem like a complex process, it is really not so difficult to understand. Figure 2-6 shows how the first six steps in the process operate in converting the number ten in BCD to ten in true binary (for convenience, the digit initially coding for 10 is shaded and the place values of all digits are listed). The key to the conversion process is found in steps 3-6, which convert the digit coding for ten in BCD by adding an "8" and a "2" in the appropriate places of the binary coded digits. Thus, the basic mathematical truth at the heart of the process is that 10 = 8 + 2.

Step 1: Place BCD Number in Reentrant Shift Register (Place Values Shown Below)

0	0	0	1	0	0	0	0
80's	40's	20's	10's	8's	4's	2's	1's

Step 2: Shift to the Right by at Least Three Places Until "1" Fills Second Position



0	0	0	0	0	0	1	0
4's	2's	1's	80's	40's	20's	10's	8's

Step 3: Mask Out the "1" in Second Position

0	0	0	0	0	0	0	0
4's	2's	1's	80's	40's	20's		8's

Step 4: Add "1" to First Position

0	0	0	0	0	0	0	1
4's	2's	1's	80's	40's	20's		8's

Step 5: Shift to the Left by Two Positions

0	0	0	0	0	1	0	0
1's	80's	40's	20's		8's	4's	2's

Step 6: Add "1" to First Position

0	0	0	0	0	1	0	1
1's	80's	40's	20's	16's	8's	4's	2's

Figure 2-6: The First Six Steps in the BCD-Binary Conversion Process

Step 7: Shift to the Right Three Positions and Then Keep Shifting Right Until "1" Appears in Second Position (or the Cycle is Complete)

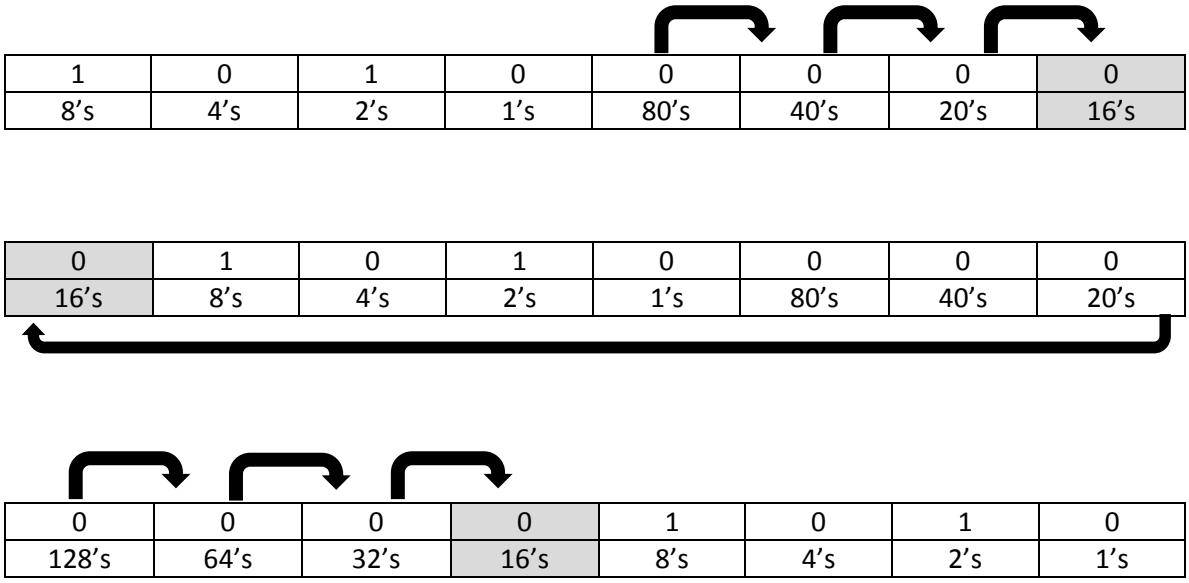


Figure 2-7: The Seventh Step in the BCD-Binary Conversion Process

The final step in the process—step 7—merely continues to shift the digits to the right in the reentrant shift register (with the right-most digit being moved to the left-most position during each shift), until another '1' is detected for conversion or, as is the case in the example, the cycle is complete. See Figure 2-7.

While this process could be done in a computer having components such as "reentrant shift registers," it could also be done by hand. Indeed, another claim in the patent application (the perhaps unlucky claim 13) did describe the conversion process as a purely mathematical process untethered to any computer components whatsoever, and the Court noted that "mathematical procedures" claimed in the patent could "be performed without a computer." 409 U.S. at 67.

While the Supreme Court held the process to be patent ineligible, the Court's reasoning was not exactly clear. As in many cases involving the "abstract idea" exception to patentable subject matter, the Court emphasized the breadth of the proposed patent claims and the generality of their application:

> Here the "process" claim is so abstract and sweeping as to cover both known and unknown uses of the BCD to pure binary conversion. The end use may (1) vary from the operation of a train to verification of drivers' licenses to researching the law books for precedents and (2) be performed through any existing machinery or future-devised machinery or without any apparatus.

409 U.S. at 68. After denying that its opinion foreclosed patents on computer programs or limited patents on old technologies, the Court explained its holding as prohibiting the patent because it would "pre-empt" a mathematical formula:

> It is said that the decision precludes a patent for any program servicing a computer. We do not so hold. … It is said we freeze process patents to old technologies, leaving no room for the revelations of the new, onrushing technology. Such is not our purpose. What we come down to in a nutshell is the following.
>
> It is conceded that one may not patent an idea. But in practical effect that would be the result if the formula for converting BCD numerals to pure binary numerals were patented in this case. The mathematical formula involved here has no substantial practical application except in connection with a digital computer, which means that if the judgment below is affirmed, the patent would wholly pre-empt the mathematical formula and in practical effect would be a patent on the algorithm itself.

Id. at 71-72. The opinion concluded by stating that, if "the patent laws should be extended to cover these programs," Congress should make the extension. Id. at 72.

The exact scope and meaning of the *Benson* decision was (and perhaps still is) a hotly debated subject.[1] One relatively clear point is, however, that the opinion shows the deep connection between the various sub-components of the judge-made limits on patentable subject matter. Though later cases such as *Alice* freely cite *Benson* as an "abstract idea" case, the opinion itself rests at least as much on the grounds that mathematical formulas are unpatentable, and mathematical formulas might be considered to be laws of nature.

b. *Flook*. Six years after *Benson*, the Court decided *Parker v. Flook*, 437 U.S. 584 (1978). While *Benson* had been unanimous, *Flook* divided the Court 6-3, but as in *Benson*, the Court's holding was against the patentability of the claimed process.

The patent application at issue in *Flook* disclosed a "Method for Updating Alarm Limits" and was directed generally toward the technological art associated with monitoring certain chemical processes (specifically, the catalytic conversion of hydrocarbons). In the prior art, it was known that such chemical processes should be monitored and alarms triggered if certain variables (e.g., temperature) exceeded expected values. It was also understood that the alarm values should be updated because a normal reading at one point in the process might be considered abnormal at a different stage in the process.

---

[1] Donald Chisum, the author of a leading patent law treatise, has criticized the *Benson* decision and called for it to be overruled. The result in the case, he argues, "stemmed from an antipatent judicial bias that cannot be reconciled with the basic elements of the patent system established by Congress." Chisum, *The Future of Software Protection: The Patentability of Algorithms*, 47 U. PITT. L. REV. 959, 961 (1986). Chisum states that the "awkward distinctions and seemingly irreconcilable results of the case law since *Benson* … are the product of the analytical and normative weakness of *Benson* itself." *Id*., at 961–62.

The patent application at issue in *Flook* purported to set forth a new method for updating alarm limits, but both the patent claim and the patent specification were written in highly general terms. Claim 1 in the patent application read:

> 1. A method for updating the value of at least one alarm limit on at least one process variable involved in a process comprising the catalytic chemical conversion of hydrocarbons wherein said alarm limit has a current value of
>
> $B_0 + K$
>
> wherein B_0 is the current alarm base and K is a predetermined alarm offset which comprises:
>
> (1) Determining the present value of said process variable, said present value being defined as PVL;
>
> (2) Determining a new alarm base B_1, using the following equation:
>
> $B_1 = B_0(1.0 - F) + PVL(F)$
>
> where F is a predetermined number greater than zero and less than 1.0;
>
> (3) Determining an updated alarm limit which is defined as $B_1 + K$; and thereafter
>
> (4) Adjusting said alarm limit to said updated alarm limit value.

It was conceded that the only arguably novel portion of the claimed process was step 2. While step 2 of the claim may seem complex, it is in fact exceptionally easy to understand, for it covers merely the calculation of a "weighted average" between a baseline condition (B_0) and the actual observed condition (PVL) of the process variable. The weight to be assigned the baseline and the actual condition is the variable F, which (as for all weight averages) must be between 0 and 1.[2]

Two additional points deserve mention. First, the patent claim itself did not mention the use of computer, so technically *Flook* was not about the patentability of software. The Court noted this point, stating that "the computations [in the process] can be made by pencil and paper

---

[2] The concept of using a weighted average is very basic and widely used. For example, imagine a hypothetical football team that is evaluated before the season starts as having mediocre set of players and thus baseline expected winning percentage (B_0) is 50% of its game. Suppose, however, the team wins 100% of its games during the first half of the season, so the present value of its winning percentage (PVL) is 100%. At that point, rational individuals would likely "update" their expectations about the team's likely winning percentage at the end of the season, and one common way to do that is to take a weighted average between prior expectation and actual results. Thus, for example, the new predicted winning percentage (B_1) might be calculated by using a weighting factor (F) of .6 for actual results (on the theory that actual results weigh more heavily) and then .4 (1-F) for pre-season expectations (on the theory that the team's roster of players still looks mediocre). The revised expected winning percentage would then be B_1 = 50% (.4) + 100% (.6) = 80%.

calculations," though the Court also noted that the patent's "disclosure makes it clear that the formula is primarily useful for computerized calculations." 437 U.S. at 586.

Second and perhaps more importantly, the patent application was drawn in highly abstract terms, without any disclosure of how to apply the general formula claimed to the specifics of any particular chemical process or even how much weight to assign to the baseline expected condition (B_0) and the present observed condition (PVL). As the Court emphasized:

> The patent application does not purport to explain how to select the appropriate margin of safety, the weighting factor, or any of the other variables. Nor does it purport to contain any disclosure relating to the chemical processes at work, the monitoring of process variables, or the means of setting off an alarm or adjusting an alarm system.

Id.

In holding the claimed process unpatentable, the Court explained that, whatever the novelty of the mathematical formula, the process contained no "inventive concept" within the meaning of the Court's precedents:

> Respondent's process is unpatentable under § 101, not because it contains a mathematical algorithm as one component, but because once that algorithm is assumed to be within the prior art, the application, considered as a whole, contains no patentable invention. Even though a phenomenon of nature or mathematical formula may be well known, an inventive application of the principle may be patented. Conversely, the discovery of such a phenomenon cannot support a patent unless there is some other inventive concept in its application.
>
> Here it is absolutely clear that respondent's application contains no claim of patentable invention. The chemical processes involved in catalytic conversion of hydrocarbons are well known, as are the practice of monitoring the chemical process variables, the use of alarm limits to trigger alarms, the notion that alarm limit values must be recomputed and readjusted, and the use of computers for "automatic monitoring-alarming." Respondent's application simply provides a new and presumably better method for calculating alarm limit values. If we assume that that method was also known, as we must under the reasoning in *Morse*, then respondent's claim is, in effect, comparable to a claim that the formula $2\pi r$ can be usefully applied in determining the circumference of a wheel.

Id. at 594-95.

c. *Diehr*. *Diamond v. Diehr*, 450 U.S. 175 (1981), was the first—and still the only—Supreme Court decision to sustain the patentable eligibility of an invention having anything even remotely related to computers. *Diehr* continues to be an important case on patentable subject matter, but it also provides only a weak foundation for the patentability of software.

The patent claimed not software *per se* but merely a "method of operating a rubber-molding press for precision molded compounds with the aid of a digital computer."[3] A 5-4 majority of the Court rule that the claimed invention was patentable subject matter, but the majority based its holding on the on the ground that the method was, after all, an industrial manufacturing process of the sort that has long been patentable:

> [W]e think that a physical and chemical process for molding precision synthetic rubber products falls within the § 101 categories of possibly patentable subject matter. That respondents' claims involve the transformation of an article, in this case raw, uncured synthetic rubber, into a different state or thing cannot be disputed. The respondents' claims describe in detail a step-by-step method for accomplishing such, beginning with the loading of a mold with raw, uncured rubber and ending with the eventual opening of the press at the conclusion of the cure. Industrial processes such as this are the types which have historically been eligible to receive the protection of our patent laws sustained the patent.

---

[3] The Supreme Court's opinion (450 U.S. at 179 n.5) sets forth claim 1 of the patent application:

> 1. A method of operating a rubber-molding press for precision molded compounds with the aid of a digital computer, comprising:
>
> providing said computer with a data base for said press including at least,
>
> natural logarithm conversion data (ln),
>
> the activation energy constant (C) unique to each batch of said compound being molded, and
>
> a constant (x) dependent upon the geometry of the particular mold of the press,
>
> initiating an interval timer in said computer upon the closure of the press for monitoring the elapsed time of said closure,
>
> constantly determining the temperature (Z) of the mold at a location closely adjacent to the mold cavity in the press during molding,
>
> constantly providing the computer with the temperature (Z),
>
> repetitively calculating in the computer, at frequent intervals during each cure, the Arrhenius equation for reaction time during the cure, which is
>
> ln v=CZ+x
>
> where v is the total required cure time,
>
> repetitively comparing in the computer at said frequent intervals during the cure each said calculation of the total required cure time calculated with the Arrhenius equation and said elapsed time, and
>
> opening the press automatically when a said comparison indicates equivalence.

Id. at 184.

The Court did, however, add three elements to patentable subject matter jurisprudence that, on the whole, helped parties seeking to patent software. First, the Court suggest that computerization could be the source of more efficient industrial processes and that such advances were not necessarily unpatentable:

> Obviously, one does not need a "computer" to cure natural or synthetic rubber, but if the computer use incorporated in the process patent significantly lessens the possibility of "overcuring" or "undercuring" the process as a whole does not thereby become unpatentable subject matter.

Id. at 187.

Second, the Court emphasized that a patent claim must be considered "as a whole" in deciding whether it was effective patenting an abstract idea:

> 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. This is particularly true in a process claim because a new combination of steps in a process may be patentable even though all the constituents of the combination were well known and in common use before the combination was made. The "novelty" of any element or steps in a process, or even of the process itself, is of no relevance in determining whether the subject matter of a claim falls within the § 101 categories of possibly patentable subject matter.

Id. at 188-89. The Court held that the appropriate way to evaluate the novelty and obviousness of the claim was for a court to consider those issues in connection with the statutory standards codified in § 102 and § 103 of the patent act. *See id.* 190-91.

Third, the Court majority interpreted *Flook* narrowly:

> It is argued that the procedure of dissecting a claim into old and new elements is mandated by our decision in *Flook* which noted that a mathematical algorithm must be assumed to be within the "prior art." It is from this language that the petitioner premises his argument that if everything other than the algorithm is determined to be old in the art, then the claim cannot recite statutory subject matter. The fallacy in this argument is that we did not hold in Flook that the mathematical algorithm could not be considered at all when making the § 101 determination. To accept the analysis proffered by the petitioner would, if carried to its extreme, make all inventions unpatentable because all inventions can be reduced to underlying principles of nature which, once known, make their implementation obvious.

Id. at 189 n.12.

There's a natural tension between *Diehr* and *Flook*, especially on the issue of whether, and to what extent, claims should be "dissected" into their constitute elements in applying

patentable subject matter doctrine. Indeed, not only *could* reasonable people believe that *Diehr* and *Flook* point in opposite directions, but reasonable people *do* believe just that, for the author of *Flook* itself (Justice Stevens) accused the majority of embracing reasoning that "was expressly rejected in Flook." Id. at 212 n.36 (Stevens, J., dissenting). Despite that tension, the Supreme Court did not issue another significant patentable subject matter decision until *Bilski* in 2010 and did not issue an opinion concerning a software patent until *Alice* in 2014.

One final point about *Diehr*: In his dissent, Justice Stevens frankly acknowledged the incoherence of Court's patentable subject matter case law and argued that the Court should issue "an unequivocal holding" that would have precluded virtually all patents on computer programs. His proposal in *Diehr* bears an obvious similarity to his similar proposal in *Bilski* to ban business method patents. In both cases, he was one vote shy of that result. Would Justice Stevens's proposed solutions have provided desirable clarity to the law?

3. The Opening of the Floodgates. In the ten-year period between January 1, 1978 and December 31, 1987, the PTO issued 262 software patents, of which 26% were issued to IBM. *See* John T. Soma & B.F. Smith, *Software Trends: Who's Getting How Many of What? 1978 to 1987*, 71 J. PAT. & TRADEMARK OFF. SOC'Y 415 (1989). Yet by 1994, the agency would issue approximately 4,500 software patents in a single year. *See* Jeffrey J. Blatt, *Software Patents: Myth Versus Virtual Reality*, 17 HASTINGS COMM. & ENT. L.J. 795, 816 (1995). As had been the case earlier, a preponderance of these patents were issued to large firms such as IBM, which alone accounted for 8% of the total. *Id* at 817; *see also* U.S. PTO, *Technology Assessment and Forecast, Electrical Classes, 1977-December 2005* p. B-3 (2006), available at http://www.uspto.gov/web/offices/ac/ido/oeip/taf/stelec.pdf (showing that Microsoft, which had obtained fewer than 100 patents between 1986 and 1995, was granted 194 patents in 1997, 330 in 1998, 348 in 1999, 495 in 2002, and 731 in 2005). The boom in software patents reflects not only the growing importance of software to the nation's economy, but also the more favorable attitude toward such patents at the PTO and in the courts. *Diehr* provided the primary basis for such patents. Are such patents—which now number into the tens of thousands—subject to being invalidated in the same way that DNA patents were?

4. Are Software and Computer Inventions Always Abstract? At least at the Federal Circuit, software and other computer-related inventions remain patentable. A good example is found in *Enfish LLC v. Microsoft*, 822 F.3d 1327 (Fed. Cir. 2016) (Hughes, J.), which involved a patented "self-referential" data structure such as a table in which the type of data in columns can be defined by entries in the rows.[4] The court interpreted the first step in the *Mayo*/*Alice* analysis

---

[4] The court recited claim 17 as a representative claim in the patent:

> A data storage and retrieval system for a computer memory, comprising:
>
> means for configuring said memory according to a logical table, said logical table including:
>
> > a plurality of logical rows, each said logical row including an object identification number (OID) to identify each said logical row, each said logical row corresponding to a record of information;
> >
> > a plurality of logical columns intersecting said plurality of logical rows to define a

as being triggered only where a claim is "directed to" an abstract idea, not where the claim merely "involves" such an idea:

> In setting up the two-stage *Mayo/Alice* inquiry, the Supreme Court has declared: "We must first determine whether the claims at issue are directed to a patent-ineligible concept." *Alice*, 134 S. Ct. at 2355. That formulation 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. The "directed to" inquiry, therefore, cannot simply ask whether the claims *involve* a patent-ineligible concept, because essentially every routinely patent-eligible claim involving physical products and actions involves a law of nature and/or natural phenomenon—after all, they take place in the physical world.

822 F.3d at 1335.

The court then held that inventions directed to "improvements in computer capabilities" were not abstract ideas:

> We do not read *Alice* to broadly hold that all improvements in computer-related technology are inherently abstract and, therefore, must be considered at step two. Indeed, some improvements in computer-related technology when appropriately claimed are undoubtedly not abstract, such as a chip architecture, an LED display, and the like. Nor do we think that claims directed to software, as opposed to hardware, are inherently abstract and therefore only properly analyzed at the second step of the *Alice* analysis. Software can make non-abstract improvements to computer technology just as hardware improvements can …. Therefore, we find it relevant to ask whether the claims are directed to an improvement to computer functionality versus being directed to an abstract idea, even at the first step of the Alice analysis.
>
> For that reason, the first step in the *Alic*e inquiry in this case asks whether the focus of the claims is on the specific asserted improvement in computer capabilities (i.e., the self-referential table for a computer database) or, instead, on a process that qualifies as an "abstract idea" for which computers are invoked merely as a tool. As noted infra, in *Bilski* and *Alice* and virtually all of the computer-related § 101 cases we have issued in light of those Supreme Court decisions, it was clear that the claims were of the latter type—requiring that the analysis proceed to the second step of the *Alice* inquiry, which asks if nevertheless there is some inventive concept in the application of the abstract idea. In this case, however, the plain focus of the claims is on an improvement to computer functionality itself, not on economic or other tasks for which a computer is used in its ordinary capacity.

> plurality of logical cells, each said logical column including an OID to identify each said logical column; and
>
> means for indexing data stored in said table.

> Accordingly, we find that the claims at issue in this appeal are not directed to an abstract idea within the meaning of Alice. Rather, they are directed to a specific improvement to the way computers operate, embodied in the self-referential table.

822 F.3d at 1335-36.

Finally, the court rejected attempts to formulate the "abstract idea" inquiry at a high level of generality:

> The district court concluded that the claims were directed to the abstract idea of "storing, organizing, and retrieving memory in a logical table" or, more simply, "the concept of organizing information using tabular formats." Likewise, Microsoft urges the court to view the claims as being directed to "the concepts of organizing data into a logical table with identified columns and rows where one or more rows are used to store an index or information defining columns." However, describing the claims at such a high level of abstraction and untethered from the language of the claims all but ensures that the exceptions to § 101 swallow the rule.

822 F.3d at 1337.

Given the Supreme Court's decision in *Benson*, is the *Enfish* court correct in holding that "improvements in computer capabilities" should not be viewed as abstract ideas? Didn't the alleged invention in *Benson* improve computer capabilities by allowing faster BCD-to-binary conversions?

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

6. Patent "Quality" and Patentable Subject Matter. The Supreme Court's decisions in *Bilski* and *Alice* could also be viewed as decisions against relatively "low-quality" patents—patents that implement a very basic idea in one particular technological environment. Thus, *Bilski* purported to claim the very basic idea of risk hedging in the particular context of energy contracts, and *Alice* purport to claim the very basic idea of intermediated settlement implemented on a computer. While such patents could also be invalidated under doctrines examined in later chapters of this casebook, that remedy does not necessarily preclude also using patentable subject matter.

The lower courts seem to be applying *Alice* in this way, and thus using patentable subject matter doctrine to invalid some really terrible patents. Consider, for example, the patent at issue

in *In re TLI Communication*, LLC, ___ F.3d ___ (Fed. Cir. 2016) (Hughes, J.), which claimed in essence any method of storing digital cellphone photos on a computer, provided that the storage system used some sort (any sort!) of organization.[5] The extreme breadth of the patent was obvious from the very structure of the infringement litigation, as the patentee sued a veritable who's who of high tech (Google, Yahoo!, Facebook, Instagram, Yelp, Dropbox, etc.)—essentially any company that might store digital images taken by cellphone. The Federal Circuit held the patent invalid, reasoning:

> On its face, representative claim 17 is drawn to the concept of classifying an image and storing the image based on its classification. While claim 17 requires concrete, tangible components such as "a telephone unit" and a "server," the specification makes clear that the recited physical components merely provide a generic environment in which to carry out the abstract idea of classifying and storing digital images in an organized manner.

___ F.3d at ___.

One interesting question to ask is how such a broadly defined patent could satisfy any of the other statutory requirements for patentability. The first part of the answer is to recognize that, at the time the patent application was filed, telephone cameras were very new (perhaps even just test products) so the patent claim might pass the novelty requirement of patent law. In the best of possible worlds, such claims should be stopped by the nonobviousness requirement. After all, once telephone cameras are available, surely it is obvious that people will want to store the resulting digital pictures, and they are likely to store them on a computer in some organized manner (e.g., by the date they were taken). Chapter 7 will examine the nonobviousness requirement in more detail, but suffice to say here that merely because one legal doctrine bars a patent, that alone does not mean that another legal doctrine might also bar the patent.

---

[5] A representation claim from the patent (U.S. Patent No. 6,038,295) is:

> 17. A method for recording and administering digital images, comprising the steps of:
>
> recording images using a digital pick up unit in a telephone unit,
>
> storing the images recorded by the digital pick up unit in a digital form as digital images,
>
> transmitting data including at least the digital images and classification information to a server, wherein said classification information is prescribable by a user of the telephone unit for allocation to the digital images,
>
> receiving the data by the server,
>
> extracting classification information which characterizes the digital images from the received data, and
>
> storing the digital images in the server, said step of storing taking into consideration the classification information.

7. Software, New Uses, and Section 100(b). In the 19th century, one rule of unpatentability was the prohibition against the patenting of new uses. The rule was once supported by Supreme Court precedent. *See*, *e.g.*, *Roberts v. Ryer*, 91 U.S. 150, 157 (1875) (stating categorically that "it is no new invention to use an old machine for a new purpose"). Perhaps even more impressive, the rule dated back to Thomas Jefferson, who in a famous 1813 letter stated as a "general rule[]" of U.S. patent law "that a machine, of which we were possessed, might be applied by every man to any use of which it is susceptible, and that this right ought not to be taken from him, and given to a monopolist, because he first perhaps had occasion so to apply it." Letter from Thomas Jefferson to Isaac McPherson (Aug. 13, 1813), http://memory.loc.gov/master/mss/mtj/mtj1/046/1000/1063.jpg. The rule thus seems to have rested on a simple intuition that a patent should not issue merely because someone had developed a new set of instructions for using an old machine, provided that nothing about the machine changed.

Two interesting things happened to this venerable rule. First, as the 19th century drew to a close, the Supreme Court itself began to cut back on the rule and to allow patents where the new use was "an entirely new use" based on "original thought" — a use not "at all analogous to any before." *Busell Trimmer Co v. Stevens*, 137 U.S. 423 (1890). Second, in the 1952 Patent Act, Congress specifically overturned whatever was left of the old prohibition on patenting new uses. Section 100(b) of the 1952 Act specifically provides that patent-eligible process "includes a new use of a known process, machine, manufacture, composition of matter, or material." Is this provision a good textual basis for software patents? Does a new piece of software provide a "new use" for a "known … machine" (a general purpose computer)?

E. FIELD RESTRICTIONS: DISFAVORED AREAS OF PATENTING

Though the judicial doctrine barring patents on physical phenomena, natural principles and abstract ideas is the chief legal mechanism by which the courts control patentable subject matter, it is a clumsy tool for deciding whether permitting patents in a particular area is sound policy. At least on its surface, the judicial doctrine requires no inquiry into the basic economic considerations that would seem relevant to the appropriate scope of patentable subject matter.

Patentable subject matter need not necessarily be defined with a single transcendent doctrine; it may also be decided on an industry-by-industry or field-by-field basis. Such an approach may encourage careful inquiry into the economic effect of patents in each field, though the resulting limits on patentability might appear ad hoc, without any overarching intellectual theme.

In general, the courts have not taken a field-based approach to defining the limits of patentability. Indeed, the cases tend to show that, even where the courts have created field restrictions on patentability, those restrictions have not been enduring. Field restrictions have, however, been enacted by legislative bodies, which may be better able than courts to assess the economic impact of patents in an entire field or industry.

This subchapter will, therefore, differ from the last in several important respects. First, legislative materials (e.g., statutes and treaties) will be at least as important as judicial decisions. Second, the policy questions concerning the effect of patents in an area can be addressed here more directly. Third, the subchapter will include a greater emphasis on international legal materials — including international treaties and comparisons of the different legislative solutions of different countries.

We will begin with Article 27 of the TRIPs Agreement — the highly important international agreement introduced in Chapter 1:

Article 27

Patentable Subject Matter

1. Subject to the provisions of paragraphs 2 and 3 below, patents shall be available for any inventions, whether products or processes, in all fields of technology, provided that they are new, involve an inventive step and are capable of industrial application.[1] Subject to paragraph 4 of Article 65, paragraph 8 of Article 70 and paragraph 3 of this Article, patents shall be available and patent rights enjoyable without discrimination as to the place of invention, the field of technology and whether products are imported or locally produced.

2. Members may exclude from patentability inventions, the prevention within their territory of the commercial exploitation of which is necessary to protect *ordre public* or morality, including to protect human, animal or plant life or health or to avoid serious prejudice to the environment, provided that such exclusion is not made merely because the exploitation is prohibited by domestic law.

3. Members may also exclude from patentability:

(a) diagnostic, therapeutic and surgical methods for the treatment of humans or animals;

(b) plants and animals other than microorganisms, and essentially biological processes for the production of plants or animals other than non-biological and microbiological processes. However, Members shall provide for the protection of plant varieties either by patents or by an effective *sui generis* system or by any combination thereof. The provisions of this sub-paragraph shall be reviewed four years after the entry into force of the WTO Agreement.

---

[1] For the purposes of this Article, the terms “inventive step” and “capable of industrial application” may be deemed by a Member to be synonymous with the terms “non-obvious” and “useful” respectively.

33 I.L.M. 1197, 1208 (1994).

The first sentence in Article 27 boldly declares that patent protection shall be made available for all inventions, "whether products or processes, in all fields of technology." To reinforce the point, the second sentence requires that patents be "enjoyable without discrimination as to … the field of technology."

Yet to this general rule, Article 27 creates three exceptions. The first, contained in paragraph 2, allows nations to bar the patenting of socially harmful or immoral inventions, an issue covered by American law under the utility doctrine, *see* Chapter 3, *infra*. That prohibition cuts across all fields of technology and does not necessarily contradict the general prohibition against field restrictions found in paragraph 1. The same cannot be said about the two exceptions found in paragraph 3. The exceptions surgical methods and macroscopic organisms are not tied to a larger doctrine; they are simply defined by the field of technology. Thus, paradoxically, the TRIPs agreement promulgates at once one of the clearest prohibitions against field restrictions and two of the most explicit field restrictions found in the law. (Could this apparent inconsistency be a political compromise?)

For each of the various fields of technology discussed below, consider the legal implications of TRIPs Article 27 as well as the economic need for patents in the field. Our study begins with the U.S. law on medical procedures, which remain patentable but heavy disfavored.

---

1. Medical Procedures

NOTES ON PATENTING OF MEDICAL PROCEDURES

1. The Medical Procedures Exception under TRIPs. Article 27(3)(a) of TRIPs permits (but does not require) member countries to exclude from patentability "diagnostic, therapeutic and surgical methods for the treatment of humans or animals." Europe takes advantage of this exception. *See* European Patent Convention, Art. 54(2), available at http://www.european-patent-office.org/legal/epc/e/ar54.html. The exception is based on the view that property rights should not prevent patients from having access to the very best medical treatment; humanitarian concerns, it is thought, "trump" the claims of a potential patentee.

The U.S. permits medical procedure patents but, under legislation enacted in 1996, the remedies for infringing such patents are severely limited. Let us examine the history leading up to the enactment of that provision.

2. Dr. Morton's Patent. The earliest controversy concerning a U.S. patent on a surgical technique arose out of U.S. Patent No. 4,848 issued in 1846 to Dr. William G. Morton, a Boston dentist who discovered that ether could be used safely to anesthesize patients during surgery. Prior to Morton's work, the painkilling and sleep-inducing qualities of ether "were commonly

known, though considered only for their entertainment value." J.M. Fenster, *How Nobody Invented Anesthesia*, INVENTION & TECHNOLOGY, Summer 1996, 24, 28. Morton discovered only the medical uses of ether, although even on this point his claim to being first was hotly disputed. *See id.* at 35.

The controversy sparked by Morton's patent produced two opinions on the legality of the patent. In 1856, Attorney General Caleb Cushing issued an opinion stating that the U.S. Government should not pay Morton for "the alleged use of his patent right" in army hospitals. *See Morton's Anaesthetic Patent*, 8 Op. Att'y Gen. 269, 270 (1869). Cushing gave several reasons for questioning the validity of the patent, most of which concerned the priority and scope of Morton's invention. But Cushing also expressed his doubt as to whether "the suggestion of the practicability of performing surgical operations, under insensibility of the patient produced by anaesthetic agents, [is] a patentable invention." *Id.* at 272.

Later Morton's patent was judicially invalidated, although the court did not announce any rule barring patents on surgical methods. *See Morton v. New York Eye Infirmary*, 17 F. Cas. 879 (C.C. S.D.N.Y. 1862). The court noted that, prior to Morton, it had "long been known" that the inhalation of ether "produced an effect like that of intoxication, exhilaration, and more or less stupefaction." *Id.* at 882. In the court's view, Morton had discovered a new use for ether but "the application of a well-known agent, by well-known means, to a new or more perfect use" was not patentable. *See id.* at 883.

3. *Ex parte Brinkerhoff.* More than two decades after the invalidation of Morton's patent, the Patent Office relied on the court's opinion in *Morton* to announce that "methods or modes of treatment of physicians of certain diseases are not patentable." *See Ex part Brinkerhoff*, 24 Comm'n Manuscript Decision 349 (Pat. Comm'n 1883) (Case No. 182), *reprinted in* 27 J. PAT. OFF. SOC'Y 797, 798 (1945). The Patent Commissioner reasoned that, since treatment methods do not always produce the desired result, patents on such methods "would have a tendency to deceive the public by leading it to believe that the method therein described and claimed would produce the desired result in all cases." *Id.* at 798.

Brinkerhoff's questionable logic was officially abandoned in *Ex parte Scherer*, 103 U.S.P.Q. (BNA) 107 (Pat. Off. Bd. App. 1954). Yet even before *Scherer*, the Patent Office had issued patents on medical treatments. *See* William D. Noonan, *Patenting Medical and Surgical Procedures*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 651, 658–61 (1995) (listing 48 selected medical process patents, five of which were issued prior to *Scherer*, and maintaining that such patents are not a "recent phenomenon").

4. *Pallin v. Singer.* The litigation of *Pallin v. Singer*, 36 U.S.P.Q.2d 1050 (D. Vt. 1995) was the signal event that precipitated the 1996 restrictions on medical patents. Dr. Pallin's patent — U.S. Pat. No. 5,080,111, "Method of Making Self-Sealing Episcleral Incision," (Jan.14, 1992) — covered a new way to make incisions in eye surgery. *See* Figure 2-8, which shows the shape of the incisions to be cut in the eye according to the claimed technique.

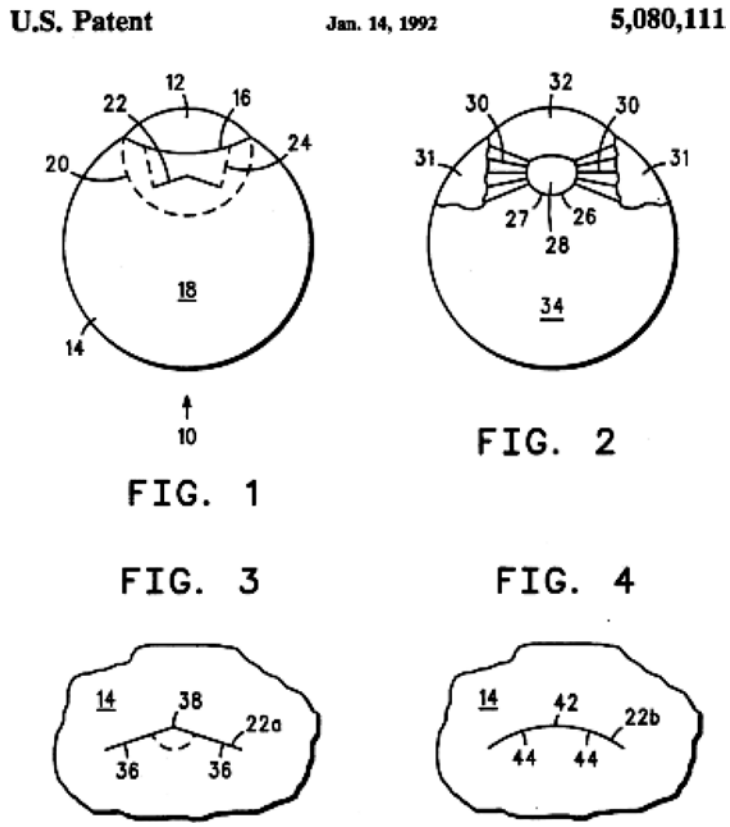


Figure 2-8: Dr. Pallin's Technique

Pallin was an odd case to generate controversy. The published district court opinion merely denied summary judgment without ever addressing § 101 issues. Thereafter, the litigation ended when the parties stipulated to the patent's invalidity due to prior art uses of the claimed technique. *See Pallin v. Singer*, Consent Order, Mar. 28, 1996 (D. Vt. 1996), reported at 1995 U.S. Dist. LEXIS 20824 (D. Vt.). Nevertheless, the litigation caused a shudder in the medical community if only because it called attention to the PTO's practice of allowing surgical patents.[1]

[1] While the *Pallin v. Singer* litigation was pending, a number of articles in the popular press fueled a steady interest in medical procedure patents. *See* Edward Felsenthal, *Medical Patents Trigger Debate Among Doctors*, WALL ST. J., Aug. 11, 1994, at B1; Lauran Neergaard, *Move to Patent Surgical Procedure Sparks Fight Over Royalties: Doctors Say Controlling the Way They Practice Medicine in Such a Way Is Unethical and Drives Up Health Care Costs*, L.A. TIMES, Apr. 2, 1995, at A14; Sabra Chartrand, *A Detection Method for Breast Tumors May Add Fire to a Debate Over Patents for Medical Procedures*, N.Y. TIMES, Jan. 30, 1995, at D2. For a good overview of the debate, see William D. Noonan, *Patenting Medical and Surgical Procedures*, 77 J. PAT. & TRADEMARK OFF. SOC'Y 651 (1995). The topic was also discussed in law journals, where some modest limitations on a medical patentee's rights were proposed. *See, e.g.*, Joseph M. Reisman, *Physicians and Surgeons as Inventors: Reconciling Medical Process Patents and Medical Ethics*, 10 HIGH TECH. L.J. 355, 397–98 (1995); Gregory F. Burch, Note, *Ethical Considerations in the Patenting of Medical Processes*, 65 TEX. L. REV. 1139 (1987).

5. Section 287(c). Section 287(c) was a last minute legislative amendment tucked into a complex appropriations bill. *See Bill With PTO Funding and Patent Reform on Medical Procedures Is Signed into Law*, 52 PAT. TRADEMARK & COPYRIGHT J. (BNA) 597 (Oct. 3, 1996).[2] The key portion of § 287(c) is paragraph (1), which drastically limits the remedies available for infringement of medical procedure patents:

> (c)(1) With respect to a medical practitioner's performance of a medical activity that constitutes an infringement under section 271 (a) or (b) of this title, the provisions of sections 281, 283, 284, and 285 of this title shall not apply against the medical practitioner or against a related health care entity with respect to such medical activity.

Paragraphs (c)(2) and (c)(3) tailor the effect of the statute. For example, paragraph (c)(2)(A) defines the "medical activity" subject to § 287(c)(1) to include the performance of a surgical procedure, but to exclude uses of patented machines or drugs. A special exemption for processes covered under any "biotechnology patent" was also included to placate the biotechnology industry. Unfortunately, the statute nowhere defines the term "biotechnology patent." (Would Dr. Pallin's patent qualify as a biotechnology patent?)

Paragraph (3) of § 287(c) creates what may be termed an "anti-research" exemption: Researchers "engaged in the commercial development … of a machine, manufacture, or composition of matter" generally do not get the protection of the statute. In many ways, this exception seems precisely backwards: Many scholars believe that the law should encourage R&D by protecting researchers against patent infringement. *See* Chapter 8.E, *infra*.

Finally, Subsection (c)(4) exempts patents "based on an application the earliest effective filing date of which is prior to September 30, 1996" (the date of the new statute's enactment), so the limitation on remedies has prospective application only.

6. Still Infringement. One interesting point about § 287(c) is that it only limits remedies. Technically, performing an operation covered under a surgical method patent still constitutes an

---

[2] Senator Hatch, Chairman of the Senate Subcommittee on Patents, Copyrights and Trademarks, criticized the process by which the statute was enacted:

> This measure was added notwithstanding the fact that there were no Senate hearings, and over the objections of myself, the chairman of the Finance Committee and the U.S. Trade Representative. It is an unprecedented change to our patent code and it is my intention to closely scrutinize the implementation of this new law.

See 142 CONG. REC. S. 11,843 (Sept. 30, 1996). A number of articles detail the legislative process by which § 287(c) was enacted. *See* Chris J. Katopis, *Patients v. Patents?: Policy Implications of Recent Patent Legislation*, 71 ST. JOHN'S L. REV. 329, 331-338 (1997), Bradley J. Meier, Note, *The New Patent Infringement Liability Exception for Medical Procedures*, 23 J. LEGIS. 265 (1997); and Scott D. Anderson, Note, *A Right Without a Remedy: The Unenforceable Medical Procedure Patent*, 3 MARQ. PROP. L. REV. 117 (1999).

act of infringement; the patentee just cannot get any remedy against the responsible doctors, nurses and related health care entities. This technical difference gives rise to the possibility that the patentee could sue parties not covered under § 287(c) for indirect patent infringement. *See* Chapter 8.F, *infra*.

Who might be indirect infringers? The statute expressly includes within the definition of "related health care entities" hospitals, clinics, HMO's, and any other such entity "with which a medical practitioner has a professional affiliation." § 287(c)(2)(C). Broad as that language is, it does not cover everyone. Perhaps patients could be sued for inducing their doctors to infringe. Alternatively, a medical supply company might be sued for supplying an unpatented device if the company knows that doctors are using the device to infringe. The case law has not yet addressed these issues.

7. Don't Try This at Home! Section 287(c) protects only "medical practitioner[s]," so it gives no defense to a lay person performing a patented emergency medical procedure (e.g., an improved Heimlich maneuver). *See* Weldon E. Havins, *Immunizing the Medical Practitioner "Process" Infringer*, 77 U. DET. MERCY REV. 51, 51–52 (1999) (discussing the potential liability of lay infringers). Does its limited applicability make the statute seem like a special rule for a powerful lobbying group?

8. Conflict with TRIPs? The TRIPs agreement allows member countries to exclude surgical procedures from patentability. Does it follow that a country allow surgical patents but drastically restrict the remedies for infringement? Consider the following argument:

> Although TRIPS Article 27:3 permits Members to exclude diagnostic, therapeutic and surgical techniques from patentability, we believe that if a member makes patents available for this field of technology, a Member must accord the full rights required under the TRIPS Agreement. Article 27:1 requires that patent rights be enjoyable without discrimination as to the field of technology. Those rights are specified in Article 28 and include the right to prevent third parties from the act of using a patented process.

Letter from Jennifer Hillman, General Counsel, Office of the U.S. Trade Representative, to Senator Orrin Hatch, *reprinted in* 142 CONG. REC. S11,843 (Sept. 30, 1996). *See also* Cynthia Ho, *Patents, Patients, and Public Policy: An Incomplete Intersection at 35 U.S.C. § 287(c)*, 33 U.C. DAVIS L. REV. 601, 672 (2000) (arguing that "[o]ther nations may be less likely to uphold the TRIPS provisions if they perceive that the United States, a major proponent of the TRIPS agreement, ignores its provisions").

9. The Efficiency of Legislation. As the judicial limitations on patentable subject matter recede, specific legislation such as § 287(c) may become a more important means of restricting the availability of patents.

The shift from judicial law-making to increased legislation raises the important question whether Congress is institutionally capable of making efficient field-by-field adjustments to the patent law. One view is that the mere possibility of such ad hoc adjustments opens up so many

opportunities for special interest lobbying that any efficiency gains are more than offset by the resources squandered in attempts to influence the legislative process.[3] On the other hand, at least one team of economists has theorized that politicians have incentives to seek *more efficient* property rights.[4]

10. Alternatives. Should the U.S. replace § 287(c) with an explicit exclusion such as Europe's? Would it be better to limit the remedies in some other way — for example, by allowing money damages but no injunctions?

11. Pharmaceutical Patents. Prior to the conclusion of the TRIPs Agreement, many developing nations excluded from patentability not only medical therapies and devices, but also pharmaceutical products. *See* JAYASHREE WATAL, INTELLECTUAL PROPERTY RIGHTS IN THE WTO AND DEVELOPING COUNTRIES 109 (2001). Indeed, until recently, even many industrialized nations would not grant pharmaceutical patents. They were first authorized in Japan in 1976, Switzerland in 1977 and Italy in 1978, and were unavailable in Finland, Greece, Iceland, Monaco, Norway, Portugal and Spain as late as 1988. *See id.*

Ending such exclusions has been described as "the most important goal and achievement of the TRIPS." *Id.* Article 27 requires nations to provide patents for pharmaceuticals, though "developing" countries are given until January of 2005 to comply if they previously did not extend patent protection to pharmaceuticals. *See id.* at 38; *see also* TRIPs Art. 65, paras. 1, 2 & 4. Why are pharmaceuticals treated so differently from surgical techniques?

---

2. Patenting of Higher Life Forms

NOTES ON PATENTING HUMANS AND CHIMERAS

1. The Rise in Animal Patents. As biotechnology advances, patents on artificially mutated animals and on processes involving such mutants increase in both the number and economic importance. For example, consider the following patents: U.S. Patent 6,013,857 (Jan. 11, 2000) describes a cow genetically engineered to produce "human milk proteins and human serum proteins" in its milk so that its milk is essentially identical to human milk for infants. U.S.

---

[3] *See, e.g.*, Robert D. Tollison, *Public Choice and Legislation*, 74 VA. L. REV. 339 (1988) (overview of the "economic theory of legislation" which views legislation as the product of "rent-seeking" special interest groups.); *see also* DOUGLASS NORTH, INSTITUTIONS, INSTITUTIONAL CHANGE AND ECONOMIC PERFORMANCE 110 (1990) ("Because politics make and enforce economic rules, it is not surprising that property rights are seldom efficient."). For a general survey of the literature on legislative rent-seeking, see William N. Eskridge, Jr., Philip Frickey, and Elizabeth Garrett, Legislation and Statutory Interpretation 81-97 (2000).

[4] *See* William Riker and Itai Sened, *A Political Theory of the Origin of Property Rights: Airport Slots*, in EMPIRICAL STUDIES IN INSTITUTIONAL CHANGE 283, 300 (Lee J. Alston, Thrainn Eggertsson and Douglass C. North, eds., 1996) ("property rights increase efficiency by encouraging owners to use assets most productively. Efficiency makes for prosperity, which redounds to politicians' credit."); ITAI SENED, THE POLITICAL INSTITUTION OF PRIVATE PROPERTY (1997) (providing a comprehensive version of this theory). For some discussion in the intellectual property context, see Robert P. Merges, *Intellectual Property Rights and the New Institutional Economics*, 53 VAND. L. REV. 1857 (2000).

Patent 6,018,097 (Jan. 25, 2000) claims mice that have been genetically altered to manufacture human insulin. Finally, the so-called "onco-mouse" patent, U.S. Patent 4,870,009 (Apr. 12, 1988), claims non-human mammals in which a specific gene has been introduced to make the mammal more susceptible to cancer.

Are any of these patents troubling? Does it matter whether the genetically altered animal suffers more than a normal animal of its species?

2. The Approach of U.S. Law. Questions regarding the impact of patents on a particular industry, the economy, or even society as a whole are generally not considered when "patentability" under 35 U.S.C. § 101 is the issue. *See, e.g.*, Markey, *Patentability of Animals in the United States*, 20 INT'L REV. INDUS. PROP. & COPYRIGHT L. 372 (1989). Advocates of "technology assessment," however, would like to change what they view as the overly "narrow" approach to such issues. *See, e.g.*, HENDERSON HAZEL, CREATING ALTERNATIVE FUTURES (1978); THEODORE ROSZAK, THE CULT OF INFORMATION (1986); LANGDON WINNER, AUTONOMOUS TECHNOLOGY (1977).

Patent law is not wholly devoid of any discussion of the impact of the technologies it aims to foster. For example, the utility requirement has been interpreted in some cases as calling for an assessment of whether the "useful" properties of a technology outweigh its potential for harmful effects. *See* Chapter 3.B, "Beneficial Utility," *infra*.

3. The Approach of European Law and the *Harvard/Onco-mouse* Case. Article 53(b) of the European Patent Convention (EPC) prohibits the patenting of plant or animal "varieties." The scope of this provision was put to the test in the celebrated *Harvard/Onco-mouse* case. Doctors Philip Leder and Timothy Stewart of the Harvard Medical School successfully isolated a gene associated with cancer in mammals (including humans) and injected the gene into fertilized mouse eggs. The process yielded transgenic mice that are extremely sensitive to carcinogens and thus useful for studying the effects of cancer drugs. Leder and Stewart claimed all "non-human transgenic mammals" produced by their technique. They succeeded in winning U.S. Patent No. 4,736,866 (1988) but endured a protracted fight in Europe.

In denying the Leder and Stuart application, the Examining Division of the European Patent Office (EPO) held that Article 53(b) required "exclusion of animals in general" from patentability. *See Harvard/Onco-mouse*, V 0004/89-Examining Division, ¶ 7.1.4 (EPO July 14, 1989), available at http://legal.european-patent-office.org/dg3/biblio/v890004ep1.htm. In reversing, the EPO's Technical Board of Appeal held that Article 53(b) did not bar all patents on animal life. *See Harvard/ Onco-mouse*, T 0019/90-3.3.2, (EPO Bd. of Appeal Oct. 3, 1990, available at http://legal.european-patent-office.org/dg3/biblio/t900019ep1.htm. On remand, the Examining Division reversed course and held that the term "animal variety" refers only to "a sub-unit of a species and therefore of even lower ranking than a species." *See Harvard/Onco-mouse*, V 0006/92-Examining Division (EPO April 3, 1992), available at http://legal.european-patent-office.org/dg3/biblio/v920006ep1.htm. Since the Leder and Stewart claims covered more than just a single subspecies, they were not barred by Article 53(b). The European patent ultimately issued on March 13, 1992. *See* EPO Patent 169,672. The patent then went through post-grant opposition procedures and, though for other reasons the claims in the patent had to be narrowed to cover only transgenic mice, the Board of Appeals reaffirmed the rule that Article 53(b)'s prohibition on patent animal varieties did not apply where "the technical feasibility of the

invention is not confined to a particular animal variety (or species or race)." T 0315/03-3.3.8 ¶ 11.8 (EPO Bd. App. 2004).

In a 1998 Directive on the "Legal Protection of Biotechnological Inventions", the European Union endorsed the basic holding of *Harvard/Onco-mouse* and required all EU Member nations to "protect biotechnological inventions under national patent law." *See Directive 98/44/EC of the European Parliament*, Article 1 (July 30, 1998), *reprinted in* 1999 O. J. EPO 101, 111, available at http://www.european-patent-office.org/epo/pubs/oj99/2_99/2_1019.pdf.

Incidentally, Professor Leder later invented an even better mouse, and the world no doubt beat a path to his door. *See* U.S. Patent 5,175,383 (Dec. 29, 1992) ("Animal Model for Benign Prostatic Disease").

4. The Contrasting Approach of European Law to Stem-cell Research. The 1998 Directive of the E.U., which required all member nations of the E.U. to protect biotechnological inventions under national patent law, also specifically prohibits certain classes of biotechnology related inventions from being patented. Under Article 53(a) of the European Patent Convention, which dealt with the "*ordre public*" and morality exclusions to patent law, together with Rule 28 of the 1998 Directive, the E.U. specifically prohibits the patenting of processes for human cloning, processes for modifying the germ line genetic identity of human beings, uses of human embryos for industrial or commercial purposes, and the process of modifying germ line genetic identity for animals if there was no substantial medical benefit from the modification. This provision has been used by the European Patent Office to revoke patents or patent claims issued to the University of Edinburgh and the Wisconsin Alumni Research Foundation (WARF), both of which had claimed inventions relating to embryos and stem-cells. *See* S. Sterckx & J. Cockbain, *Assessing the Morality of the Commercial Exploitation of Inventions Concerning Uses of Human Embryos and the Relevance of Moral Complicity: Comments on the EPO's WARF Decision*, 7:1 *SCRIPTed* 83 (2010).

5. The Animal-Human Chimera. In December 18, 1997, Stuart Newman, a biology professor at New York Medical College, filed a patent application on animal-human hybrids or "chimeras" and on a process for producing such creatures. *See* David Dickerson, *Legal Fight Looms over Patent Bid on Human/Animal Chimaeres*, 392 NATURE 423 (April 2, 1998).; Rick Weiss, *Patent Sought on Making of Part-Human Creatures; Scientists Seeks to Touch Off Ethics Debate*, WASH. POST, Apr. 2, 1998, at A12. Newman had not actually produced such an organism. Indeed, he filed the patent application to trigger a debate about the morality of patenting such life forms and publicly stated that, if the application were granted, he would use the patent to exclude anyone from the technology for the duration of the patent. *See id.*

Newman made the application public in April of 1998, and the PTO immediately issued a statement suggesting that an animal-human chimera could be denied a patent on the basis of the utility doctrine. *See* U.S. PTO, *Media Advisory* (Apr. 1, 1998), available at http://www.uspto.gov/web/offices/com/speeches/98-06.htm; *see also* Chapter 3, *infra* (discussing the morality component of the utility requirement). However, when the agency officially acted on the matter, it rejected Newman's application on the grounds that such creatures were not patentable subject matter:

> The claimed invention is not considered to be patentable subject matter under 35 U.S.C. 101 because the broadest reasonable interpretation of the claimed inventions as a whole embraces a human being. In particular, applicant's claimed invention as set forth in all the independent claims is not limited to non-humans but rather includes within its scope a human being and as such falls outside the scope of protection under 35 U.S.C. 101… .
>
> While the PTO recognizes that the scope of protection covered by 35 U.S.C. 101 is expansive and the fact that a claimed invention which embraces a human being is not within one of the exclusions enumerated by the Supreme Court in *Chakrabarty*, i.e., the laws of nature, physical phenomena and abstract ideas, the PTO believes that Congress did not intend 35 U.S.C. 101 to include the patenting of human beings.

Patent Application Is Disallowed as 'Embracing' Human Being, 58 PAT. TRADEMARK & COPYRIGHT J. (BNA) 203 (June 17, 1999) (quoting PTO's first office action on Newman's application). (The PTO does not make its office actions public, but there is nothing to stop the applicant from disclosing the PTO's action, as Newman did.) In 2004, the PTO made this rejection final, again holding that humans are not patentable subject matter and that the claimed invention covered creatures that were substantially human. Office Action for Application No. 10/308,135 (Aug. 11, 2004), at 20–22 (available at http://patentlaw.typepad.com/patent/files/chimera_final_rejection.pdf).

How persuasive is the PTO's reasoning? Is it consistent with *Chakrabarty*? What fraction of human genetic material must an organism possess before the PTO will consider it to "embrace[] a human being"? Consider U.S. Patent 6,018,097 (mentioned above), which claims a transgenic mouse that has the human gene for producing insulin. Is that an animal-human chimera?

In an interview occurring shortly after Professor Newman made his application public, Commissioner of the PTO Bruce Lehman stated that "there will be no patents on monsters, at least not while I'm commissioner." *'Morality' Aspect of Utility Requirement Can Bar Patent for Part-human Inventions*, 55 PAT. TRADEMARK & COPYRIGHT J. (BNA) 555 (Apr. 9, 1998). Was the oil-eating bacterium in *Chakrabarty* a "monster"? For further commentary and documentation on this fascinating topic *see* Cynthia M. Ho, *Splicing Morality and Patent Law: Issues Arising from Mixing Mice and Men*, 2 WASH. U. J. L. & POL'Y 247 (2000); Dan L. Burk, *Patenting Transgenic Human Embryos: A Nonuse Cost Perspective*, 30 HOUS. L. REV. 1597 (1993).

In 2004, Congress enacted an appropriations rider (a legal limitation found in an appropriations bill) that precludes the patenting of a human organism. The rider — popularly known as the "Weldon Amendment" — reads: "None of the funds appropriated or otherwise made available under this Act may be used to issue patents on claims directed to or encompassing a human organism." Consolidated Appropriations Act, 2004, Pub. L. No. 108-199, Div. B, Title VI, § 634 (Jan. 23, 2004). This limitation was repeatedly reenacted in subsequent years. Finally, in 2011, in § 33 of the AIA, Congress added the following provision: "33(a) Limitation Notwithstanding any other provision of law, no patent may issue on a claim directed to or

encompassing a human organism." This applies to all applications filed after the effective date of the AIA (Sept. 16, 2011), but not to applications pending as of that date. § 33(b).

NOTES ON PROPERTY RIGHTS IN PLANT DISCOVERIES

1. The Value of Naturally Occurring Plants. Naturally occurring plants have always been an important medical and economic resource. Consider the following:

> There are about 121 clinically useful prescription drugs worldwide that are derived from higher plants. About 74% of them came to the attention of pharmaceutical houses because of their use in traditional medicine. Among the drugs derived from plants are the anticancer agents vinblastine and vincristine. Morphine, codeine, quinine, atropine, and digitalis come from plants… . In 1985, worldwide, a total of 3500 new chemical structures were discovered. Some 2619 of the chemicals were isolated from higher plants.

Philip Abelson, *Medicine From Plants (Editorial)*, 247 SCI. 513 (2 Feb. 1990). *See also* Constance Holden, *Entomologists Wane as Insects Wax*, 246 SCI. 754 (10 Nov. 1989) (reporting the views of Thomas Eisner, a professor of chemical ecology at Cornell, who argues in favor of "chemical prospecting" to discover new naturally occurring biological substances and thereby to avoid "biological impoverishment"). Indeed, much of the diplomatic wrangling surrounding the 1992 Ecological Summit in Rio de Janeiro centered on whether some form of property rights should be granted for tropical plants found to have medical or other uses.

> If plants are such a valuable resource, why should the law confer property rights only to plants that are artificially created or bred? Wouldn't extending property rights to *all* newly discovered plants provide the correct incentives for seeking out and protecting this valuable resource?

2. The Philosophical and Legal Case for Protecting Plant Discoveries. Consider the following passage written by the noted libertarian philosopher Robert Nozick, in which he sets forth the reasons why one who discovers a new plant is entitled to assert property rights over it:[1]

---

[1]The passage comes in the midst of a section discussing John Locke's theory of property; thus the emphasis is on not worsening anyone else's position, one of the "Lockean provisos" that must be met under this theory for property rights to be defensible. *See* J. LOCKE, TWO TREATISES OF GOVERNMENT 129, 131 (Everyman ed. 1924):

> [T]hough all the fruits [the earth] naturally produces, and beasts it feeds, belong to mankind in common, as they are produced by the spontaneous hand of Nature, and nobody has originally a private dominion exclusive of the rest of mankind in any of them, as they are thus in their natural state, yet being given for the use of men, there must of necessity be a means to appropriate

> He does not worsen the situation of others; if he did not stumble upon the substance no one else would have, and the others would remain without it. However, as time passes, the likelihood increases that others would have come across the substance; upon this fact might be based a limit to his property right in the substance so that others are not below their baseline position; for example, its bequest might be limited.

R. NOZICK, ANARCHY, STATE AND UTOPIA 181 (1974). Persuasive?

Whatever its merits, Noziak's view is not embraced by current law, which is summarized in *Chakrabarty*: "[A] new mineral discovered in the earth or a new plant found in the wild is not patentable subject matter… . Such discoveries are 'manifestations of … nature, free to all men and reserved exclusively to none.' " 447 U.S. at 309 (quoting *Funk Brothers*).

It is not clear, however, whether this bar to patenting plants that are merely "discovered," as opposed to "invented," is required by the federal Constitution. Article I, § 8 of the Constitution gives Congress power to secure to "Inventors the exclusive Right to their … Discoveries." One view is that, because the Constitution requires the recipient of the right to be an inventor, rights can be granted only for discoveries that constitute invention, i.e., that were produced by the creative act of an inventor. Dicta in various Supreme Court opinions support this position. For example, in *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 279 (1976), the Court stated that "the Constitution requires that there be some 'invention' to be entitled to patent protection," and it defined some "degree of skill and ingenuity" to be an essential element of invention. Requiring creativity would also be consistent with the Court's interpretation of the Copyright Clause, where the Court has distinguished between "creation and discovery" and stated that "at least some minimal degree of creativity" is a constitutional requirement for copyright protection. *Feist Publications v. Rural Tel. Serv. Co.*, 499 U.S. 340, 347, 345 (1991).

The alternative view is that the constitutional clause embraces both discovery and invention, so Congress could, if it wanted, extend exclusive rights to cover newly discovered products of nature. An argument in support of this position is nicely set forth in the legislative history of the Plant Protection Act (PPA):

> At the time of the adoption of the Constitution the term "inventor" was used in two senses. In the first place the inventor

---

> them some way or other before they can be of any use, or at all beneficial, to any particular men… .
>
> Nor was this appropriation of any parcel of land, by improving it, any prejudice to any other man, since there was still enough and as good left, and more than the as yet unprovided could use. So that, in effect, there was never the less left for others because of his enclosure for himself. For he that leaves as much as another can make use of does as good as take nothing at all.

See generally Hettinger, *Justifying Intellectual Property*, 18 PHIL. & PUB. AFF. 31 (1989) (discussing Lockean property rights theory and intellectual property).

> was a discoverer, one who finds or finds out. In the second sense an inventor was one who created something new. All the dictionaries at the time of the framing of the Constitution recognized that "inventor" included the finder out or discoverer as well as the creator of something new. [The analysis cites and discusses over twenty dictionaries from the 17th, 18th and early 19th centuries, and continues:] The distinction between discovering or finding out on the one hand and creating or producing on the other hand, being recognized in the dictionaries current at the time of the framing of the Constitution, it is reasonable to suppose the framers of the Constitution attributed to the term "inventor" the then customary meaning. That they did not ignore the meaning of inventor as "a discoverer or finder out" is furthermore indicated by the fact that in the Constitution itself the framers referred to the productions of inventors as "discoveries."

H.R. Rep. 1129, 71st Cong., 2d Sess. 8–9 (1930); S. REP. NO. 315, 71st Cong., 2d Sess. 8 (1930) (same analysis).[2]

Which of the two views is more persuasive? Note that to some extent the second view is incorporated in the PPA which, as amended in 1954, does extend property rights to those who "*discover* and asexually reproduce … newly *found* seedlings," provided the plant is not found in an "uncultivated state." 35 U.S.C. § 161. *See also* S. REP. NO. 1937, 83d Cong., 2nd Sess. (1954), *reprinted* 1954 U.S. Code Cong. & Admin. News 3981, 3982 ("a grower of plants who, through no particular efforts of his own other than perhaps by accident, develops a new plant which is, nevertheless, due to his activity, should be entitled to patent such plant in the same manner as though he had deliberately planned the result achieved"). Thus, under the statute, the chance find by a farmer is patentable even though the chance find by an explorer is not. Is this aspect of the PPA constitutional?

If patent rights can be granted for newly discovered plants, are such property rights a good idea? Are fewer incentives needed for encouraging the discovery of new plants than for their artificial creation?

3. Owning Biodiversity. Some countries have asserted that they "own" the genetic material from plants that grow inside their borders. Many are poor countries from tropical regions where a great variety of plant species grow. These countries insist that companies from developed countries pay "royalties" for the right to remove genetic material for research or the development

---

[2] Congress considered the constitutional issue because one early version of the bill covered any "discovery in the sense of finding a thing already existing," *see* H.R. Rep. 1129, 71st Cong., 2d Sess. 10 (1930). The Hoover Administration supported that version of the bill because the "possibility of reward would undoubtedly influence the public to be more observant of plants and thus tend to prevent the waste of many valuable new varieties which occur naturally but are now lost to mankind through neglect or lack of appreciation of value." *Id.* at 10 (setting forth letter from President Hoover's Secretary of Agriculture). As enacted in 1930, the text of PPA seemed to cover all newly discovered planted varieties, but the legislative history suggested that Congress had intended to exclude "the chance find of the plant explorer." H.R. Rep.1129, at 4; S. Rep. No. 315, at 3.

of new products. *See* Marlise Simons, *Poor Nations Seeking Rewards for Contributions to Plant Species*, N.Y. TIMES, May 16, 1989, at 4, col. 4. Is this a form of "intellectual" property?

4. Protecting Biodiversity. The notion of granting intellectual property rights over the genetic material in native species may seem strange to some, but it might actually serve two purposes. In addition to more fairly distributing the gains from recombinant genetic products based on those species, it would also give developing countries an incentive to protect rainforests and other genetically rich areas. In general, the granting of property rights over a resource can be expected to lead to more efficient use of the resource; at the very least, it will prevent over-exploitation of the resource due to its free (or "public good") quality. *See, e.g.*, Harold Demsetz, *Toward a Theory of Property Rights*, in OWNERSHIP, CONTROL, AND THE FIRM 104 (1988); Anthony T. Charles, *Fishery Socioeconomics: A Survey*, 64 LAND ECON. 276, 279–80 (1988) (describing allocation of fish catches via property rights).

Over the last decade, developing countries have been trying to get developed nations to enforce a mandatory disclosure requirement in their patent law which would require all patent applicants to disclose the source of any possible biological material used in an invention. Such a disclosure is meant to act as an enforcement mechanism against any possible attempt to circumvent biodiversity laws in developing nations. *See* REPORT ON DISCLOSURE OF ORIGIN IN PATENT APPLICATIONS (2004), *available at* http://trade.ec.europa.eu/doclib/docs/2005/june/tradoc_123533.pdf. For a broad-ranging discussion of these issues, see MADHAVI SUNDER, FROM GOODS TO A GOOD LIFE: INTELLECTUAL PROPERTY AND GLOBAL JUSTICE (2012).

5. Property Rights in Natural Products: A Shaman's View. Is current intellectual property law "systematically biased" against the knowledge developed by indigenous peoples? In *Of Seeds and Shamans: The Appropriation of the Scientific and Technical Knowledge of Indigenous and Local Communities*, 17 MICH J. INT'L L. 919 (1996), Professor Naomi Roht-Arriaza makes the case that it is, and that the bias is reflected in, among other doctrines, the law of patentable subject matter:

> The substance of a patent may not be the discovery of some natural phenomenon. Thus medicinal plants in their natural state, or even diluted or otherwise processed, are not patentable. However, if a Western scientist isolates the plant's active substance in a way that does not occur in nature, it becomes patentable. The knowledge gained outside a chemical laboratory is therefore downgraded to a substance "which nature has intended to be equally for the use of all men," [quoting *Ex parte Latimer*, *supra*] even though there may be no reason for indigenous peoples to isolate or extract the exact chemical compounds which give a substance its utility.

Id. at 938. Among her proposed solutions to this problem, Professor Roht-Arriaza proposes to extend intellectual property rights to protect "innovations involving traditional or nonlaboratory technologies." *Id.* at 953.

Another approach to this issue is outlined in the Convention on Biological Diversity, 31 I.L.M. 818 (opened for signature June 5, 1992), available at http://www.biodiv.org/convention/convention.shtml. That multinational agreement "obligates countries (primarily those in the developing world) to conserve, sustainably use, and guarantee access to genetic resources, in return for a fair and equitable sharing of the benefits arising out of the utilization of those resources." Charles R. McManis, *The Interface Between International Intellectual Property and Environmental Protection: Biodiversity and Biotechnology*, 76 WASH. U. L.Q. 255, 260 (1998). Though the Biodiversity Convention has been ratified by 189 nations, it has remained controversial, in part because of perceived tensions between the Convention and the intellectual property rights required under the TRIPs agreement. *See id.* at 255–256 (noting the apparently "conflicting visions" provided by TRIPs and the Biodiversity Convention but suggesting that the two agreements could be reconciled with a more "cooperative" approach); Nuno Pires de Carvalho, *Requiring Disclosure of the Origin of Genetic Resources and Prior Informed Consent in Patent Application Without Infringing the TRIPS Agreement: The Problem and the Solution*, 2 WASH. U. J.L. & POL'Y 371 (2000) (discussing the tension between the TRIPs agreement and the requirement under the Biodiversity Convention that patent applicants disclose the origin of any genetic materials used in an invention). In addition, the Biodiversity Convention has been viewed as a possible threat to the biotech industry, with perhaps some justification. *See* Shayana Kadidal, Note, *Plants, Poverty and Pharmaceutical Patents*, 103 YALE L.J. 223 (1993) (arguing that Rio Convention requires that developing countries receive property rights in their biodiversity). While the Convention was signed by the Clinton Administration in 1993, it has yet to be ratified by the Senate (as of March 2007).

3. Comparative Notes on Software and Business Methods

As we saw in subchapter B.3, *supra*, the judicially-created restrictions on software patents in the U.S. have all but vanished in the last decade. Yet the economic effect of patents in the software industry remains a subject of considerable debate, and the possibility remains real that Congress could create an explicit field restriction on the patenting of software. Though such a restriction would be new to the law of the United States, one already exists in Article 52 of the European Patent Convention (EPC):

Article 52-Patentable Inventions

> 1) European patents shall be granted for any inventions which are susceptible of industrial application, which are new and which involve an inventive step.
>
> (2) The following in particular shall not be regarded as inventions within the meaning of paragraph 1:
>
> > (a) discoveries, scientific theories and mathematical methods;
> >
> > (b) aesthetic creations;

> (c) schemes, rules and methods for performing mental acts, playing games or doing business, and *programs for computers*;
>
> (d) presentations of information.
>
> (3) The provisions of paragraph 2 shall exclude patentability of the subject-matter or activities referred to in that provision only to the extent to which a European patent application or European patent relates to such subject-matter or activities as such.

Convention on the Grant of European Patents, Art. 52 (emphasis added; paragraph (4) omitted), available at http://www.european-patent-office.org/legal/epc/e/ar52.html#A52.[1] The following case shows how this field restriction has been interpreted by the European Patent Office (EPO):

2. The International Rise of Software Patents. The EPC, with its explicit restriction on computer program patents, came into force in 1973, one year after the U.S. Supreme Court decided *Benson*. That era marked the zenith of hostility toward software patents. By the early 1990's, the *de facto* practice of the EPO in the software field was not radically different from that of the U.S. PTO. *See* Alfred P. Meijboom, *Software Protection in "Europe 1992*," 16 RUTGERS COMPUTER & TECH. L.J. 407, 409–20 (1990); *see also* EEC Directive for Legal Protection of Software, Directive 91/250, January 1, 1993 (setting forth harmonized, European-wide standards for protecting software). Starting with the decision of the EPO Board of appeals in *A Computer Program Product/IBM* T 1173/97-3.5.1 (EPO Board of Appeals July 1, 1998), the EPO has been liberalizing its policies with respect to software patents over the years. The test for patent eligibility is whether or not the computer program has a 'technical effect.' The trend is clear: In 1999, the EPO issued 3,942 patents in the computing field, a 30% increase over the last two years. *See* EPO, 1999 ANNUAL REPORT 48 (Figure 11), *available at* http://www.european-patent-office.org/epo/an_rep/1999/pdf/fulldoc.pdf. In 2011, the EPO had issued over 7,561 patents in the computing field, almost double the number the EPO had granted a decade ago. *See* EPO, 2011 ANNUAL REPORT, *available at* http://www.epo.org/about-us/annual-reports-statistics/annual-report/2011/statistics-trends/key-trends.html#asia

The national patent offices in Europe seem to be following the lead of the EPO. For example, the Head of the Data Processing examination department in the Germany Patent Office recently noted that "of approximately 1,500 requests for examination received every year in the field of data processing, only about 5 to 10 are rejected for lack

---

[1] On November 29, 2000, the Diplomatic Conference to Revise the European Patent Convention agreed to a revised version of Article 52. *See* Act Revising the Convention on the Grant of European Patent 9–10 (www.european-patent-office.org/epo/dipl_conf/pdf/em00003a.pdf). However, only stylistic changes were made to paragraphs 1&3 of Article 52.

of technical character," and that "those rejected would for the most part also fail on the grounds of inventive step [*i.e.*, obviousness]." Wolfgang Tauchert, *Patent Protection for Computer Programs — Status and Current Developments*, 31 INT'L REV. INDUS. PROP. & COPYRIGHT L. (IIC) 812, 818–819 (2000). Thus, even though the German law (like the EPC) expressly lists computer programs as an unpatentable subject, *see id*. at 812, programs are now commonly patented in day-to-day practice. *Id.* at 819.

Over the last decade there have been some efforts at reforming the protection offered to computer programs under the EPC, but these have met with little success. *See* Arnoud Engelfriet, *The Mess That Is the European Software Patent*, IPKAT.COM, Oct. 28, 2012, *available at* http://ipkitten.blogspot.com/2012/10/the-mess-that-is-european-software.html.

Japan too has followed the trend, although it has moved more slowly than the United States and Europe. *See* Jack M. Haynes, *Computer Software: Intellectual Property Protection in the United States and Japan*, 13 J. MARSHALL J. COMPUTER & INFO. L. 245, 261 (1996): (asserting that "many" computer programs "patentable under *Diehr* would be patentable in Japan" but many others would not be); Rieko Mashima, *Examination of the Interrelationship among Japanese I.P. Protection for Software, the Software Industry, and Keiretsu*, 82 J. PAT. & TRADEMARK OFF. SOC'Y 33 (part I), 70 (2000) (concluding that in the mid-1990's, "the U.S. clearly has trended toward wider protection for software-related inventions than Japan"). In December of 2000, the JPO went even further; it published new guidelines permitting "computer programs" to be claimed as products. *See* JPO, *Examination Guidelines for Computer Software-Related Inventions* 3-4, available at http://www.jpo.go.jp/tetuzuki_e/t_tokkyo_e/Guidelines/PartVII-1.pdf (setting forth proper claim formats for computer programs). These guidelines were updated in 2005.

3. The European Parliament's Rejection of a Directive on the Patentability of Computer-Implemented Inventions. In July 2005, the European Parliament rejected a proposed measure, the Directive on the Patentability of Computer-Implemented Inventions, that would have removed some obstacles to software patents in the European Union by allowing patents for "computer-implemented inventions" that involved a "technical contribution."

Originally proposed in 2002, the directive was modified over time, such that the common position presented by the European Council to the Parliament for a vote stated that "A computer program as such cannot constitute a patentable invention." It also stated that:

> [I]nventions involving computer programs, whether expressed as source code, as object code or in any other form, which implement business, mathematical or other methods and do not produce any technical effects beyond the normal physical interactions between a program and the computer, network or

> other programmable apparatus in which it is run shall not be patentable.

General opposition to software patents, together with unhappiness at the compromise language, combined to produce a resounding defeat for the measure.[2] 648 out of 729 Members of the European Parliament (MEPs) voted to reject the proposed directive.

In the wake of the rejection, the European Commission indicated that it would not immediately press for a new proposal. The European Patent Office, on the other hand, continues to support a proposal to harmonize the treatment of software patents across the EU.

However, in January 2006, the European Commission began a new set of consultations regarding intellectual property protection, including an effort to harmonize patent litigation across member states under the European Patent Litigation Agreement. Critics of software patents immediately raised alarms, and the legislative efforts appear now to be stalled.

4. A Contrast: The EPO's Business Method Stance. The EPO's case law on EPC Article 52(2)'s business method exclusion provides a stark contrast to the treatment of computer programs.

In August of 2000, the EPO appeared poised to eviscerate the business method exclusion in much the same fashion as it has done with the computer program exception. *See Patentability of methods of doing business* (EPO Aug. 18, 2000) (available at www.european-patent-office.org/news/pressrel/2000_08_18_e.htm). Yet one month later, the EPO Board of Appeals held unpatentable a method for administering pension benefits. *See Controlling Pension Benefit Systems/PBS Partnership*, T 0931/95 -3.5.1, slip op. at 11, 19 (EPO Bd. of Appeals Sept. 8, 2000) (available at http://legal.european-patent-office.org/dg3/pdf/t950931eu1.pdf). The inventor in the case urged the EPO to follow *State Street* and noted that "the USPTO had granted a patent on the appellant's pension system." *Id.*, slip op., at 7. But the Board was willing to diverge from the U.S. position and to distinguish its previous *Computer Program Product/IBM* decision:

> *The requirement of technical character*
>
> 2. According to the case law of the boards of appeal the use of the term "invention" in Article 52(1) EPC in conjunction with the so-called "exclusion provisions" of Article 52(2) and (3) EPC, which mention subject-matter that "in particular shall not be regarded as inventions within the meaning of paragraph 1", is understood as implying a "requirement of technical character" or "technicality" which is to be fulfilled by an invention as claimed in order to be patentable. Thus an invention may be an invention

---

[2] *Compare* the original proposal, available at http://europa.eu.int/eur-lex/lex/LexUriServ/site/en/com/2002/com2002_0092en01.pdf, *with* the common position that was voted down, available at http://register.consilium.eu.int/pdf/en/04/st11/st11979.en04.pdf.

> within the meaning of Article 52(1) if for example a technical effect is achieved by the invention or if technical considerations are required to carry out the invention.
>
> For instance also in its most recent decision[] concerning case[] T 1173/97, Computer program product/IBM (OJ 1999, 609) … the Board of Appeal assumed that technical character of an invention was to be considered as a generally accepted requirement of patentability… .
>
> 3. Following these decisions the question to be answered in the present case is, whether the method according to claim 1 represents a method of doing business as such. If the method is technical or, in other words, has a technical character, it still may be a method for doing business, but not a method for doing business as such.
>
> Claim 1 of the [application] is, apart from various computing means mentioned in that claim, directed to a "method for controlling a pension benefits program by administering at least one subscriber employer account". All the features of this claim are steps of processing and producing information having purely administrative, actuarial and/or financial character. Processing and producing such information are typical steps of business and economic methods. Thus the invention as claimed does not go beyond a method of doing business as such and, therefore, is excluded from patentability under Article 52(2)(c) in combination with Article 52(3) EPC; the claim does not define an invention within the meaning of Article 52(1) EPC.

Id., slip op., at 8–10. Why is the computer program in the *IBM* case considered "technical" but not actuarial, financial and economic methods? How precisely has the Board defined "technical character"? What happened to the "highly desirable (world-wide) harmonisation of patent law" that the Board referred to in *Computer Program Product/IBM*?

In another portion of the *Pension Benefit* opinion, the Board held that improvements "in the field of economy … cannot contribute to inventive step" requirement of European law. *Id.*, slip op. at 19. Because an "inventive step" (which is similar to the U.S. nonobviousness requirement) is a prerequisite to obtaining a valid patent, that holding created a second barrier to patenting business methods in Europe. In 2001, the EPO announced that it will not even "carry out an international search [pursuant to the Patent Cooperation Treaty] on an application to the extent that its subject-matter relates to no more than a method of doing business, in the absence of any apparent technical effect." *International Treaties — PCT: Business Methods*, 2001 O. J. EPO 482, available at http://www.european-patent-office.org/epo/pubs/oj001/10_01/10_4821.pdf.

To the extent that business methods patents are unavailable in Europe, the United States could invoke the WTO's dispute resolution mechanism. As previously discussed, this mechanism does not offer any direct relief to the intellectual property owners. On the other hand, European nations might rethink any ban on business method patents if trade sanctions by a major trading partner were looming.

---

4. Pure Science

NOTE ON PATENTING SCIENTIFIC PRINCIPLES AND DISCOVERIES

1. Scientific Principle Patents? As discussed in this chapter, the Supreme Court has long maintained that pure scientific principles (such as $E=mc^2$) are not patentable subject matter. But should this feature of the patent law be changed so that basic scientific discoveries are patentable?

During the twentieth century, several scholars proposed awarding patent-like rights to researchers who discover basic scientific principles. *See* 3 STEPHEN LADAS, PATENTS, TRADEMARKS, AND RELATED RIGHTS: NATIONAL AND INTERNATIONAL PROTECTION 1850-1875 (1975) (detailing such proposals). Under such systems, a discoverer of a basic scientific principle would have a claim to royalties from those making practical use of the principle. *See id*.

2. Critical Views. Stephen Ladas has raised several pragmatic objections to these proposals, including (1) that the scientific origins of a particular industrial application can be difficult to trace; and (2) that such rights would create very significant burdens on the open communication that is necessary in scientific communities. As we will see in Chapter 3, *infra*, these and similar arguments appear frequently in debates about existing patent law — debates which have arisen precisely because many basic researchers are seeking and obtaining patent rights to their discoveries.

3. Incentives and the Altruistic Scientist. Judge Jerome Frank advanced another pragmatic objection to rights for basic research:

> Epoch-making "discoveries" or "mere" general scientific "laws," without more, cannot be patented … . So the great "discoveries" of Newton or Faraday could not have been rewarded with such a grant of monopoly. Interestingly enough, apparently many scientists like Faraday care little for monetary rewards; generally the motives of such outstanding geniuses are not pecuniary… . Perhaps (although no one really knows) the same cannot be said of those lesser geniuses who put such discoveries to practical uses.

Katz v. Horni Signal Mfg. Corp., 145 F.2d 961, 63 U.S.P.Q. (BNA) 190 (2d Cir. 1944). Assuming that basic researchers are motivated less by money and more by a passion for their work, could patents still serve a function? Note that patent royalties can be used to buy more lab equipment and research assistants rather than expensive houses and cars. Also, the *potential* for patent rewards may help a scientist attract venture capital so that the research can occur in the first place. Michael Polanyi, *Patent Reform*, 1 REV. ECON. STUDIES 61 (1944) (arguing that patents generate new, socially useful knowledge by overcoming uncertainty and attracting "speculative capital"). Patents on basic research may be less necessary, however, where the government funds a significant amount of basic research (as the U.S. does).

4. Informal Scientific Norms as Quasi-Property Rights. Proposals to grant property rights for the findings of basic scientific researchers are described in Robert P. Merges, *Property Rights Theory and the Commons: The Case of Scientific Research*, 13 J. SOC. PHIL. & POL'Y 145 (1996). This article describes some "informal norms" commonly practiced by scientific researchers, and points out that these norms serve to define quasi-property rights to basic scientific research. The article then argues that good reasons still remain for refusing patents for the results of such research. For an extended investigation on the effect of patents on the traditional norms of basic research, *see* Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 136 (1999) (arguing that law should "reinforce residual academic norms that continue to militate against expansive patenting"); *see also* Rebecca S. Eisenberg, *Patents and the Progress of Science: Exclusive Rights and Experimental Use*, 56 U. CHI. L. REV. 1017 (1989) (describing interaction between scientific research ethos and intellectual property rules).

Should society extent something like the patent system to cover the discovery of new scientific principles? If you are opposed to such an extension, which arguments appeal to you? If in favor, how could such a system be implemented?

U.S. PATENT NO. 5,913,738
Repeatable and Accurate Golf Putting Apparatus And Method
(issued June 22, 1999 to Steven Carlucci)
[Specification omitted.]

What is claimed is:

1. A method for putting a golf ball [*see* Figure 2-9], comprising the steps of:

gripping a putter such that both forearms of a player using the putter are parallel to a putting surface;

taking a backswing by rotating an upper body of the player without wrist and elbow movement;

taking a downswing by rotating the upper body of the player without wrist and elbow movement; [and]

striking the golf ball.

[The patent contains five more claims all drawn to methods of putting. Despite its title, the patent includes no claims to a golf putting apparatus.]

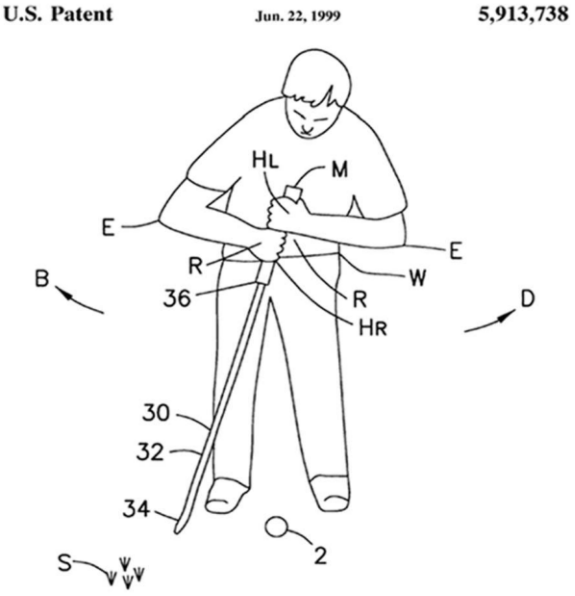


Figure 2-9: A Patented Golf Swing

NOTES ON PATENTS IN SPORTS AND OTHER FIELDS

1. Sports Moves. There are a number of historical examples where a single individual originated a particular sports maneuver. Candy Cummings has generally been credited with introducing the curveball to baseball in the 1860s. *See* ROBERT G. WATTS & A. TERRY BAHILL, KEEP YOUR EYE ON THE BALL: THE SCIENCE AND FOLKLORE OF BASEBALL 7-8 (1990). In the 1960's, high-jumper Dick Fosbury perfected the back-first high-jump technique now known as the "Fosbury Flop." Fosbury used his technique to set an Olympic record and win the gold medal in the 1968 Olympics at Mexico City. His technique soon became the standard for the sport; it was used by all three medalists in the 1976 Games and by 13 of 16 of the high jump finalists in the 1980 Games. *See Richard Fosbury: high jump revolution!* Olympic News (March 6, 2007), http://www.olympic.org/uk/news/olympic_news/full_story_ uk.asp?id=2095. In 1964, Pete Gogolak introduced the now dominant "soccer style" method of kicking field goals to American football. Gogolak has since stated that his "one regret is that I didn't patent it." Tim Crothers, *Side Kicks*, SPORTS ILLUSTRATED (Nov. 28, 1994), available at http://sportsillustrated.cnn.com/features/cover/news/2000/07/21/gogolak_flash/.

Should Cummings, Fosbury and Gogolak have been entitled to patents on their innovations? As the patent issued on Mr. Carlucci's golf swing demonstrates, such patents are no longer hypothetical. But are such patents a good idea? Consider the following argument by Professor Dreyfuss:

> [S]hould sports moves be patentable? What, for example, if Candy Cummings had patented the curve ball or Dick Fosbury, his high jump "flop?" Would sporting events be as popular? It seems unlikely. After all, sporting events are interesting because they pit humans against one another to determine whose abilities are superior. For that competition to be true, participants need to compete — literally — on a level playing field. Allowing one athlete to use a move that is denied to others would destroy the essence of the event.

Rochelle Cooper Dreyfuss, *Are Business Method Patents Bad for Business?*, 16 COMPUTER & HIGH TECH. L.J. 263, 276 (2000). Why is Professor Dreyfuss's argument limited to sports moves? Couldn't the same argument be made for patents on sporting *equipment*? Yet the PTO has issued hundreds of patents on innovative equipment designed to give players a competitive edge. *See*, *e.g.*, U.S. Patent Class 473 ("Games Using Tangible Projectile"), Subclass 365 (golf ball covers), available at http://www.uspto.gov/web/offices/ac/ido/oeip/taf/def/473.htm#365 (listing over 100 patents on golf ball covers).

Do patents on sports techniques and equipment "promote the Progress of Science and useful Arts"? The rules of sporting events are, after all, arbitrary; they are designed only to establish competition that is fun for the participants and for the audience. *See* Roger G. Noll, *Attendance and Price Setting*, in GOVERNMENT AND THE SPORTS BUSINESS 115, 156 (Noll, ed., 1974) (analyzing statistical data and concluding that "a league benefits from lessening the quality differences among teams"); Jeffrey A. Smith, Note, *It's Your Move — No It's Not! The Application of Patent Law to Sports Moves*, 70 U. Colo. L. Rev. 1051, 1082 (1999) (surveying

economic data showing that interest in a sport increases "where there is relative parity among the teams").

Do innovations that improve performance necessarily increase the value of the sport? If a particular innovation changes the balance of the contest too much, the rules of the game might be adjusted to account for the improvement. *See* Carl A. Kukkonen, III, *Be a Good Sport and Refrain from Using My Patented Putt: Intellectual Property Protection For Sports Related Movements*, 80 J. PAT. & TRADEMARK OFF. SOC'Y 808, 828 (1998) (predicting that sports leagues would change their rules in response to any patent protection of sport moves); *see also* Michael E. Canes, *The Social Benefits of Restrictions on Team Quality*, in GOV'T & THE SPORTS BUS. 81, 94–96, 99–100 (Noll, ed., 1974) (noting that efficient sports league rules try to reduce investments in performance because the investments by one team produce negative externalities on all other teams and thus, without league regulation, individual teams would overinvest in improving performance).

2. Comparison with Europe. Article 52(2) of the European Patent Convention precludes patents on "methods for … playing games." Yet, as we have already seen, the ban on computer program patents in the same Article has been interpreted so narrowly as to have little effect. Is there reason to think that the EPO will more faithfully enforce the bar on patenting methods for playing games? Does a ban on sports method patents violate TRIPs?

3. You Can Patent THAT! Early editions of this casebook posed the question whether patents should be available for various categories of innovations, with the categories chosen to test the limits of patentability. In almost all of these categories, however, the PTO is now issuing patents:

a. A new tennis stroke, baseball pitch, or basketball move. The PTO has now issued a number of patents on golf swings and techniques. In addition to the Carlucci patent, *see, e.g.*, U.S. Patent No. 6,019,689, "Method of Putting" (issued Feb. 1, 2000 to Charles Nelson Hogan and assigned to Holey-Moley L.L.C. of Redmond, Oregon); U.S. Patent No. 5,616,089, "Method of Putting" (issued Apr. 1, 1997, to Dale D. Miller). Patents on techniques in other sports would therefore seem to be patentable.

b. A new chess move. Chess moves — especially openings — are widely studied. A characteristic move may even prove decisive in particular matches. Is there any way to distinguish chess moves from the putting methods that the PTO has already allowed to be patented? Although our research shows that the PTO has not yet issued any patents on chess moves, numerous patents have been issued on different forms of the basic chess game. *See, e.g.*, U.S. Patent No. 6,102,399, "Four Way Chess Game" (issued Aug. 15, 2000).

c. Overnight package delivery, or other business concept. *Bilski* obviously establishes the patentability of business methods, but the full implications of the decision have yet to be determined. For example, could a patent issue merely on the idea of running an overnight package delivery system? A good account of the origins of Federal Express — the first integrated, overnight package delivery company — can be found in JOHN DIEBOLD, THE INNOVATORS ch. 2, at 25 et seq. (1990). If the description is accurate, there was certainly no lack of risk involved in starting up this venture; indeed, the story includes a few close brushes with bankruptcy early on.

Though the market ultimately rewarded FedEx, a patent would have provided an even greater reward by protecting the company from the competition that inevitably followed the company's success. Would there be any practical problems in patenting the general concept of overnight package delivery? How would the claims to such a system be drafted?

d. A recipe. One often hears the expression, "his patented chili," or chicken stir-fry, etc. The traditional view has been that a "recipe whereby well-known ingredients are mixed or blended" is not patentable because:

> It is a matter of common knowledge that new recipes for cooking and for the production of food products are constantly being developed by adding or eliminating well known ingredients or treating them in ways differing from former practice. To hold all these patentable would unsettle the arts of cooking and of preparing food products.

In re White, 39 F.2d 974 (C.C.P.A. 1930) (quoting *Ex parte Walker*, 1923 Dec. Comm. Pat. 39). In modern practice, that reasoning would be articulated under the "nonobviousness" doctrine. *See* Chapter 7, *infra*; *see also General Mills, Inc. v. Pillsbury Co.*, 378 F.2d 666 (8th Cir. 1967) (holding Pillsbury's cake mix patent invalid for obviousness under § 103). But an obviousness objection to some recipes is quite different from a holding that recipes in general do not constitute patentable subject matter and, in fact, the PTO is issuing patents on edible "compositions of matter." *See*, *e.g.*, U.S. Patent No. 5,789,012 (1998), "Products from Sweet Potatoes, Cassava, Edible Aroids, Amaranth, Yams, Lotus, Potatoes and Other Roots, Seeds and Fruit (providing, as part of the patent specification, 168 "examples" that read like conventional recipes); U.S. Patent No. 5,175,013 (1992), "Frozen Dessert Compositions and Products" (now assigned to Häagen-Dazs Co.).

e. A "social innovation," such as the concept of the "designated driver." It can take a certain amount of time and effort to improve some aspect of social life, and it no doubt takes a great deal of effort — and sometimes money — to diffuse a new idea sufficiently to reach acceptance. Occasionally, these ideas are very valuable indeed, as the example of the designated driver demonstrates. (Imagine the lives saved, and economic devastation avoided, by this simple idea — which really was the brainchild of a single individual.) Why not provide a special form of protection for them?

The PTO has not yet (so far as we can tell) issued any patents that would fall into this category. Of course, the social innovator would have no incentive to apply for a patent unless he or she has also devised a way to profit from such a patent, which may not be easy. Yet if a social innovator did have a way to profit from the idea, the innovation would be indistinguishable from a business method patent, wouldn't it?

f. A legal innovation, such as a new development in regulatory law. Could a patent be issued on a legal innovation? As an example of such an innovation, consider the case of spectrum auctions. In 1951 Leo Herzel, then a student at the University of Chicago Law School, wrote an unconventional student note putting forward the radical idea of auctioning the nation's radio waves to the highest bidder. *See* Leo Herzel, Note, *"Public Interest" and the Market in Color Television Regulation*, 18 U. CHI. L. REV. 802 (1951). A former chief economist at the Federal Communication Commission (FCC) immediately dismissed the idea as an "intellectual game"

that should be left in "the realm in which it is merely the fashion of economists to amuse themselves." *See* Dallas W. Smythe, *Facing Facts about the Broadcast Business*, 20 U. CHI. L. REV. 96, (1952). Ronald Coase, who would later win the Nobel Prize in economics, independently arrived at Herzel's regulatory innovation in 1959, *see* R. H. Coase, *The Federal Communications Commission*, 2 J. LAW & ECON. 1 (1959), but he was ridiculed for embracing the idea. A Commissioner of the FCC asked him, "Are you spoofing us? Is this all a big joke?" R. H. Coase, *Why Did FCC License Auctions Take 67 Years?*, 41 J. LAW & ECON. 577, 579 (1998). An economist from the RAND corporation commented that there was "no country on the face of the globe — except for a few corrupt Latin American dictatorships — where the 'sale' of the spectrum could even be seriously proposed." *Id.* (quoting RAND comments). The U.S. began spectrum auctions in 1993, and the FCC has since auctioned off billions of dollars in spectrum.

Should the inventor of such a legal innovation be entitled to a patent? Would such patents hasten the advent of valuable legal technology? Note that Section 14 of the recently enacted American Invents Act specifically prohibits the issuance of patents for "any strategy aimed at reducing, avoiding or deferring tax liability." This prohibition is achieved by deeming all such tax avoidance strategies to be within prior art.

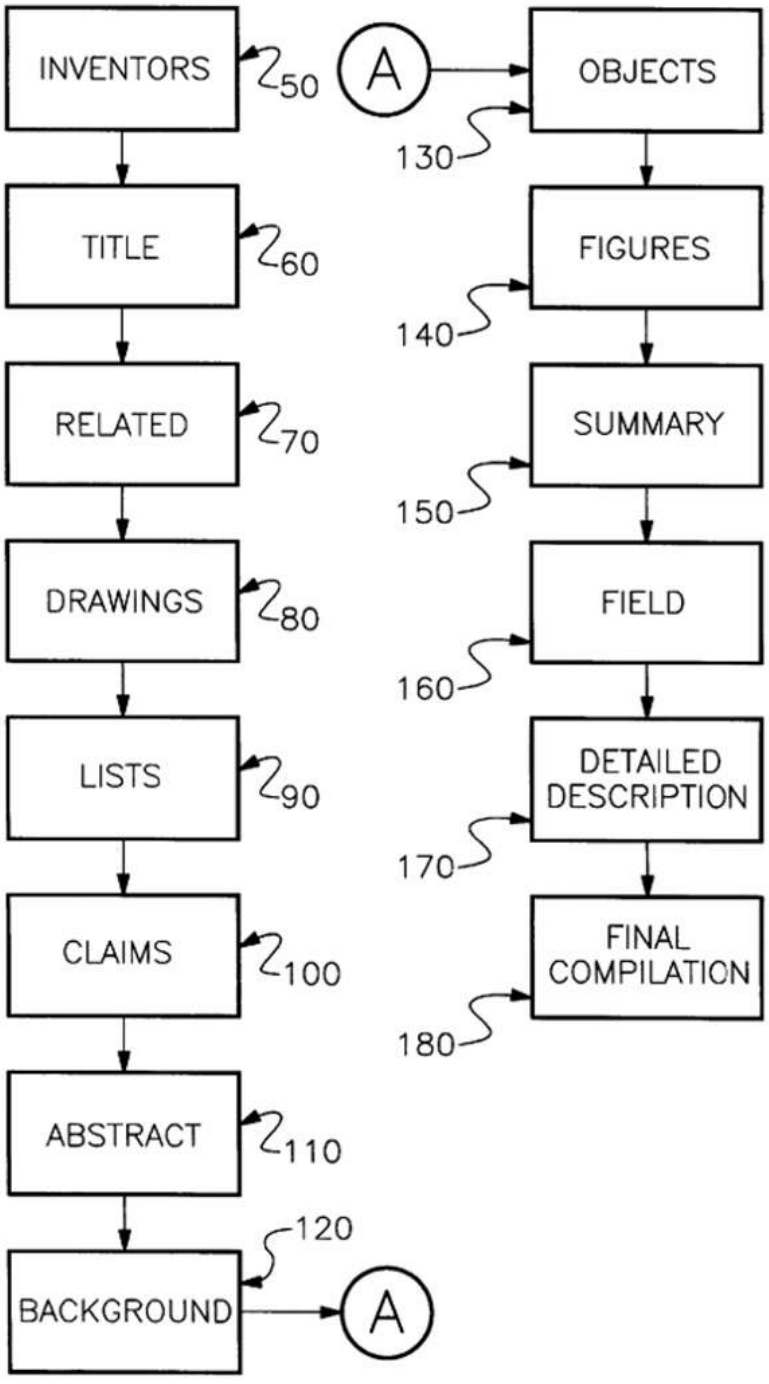


Figure 2-10: A Patented Patenting Process